K111170 pg 1 of 6

DEC 15 2011

510(k) SUMMARY

PICO Single Use Negative Pressure Wound Therapy System

1. **Submitter:** Smith & Nephew, Inc.
   970 Lake Carillon Drive, Suite 110
   St. Petersburg, FL 33716

2. **Contact:** Terry McMahon
   Director of Regulatory Affairs & Quality, North America
   727-399-3785
   Email: terry.mcmahon@smith-nephew.com

3. **Device name:** PICO Single Use Negative Pressure Wound Therapy System
   Common name: Negative Pressure Wound Therapy powered suction pump
   Classification name: Powered suction pump (21 CFR 878.4780)
   Product Classification/Code: Class II, OMP

4. **Date summary prepared:** December 15, 2011

5. **Predicate Device Information:**
   NPD 1000 Negative Pressure Wound Therapy System (K080275)
   Kalypto Medical
   6393 Oakgreen Avenue
   Hastings, MN 55033

   Renasys Go (K083375)
   Smith & Nephew Inc,
   St. Petesburg, FL

Prevena Incision Management System (K100821)
KCI USA, INC.
6203 Farinon Dr.
San Antonio, TX 78249

6. **Device Description:**

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable suction device consisting of a electric motor driven, twin-diaphragm, vacuum pump connected to a super-absorbent, gentle adhesive dressing. The pump is supplied non-sterile and single use, the dressing and secondary fixations strips are supplied sterile and single use. The dressing is applied to the wound and secondary fixation strips are placed over the outside edges to help hold the dressing in place. When the suction pump is turned on, air is pulled out of the dressing creating negative pressure and drawing excess fluid from the wound into the dressing. The pump is battery operated and is supplied with two AA lithium batteries which provide up to 168 hours (7 days) of battery life depending upon leak rate. The batteries can be replaced if required. The pump is designed to stop working after 168 hours (7 days) of use and will not re-start after this time, even with new batteries. Negative pressure will not be applied at this point. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. A carry bag is not provided with the system however will be available to order separately.

7. Intended Use

7a. Low and moderately exuding wounds

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Product Codes: 66800862, 66800863, 66800865 and 66800866 are indicated for use on low and moderately exuding wounds.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

7b. Low exuding wounds

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low levels of exudate and infectious materials.

Product Codes: 66800864, 66800867, 66800868 and 66800869 are indicated for use on low exuding wounds,

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

8. **Summary of Non-Clinical Testing**

The biocompatibility of the PICO Single Use Negative Pressure Wound Therapy System has been demonstrated through assessment according to ISO 10993-1: 2003 and appropriate *in vivo* and *in vitro* tests have been conducted using product that has been packaged and sterilised. These tests include cytotoxicity, sensitization and irritation and cover the PICO dressing and secondary fixation strips. These studies indicated that the PICO Single Use Negative Pressure Wound Therapy System is safe for its intended use.

Test	Description of Method	Result
Cytotoxicity	**PICO Dressing** In order to determine the cytotoxic potential of the dressing, a Minimum Essential Medium (MEM) elution assay was conducted in accordance with ISO 10993-5. **Secondary Fixation Strips** Cytotoxicity testing has been performed on the secondary fixation strips, tested in accordance with ISO 10993-5. The test article extract was diluted in supplemented EMEM 1X and placed onto triplicate confluent monolayers of L-929 mouse fibroblast cells at the 100%, 50%, 25% and 5% solutions (v/v).	N to 1:16, all non-cytotoxic (Grade 0) N to 1:16, all non-cytotoxic (Grade 0)
Sensitisation	**PICO Dressing** A Guinea Pig Maximisation Test was performed on the dressing in accordance with ISO 10993-10. **Secondary Fixation Strips** A guinea pig maximisation test was performed on the secondary fixation strips in accordance with ISO 10993-10.	Non-sensitising Non-sensitising
Irritation	**PICO Dressing** The dressing was evaluated for irritation in accordance with ISO 10993-10. **Secondary Fixation Strips** Irritation testing has been performed on the secondary fixation strips in accordance with ISO 10993-10.	PII SC = 0.0 PII SC = 0.1 Negligible irritant 0.9% NaCl extract: Primary Irritation Index: 0.11 (Negligible)

Additionally, the effects of the dressing wound contact layer have been assessed during a wound healing study on ALLEVYN Gentle Border dressings, report reference which have the same wound contact layer as the dressing included in the PICO Single Use Negative Pressure Wound Therapy System.

Testing has been completed in accordance with IEC / UL 60601-1; General Requirements for Safety of Electrical Medical Equipment and IEC 60601-1-2; Electromagnetic Safety Requirements For Electrical Medical Equipment. Software validation has been completed in accordance with IEC 62304 Software for Medical Devices.

9. **Conclusions Drawn**

Based on results of testing performed the subject device is substantially equivalent to the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275), Renasys Go (K083375) and Prevena Incision Management System (K100821).

PICO has similar design characteristics and provides similar functions to NPD 1000 Negative Pressure Wound Therapy System (K080275), Renasys Go (K083375) and Prevena Incision Management System (K100821). The intended use, indications and instructions for use for the subject and predicate devices are similar.

PICO does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2011

Smith and Nephew, Inc.
% Mr. Terry McMahon
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K111170
Trade/Device Name: PICO Single Use Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 12, 2011
Received: December 13, 2011

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111170

Device Name: PICO Single Use Negative Pressure Wound Therapy System

Indications for Use:

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Product Codes: 66800862, 66800863,66800865 and 66800866 are indicated for use on low and moderately exuding wounds.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kazen for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111170

INDICATIONS FOR USE STATEMENT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111170

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2011

Smith and Nephew, Inc.
% Mr. Terry McMahon
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

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Mark N. Melkerson
Director
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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kane for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111170

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111170

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 13, 2011

SMITH & NEPHEW, INC.
WOUND MANAGEMENT
970 LAKE CARILLON DR.
SUITE 110
ST. PETERSBURG, FLORIDA 33716
ATTN: TERRY MCMAHON

510k Number: K111170

Product: PICO

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Fife, Elizabeth *

From: Microsoft Exchange
To: 'terry.mcmahon@smith-nephew.com'
Sent: Tuesday, December 13, 2011 3:24 PM
bject: Relayed: K111170 AI

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'terry.mcmahon@smith-nephew.com'

Subject: K111170 AI

Sent by Microsoft Exchange Server 2007

66

Williams, Michael *

From: Microsoft Exchange
To: 'terry.mcmahon@smith-nephew.com'
Sent: Tuesday, November 22, 2011 1:05 PM
Subject: Relayed: Hold Letter for K111170

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'terry.mcmahon@smith-nephew.com'

Subject: Hold Letter for K111170

Sent by Microsoft Exchange Server 2007

67

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 22, 2011

SMITH & NEPHEW, INC.
WOUND MANAGEMENT
970 LAKE CARILLON DR.
SUITE 110
ST. PETERSBURG, FLORIDA 33716
ATTN: TERRY MCMAHON

510k Number: K111170
Product: PICO

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 21, 2011

SMITH & NEPHEW, INC.
WOUND MANAGEMENT
970 LAKE CARILLON DR.
SUITE 110
ST. PETERSBURG, FLORIDA 33716
ATTN: TERRY MCMAHON

510k Number: K111170

Product: PICO

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 28, 2011

SMITH & NEPHEW, INC.
WOUND MANAGEMENT
970 LAKE CARILLON DR.
SUITE 110
ST. PETERSBURG, FLORIDA 33716
ATTN: TERRY MCMAHON

510k Number: K111170

Product: PICO

Extended Until: 11/22/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Wound Management
Smith & Nephew, Inc.
970 Lake Carillon Drive
Suite 110
St. Petersburg, FL 33716

T 727 392-1261
F 727 392-6914 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com

We are **smith&nephew**

August 23, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
AUG 24 2011
Received K34

RE: 510(k) #K111170;Trade Name: PICO Single Use Negative Pressure Wound Therapy System; Request for Extension to Respond to Questions

Dear Sir or Madame:

Smith & Nephew, Inc. respectfully request additional time to respond to questions identified by FDA in its letter date July 25, 2011 requesting additional information for the review of Pre-Market Notification, 510(k) K111170. Smith & Nephew requests an extension of ninety (90) days to ensure sufficient time is allowed to prepare a full response to FDA's questions. We expect to have our responses complete well in advance of the time requested and will file a formal response as soon as practical.

Sincerely,

Terry C. McMahon
Director, Regulatory Affairs and Quality

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Director, Regulatory Affairs & Quality Assurnace
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

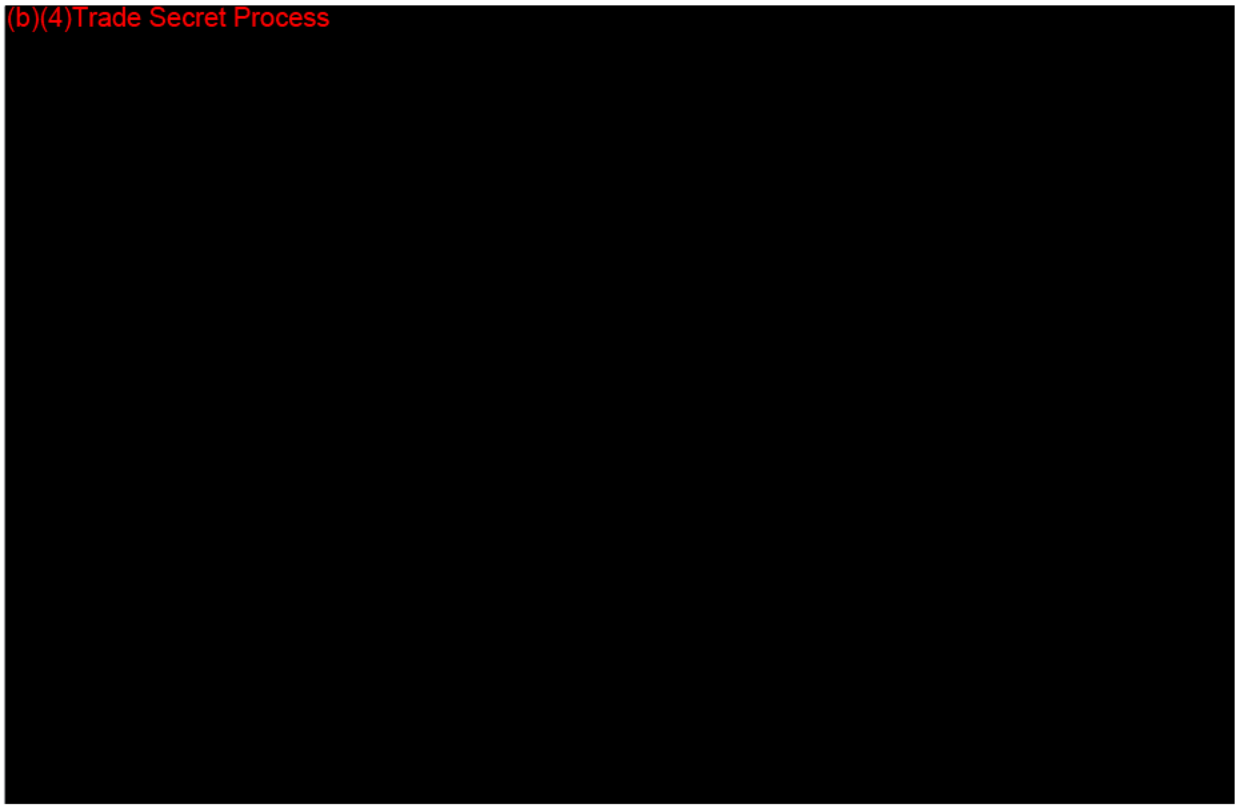
JUL 25 2011

Re: K111170
Trade Name: PICO Single Use Negative Pressure Wound Therapy System
Dated: April 21, 2011
Received: April 26, 2011

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following issues:

(b)(4)Trade Secret Process



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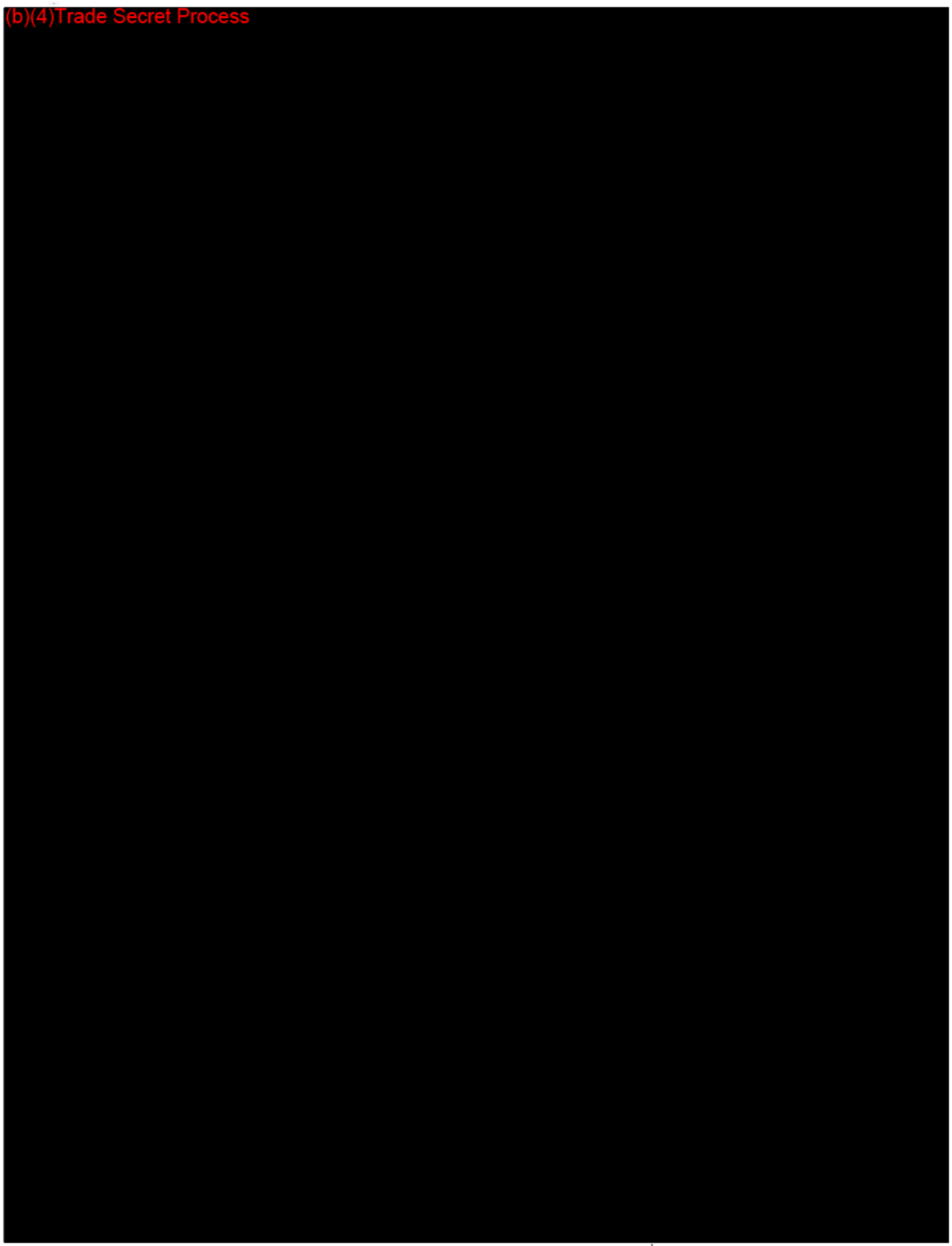
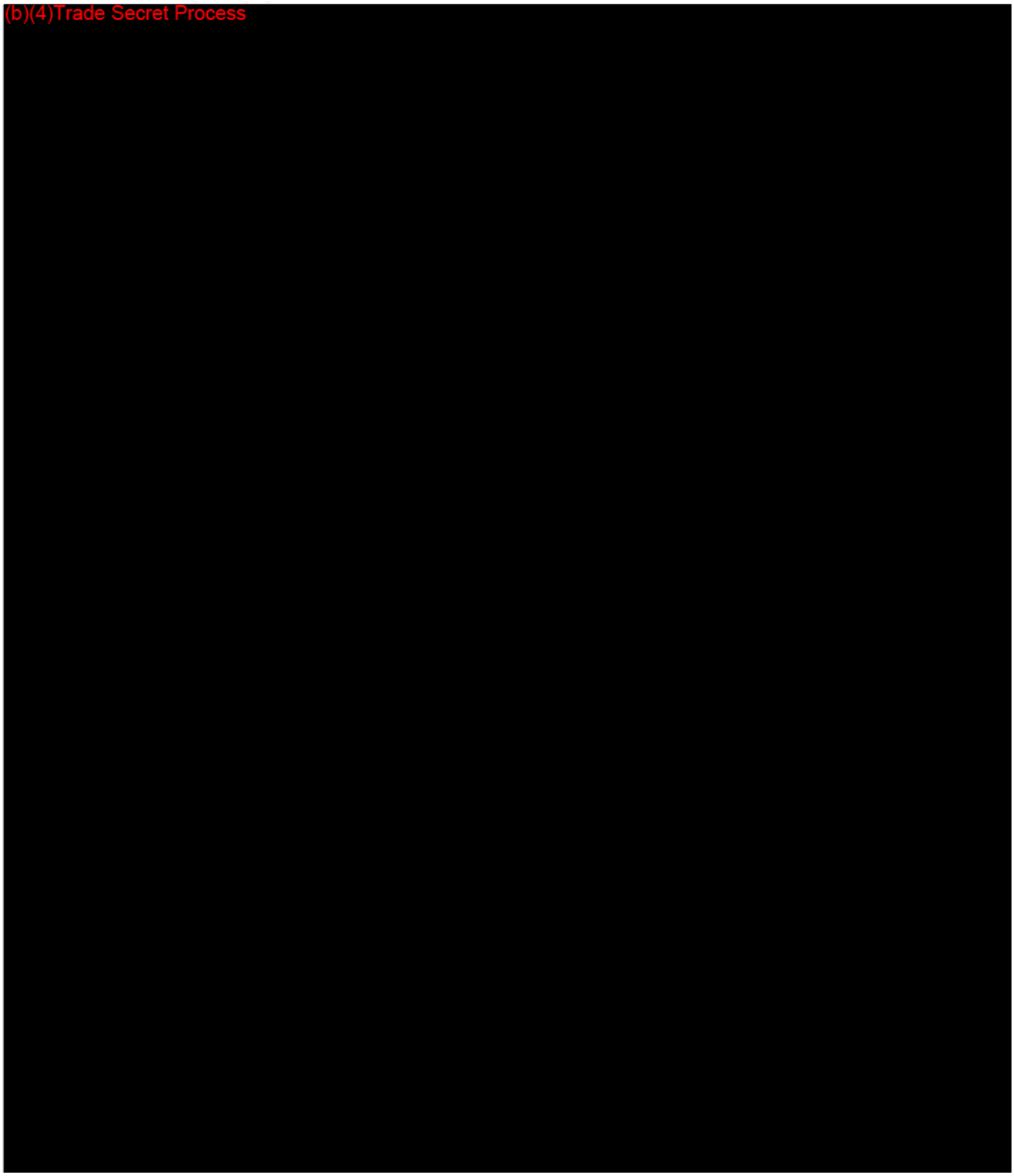
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf**

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Kelley Burridge, PhD at (301) 796-7630. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at

its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause, PhD
Chief, Plastic and Reconstructive
Surgery Branch
Division of Surgical, Orthopedic
and Restorative Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 26, 2011

SMITH & NEPHEW, INC.
WOUND MANAGEMENT
970 LAKE CARILLON DR.
SUITE 110
ST. PETERSBURG, FLORIDA 33716
ATTN: TERRY MCMAHON

510k Number: K111170

Received: 4/26/2011

Product: PICO

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

INFORMATION FOR THE 510(k)
OF
PICO
IN THE UNITED STATES

K5
4-26

Smith & Nephew, Inc.

April 2011

K111170

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I	1.	Medical Device User Fee Cover Sheet (Form FDA 3601)
I	2.	CDRH Premarket Review Submission Cover Sheet
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I	5.	510(k) Cover Letter
I	6.	Indications for Use Statement
I	7.	510(k) Summary
I	8.	Truthful and Accuracy Statement
I	9.	Class III Summary and Certification
I	10.	Financial Certification or Disclosure Statement
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		Testing – Animal
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K S

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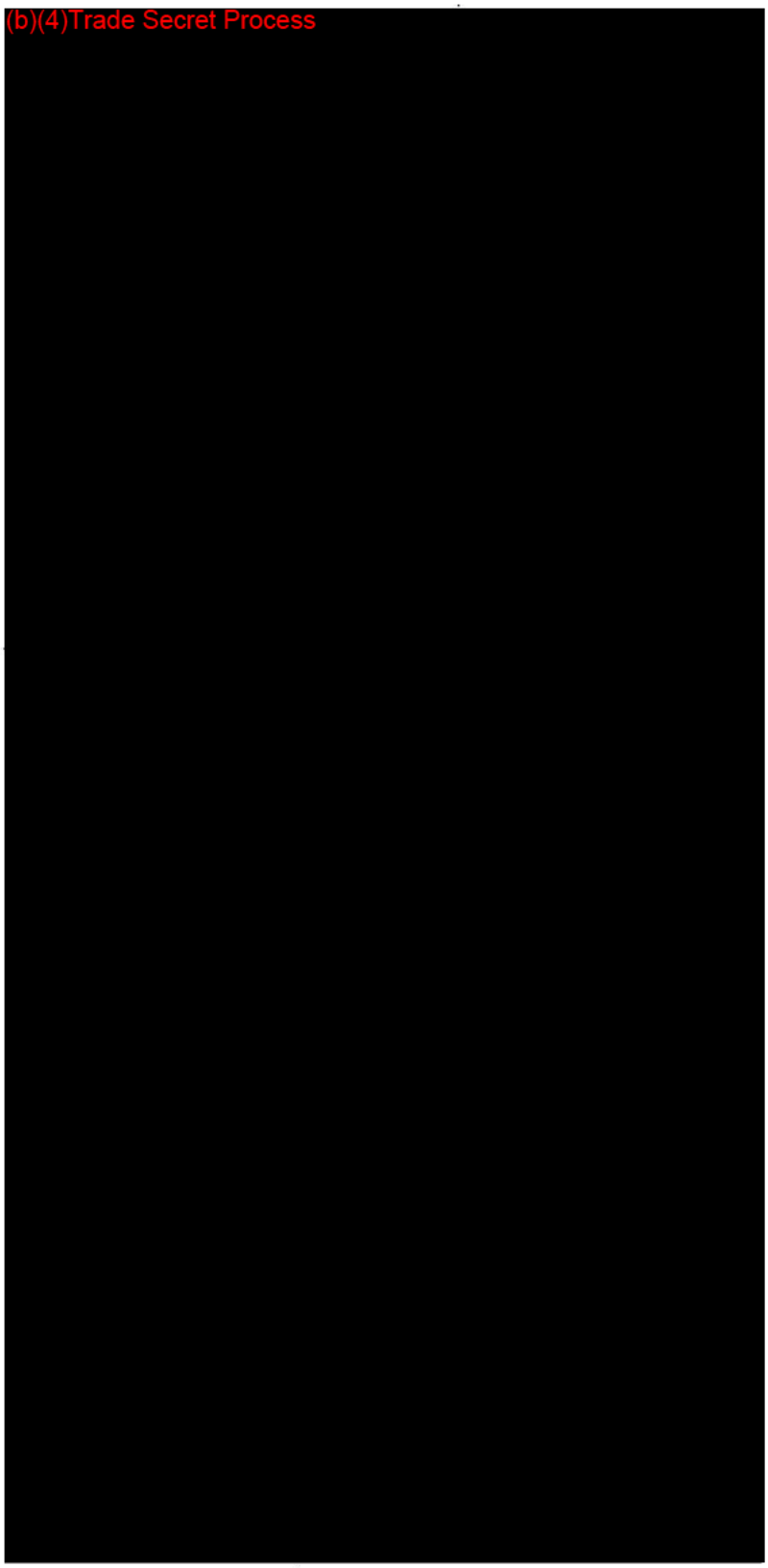
(b)(4)Trade Secret Process

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade S(e Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
SMITH AND NEPHEW INC 970 Lake Carrilon Dr. St Petersburg FL 33716 US	Terry McMahon
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3924	2.1 E-MAIL ADDRESS *terry.mcmahon@smith-nephew.com* 2.2 TELEPHONE NUMBER (include Area code) 727-399-3785 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 727-329-5613

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the Instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)

11-Jan-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
4/21/2011	(b)(4)Trade Secret P	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☒ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ *Original* Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Smith & Nephew, Inc	3006760724		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Wound Management	727-392-1261		
Street Address	**FAX Number *(including area code)***		
970 Lake Carillon Dr. Suite 110	727-399-3468		
City	**State / Province**	**ZIP/Postal Code**	**Country**
St. Petersburg	Florida	33716	USA
Contact Name			
Terry McMahon			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs & Quality Assurance, North America	terry.mcmahon@smith-nephew.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	66800164	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K080275	1	NPD 1000 Negative Pressure Wound Therapy System	1	Kalypto Medical
2	K083375	2	Renasys Go	2	Smith & Nephew Inc,
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Negative Pressure Wound Therapy powered suction pump

	Trade or Proprietary or Model Name for This Device		Model Number
1	PICO	1	66800882, 66800864
2		2	66800866, 66800868
3		3	66800863, 66800865
4		4	66800867, 66800869
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OMP	21 CFR 878.4780	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General & Plastic Surgery Devices Panel		

Indications *(from labeling)*

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

Examples of appropriate wound types include:Incision sites, Chronic, Acute, Traumatic, Subacute and dehisced wounds,Partial-thickness burns, Ulcers (such as diabetic or pressure), Flaps and grafts

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. 13485	Standards Organization ISO	Standards Title Medical Devices - Quality Management Systems - Requirements For Regulatory Purpose	Version 2ed 2003	Date 7/13/2003
2	Standards No. 11135	Standards Organization AAMI/ISO	Standards Title Sterilization of Health Care Products - Ethylene Oxide	Version 2007	Date 05/05/2010
3	Standards No. 10993-1	Standards Organization AAMI/ISO	Standards Title Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing	Version 2009	Date 10/04/2010
4	Standards No. 10993-3	Standards Organization AAMI/ISO	Standards Title Biological Evaluation and Medical Devices - Part 3 tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity	Version 2003	Date 03/18/2011
5	Standards No. 10993-5	Standards Organization AAMI/ISO	Standards Title Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	Version 2009	Date 05/05/2010
6	Standards No. 10993-10	Standards Organization AAMI/ISO	Standards Title Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Delayed-Type Hypersensitivity	Version 2002 and 1 2006	Date 7/1/2006
7	Standards No. 14971	Standards Organization ISO	Standards Title Medical Devices - Applicable Risk Management to Medical Devices	Version 2009	Date 01/01/2009

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including *suggestions for reducing* this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. *A separate report is required for each standard referenced in the 510(k).*

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1: 2007 - Sterilisation of health care products - ethylene oxide.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? *If no, complete a summary report table.*	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? *If no, include the results of testing in the 510(k).*	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? *If yes, report these exclusions in the summary report table.*	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] *The formatting convention for the title is:* [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at *www.fda.gov/cdrh/guidance.html*

PSC Graphics (301) 443-1090 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135-1: 2007 - Sterilisation of health care products - ethylene oxide.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 11135-1	ISO 11135-1: 2007 - Sterilisation of health care products - ethylene oxide.	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Conformance with the complete standard as applicable to device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971: 2007 - Medical Devices - Application of Risk Management

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 14971: 2007 - Medical Devices - Application of Risk Management

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 14971	ISO 14971: 2007 - Medical Devices - Application of Risk Management	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Conformance with complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1 : Evaluation and Testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1 : Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 10993-1	ISO 10993-1 Biological Evaluation of Medical Devices - Part 1 : Evaluation	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

No deviation

DESCRIPTION

Conformance with complete standard as applicable to the device

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-3:2003 Biological Eval of Medical Devices - Part 3: Tests for Genotoxicity, carcinogenicity & reproductive toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-3:2003 Biological Eval of Medical Devices - Part 3: Tests for Genotoxicity, carcinogenicity & reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 10993-3	Part 3: Tests for Genotoxicity, carcinogenicity & reproductive toxicity	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Conformance with the complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5 2009 - Biological Evaluation of Medical Devices - Part 5 : Tests for In Vitro Cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-5 - Biological Evaluation of Medical Devices - Part 5 : Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 10993-5	ISO 10993-5 - Part 5:Tests for In Vitro Cytotoxicity	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Conformance with complete standard

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10 : Tests For Irritation and Delayed-Type Hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-10 - Biological Evaluation of Meidcal Devices - Part 10 : Tests For Irritation and Delayed-Type Hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 10993-10	Part 10 : Tests For Irritation and Delayed-Type Hypersensitivity	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Conformance with complete standardas applicable

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1 : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1 : Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

No deviation

DESCRIPTION

Compliance with complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

UL 60601-1 : Medical Electrical Equipment Part 1 : General requirements for safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
UL 60601-1	Medical Electrical Equipment Part 1 : General requirements for safety	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

No deviation

DESCRIPTION

Compliance with complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

UL 60601-1 : Medical Electrical Equipment Part 1 : General requirements for safety

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

311

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2 - Medical Electrical Equipment Part 1-2: General requirements for safety. Collateral standard: EMC

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-34	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2 - Medical Electrical Equipment Part 1-2: General requirements for safety. Collateral standard: EMC

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1-2	Medical Electrical Equipment Part 1-2: General requirements for safety.	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviation

DESCRIPTION

Compliance with complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 : Medical Device Software - Software life cycle processes

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority (21 U.S.C. 360d), www.fda.gov/cdrh/stdsprog.html

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

ISC Graphics (301) 443-1090 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 62304 : Medical Device Software - Software life cycle processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 62304	IEC 62304 : Medical Device Software - Software life cycle processes	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

No deviation

DESCRIPTION

Conformance with complete standard as applicable to the device

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Smith & Nephew, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Apr 21, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
970 Lake Carillon Drive, Suite 110
St Petersburg, FL 33716

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 727-399-7785
(Fax) 727-399-3468

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

PICO Single Use Negative Pressure Wound Therapy

Product Codes: 66800862, 66800863, 66800864, 66800865, 66800866, 66800867, 66800868, 66800869

Common Name: Negative Pressure Wound Therapy Powered Suction Pump

Classification: Class II

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Terry McMahon
(Title) Director of Regulatory Affairs & Quality, North America

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
970 Lake Carillon Drive, Suite 110
St Petersburg, FL 33716

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 727-399-3785
(Fax) 727-399-3468

15. DATE OF CERTIFICATION
21/04/2011

K111170

Smith & Nephew
Wound Management
970 Lake Carillon Drive
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St. Petersburg, Florida 33716
USA

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F 727 399 3498
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We are smith&nephew

FDA CDRH DMC

APR 2 6 2011

Received

April 21, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: 510(k) Traditional Submission
Trade Name: PICO Single Use Negative Pressure Wound Therapy System

Dear Sir/Madame:

As per part 807, Subpart E of Title 21 of the Code of Federal Regulations, Smith & Nephew is hereby submitting two copies of 510(k) Premarket Notification concerning a new device, PICO Single Use Negative Pressure Wound Therapy System.

The principal factors about the design and use of our device are shown in the table below:

QUESTION	YES	NO
Is the device intended for prescription use?	√	
Is the device intended for over-the-counter use?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?	√	
Does the submission include clinical information?	√	
Is the device implanted?		√

We consider our intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure by the FDA. We have not disclosed our intent to market this device to anyone except employees of our establishment and have taken precautions to protect this confidentiality. Please address any questions concerning this submission to Terry McMahon, Director of Regulatory Affairs & Quality, North America, telephone number 727-399-3785 or by e-mail at terry.mcmahon@smith-nephew.com.

Sincerely
Terry McMahon
Director of Regulatory Affairs & Quality, North America

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

PREMARKET NOTIFICATION TRUTHFUL AND ACCURACY STATEMENT

I certify that, in my capacity as Director of Regulatory Affairs and Quality, North America of Smith & Nephew Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature:

Name: Terry McMahon Director of Regulatory Affairs and Quality, North America

Date: 04/21/2011

CLASS III SUMMARY AND CERTIFICATION

This section does not apply. This device is not a class III device.

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

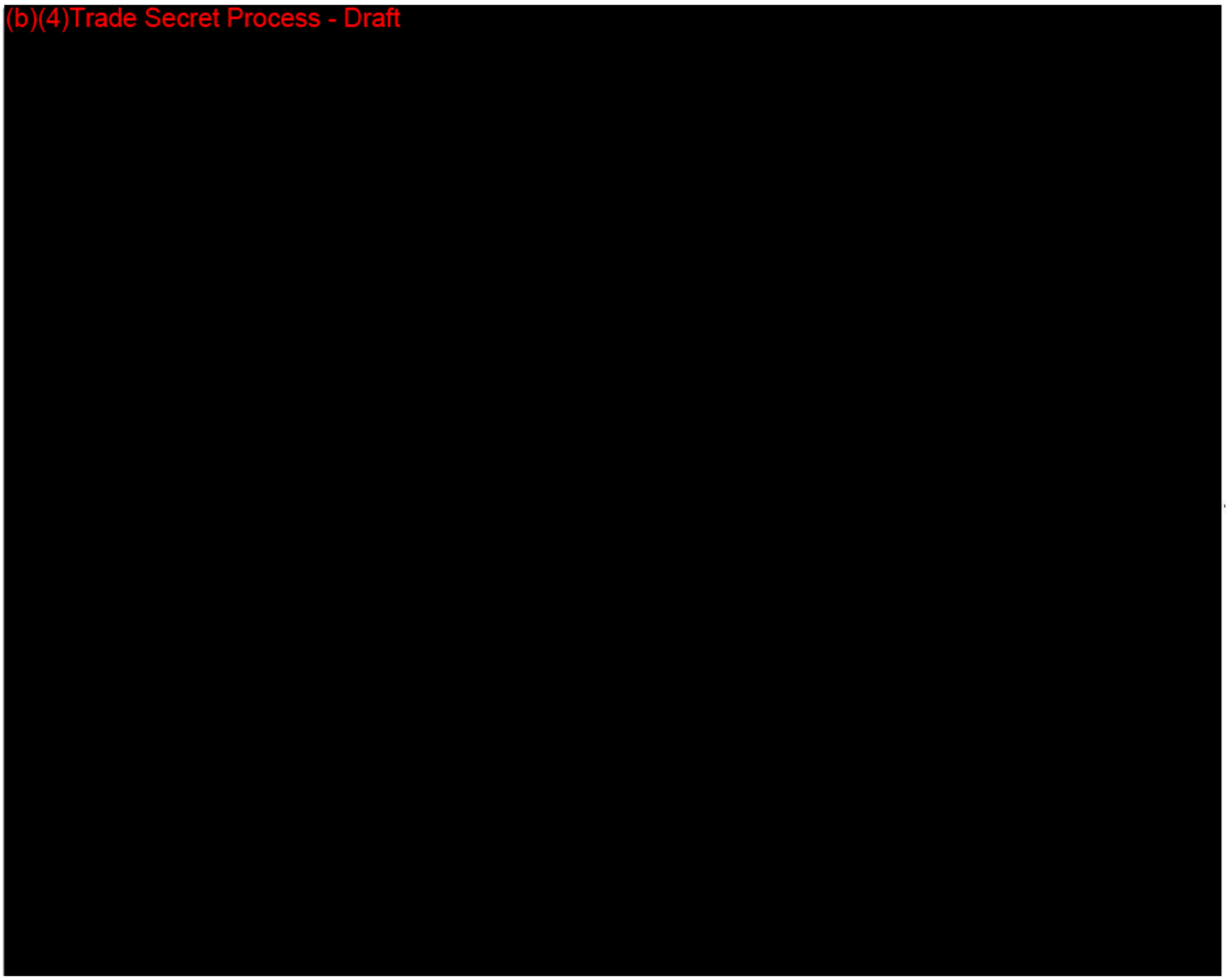
This section is not applicable to this device.

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section is not applicable to this device.

EXECUTIVE SUMMARY

(b)(4)Trade Secret Process - Draft



Device Description

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable, electro-mechanical pump system connected through a flexible tube to a super-absorbent, gentle adhesive dressing. Secondary fixation strips are also provided to ensure an adequate seal of the dressing is achieved. The pump is supplied non-sterile, the dressing and fixation strips are supplied sterile and all are supplied as single use. PICO delivers negative pressure wound therapy to a range of acute and chronic wound types. PICO achieves this in the same way as the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275) and Renasys Go (K083375).

PICO Single Use Negative Pressure Wound Therapy System comprises of two tray sets to provide therapy for up to 7 days. Both trays contain one dressing and 5 secondary fixation strips. The trays are manufactured from (b)(4)Trade Secret Process and are sealed with a Tyvek lid. The trays are placed into a carton and sent for ethylene oxide sterilisation. Once sterilisation is complete the product is returned to Smith & Nephew Medical Ltd where a third tray containing a non-sterile pump, two lithium batteries and the Instructions for Use are placed into the carton; along with the two dressing trays. The tray containing the pump and batteries is manufactured from the same material as the dressing tray. The tray is contained within a tray sleeve to ensure the pump and batteries remain in place. Drawings of the dressing tray and pump tray are enclosed in the Sterilisation, Shelf Life and packaging section.

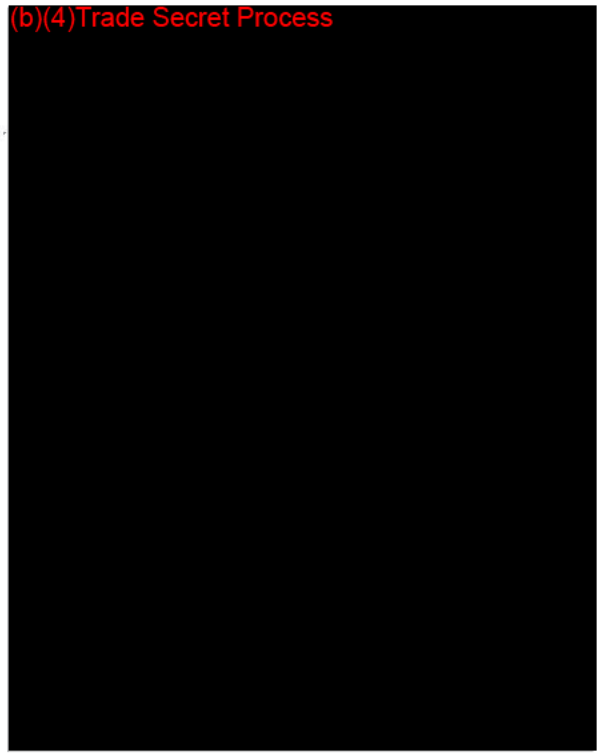
Pump

The PICO pump unit incorporates an electric motor driven twin-diaphragm vacuum pump, this is connected through a 1-way valve to minimise air leaks from the pump mechanism. The pump is powered by 2 AA Lithium batteries which can provide up to 168 hours (7 days) of battery life; this is dependent upon the leak rate of the attached dressing. The batteries can be replaced if required by removal of the battery cover. The pump is designed to stop working after 168 hours (7 days) of use; this is achieved through a timer (b)(4)Trade Secret The pump will stop and not re-start after this time, even with new batteries. Negative pressure will not be applied following this. PICO is initiated by insertion of the batteries, the device automatically performing a self-test. Pressing the orange button then initiates the pump. PICO operates within a pressure range of (b)(4)Trade Secret Process (80mmHg nominal) and is non-adjustable. The pump incorporates a hardware circuit on the PCBA that de-activates the pump for vacuum exceeding levels which may cause discomfort or harm (b)(4)Trade Secret Process The pump also includes a mechanism in the software that suspends operation after a period of 30 minutes if the leak rate (as derived in software from the pump duty cycle) is above a pre-set level; this

condition initiates the amber 'leak' alarm and suspends operation of the pump. Re-activation is achieved by pressing the orange button. PICO is equipped with two alarms; low battery and leak, these are amber blinking LED's. When PICO is operating under normal conditions; with no leaks and the battery level is not low; this is indicated by a green blinking LED.

Figure 1 below shows the internal and external view of the pump. Drawings of the main components and sub-assemblies are enclosed in the Device Description section.

Component Parts



1	Rear Housing
2	Front Housing
3	Pump Assembly
4	Inlet Tube
5	Inlet Manifold
6	1-Way Valve
7	Battery Cover
8	PCBA
9	Battery Contacts
10	Screws
11	Label
12	Label for Serial Number

Figure 2: External View

Pump Casing Materials

The table below lists the materials used in the manufacture of the pump case, and includes the corresponding specification reference.

Table 1

Material	Function	Specification Reference
(b)(4)Trade Secret Process	Front case housing	(b)(4)Trade Secret Process
	Rear Case Housing	
	Battery Cover	
	Tube Connection/Inlet	
	Button	
	Light pipe/led lens	
	Label	

Dressing

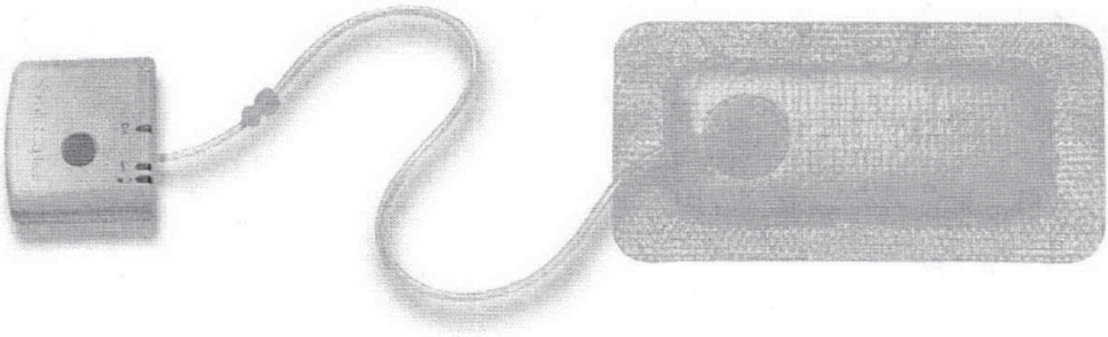
The construction of the dressing is illustrated below in Figure 3 and a photograph of the dressing, connected to the pump, is shown in Figure 4. The dressing construction is comprised of four layers. Firstly, contacting the wound bed, skin or wound filler, is a (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

which negative pressure is delivered to the wound (even when negative pressure is being delivered). Under negative pressure, exudate is removed; flowing through the lower perforated silicone layer, the airflow layer and into a third absorbent fluid holding layer that also contains super-absorbent crystals. Finally the fourth upper layer is a bacteria-impermeable, high MVTR (moisture vapour transmission rate) layer through which fluid can pass as vapour, but through which bulk fluid can not pass, either from the outside into the wound, or out of the dressing into the environment. This high MVTR film combined with the absorbent layer of the dressing is how PICO is able to operate without a canister. There is also a port and tubing attached to the dressing which connects the dressing to the pump and allows air to be removed from the dressing, through a hole in the top film, creating the NPWT effect. The hole in the top film is covered with a (b)(4)Trade Secret membrane located between the port and the top film layer of the dressing, which provides a barrier to prevent the ingress and egress of bacteria whilst allowing air to be pumped out of the dressing. Once the dressing is in place and NPWT has been activated, secondary adhesive film sealing strips are applied to each of the 4 sides to lock the dressing in place and reduce possibilities of air leaks on movement.

(b)(4)Trade Secret Process

Figure 4



A CAD drawing of the dressing (15cm x 20cm) and dressing tubing is enclosed. A copy of the specifications for the PICO Single Use Negative Pressure Wound Therapy System and the PICO Pump are enclosed in the Device Description section.

Dressing Materials

The table below lists each component part of the dressing, its purpose and corresponding specification reference.

Table 2

Material	Function	Specification Ref
(b)(4)Trade Secret Process	Top layer of film over pad – ensures dressings is waterproof and airtight whilst allowing liquid to be flashed off	(b)(4)Trade Secret Process
	Enables the air to be pulled away from the wound	
	Absorbent pad – absorbs exudate and draws it towards the top film	

(b)(4)Trade Secret Process		(b)(4)Trade Secret Process
	Wound contact facing layer – directly placed on the wound and ensures dressing is airtight by sealing the edges of the dressing	
	Construct adhesive between the top film and absorbent pad material	
	Construct adhesive between the wound contact layer and air channel layer	
	Creates an airtight connection between the dressing and the tube (thus to the pump)	
	Provides a barrier over the hole in the top film to prevent the ingress and egress of bacteria whilst allowing air to be pumped out of the dressing	
	Creates an airtight connection between the port (bonded to the dressing) and the pump, enabling air to be removed from the dressing when the pump is switched on and negative pressure wound therapy is being delivered. It also enables the pump to be situated away from the wound.	

Secondary Fixation Strips

Secondary fixation strips are provided to ensure that there are no leaks once the dressing is applied and the pump is switched on. There are 5 fixation strips provided with each dressing, one to be applied to each side of the dressing and one spare. The fixation strips are manufactured from (b)(4)T (b)(4)Trade Secret Process

Dressing and secondary fixation strip sizes are provided in the table below.

Table 3

Code	Dressing size	Fixation Strip Size	No of fixation strips
66800862	4in x 8in	2in x 8in 2in x 10in	2 3
66800863	4in x 12in	2in x 8in 2in x 14in	2 3
66800864	4in x 16in	2in x 8in 2in x 18in	2 3
66800865	6in x 6in	2in x 10in	5
66800866	6in x 8in	2in x 10in	5
66800867	6in x 12in	2in x 10in 2in x 14in	2 3
66800868	8in x 8in	2in x 12in	5
66800869	10in x 10in	2in x 14in	5

PICO is equipped with the following safety alarms:

- Low Battery - visual alarm to alert user when the remaining battery life is less than 24 hours.
- Dressing Leak –visual alarm to alert user of an unacceptable air leak in the system. If the vacuum cannot be maintained within a preset level of motor duty cycle beyond a 30 minute period the system will pause operation, this is indicated by a status (amber) LED. Once the cause of the leak has been corrected the vacuum can be restarted by pressing the orange button.

PICO utilizes software to control the operation of the device. There are 15 modules (managers): each module is responsible for a particular feature of the software. A detailed description of the software is included in section 16. Brief details of each module are provided below:

- **State Manager:** The intent of this module is to control the overall 'state' of the system, which is defined by various system attributes and inputs. The State Manager: 1 - Determines the current state such that it can direct appropriate functionality. 2 - Monitors inputs and attributes of various subsystems to ensure proper transition from one state to another.

- **Self-Test Utilities:** This module includes a set of algorithms to test the various subsystems. This would include:

    1. Application verification
    2. Memory tests
    3. Pump testing
    4. Pressure sensor
    5. LED testing

- **Button Manager:** The Button Manager handles the task of initializing the I/O subsystem to monitor the state of the Pause/Resume button. It also provides methods to report the current state of the button. In addition, it provides an abstraction of the physical momentary pushbutton as a two position slide switch.

- **WDT Manager:** The Watchdog Timer (WDT) Manager is responsible for initializing the microcontroller's internal watchdog timer and providing functionality to reset the timer and handle the timer expiration interrupt.

- **LED Manager:** The LED Manager controls the various combinations of LED illumination to communicate the current state of the system to a patient under NPWT.

- **NVM Manager:** The Non-Volatile Memory (NVM) Manager is responsible for providing the methods for writing NVM memory internal to the microcontroller. Read operations are the same as for RAM sections, but write operations require special timing and algorithms.

- **In-Circuit Test Manager:** The In-Circuit Test Manager provides the functionality to communicate with the system to: 1 - Provide debug and development support, and 2 - Provide manufacturing test support.

- **Sleep Manager:** The system is battery powered and, therefore, should conserve power whenever the system is waiting to do work. The Sleep Manager provides the functionality to put the microcontroller and unused peripherals into a low power mode until the time some useful work is required to be performed. In addition to managing the use of low power states the Sleep Manager also maintains a set of software based timers to initiate periodic actions.

- **Pump Manager:** The Pump Manager is intended to monitor the duty cycle of the pump motor and to provide functionality to turn the pump motor on and off at max speed and a lower and quieter speed.

- **Battery Manager:** The Battery Manager is intended to monitor various subsystems to ensure the system has enough power to deliver an NPWT. The primary subsystem monitored is the battery but also includes inputs from other systems to predict when the system has approximately 24 hours of power remaining.

- **Pressure Sensor Manager:** The Pressure Sensor Manager is responsible for reading the voltage output from the pressure sensor, compensating for the lack of a constant current source in the hardware, compensating for variances in temperature, and converting the compensated voltage to mmHg values.

- **Temperature Sensor Manager:** The Temperature Sensor Manager is responsible for reading the voltage output from the temperature sensor internal to the microcontroller and converting that voltage to a temperature value in degrees Centigrade.

- **CLI Manager:** The CLI Manager handles the low level tasks associated with the serial communications interface to the system. Functionality in this driver would include interfacing with the internal serial communications interface (SCI) of the microcontroller to:

  1. Initialize the SCI peripheral,
  2. Algorithms to send and receive data

- **RTC Manager:** The Real-Time Clock (RTC) Manager is responsible for initializing the microcontroller's internal RTC peripheral wake-up timer (WUT). The WUT is used to provide a variable time interrupt to the microcontroller to exit low power mode.

- **ADC Manager:** The Analog-To-Digital Convertor (ADC) Manager initializes the microcontroller's internal ADC subsystem. It also provides methods to read the values of the ADC channels.

Device Comparison

PICO Single Use Negative Pressure Wound Therapy System is equivalent to NPD 1000 Negative Pressure Wound Therapy System (K080275) in that they are both battery powered, utilise a diaphragm pump, are portable and utilise a dressing to manage exudate generated by the wound. PICO is equivalent to both NPD 1000 Negative Pressure Wound Therapy System (K080275) and Renasys Go (K083375) in that they all contain pressure controls, software controls, provide continuous negative pressure wound therapy and operate within a similar pressure range.

Device Comparison Table

The following table outlines the differences of PICO compared to the predicate devices.

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Manufacturer:	Smith & Nephew Medical Ltd.	Smith & Nephew Inc.	Kalypto Medical
Intended Use:	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. Examples of appropriate wound types include: Incision sites, Chronic Acute Traumatic Subacute and dehisced wounds	Indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	A portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudates and infectious material which may promote wound healing.

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
	(b)(4)Trade Secret Process		
Environment of use	Hospital, home	Hospital, home, long term care	Home use primarily
Patient Population	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)
Materials:	(b)(4)Trade Secret Process		Unknown
Single-use or Reusable:	Single use	Reusable	Reusable
Method of Sterilization:	Pump is non sterile Dressing and fixation strips sterilised by ethylene oxide	Pump is non sterile	Pump is non sterile Dressing is sterilised by irradiation
Biocompatibility:	Dressing complies with ISO 10993	Not applicable	Unknown
Design:	Single use negative pressure wound therapy (NPWT) system consisting of a small, portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. Exudate is collected in the dressing; there is no canister.	Portable, re-usable negative pressure wound therapy (NPWT) pump designed to be used with associated dressings and canisters for exudates collection. Delivers continuous or intermittent negative pressure at settings between	Portable, re-usable, battery operated negative pressure wound therapy (NPWT) pump designed to be used with associated wound dressings; there is no canister. Delivers continuous or intermittent negative pressure at settings between 40 - 125mmHg.

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
	Designed to deliver between (b)(4)Trade Secret Process (nominal) continuous negative pressure for up to 7 days.	40 - 200mmHg. Battery or mains powered.	
Type of Pump:	Diaphragm Pump controlled by Microprocessor	Diaphragm Pump	Microprocessor controlled pump
Battery Type:	AA lithium (2)	Lithium Ion	AA alkaline (3)
Operating Pressure Range:	(b)(4)Trade Secret Process	-40 to -200 mmHg	-40 to -125mmHg
Bacterial Filter Size:		0.2 micron filter 1.0 micron filter on canister	Unknown
Pressure Controls:	Sensors, Software	Sensors, Software	Sensors
Maximum Flow Rate:	(b)(4)Trade Secret Process	6.5 litres per minute	Unknown
Alarms:	OK Low battery Leak/Intervention required	Low Battery High Vacuum Low Vacuum Over Vacuum Tubing blocked/canister full High Flow/Leak	Low Battery Leak Full Dressing/system fault
Pump Dimensions:	3.5 x 3.5 x 1.0"	7" x 8.5" x 3.5"	3.2 x 5.1 x 1.3"
Operation:	Continuous	Continuous and Intermittent	Continuous and Intermittent
Accessories:	Carry bag	Gauze and Foam Dressing Kits Large and Small Canisters	Fluid-absorbing Dressings with Silver wound contact layer
Electrical Safety Testing:	Complies with IEC 60601-1, IEC 60601-1-2, UL	Complies with IEC 60601-1, IEC 60601-1-2, UL	Complies with IEC 60601-1, IEC 60601-1-2

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
	60601-1	60601-1	
Software controlled:	Yes	Yes	Yes
Fluid handling capacity	4" x 8" dressing 40cc – 100cc 10" x 10" dressing 200cc – 480cc	Cannisters which hold upto 300ml and 800ml	Dressings ranging from 25cc to 140cc of volume
Dressing sizes	4" x 8", 4" x 12", 4" x 16", 6" x 6", 6" x 8", 6" x 12", 8" x 8", 10" x 10"	Gauze 3" x 3", 3" x 8" Film drape 4" x 4.5", 12" x 8" Foam 4" x 3" 1", 8" x 5" x 1"	5" x 6.5", 2" x 3.5", 3.5" x 5", 8.6" x 8.7"
Dressing materials of construction	Dressing (b)(4)Trade Secret Process Secondary fixation strips: (b)(4)Trade Secret Process	PU Foam (b)(4)Trade Secret Process	Non woven pad Silver coated wound contact layer
Mode of action	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister	Removal of air and exudate from wound to create NPWT. Exudate removed to a canister.	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister

Based on comparison to the predicate devices, it has been determined that PICO Single Use Negative Pressure Wound Therapy System is substantially

equivalent to the predicate devices in terms of technology, specifications, method of operation and indications for use.

Summary of Performance Testing

Software validation has been completed on the pump and the following operations have successfully passed:

- Start up Process
- Shutdown Process
- Operating Modes and States
- Device Test State
- Common Tasks for NPWT Operating Mode
- Power-on Self Test (POST) State
- Manually Paused State
- Paused State
- Operational State
- Initial Pump Down
- Wait for Retry
- Monitor Pressure
- Maintenance Pump Down
- Non-Recoverable Error (NRE) State
- End of Life (EOL) State
- Sampling
- Visual Indicators

In addition to the software validation, performance testing has been completed to confirm the following design inputs:

Design Input	Performance requirement	Pass/Fail
System minimises the exposure of the user and environment to biohazard present in the collected wound fluid and exhaust air.	(b)(4)Trade Secret Process	PASS PASS
Dressing, port and tube will ensure NPWT is applied to the wound when the pump is switched on		PASS
Pump will operate in any orientation and whilst the patient is moving		PASS

Pump can be used for upto 7 days	(b)(4)Trade Secret Process	PASS
The dressing can manage fluid in vertical and horizontal positions throughout its wear time whilst maintaining NPWT.		PASS PASS
Wound exudate is not able to enter the pump		PASS

Dressing can manage exudate	(b)(4)Trade Secret Process	PASS
The dressing will be backed by a semi-occlusive top film to maintain a moist wound healing environment		PASS
The dressing will be backed by a waterproof barrier film to prevent liquid strike-thorough or penetration		PASS

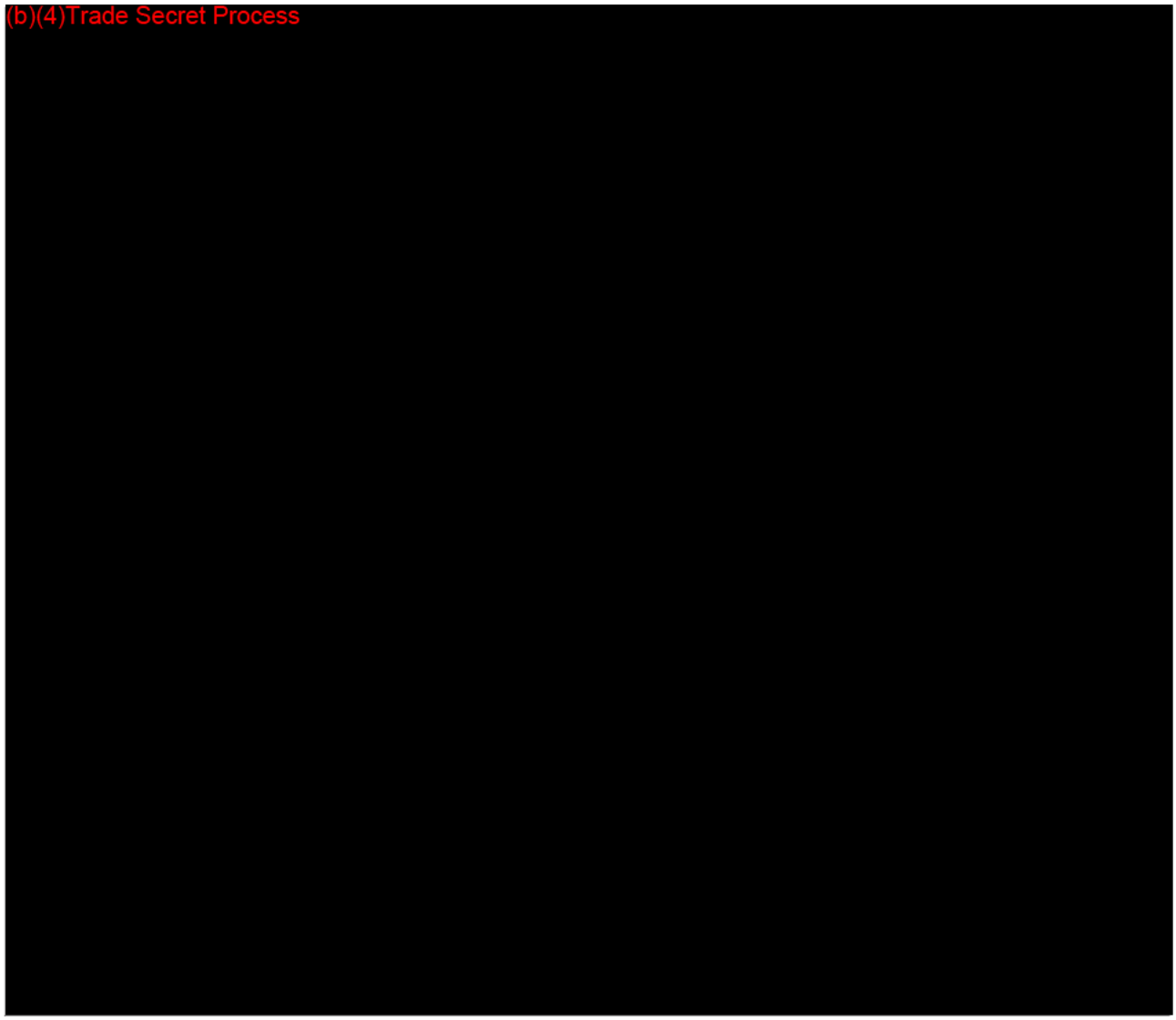
The design of the dressing is such that it provides a barrier to minimise the ingress of bacteria.	(b)(4)Trade Secret Process	PASS PASS PASS

Copies of the above referenced reports are enclosed.

DEVICE DESCRIPTION

PICO Single Use Negative Pressure Wound Therapy System is a single use Negative Pressure Wound Therapy System (NPWT) consisting of a small portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. PICO is capable of delivering 80mmHg (nominal) negative pressure to the wound surface and managing low to moderate levels of exudate generated by the wound. The super absorbent dressing absorbs exudate generated by the wound. The system comprises of 2 tray sets to provide therapy for up to 7 days.

(b)(4)Trade Secret Process



Device Description

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable, electro-mechanical pump system connected through a flexible tube to a super-absorbent, gentle adhesive dressing. Secondary fixation strips are also provided to ensure an adequate seal is achieved. The pump is supplied non-sterile, the dressing and fixation strips are supplied sterile and all are supplied as single use. PICO delivers negative pressure wound therapy to a range of acute and chronic wound types. PICO achieves this in the same way as the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275) and Renasys Go (K083375).

PICO Single Use Negative Pressure Wound Therapy System comprises of two tray sets to provide therapy for up to 7 days. Both trays contain one dressing and 5 secondary fixation strips. The trays are manufactured from (b)(4)Trade Secret Process (b)(4)Trade and are sealed with a Tyvek lid. The trays are placed into a carton and sent for ethylene oxide sterilisation. Once sterilisation is complete the product is returned to Smith & Nephew Medical Ltd where a third tray containing a non sterile pump, two lithium batteries and the Instructions for Use are placed into the carton; along with the two dressing trays. The tray containing the pump and batteries is manufactured from the same material as the dressing tray. The tray is contained within a tray sleeve to ensure the pump and batteries remain in place. Drawings of the dressing tray and pump tray are enclosed in the Sterilisation, Shelf Life and packaging section.

Pump

The PICO pump unit incorporates an electric motor driven twin-diaphragm vacuum pump, this is connected through a 1-way valve (b)(4)Trade Secret Process from the pump mechanism. The pump is powered by 2 AA Lithium batteries which can provide up to 168 hours (7 days) of battery life; this is dependent upon the air leak rate of the attached dressing. The batteries can be replaced if required by removal of the battery cover. The pump is designed to stop working after 168 hours (7 days) of use; this is achieved through a timer in the software. The pump will stop and not re-start after this time, even with new batteries. Negative pressure will not be applied following this. PICO is initiated by insertion of the batteries, the device automatically performing a self-test. Pressing the orange button then initiates the pump. PICO operates within a pressure range of -(b)(4)Trade Secret Process (80mmHg nominal) and is non-adjustable. The pump incorporates a hardware circuit on the PCBA that de-activates the pump for vacuum exceeding levels which may cause discomfort or harm (b)(4)Trade Secret Process The pump also includes a mechanism in the software that suspends operation after a period of 30 minutes if the leak rate (b)(4)Trade Secret Process is above a pre-set level; this condition initiates the amber 'air leak' alarm and suspends operation of the pump. Re-activation is achieved by pressing the orange button. PICO is equipped with two alarms; low battery and air leak, these are amber blinking LED's. When PICO is operating under normal conditions; with no air leaks and the battery level is not low; this is indicated by a green blinking LED.

Figure 1 below shows the internal and external view of the pump. Drawings of the main components and sub-assemblies are enclosed.

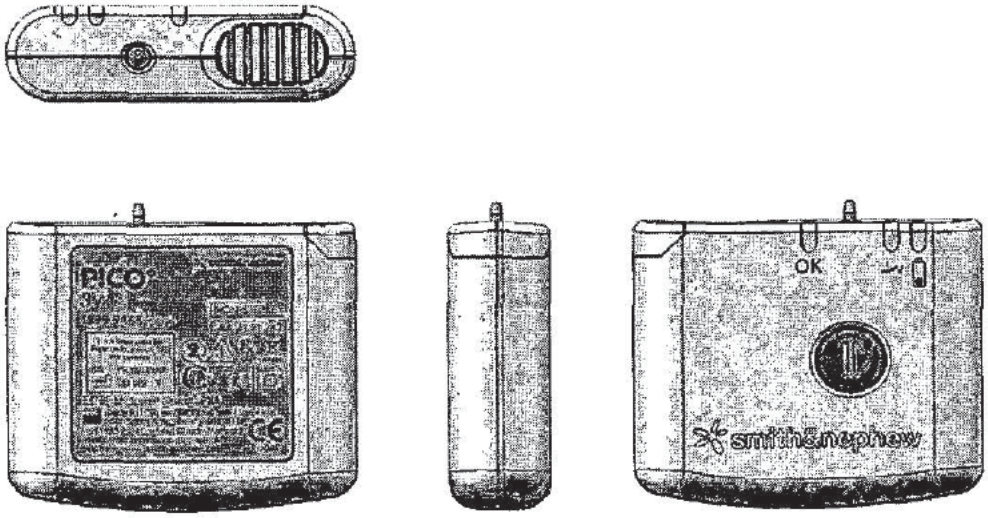
Component Parts

Figure 1: Internal Exploded View

(b)(4)Trade Secret Process

1	Rear Housing
2	Front Housing
3	Pump Assembly
4	Inlet Tube
5	Inlet Manifold
6	1-Way Valve
7	Battery Cover
8	PCBA
9	Battery Contacts
10	Screws
11	Label
12	Label for Serial Number

Figure 2: External View



Pump Casing Materials

The table below lists the materials used in the manufacture of the pump case, and includes the corresponding specification reference.

Table 1

Material	Function	Specification Reference
(b)(4)Trade Secret Process		

Dressing

The construction of the dressing is illustrated below in Figure 3 and a photograph of the dressing, connected to the pump, is shown in Figure 4. The dressing construction is comprised of four layers. Firstly, contacting the wound bed, skin or wound filler, is a perforated silicone adhesive layer which aids re-positioning of the dressing to ensure good application. Above this is a unique 3D (three dimensional) second layer composed of two knitted layers separated by vertically oriented fibres that make an open airflow layer through which negative pressure is delivered to the wound (even when negative pressure is being delivered). Under negative pressure, exudate is removed; flowing

(b)(4)Trade Secret Process

through which fluid can pass as vapour, but through which bulk fluid can not pass, either

from the outside into the wound, or out of the dressing into the environment. This high MVTR film combined with the absorbent layer of the dressing is how PICO is able to operate without a canister. There is also a port and tubing attached to the dressing which connects the dressing to the pump and allows air to be removed from the dressing, through a hole in the top film, creating the NPWT effect. The hole in the top film is covered with a (b)(4)Trade Secret membrane located between the port and the top film layer of the dressing, which provides a barrier to prevent the ingress and egress of bacteria whilst allowing air to be pumped out of the dressing. Once the dressing is in place and NPWT has been activated, secondary adhesive film sealing strips are applied to each of the 4 sides to lock the dressing in place and reduce possibilities of air leaks on movement.

(b)(4)Trade Secret Process

Figure 4

A CAD drawing of the dressing (15cm x 20cm) and dressing tubing is enclosed. A copy of the specifications for the PICO Single Use Negative Pressure Wound Therapy System and the PICO Pump are enclosed.

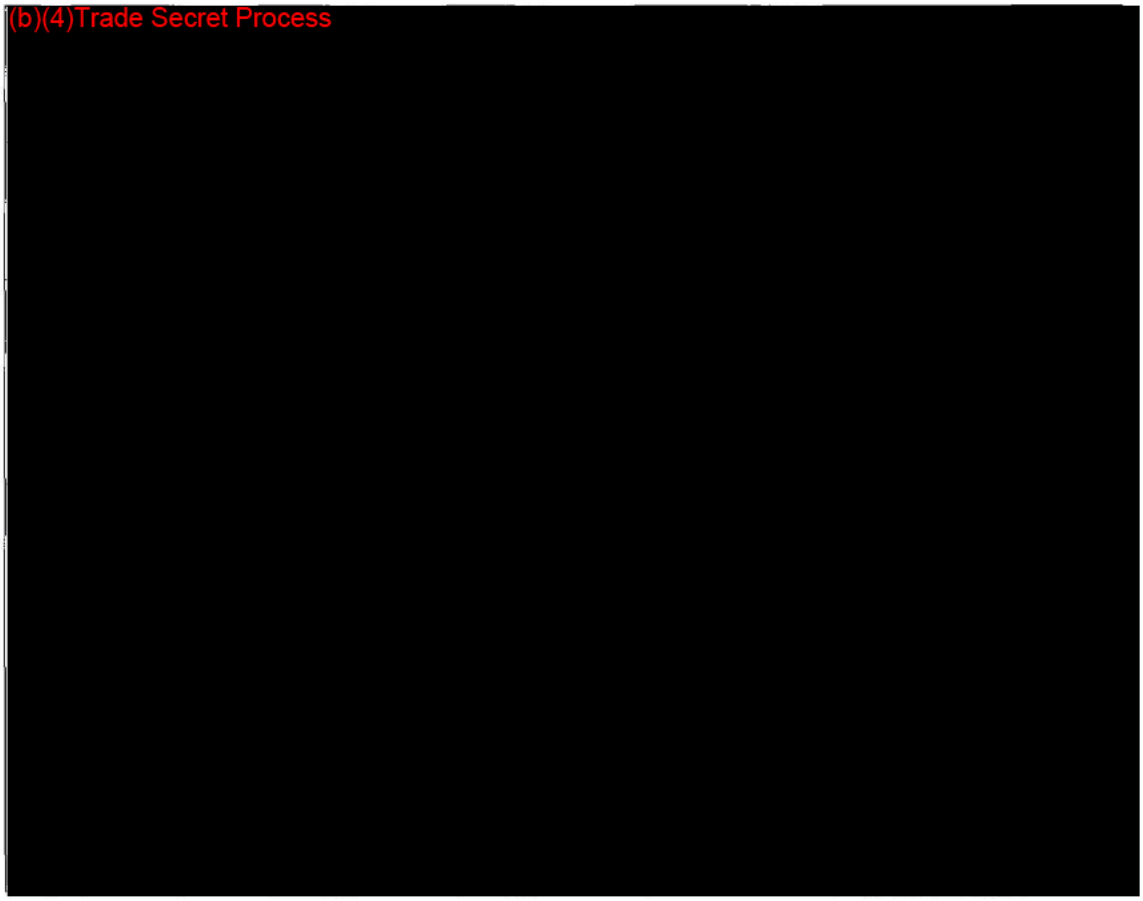
Dressing Materials

The table below lists each component part of the dressing, its purpose and corresponding specification reference.

Table 2

Material	Function	Specification Ref
(b)(4)Trade Secret Process		

(b)(4)Trade Secret Process



Secondary Fixation Strips

Secondary fixation strips are provided to ensure that there are no air leaks once the dressing is applied and the pump is switched on. There are 5 fixation strips provided with each dressing, one to be applied to each side of the dressing and one spare. The fixation strips are manufactured from a polyurethane film coated with an acrylic adhesive.

Dressing and secondary fixation strip sizes are provided in the table below.

Table 3

Code	Dressing size	Fixation Strip Size	No of fixation strips
66800862	4in x 8in	2in x 8in 2in x 10in	2 3
66800863	4in x 12in	2in x 8in 2in x 14in	2 3
66800864	4in x 16in	2in x 8in 2in x 18in	2 3
66800865	6in x 6in	2in x 10in	5
66800866	6in x 8in	2in x 10in	5
66800867	6in x 12in	2in x 10in 2in x 14in	2 3
66800868	8in x 8in	2in x 12in	5
66800869	10in x 10in	2in x 14in	5

PICO is equipped with the following safety alarms:

- Low Battery - visual alarm to alert user when the remaining battery life is less than 24 hours.
- Dressing Leak – visual alarm to alert user of an unacceptable air leak in the system. If the vacuum cannot be maintained within a preset level of motor duty cycle beyond a 30 minute period the system will pause operation, this is indicated by a status (amber) LED. Once the cause of the leak has been corrected the vacuum can be restarted by pressing the orange button.

Device Comparison Table

The following table outlines the differences of PICO compared to the predicate devices.

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Manufacturer:	Smith & Nephew Medical Ltd.	Smith & Nephew Inc.	Kalypto Medical
Intended Use:	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. Examples of appropriate wound types include: Incision sites,	Indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	A portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudates and infectious material which may promote wound healing.

	New Device: PICO Single Use Negative Pressure Wound Therapy System	Predicate Device: Smith & Nephew Renasys GO 510(k) # K083375	Predicate Device: Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System 510(k) # K080275
	(b)(4)Trade Secret Process		
Environment of use	Hospital, home	Hospital, home, long term care	Home use primarily
Patient Population	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)
Materials:	(b)(4)Trade Secret Process		Unknown
Single-use or Reusable:	Single use	Reusable	Reusable
Method of Sterilization:	Pump is non sterile Dressing and fixation strips sterilised by ethylene oxide	Pump is non sterile	Pump is non sterile Dressing is sterilised by irradiation
Biocompatibility:	Dressing complies with ISO 10993	Not applicable	Unknown
Design:	Single use negative pressure	Portable, re-usable negative pressure	Portable, re-usable, battery operated

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
	wound therapy (NPWT) system consisting of a small, portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. Exudate is collected in the dressing; there is no canister. Designed to deliver between (b)(4)Trade Secret Process (nominal) continuous negative pressure for up to 7 days.	wound therapy (NPWT) pump designed to be used with associated dressings and canisters for exudates collection. Delivers continuous or intermittent negative pressure at settings between 40 - 200mmHg. Battery or mains powered.	negative pressure wound therapy (NPWT) pump designed to be used with associated wound dressings; there is no canister. Delivers continuous or intermittent negative pressure at settings between 40 - 125mmHg.
Type of Pump:	Diaphragm Pump controlled by Microprocessor	Diaphragm Pump	Microprocessor controlled pump
Battery Type:	AA lithium (2)	Lithium Ion	AA alkaline (3)
Operating Pressure Range:	(b)(4)Trade Secret Process	-40 to -200 mmHg	-40 to -125mmHg
Bacterial Filter Size:		0.2 micron filter 1.0 micron filter on canister	Unknown
Pressure Controls:	Sensors, Software	Sensors, Software	Sensors
Maximum Flow Rate:	(b)(4)Trade Secret Process	6.5 litres per minute	Unknown
Alarms:	OK	Low Battery	Low Battery

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
	Low battery Air leak/Intervention required	High Vacuum Low Vacuum Over Vacuum Tubing blocked/canister full High Flow/Leak	Leak Full Dressing / system fault
Pump Dimensions:	3.5 x 3.5 x 1.0"	7" x 8.5" x 3.5"	3.2 x 5.1 x 1.3"
Operation:	Continuous	Continuous and Intermittent	Continuous and Intermittent
Accessories:	Carry bag	Gauze and Foam Dressing Kits Large and Small Canisters	Fluid-absorbing Dressings with Silver wound contact layer
Electrical Safety Testing:	Complies with IEC 60601-1, IEC 60601-1-2, UL 60601-1	Complies with IEC 60601-1, IEC 60601-1-2, UL 60601-1	Complies with IEC 60601-1, IEC 60601-1-2
Software controlled:	Yes	Yes	Yes
Fluid handling capacity	4" x 8" dressing 40cc – 100cc 10" x 10" dressing 200cc – 480cc	Cannisters which hold upto 300ml and 800ml	Dressings ranging from 25cc to 140cc of volume
Dressing sizes	4" x 8", 4" x 12", 4" x 16", 6" x 6", 6" x 8", 6" x 12", 8" x 8", 10" x 10"	Gauze 3" x 3", 3" x 8" Film drape 4" x 4.5", 12" x 8" Foam 4" x 3" 1", 8" x 5" x 1"	5" x 6.5", 2" x 3.5", 3.5" x 5", 8.6" x 8.7"

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Dressing materials of construction	Dressing: (b)(4)Trade Secret Process Secondary fixation strips: (b)(4)Trade Secret Process	PU Foam (b)(4)Trade Secret Process	Non woven pad Silver coated wound contact layer
Mode of action	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister	Removal of air and exudate from wound to create NPWT. Exudate removed to a canister.	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister

Based on comparison to the predicate devices, it has been determined that PICO Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate devices in terms of technology, specifications, method of operation and indications for use.

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

(b)(4)Trade Secret Process - Design Drawing

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(b)(4)Trade Secret Process - Design Drawing

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SPECIFICATION

Pico

(b)(4)Trade Secret Process

[redacted]

SPECIFICATION

Pico

Product Information

PICO is a miniaturized wound management device, where the purpose of this device will be to provide Negative Pressure Wound Therapy (NPWT). The device will comprise a self- contained and portable electro-mechanical pump system connected through a flexible tube to a dressing at the wound. The pump unit will be powered by 2 AA batteries.

The aim of the dressing is to manage exudate generated by the wound while applying negative pressure to the wound via a pump system. The exudate management will be achieved by the combination of the absorption layer drawing the exudate away from the wound and the top film flashing the moisture away. The negative pressure created by the pump system will be delivered to the dressing through an air permeable / liquid impermeable filter membrane in order to protect the pump system from the liquid exudate. The filter is adhered to a port (which allows connection between the dressing and tubing) which is adhered to the top of the dressing. An air channel layer will ensure connection between the filter membrane and the wound. The dressing (including the port, tubing and fixation strips) will be packed in a sealed tray. Two sealed trays will be placed into a carton, where one sealed tray will be sealed inside a breather bag.

The dressing and fixation strips are sterilised in accordance with 'BS EN ISO 11135-1:2007 sterilisation of healthcare products –Ethylene Oxide –part 1.'

Also inside the carton is placed a poly bag containing an IFU and a tray (containing a pump and two batteries). These items are non-sterile.

The dressing product will be manufactured in the following sizes:-
15cm x 20cm, 10cm x 30cm, 15cm x 15cm, 20cm x 20cm, 10cm x 20cm.

Shelf Life

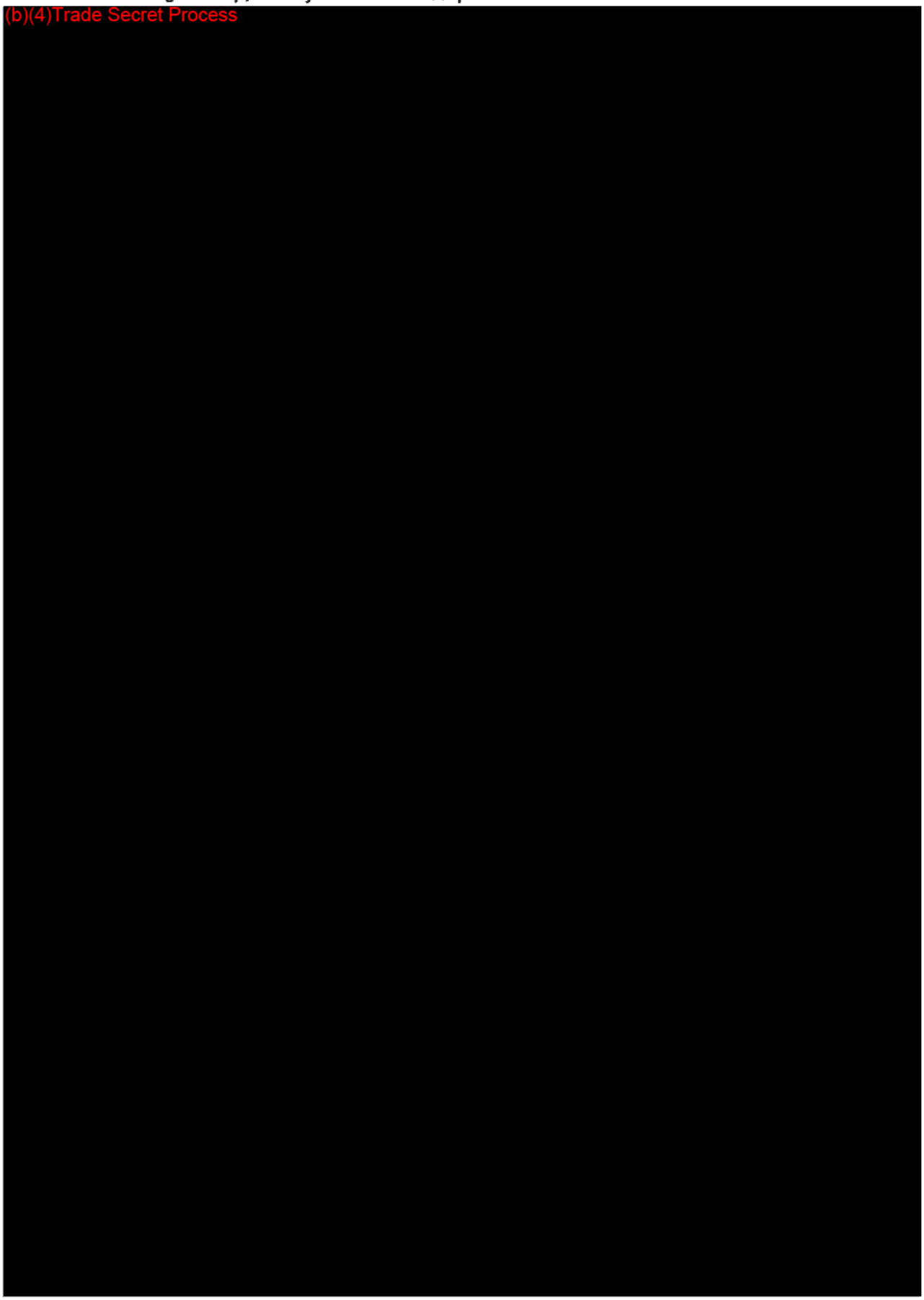
(b)(4)Trade Secret Process

Product Testing - Dressing Parameters

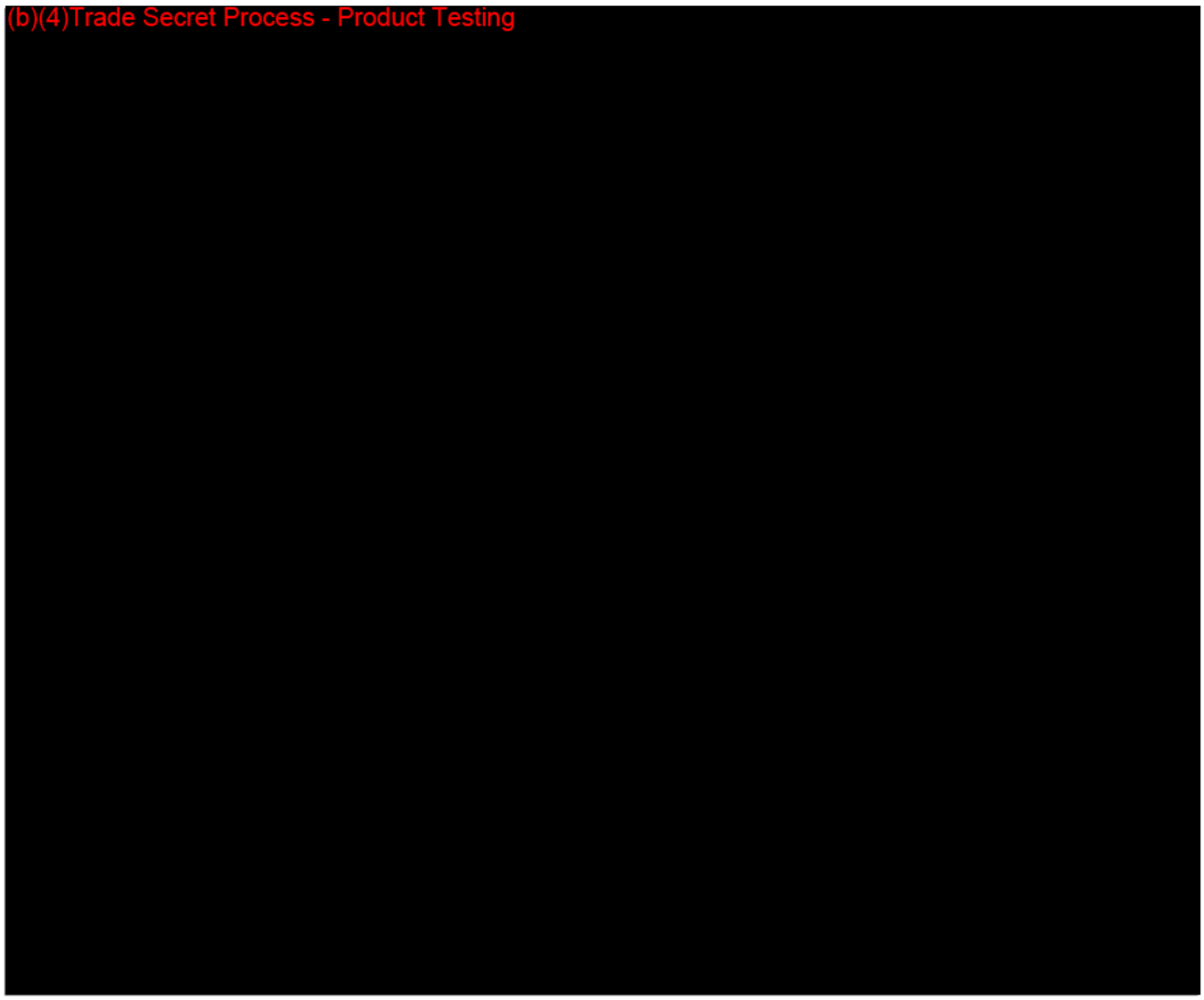
(b)(4)Trade Secret Process

Product Testing – Pump, Battery and Fixation Strip

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process - Product Testing



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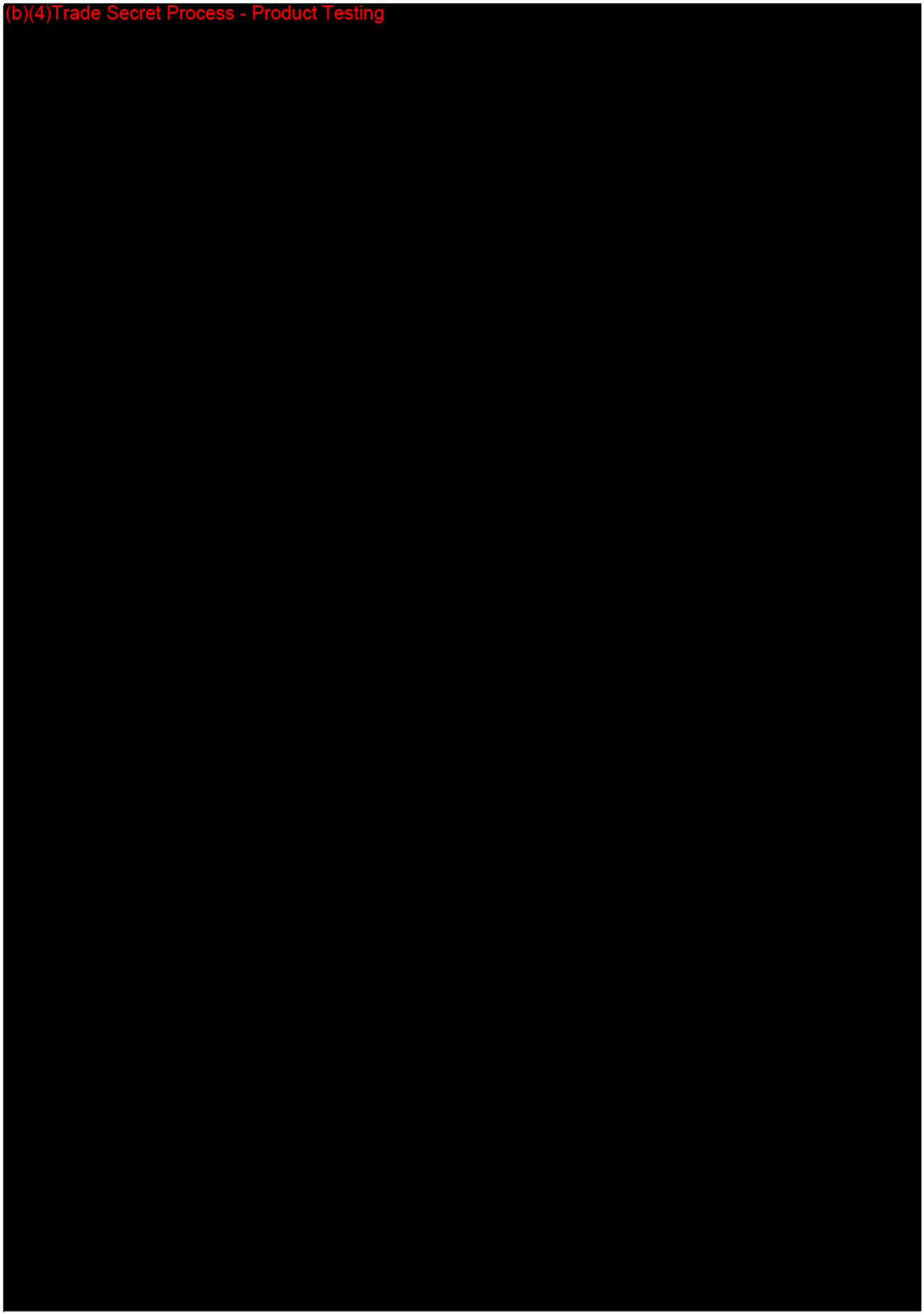

(b)(4)Trade Secret Process

[redacted]

Product Code(s):

66800862, 66800863, 66800865, 66800866, 66800868

*** END OF DOCUMENT ***

(b)(4)Trade Secret Process

[redacted]

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We are smith&nephew

SPECIFICATION

Pico Pump System (Poole)

(b)(4)Trade Secret Process

[redacted]

SPECIFICATION

Pico Pump System (Poole)

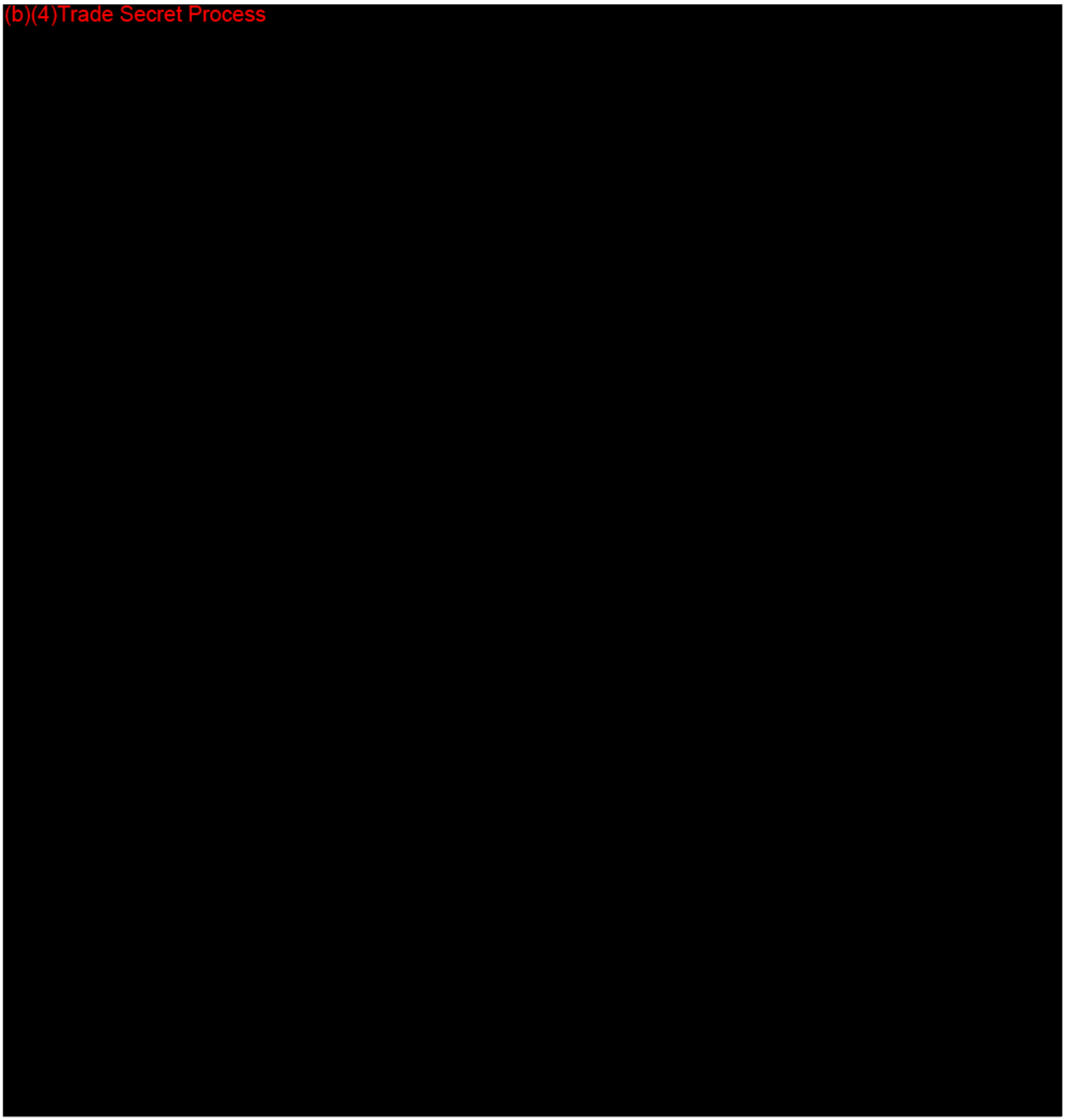
General Information

General Description: A miniaturised wound management device to provide vacuum therapy to wounds, the purpose of this device will be to provide Negative Pressure Wound Therapy (NPWT) to a range of wound types. The device will comprise a self-contained and portable electro-mechanical pump system (with minimal assembly) connected through a flexible tube to a dressing at the wound. The electro-mechanical pump system will incorporate an electrically driven diaphragm vacuum pump powered by batteries; the unit will be disposable after a single use.

Product name: Pico Pump

Grade: N/A

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process

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Device Labels

Smith & Nephew Record	
Item:	PICO Device Label (non-sterile version)
Code:	N/A
This BSC/Asset:	18999465 / 24764
Prev BSC/Asset:	N/A
Date:	24.02.2011
This Revision:	05

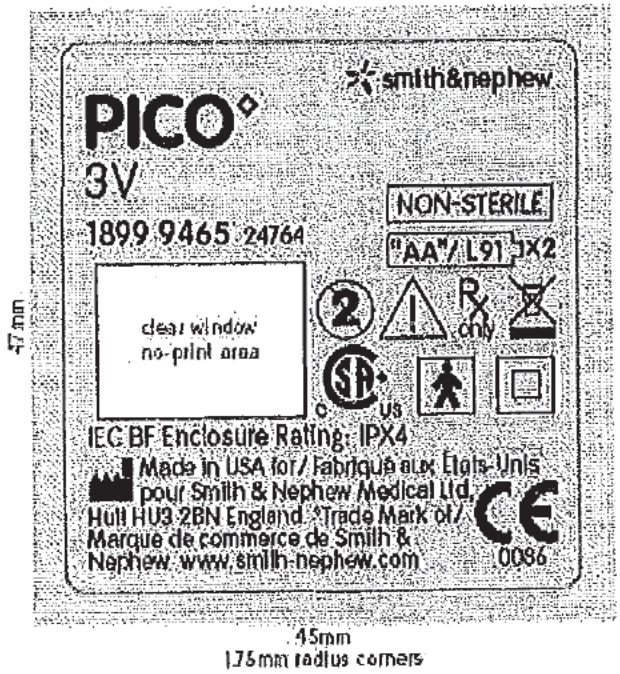
ADAMS DESIGN Record	
Job No:	TT-NP.01.00
Dims:	47mm x 45mm 1.75mm radius corners
Colours: (Match to Pantone colors)	Black PMS Cool Gray1

Underlabelling behind clear window area :-

7 x 18mm area for Flexmedical EAN 128 xxxxxxxxx

SN PRYMDNNN

DD MM YY



(b)(4)Trade Secret Process

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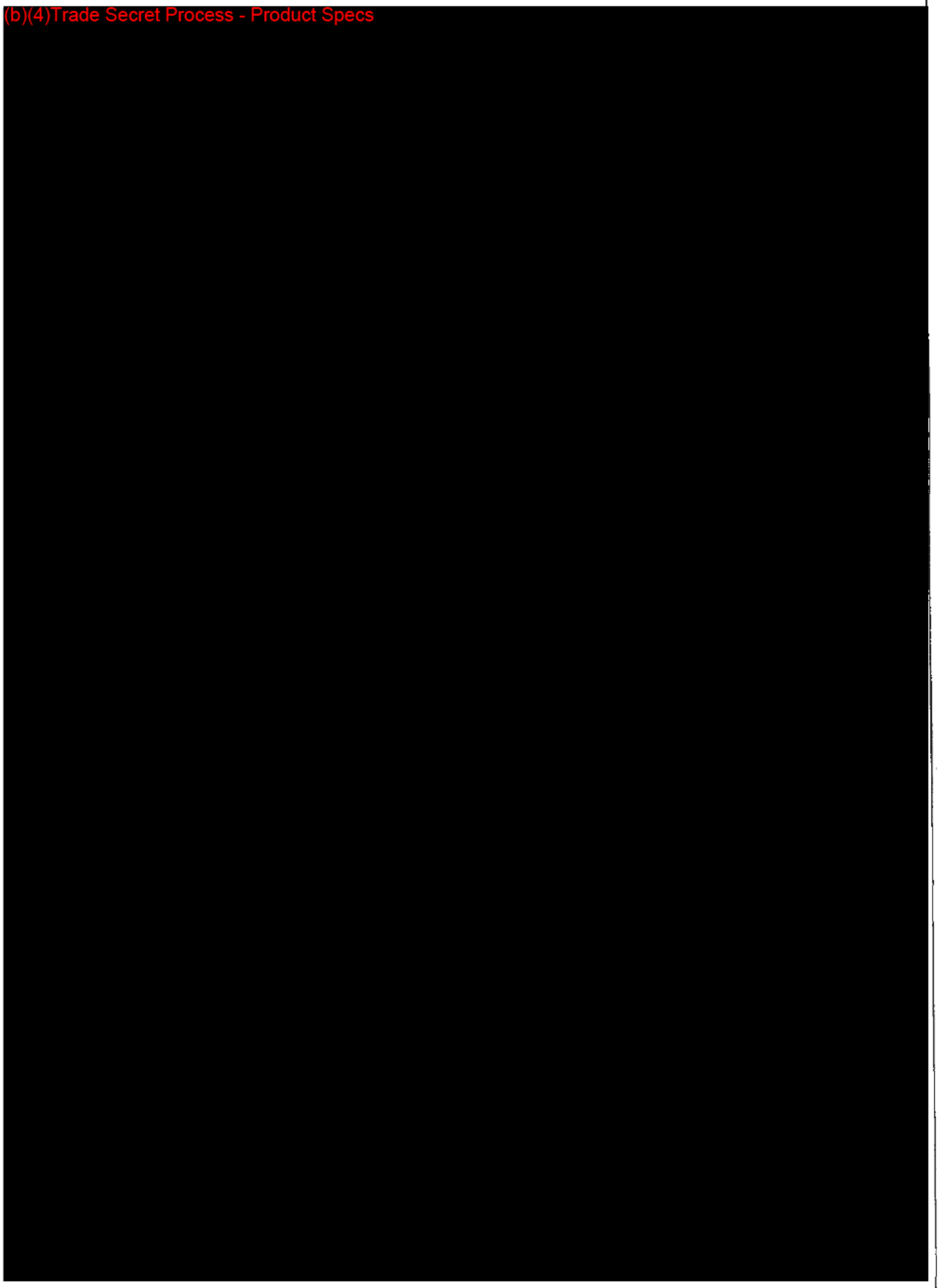
(b)(4)Trade Secret Process - Product Specs



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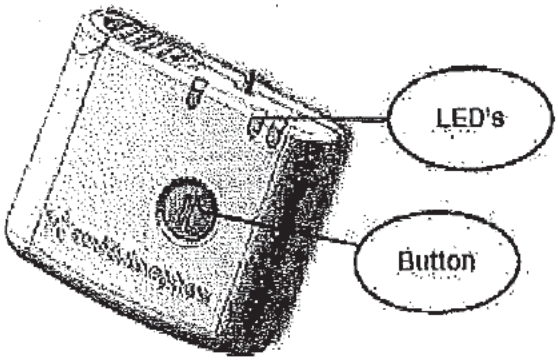
External View



(b)(4)Trade Secret Process - Product Specs

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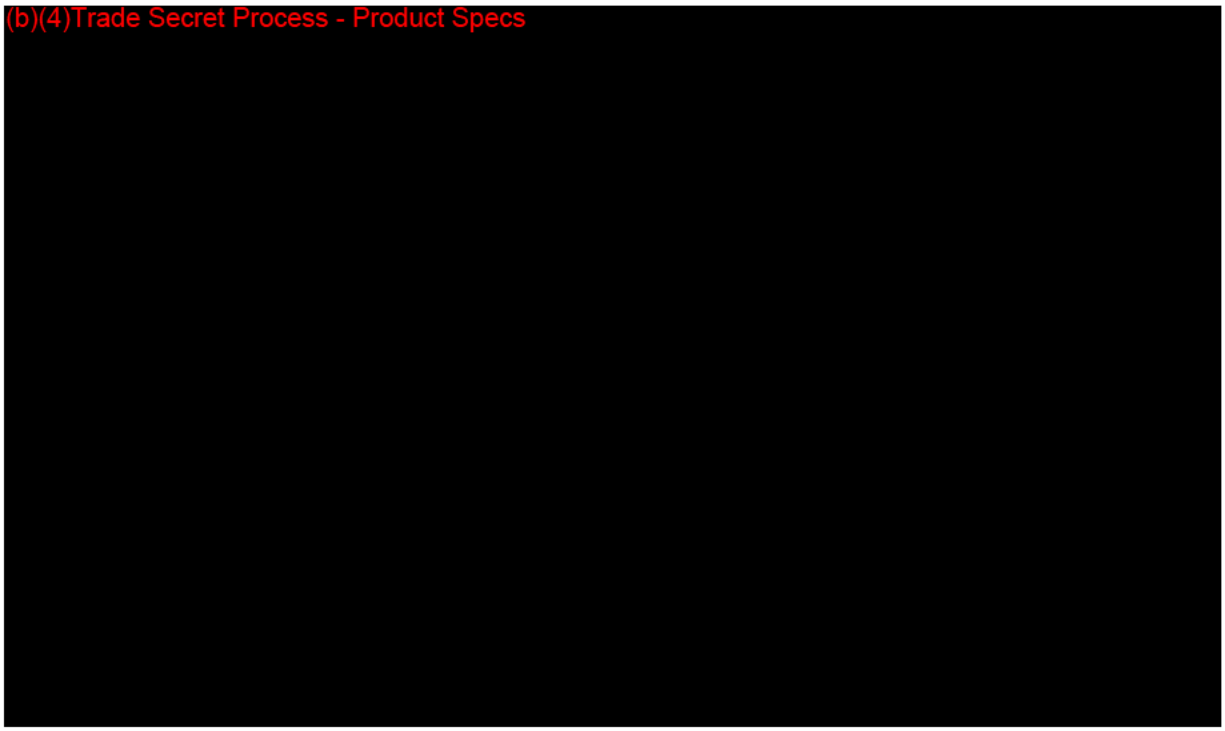
System Schematic

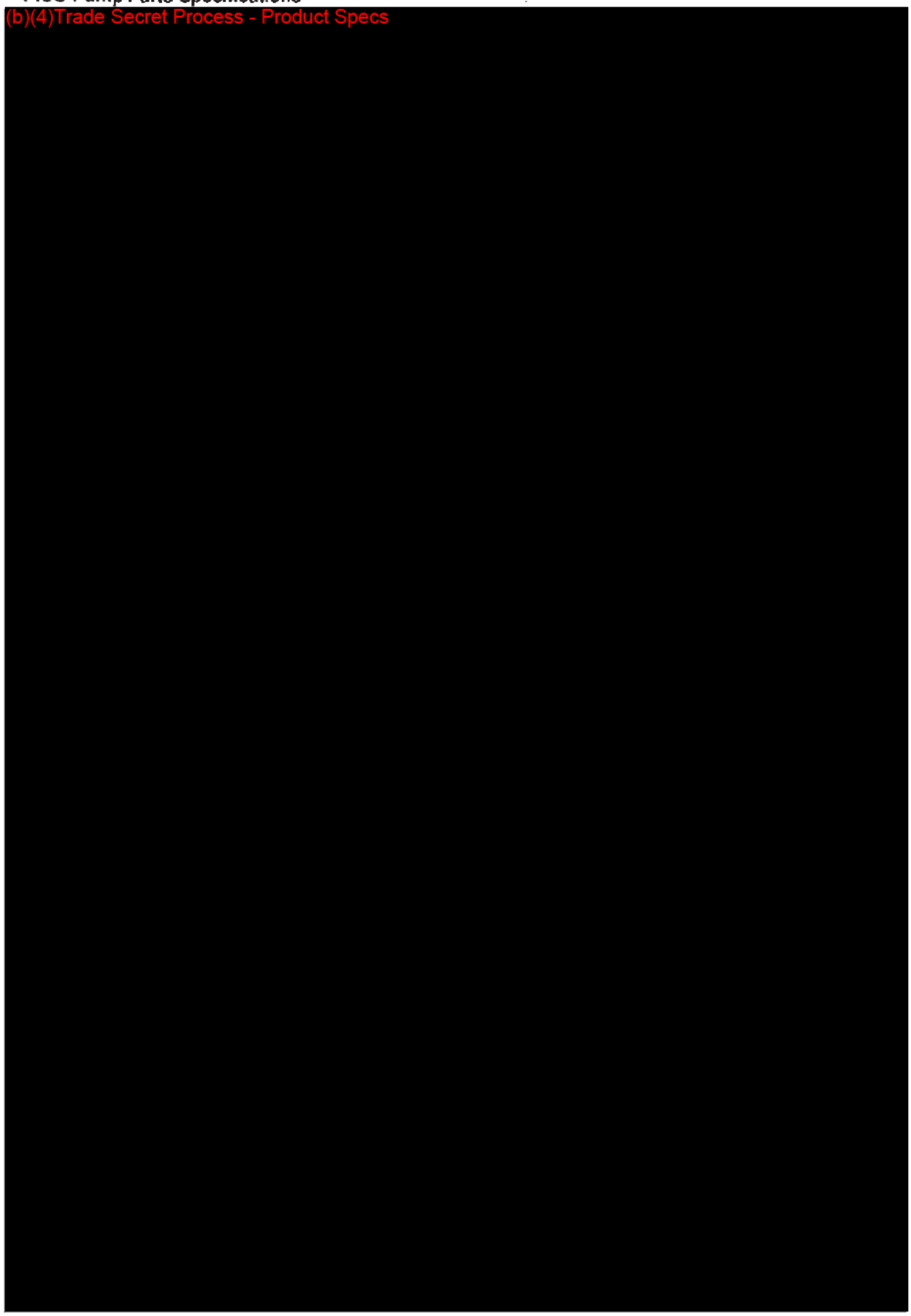
(b)(4)Trade Secret Process - Product Specs



(b)(4)

PICO Pump Parts Specifications

(b)(4)Trade Secret Process - Product Specs



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(b)(4)Trade Secret Process - Product Specs

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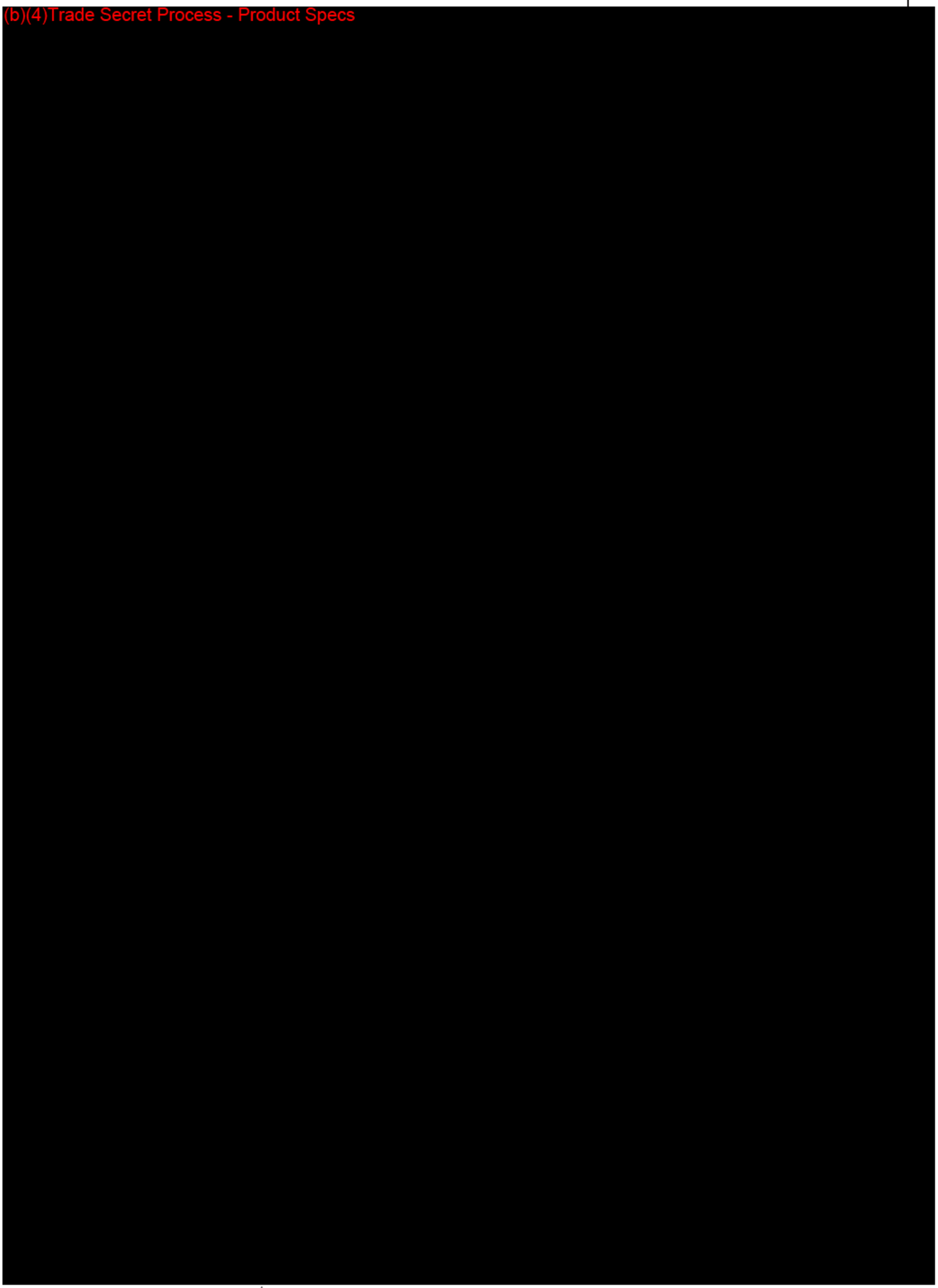
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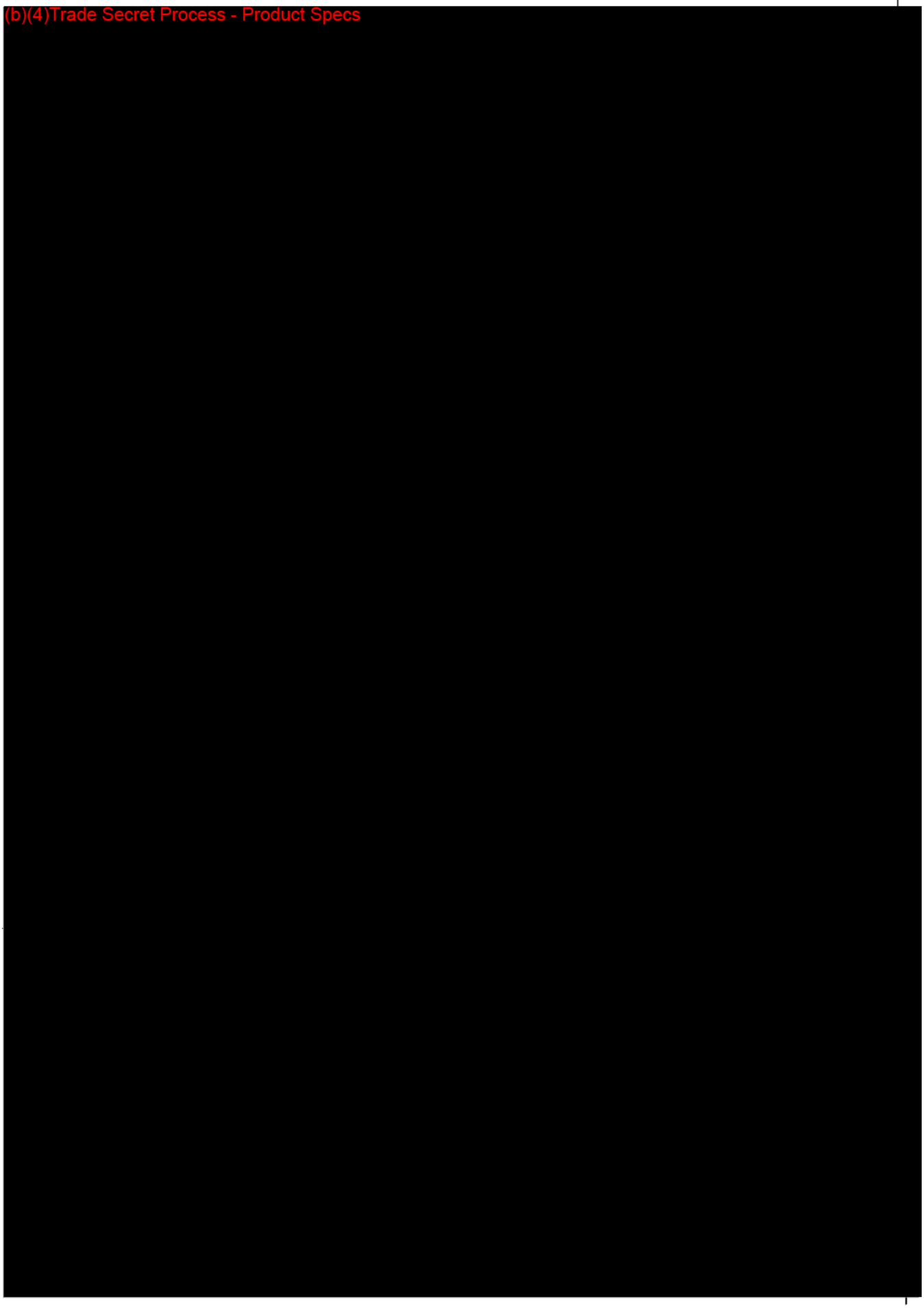
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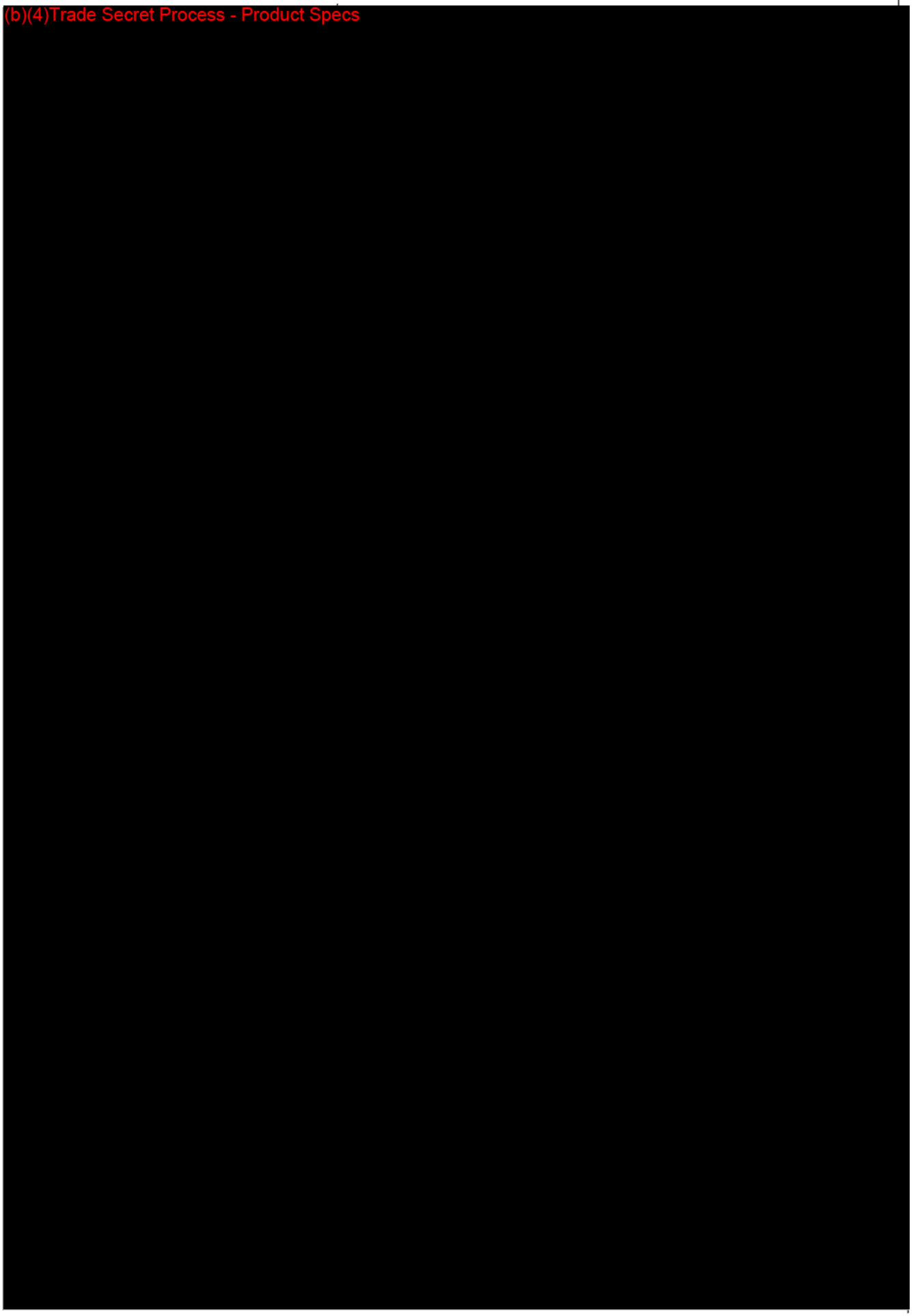
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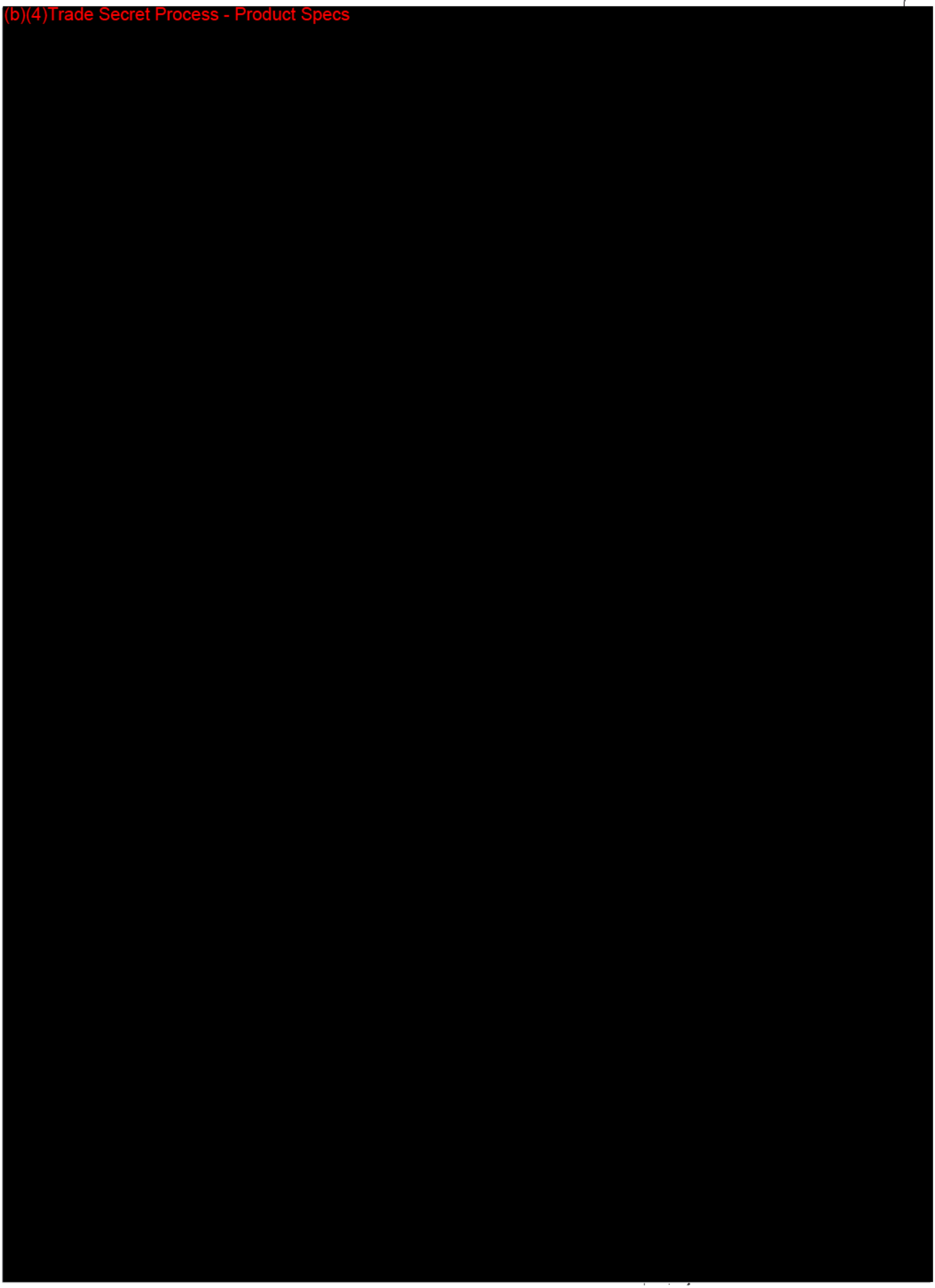
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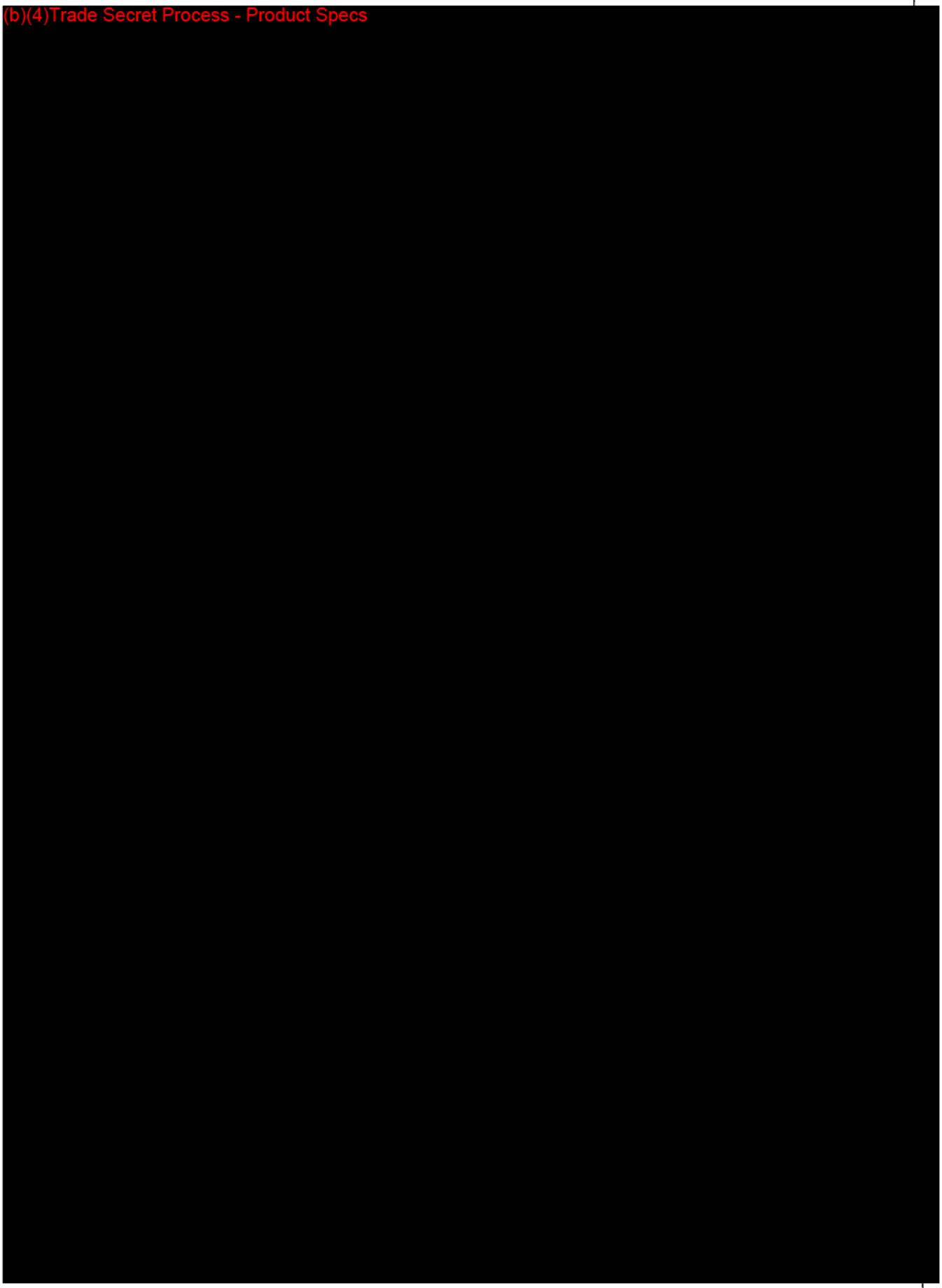
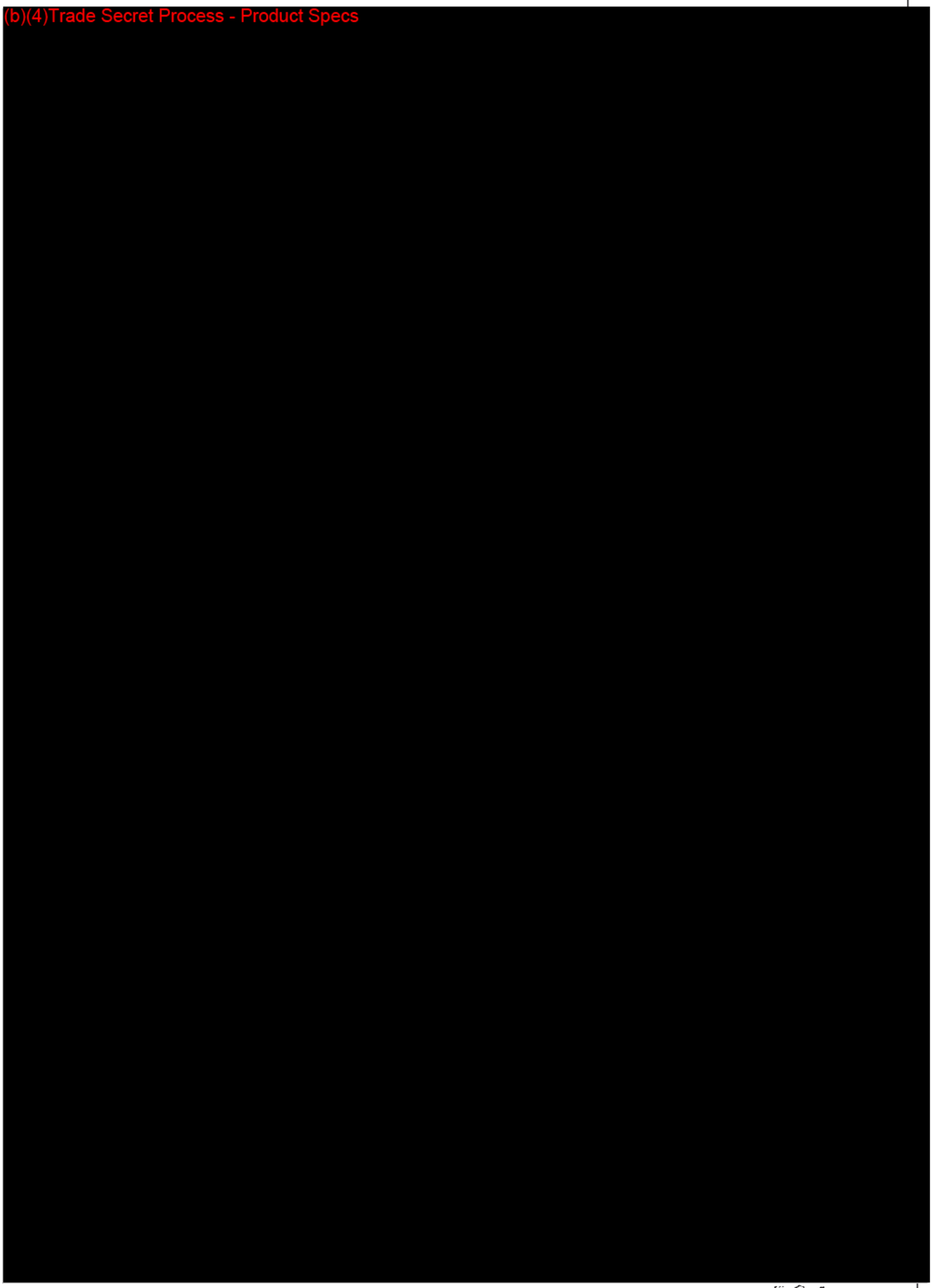


(b)(4)Trade Secret Process - Product Specs



(b)(4)Trade Secret Process - Product Specs

Product Code(s):

18999465

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(b)(4)Trade Secret Process - Product Specs

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(b)(4)Trade Secret Process - Product Specs

(b)(4)Trade Secret Process - Product Specs

SUBSTANTIAL EQUIVALENCE DISCUSSION

PICO Single Use Negative Pressure Wound Therapy System delivers negative pressure to a range of acute and chronic wound types. PICO achieves this in the same way as the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275) and Renasys Go (K083375).

Device Comparison Table

The following table outlines the differences of PICO compared to the predicate devices.

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Manufacturer:	Smith & Nephew Medical Ltd.	Smith & Nephew Inc.	Kalypto Medical
Intended Use:	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials. PICO Single Use Negative	Indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include	A portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudates and infectious material which may promote wound healing.

	New Device: PICO Single Use Negative Pressure Wound Therapy System	Predicate Device: Smith & Nephew Renasys GO 510(k) # K083375	Predicate Device: Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System 510(k) # K080275
	(b)(4)Trade Secret Process	chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	
Environment of use	Hospital, home	Hospital, home, long term care	Home use primarily
Patient Population	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)
Materials:	(b)(4)Trade Secret Process		Unknown
Single-use or	Single use	Reusable	Reusable

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Reusable:			
Method of Sterilization:	Pump is non sterile Dressing and fixation strips sterilised by ethylene oxide	Pump is non sterile	Pump is non sterile Dressing is sterilised by irradiation
Biocompatibility:	Dressing complies with ISO 10993	Not applicable	Unknown
Design:	Single use negative pressure wound therapy (NPWT) system consisting of a small, portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. Exudate is collected in the dressing; there is no canister. Designed to deliver between (b)(4)Trade Secret Process (nominal) continuous negative pressure for up to 7 days.	Portable, re-usable negative pressure wound therapy (NPWT) pump designed to be used with associated dressings and canisters for exudates collection. Delivers continuous or intermittent negative pressure at settings between 40 - 200mmHg. Battery or mains powered.	Portable, re-usable, battery operated negative pressure wound therapy (NPWT) pump designed to be used with associated wound dressings; there is no canister. Delivers continuous or intermittent negative pressure at settings between 40 - 125mmHg.
Type of Pump:	Diaphragm Pump controlled by Microprocessor	Diaphragm Pump	Microprocessor controlled pump

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** ***Kalypto Medical*** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Battery Type:	AA lithium (2)	Lithium Ion	AA alkaline (3)
Operating Pressure Range:	(b)(4)Trade Secret Process	-40 to -200 mmHg	-40 to -125mmHg
Bacterial Filter Size:		0.2 micron filter 1.0 micron filter on canister	Unknown
Pressure Controls:	Sensors, Software	Sensors, Software	Sensors
Maximum Flow Rate:	(b)(4)Trade Secret Process	6.5 litres per minute	Unknown
Alarms:	OK Low battery Air leak/Intervention required	Low Battery High Vacuum Low Vacuum Over Vacuum Tubing blocked/canister full High Flow/Leak	Low Battery Leak Full Dressing / system fault
Pump Dimensions:	3.5 x 3.5 x 1.0"	7" x 8.5" x 3.5"	3.2 x 5.1 x 1.3"
Operation:	Continuous	Continuous and Intermittent	Continuous and Intermittent
Accessories:	Carry bag	Gauze and Foam Dressing Kits Large and Small Canisters	Fluid-absorbing Dressings with Silver wound contact layer
Electrical Safety Testing:	Complies with IEC 60601-1, IEC 60601-1-2, UL 60601-1	Complies with IEC 60601-1, IEC 60601-1-2, UL 60601-1	Complies with IEC 60601-1, IEC 60601-1-2
Software controlled:	Yes	Yes	Yes

	New Device: **PICO Single Use Negative Pressure Wound Therapy System**	**Predicate Device:** **Smith & Nephew Renasys GO** **510(k) # K083375**	**Predicate Device:** **Kalypto Medical** **NPD 1000 Negative Pressure Wound Therapy System** **510(k) # K080275**
Fluid handling capacity	4" x 8" dressing 40cc – 100cc 10" x 10" dressing 200cc – 480cc	Cannisters which hold upto 300ml and 800ml	Dressings ranging from 25cc to 140cc of volume
Dressing sizes	4" x 8", 4" x 12", 4" x 16", 6" x 6", 6" x 8", 6" x 12", 8" x 8", 10" x 10"	Gauze 3" x 3", 3" x 8" Film drape 4" x 4.5", 12" x 8" Foam 4" x 3" 1", 8" x 5" x 1"	5" x 6.5", 2" x 3.5", 3.5" x 5", 8.6" x 8.7"
Dressing materials of construction	Dressing: (b)(4)Trade Secret Process Secondary fixation strips: (b)(4)Trade Secret Process	PU Foam (b)(4)Trade Secret Process	Non woven pad Silver coated wound contact layer
Mode of action	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister	Removal of air and exudate from wound to create NPWT. Exudate removed to a canister.	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound and acts as canister

All of the devices compared incorporate the same following commonalities:

- All three devices have the same intended use which is the application of negative pressure wound therapy to promote wound healing by the removal of exudate from the wound
- A suction pump to provide negative pressure to a closed environment over a wound which enables exudate to be removed from the wound for the purposes of wound healing
- Two out of the three devices (PICO and NPD 1000 Negative Pressure Wound Therapy System (K080275) incorporate a diaphragm pump
- Two out of the three devices (PICO and NPD 1000 Negative Pressure Wound Therapy System (K080275) share the same mode of action in that they both remove air from the dressing and the wound to create negative pressure wound therapy
- All three devices provide continuous negative pressure wound therapy
- Two out of the three devices (Renasys Go (K083375) and NPD 1000 Negative Pressure Wound Therapy System (K080275) provide intermittent negative pressure wound therapy
- Two out of the three devices (PICO and NPD 1000 Negative Pressure Wound Therapy System (K080275) include a dressing which absorbs the exudate rather than transfer the exudate into a canister
- Two out of the three devices (PICO and NPD 1000 Negative Pressure Wound Therapy System (K080275) provide dressings in a range of sizes for varying wound sizes
- All three devices are used in the same environment; the hospital and home settings and are aimed at the same patient population
- All three devices incorporate pressure controls
- All three devices are software controlled

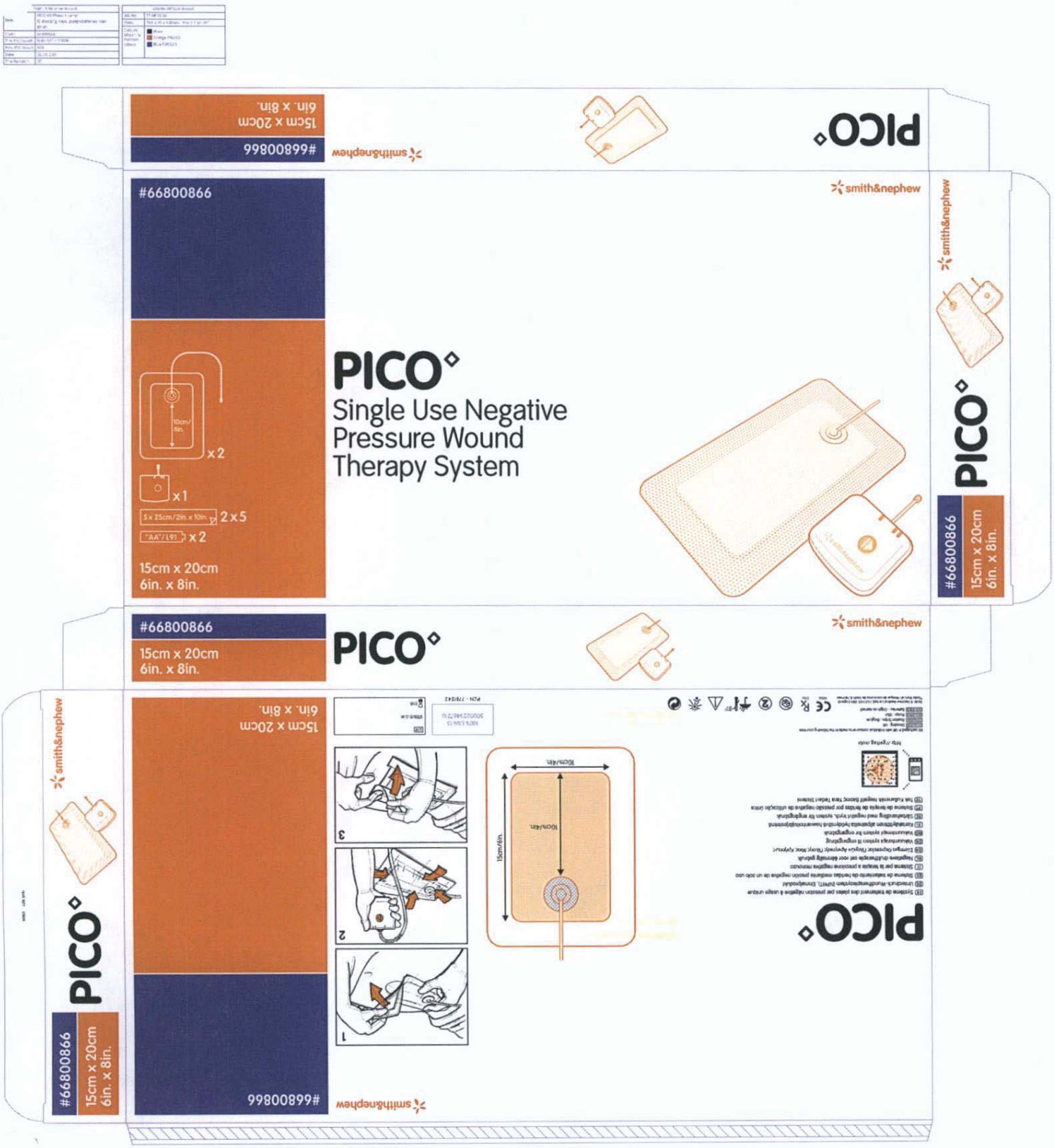
Based on comparison to the predicate devices, it has been determined that PICO Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate devices in terms of technology, specifications, method of operation and indications for use.

PROPOSED LABELING

The following draft labeling is included in this section:

- Product labeling
    - Carton artwork
    - Dressing tray lid artwork
    - Pump sleeve artwork
    - Pump label artwork
- Instructions for Use Manual

In addition to the Instructions for Use, a copy of which is provided with each product, a Patient Guide aimed specifically at patients will be made available. In order to verify that the content of the Patient Guide is appropriate and easily understood by a non-clinical professional, a usability study has been performed. This study involved providing the proposed Patient Guide and the product to number of individuals (non-clinical professionals) who were then asked to review the information and answer a series of questions. Enclosed is a copy of the patient guide, the protocol followed for the study which includes the questions asked. The patient guide was revised to incorporate some of the comments. The final version of the patient guide is enclosed.



#66800866
15cm x 20cm
6in. x 8in.
smith&nephew
PICO
Single Use Negative
Pressure Wound
Therapy System
x 2
x 1
5 x 25cm/2in. x 10in.
2 x 5
"AA"/L91
x 2
15cm x 20cm
6in. x 8in.
#66800866
15cm x 20cm
6in. x 8in.
PICO
smith&nephew
#66800866
15cm x 20cm
6in. x 8in.
PICO
smith&nephew
#66800866
15cm x 20cm
6in. x 8in.
PICO
smith&nephew
#66800866
15cm x 20cm
6in. x 8in.
PICO
smith&nephew

	Smith & Nephew Record
Item:	PICO tray lidding - no pump version (ROW)
Code:	66800866-2
This BSC/Asset:	18469865 / 24559
Prev BSC/Asset:	N/A
Date:	09.12.2010
This Revision:	07

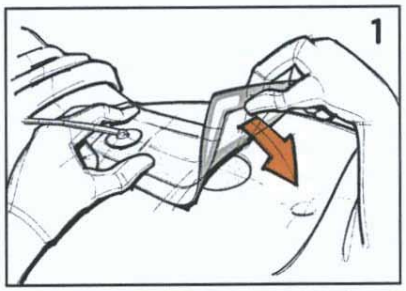
ADAMS DESIGN Record	
Job No:	TT-NP.01.00
Dims:	251 x 334mm (6mm&15mm radius corners)
Colours: (Match to Pantone colors)	Black Orange PMS151 Blue PMS265

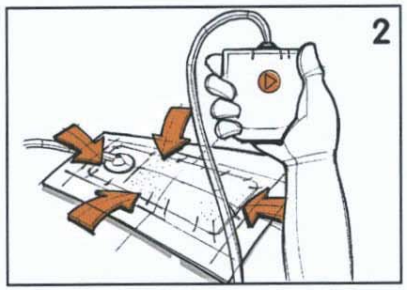
6R

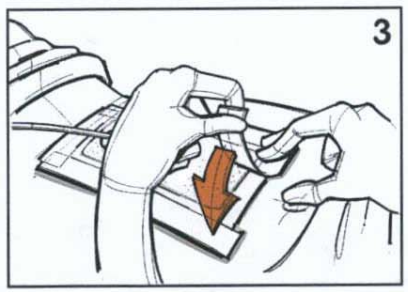
15R

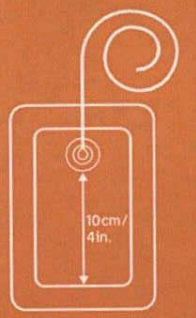
#66800866-2

smith&nephew









5 x 25cm / 2in. x 10in. x 5

15cm x 20cm
6in. x 8in.

1846 9865 24559

PICO◇

Single Use Negative Pressure Wound Therapy Dressing

(FR) Pansement pour traitement des plaies par pression négative à usage unique
(DE) Unterdruck-Wundtherapieverband (NPWT), Einmalprodukt
(ES) Apósito para tratamiento de heridas mediante presión negativa de un solo uso
(IT) Medicazione per la terapia a pressione negativa monouso
(NL) Negatieve druktherapie verband voor éénmalig gebruik
(GR) Επίδεσμος Θεραπείας Πληγών Αρνητικής Πίεσης Μιας Χρήσεως
(DK) Vakuumterapi bandage til engangsbrug
(NO) Vakuumterapi bandasje for engangsbruk
(FI) Kertakäyttöinen alipainetta hyödyntävä haavasidos
(SE) Förband till engångssystem för sårbehandling med negativt tryck
(PT) Penso para terapia de feridas por pressão negativa de utilização única
(TR) Tek kullanımlık negatif basınç yara tedavi sargısı

Kit packaged in UK with individual components made in the following countries
Dressing - UK
Fixation Strips - Belgium

Smith & Nephew Medical Limited, Hull HU3 2BN England.
*Trade Mark of / Marque de commerce de Smith & Nephew

#66800866-2

Lot box:
20 x 50mm

CE 0086 Rx Only STERILE EO

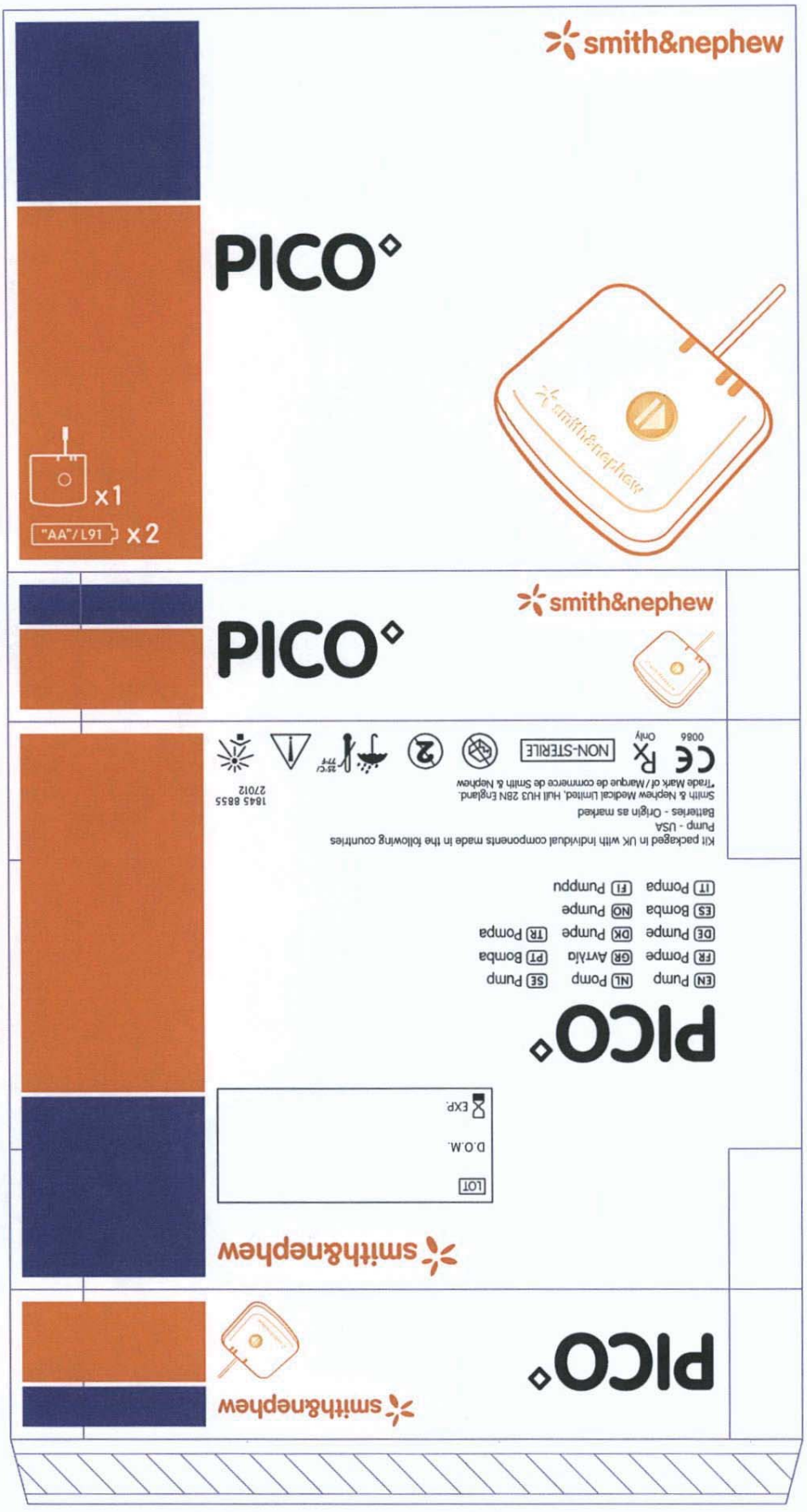
6R

15R

417

Smith & Nephew Record	
Item:	PICO Pump Sleeve
Code:	common
This BSC/Asset:	18458855 / 27012
Prev BSC/Asset:	N/A
Date:	02.03.2011
This Revision:	06

ADAMS DESIGN Record	
Job No:	TT-NP.01.00
Dims:	114 x 30 x 162.5mm
Colours: (Match to Pantone colors)	Black Orange PMS151 Blue PMS265



Smith & Nephew Record	
Item:	PICO Device Label (non-sterile version)
Code:	N/A
This BSC/Asset:	18999465 / 26909
Prev BSC/Asset:	N/A
Date:	05.04.2011
This Revision:	06

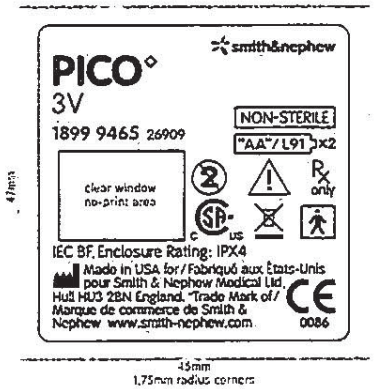
ADAMS DESIGN Record	
Job No:	TT-NP.01.00
Dims:	47mm x 45mm 1.75mm radius corners
Colours: (Match to Pantone colors)	Black PMS Cool Grey1

Underlabelling behind clear window area :-

7 x 18mm area for Flexmedical EAN 128 xxxxxxxxxx

SN PRYMDNNN

DD MM YY



Smith & Nephew Record	
Item:	PICO Manual Eng pages PHASE 1
Code:	N/A
This BSC/Asset:	16937974 / 25357
Prev BSC/Asset:	N/A
Date:	29.03.2011
This Revision:	10

ADAMS DESIGN Record	
Job No:	TT-NP.01.00
Dims:	148.5 x 210mm (A5) wirebound
Colours: (Match to Pantone colors)	☐ 4-colour process

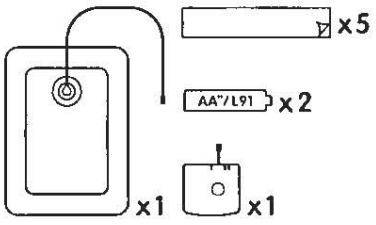
(EN)

The PICO® pump is supplied non-sterile, single use. The dressings and strips are supplied sterile, single use. Do not use if package is open or damaged.

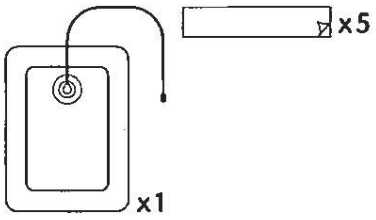
1. Description

PICO is a Single Use Negative Pressure Wound Therapy (NPWT) System consisting of a small portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. PICO is capable of delivering 80mmHg (nominal) negative pressure to the wound surface and managing low to moderate levels of exudate generated by the wound. The system comprises of 2 tray sets to provide therapy for up to 7 days. The tray for first use is contained within a secondary barrier for use in the sterile area.

First use



Replacement dressing pack



2. Indications for use

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and home care setting.

Examples of appropriate wound types include:

- Acute.
- Chronic.
- Flaps and grafts.
- Incision sites.
- Partial-thickness burns.
- Subacute and dehisced wounds.
- Traumatic.
- Ulcers (such as diabetic or pressure).

3. Contraindications

PICO is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
- Previously confirmed and untreated osteomyelitis.
- Non-enteric and unexplored fistulas.
- Use on necrotic tissue with eschar present.
- Use over exposed blood vessels, nerves or organs.
- Exposed anastomotic sites.

(EN)

4. Warnings

1. The use of anticoagulants does not deem a patient inappropriate for treatment with PICO, however haemostasis must be achieved before applying the dressing and continued frequent assessment must be maintained and considered through out the therapy.
2. At all times care should be taken to ensure that the pump and tubing does not:
   - Lie in a position where it could cause pressure damage to the patient.
   - Trail across the floor where it could present a trip hazard or become contaminated.
   - Present a risk of strangulation or a tourniquet to patients.
   - Rest on or pass over a source of heal.
   - Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.
3. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO due to risk of puncturing organs or blood vessels while under negative pressure.
4. In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.
5. PICO is not MRI compatible. Do not take PICO into the MRI suite.
6. PICO has not been studied on paediatric patients. Patient size and weight should be considered when prescribing this therapy.
7. PICO is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
8. PICO is not suitable for use in the presence of a flammable anaesthetic mixture or with oxygen or nitrous oxide.

5. Precautions

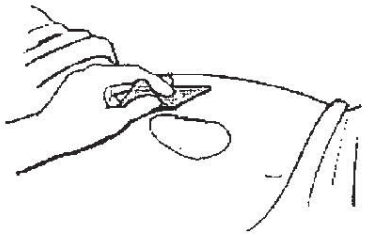
1. Care should be taken for patients who are or may be:
   - Untreated for malnutrition.
   - Non-compliant or combative.
2. Where PICO is used on infected wounds, the infection should be inspected and treated as per local clinical protocol.
3. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise circulation.
4. Inappropriate use or too frequent dressing changes, particularly in patients with fragile skin, can result in skin stripping.
5. If reddening or sensitisation occurs discontinue use.
6. PICO may not be compatible with oil based products such as petrolatum.
7. Ensure that the position of deep drain and surface NPWT applications do not allow adverse interaction which may compromise their operation. Any surgical drain should exit the skin away from the edge of the dressing and function independently of the PICO dressing.
8. Do not take the pump apart.
9. The dressing should not be used with any other suction pump.
10. Do not alter or cut tubing configuration or pull on the tubing.
11. Do not cut the dressing as this may lead to loss of NPWT application.
12. Always ensure that the dressing is positioned centrally over the wound. The port should sit uppermost so that the risk of fluid sitting around the port and potentially blocking the negative pressure is minimised.
13. If PICO is used within CT scanner range, care must be taken that the pump is not within the field of view.

EN

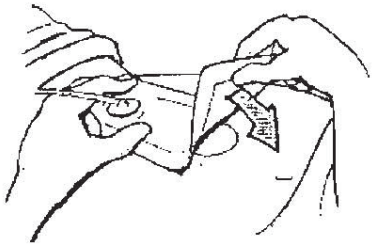
6. Instructions for use

6.1 Application

1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary irrigate the wound with sterile saline and pat the wound dry. If required, wipe peri-wound area with SKIN-PREP® and allow skin to dry.

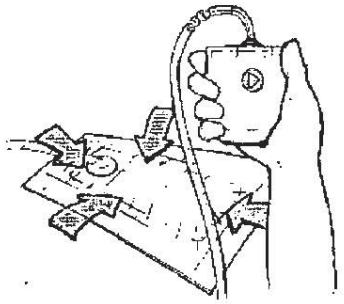


2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. (See diagram A in section 6.2). The port should be uppermost from the wound (depending on patients primary position) to prevent fluid pooling around the port and blocking the negative pressure. Remove the other two handles and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

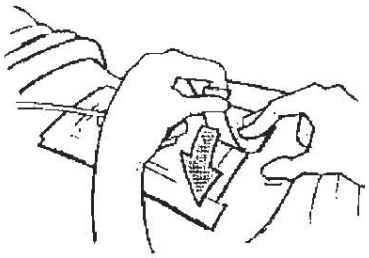


3. Once the dressing is in place, remove the pump and the batteries from the tray. Slide back the battery cover on the top of the pump and place the batteries inside. The direction in which the batteries should be placed is indicated inside the battery compartment. Replace the cover. Following this all three lights should flash once. (Refer to Table 1).

4. Join the pump to the dressing by twisting together the tubing connectors. Press the orange button to start the application of negative pressure. The green light will start to flash (indicates system working OK, see Table 1). Depending on the size of the wound, the pump should take up to 30 seconds to establish NPWT. If it takes longer than this, refer to Table 1.



5. Once the negative pressure has been established, apply the fixation strips to each of the four sides of the dressing. Remove top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing. In awkward areas, it maybe useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps dressing border by approximately 1cm. Ensure tubing is not twisted or trapped between clothing.



Please note that if at any time the fixation strips are removed, the dressing should also be replaced.

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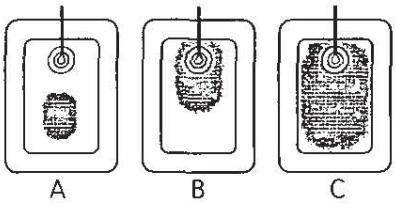
6.2 Dressing change

1. The pump has a 7 day life and the dressing may be left in place for up to 7 days depending on the level of exudate.
2. If the dressing appears ready for changing (see diagrams A – C) within the 7 day life of the pump, press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing as per section 6.1, connect to the pump and press the orange button to reinitiate the therapy.



(A) Dressing properly positioned and is acceptable to be left in place
(B) Dressing requires change
(C) Dressing requires change

The pump will automatically stop functioning after 7 days of use. All the lights will turn off at this point. The dressing should be removed as therapy is not being delivered and another system applied if appropriate.
3. The dressing should be disposed of as clinical waste. The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.
4. For additional information on disposal requirements see: www.mypico.co

6.3 Use with fillers and wound contact layers

PICO is compatible with standard gauze and foam fillers used in traditional NPWT where this is clinically appropriate – for example on a defect wound. When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to local clinical protocol and manufacturers instructions. Gauze should loosely fill to surface of wound. Avoid over packing.

PICO may be used over the top of a non adherent layer if required, for example over a skin graft.

PICO is compatible with ACTICOAT® Flex nanocrystalline silver dressings.

7. General use

7.1 Showering and bathing

Light showering is permissible but care must be taken that the dressing is not saturated. The pump and dressing should not be exposed to a direct spray nor must they be submerged. The pump may be disconnected from the dressing prior to showering. In this case, place the pump in a safe location where it will not get wet. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.

7.2 Cleaning

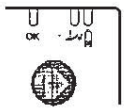
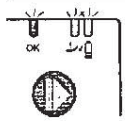
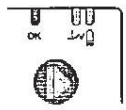
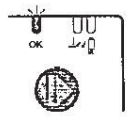
Adherence to clinical directives concerning hygiene is of prime importance. The pump may be wiped clean with soapy water or a weak disinfectant solution.

8. Faults and technical assistance

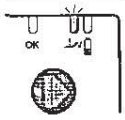
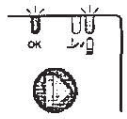
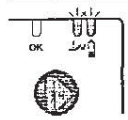
If your device develops a fault or there are signs of damage, refer to Table 1.

Table 1 – Pump status indication, alarms and errors

PICO has visual alarms to let the user know when there is an issue. PICO does not contain audible alarms. The pump should be carried so that it is accessible and the patient/clinician can check the status routinely.

Alarm display	Light status	Possible cause	Trouble shooting suggestion
	All lights off.	The pump is OFF.	The therapy has been paused. Pressing the orange button will restart the therapy and the green light will flash.
		The pump has reached the end of its life.	After 7 days of therapy the pump will automatically cease functioning, in this case all the lights will turn off. Pressing the orange button will not provide a green flashing light.
		The batteries are no longer functional.	If the pump has had less than 7 days usage, the batteries may not be functional and should be replaced as below.
	All lights flash once.	*This reflects* the pump self test once batteries have been inserted and the cover has been replaced.	This is expected.
	All lights solidly illuminated.	Pump failed.	Contact S&N representative.
		System is not usable.	Apply new pump and dressing.
	Green 'OK' light flashes.	Dressing applied, no air leaks and full system is functioning properly.	Not applicable.
		No issues.	

(EN)

Alarm display	Light status	Possible cause	Trouble shooting suggestion
	Amber 'leak' light flashes.	Air leak detected possibly due to a creased dressing/ border/strip.	Smooth down the dressing and the strips to remove any creases that are allowing air into the system.
		Pump is in Auto Pause. NPWT is not being applied to the wound.	Press the orange button to restart the therapy. The green "OK" light will flash as the pump tries to establish therapy.
		The pump will auto pause for 1 hour and then will automatically try to re-establish therapy if no remedial action is taken.	If the air leak remains, the amber leak light will start to flash after approximately 30 seconds. If this happens, repeat smoothing actions and press the orange button. If the leak is resolved the green light will continue to flash.
	Green 'OK' light flashes.	System on and functioning properly.	Change of batteries required in <24 hours. Pause the therapy by pressing the orange button.
	Amber 'battery low' light flashes.	Battery power low. No issues with air leaks.	Push open the battery cover at the top of the pump and remove the old batteries. Insert 2 new lithium AA batteries. Replace the cover. Press the orange button, the therapy will re-start and the green light will flash.
	Amber 'leak' light flashes.	Creased dressing/ border/strip.	Address air leak as above.
	Amber 'battery low' light flashes.	Battery power low.	Change of batteries or device required in <24 hours as above.

(EN)

9. Specifications

Dimensions	85 x 85 x 25mm (3.5 x 3.5 x 1.0")	**Maximum Vacuum**	100mmHg
Weight	<120g	**Mode of Operation**	Continuous
Operating time	7 days	**Patient Protection**	Type BF
Battery Type	Lithium AA (L91)	**Storage/Transport**	5 – 25°C, 10 – 75% RH 700 to 1060 mbar atmospheric pressure
Power (Battery)	3V DC	**Operating environment**	5 – 35°C, 10 – 95% RH 700 to 1060 mbar atmospheric pressure
Ingress Protection	IPX4	**Compliance**	UL 60601-1 IEC 60601-1 IEC 60601-1-2 CAN/CSA C22.2

10. Safety and electromagnetic compatibility

When used in accordance with the manufacturer instructions, PICO complies with the general requirements for safety of electrical medical equipment IEC 60601-1 and the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2.

Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation and home use environment.

This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

(EN)

Guidance and manufacturer's declaration – electromagnetic immunity

PICO is intended for use in the electromagnetic environment specified below. The customer or the user of PICO should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of PICO including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	**Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which PICO is used exceeds 3V/m, PICO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating PICO.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EN

Guidance and manufacturer's declaration – electromagnetic emissions

PICO is intended for use in the electromagnetic environment specified below. The customer or the user of PICO should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11.	Group 1.	PICO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11. Harmonic emissions IEC 61000-3-2. Voltage fluctuations/flicker emissions. IEC 61000-3-3.	Class B. Not applicable. Not applicable.	PICO is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING: PICO should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, PICO should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and PICO. PICO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of PICO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and PICO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(EN)

Cautions

This User Guide is not intended as a guarantee or warranty. It is intended only as a guide. For medical questions please consult a physician.

The product must be used in accordance with this User Guide and all applicable labeling.
PICO is packed in the UK with individual components made in the following countries:
Dressing – UK
Fixation strips – Belgium
Pump – USA
Batteries – Origin as marked

Smith & Nephew Medical Limited
Hull, HU3 2BN England
*Trade Marks of Smith & Nephew
www.smith-nephew.com
©Smith & Nephew
Date of issue 03/2011

11. System variants

5 sizes of dressing are available in kits which contain 2 dressings, 1 pump and 10 secondary fixation strips:

10cm x 20cm / 4in. x 8in.	66800862
10cm x 30cm / 4in. x 11¾in.	66800863
15cm x 15cm / 6in. x 6in.	66800865
15cm x 20cm / 6in. x 8in.	66800866
20cm x 20cm / 8in. x 8in.	66800868

Carry bag

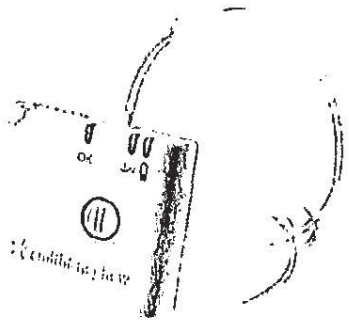
The pump may be carried in the patient's pocket. Alternatively, a bag for carrying the pump is also available. This can be ordered with the following code:
PICO Carry bag 66800918

12. Glossary of symbols

	Equipment Classification: Isolation type BF applied part
	Single use. Do not re-use
	Manufacturer
	International classification
	Keep dry
LOT	Lot Number
	EU: Not for general waste
	Storage Temperature
CE 0086	CE mark
	Caution: See instructions for use
	Do not use if the package is opened or damaged
	Keep product out of sunlight
	Leak alert
	Date of Manufacture
STERILE EO	Product is sterilised by Ethylene Oxide
	Battery power indication
OK	Pump is functioning properly
Rx only	Federal (USA) law restricts this device to sale by or on order of a physician
NON-STERILE	Product is non-sterile
	Start/pause/resume therapy

smith&nephew

PICO®
Single Use Negative Pressure Wound Therapy System



Patient Home Care Information

Date:

Your nurse:

Your doctor:

Other useful numbers:

Distributor Information

Specific distributor contact information to be placed here

Introduction

This patient handbook will provide you with important information while you are receiving negative pressure wound therapy (NPWT) from Smith & Nephew's PICO® system. The handbook will answer basic questions about the therapy. Please keep it in a safe place with other healthcare documents. The handbook includes instructions about how to use the product including:

- Information on what PICO is for
- When not to use the product
- Warnings and precautions for safe and effective use of PICO
- General operation of PICO.

What does PICO do?

PICO provides suction known as negative pressure wound therapy (NPWT) which draws out excess fluid from a wound and protects the injured area from getting dirty to ultimately help promote healing.

How does PICO work?

PICO consists of an NPWT pump connected to an absorbent gentle adhesive dressing.

The dressing is applied to the wound bed and extra strips are placed over the outside edge to help hold the dressing in place. When the pump is turned on, air is pulled out of the dressing and excess fluid from the wound will start to enter the dressing. The dressing helps to prevent bacteria from entering the wound. It may also improve blood flow to the wound which will help it to heal.

The therapy pump is battery operated. The batteries may be changed with 2 lithium AA batteries if required. They should only be changed if the battery indicator flashes (see section regarding pump alarms).

How many hours a day do you need to use the therapy?

To get the full benefit, we recommend that you maintain use of the therapy as prescribed by your physician or nurse.

How long will it take to improve your wound?

The length of time that the therapy takes to improve a wound is different for every patient. It will depend on your general health, the size and type of wound that you have and the treatment you have been prescribed. In many cases, an improvement in the wound can be seen when the first dressing is changed, but in some cases, it may take several weeks. The therapy may be used to close the wound completely, or may be stopped sooner than this and replaced with a different type of dressing. If your wound shows no improvement, the therapy might be stopped. Your nurse or doctor will discuss when and why it will be stopped when they assess your wound at each dressing change.

Will it be painful?

The first time the PICO® pump is turned on, you may feel a slight pulling or drawing sensation.

If you experience any pain, please speak to your nurse or doctor for advice. They may prescribe pain-relief medication.

What will the dressings look like when the therapy is working?

The dressing will pull down against your skin when the therapy is working and be firm to the touch.

How often will the dressings have to be changed?

The dressings may be left in place for up to 7 days depending on the amount of fluid from the wound. This will depend on the size, type, drainage amount and position of your wound. Your nurse or doctor will determine how often your dressings should be changed.

Will the dressing changes hurt?

Some people may experience slight discomfort during dressing changes, specifically during cleaning of the wound, depending on the type and position of the wound. If you feel any discomfort, please tell the person who is changing your dressing. This way, they will be able to give you advice and, if necessary, pain-relief medication to help ease the discomfort.

Can you move around while on the therapy?

Patients using PICO® can move around but this will depend on recommendations provided by your nurse or doctor. The PICO pump is small and discrete and can be easily carried around in a pocket or the PICO bag to allow maximum movement.

When you are asleep.

Make sure that the PICO pump is placed somewhere safe and cannot be pulled off a table or cabinet onto the floor during sleep.

Disconnection of the pump from the dressing

The pump may be disconnected from the dressing. There is a connector built into the tubing between the pump and dressing. This should be left screwed together all the time unless there is a requirement to disconnect the pump – such as the need to have a shower.

Press the orange button to pause the therapy. Unscrew the two parts of the connector. Place the pump somewhere safe.

Once you are ready to reconnect the pump, screw the two halves back together. Ensure your dressing is smoothed down to make sure there are no creases that could cause air leaks. Press the orange button to restart the therapy. The green light will start flashing to show that the pump is starting to apply therapy. If after one minute the orange "air leak" light starts to flash refer to the section regarding alarms.

Showering and washing

The PICO° pump is splash proof but should not be exposed to jets of water. It may be disconnected from the dressing if showering is required, as above.

Make sure the tube attached to the dressing is held out of the water and that the end of the tube is pointing downwards so that water cannot enter the tube.

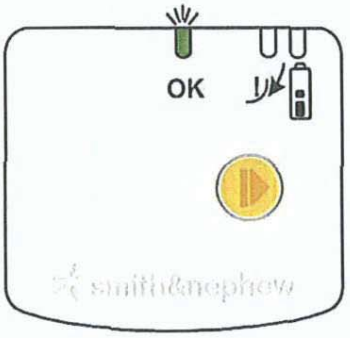
The dressing on top of the wound is water resistant. You can shower or wash with the dressing in place, as long as you take care not to expose it to direct jets of water and not to soak it. Soaking the dressing may cause it to fall off.

Position of the pump, while therapy is being delivered

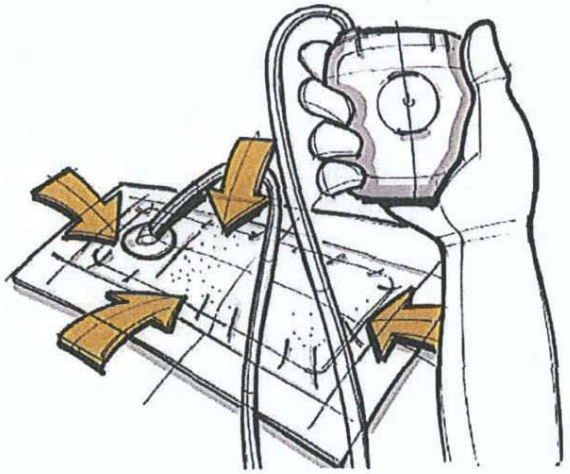
The PICO® pump may be carried with you in your pocket or wherever is the most comfortable for you, considering the size and location of the wound. A PICO bag is available if you would prefer to carry it in that way.

How do I know if the PICO system is working?

While the PICO pump is working correctly a green light located at the top of the device will flash continuously.



The dressing should have a slightly wrinkled appearance and feel firm to the touch.



What happens if the PICO° pump alarms?

The PICO pump has a visual alarm for "Low Battery" and "Low Vacuum". These issues are easily solved, for example:

• "Low Battery" – The pump will begin to alert you with a flashing orange light (above the battery symbol) when there are 24 hours and less of battery life. The batteries should be changed at this point. Press the orange button to pause the therapy. Take the battery cover from the top of the pump and replace with two new lithium AA batteries. The way in which the batteries should be positioned is displayed inside the battery compartment. Put the cover back on and press the orange button again to restart your therapy.

The green light and the orange light above the battery will flash together when the batteries need changing.

• "Low Vacuum" – If there is a low vacuum (low suction) in the dressing, a flashing orange light (above a symbol) will alert you and you will hear the pump make a buzzing sound as it tries to get to the right vacuum.

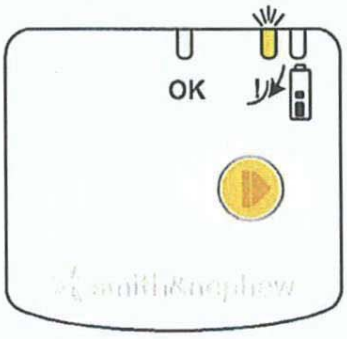
The dressing is still capable of absorbing fluid with a low vacuum but the therapy is not being delivered.

The vacuum may be low due to an air leak in the seal around the dressing. Check for any small lifts in the dressing and smooth down around the outside of your dressing including the strips with your hands.

Press the orange button to restart your therapy. The green light will flash to indicate that the pump is trying to apply therapy. After about one minute, if the orange low vacuum light starts to flash again, the air leak is not yet resolved. Continue to smooth the dressing and strips to ensure there is no entrance for the air and repress the orange button.

After one minute, if the green light continues to flash the air leak has been resolved.

Contact your nurse or doctor if you have continuous issues with the flashing low vacuum light.



The orange light will flash like this if the pump cannot reach the proper vacuum level.

When will I need a new pump?

The pump is designed to stop working after seven days of continuous use. After this time it will stop and will not restart even with new batteries. All the lights will go off and stay off.
Negative pressure therapy is not being applied at this point so your nurse or doctor will need to apply a new PICO° therapy system if needed.

The pump will look like this when it has come to the end of its life.

Call your nurse or doctor immediately if:

- You notice a big change in the colour or amount of the fluid in the dressing, for example

  If it changes from clear to cloudy or bright red.

  You see the dressing fill rapidly with blood.

- Your wound looks more red than usual or has a foul smell.
- The skin around your wound looks reddened or irritated.
- The dressing feels or appears loose.
- You experience pain.
- The alarm does not turn off.

If you have any other questions, please speak to your nurse or doctor.

For your notes.

◊Trademark of Smith&Nephew
Asset ref 27709

SMITH AND NEPHEW MEDICAL LTD

TECHNICAL STUDY PROTOCOL

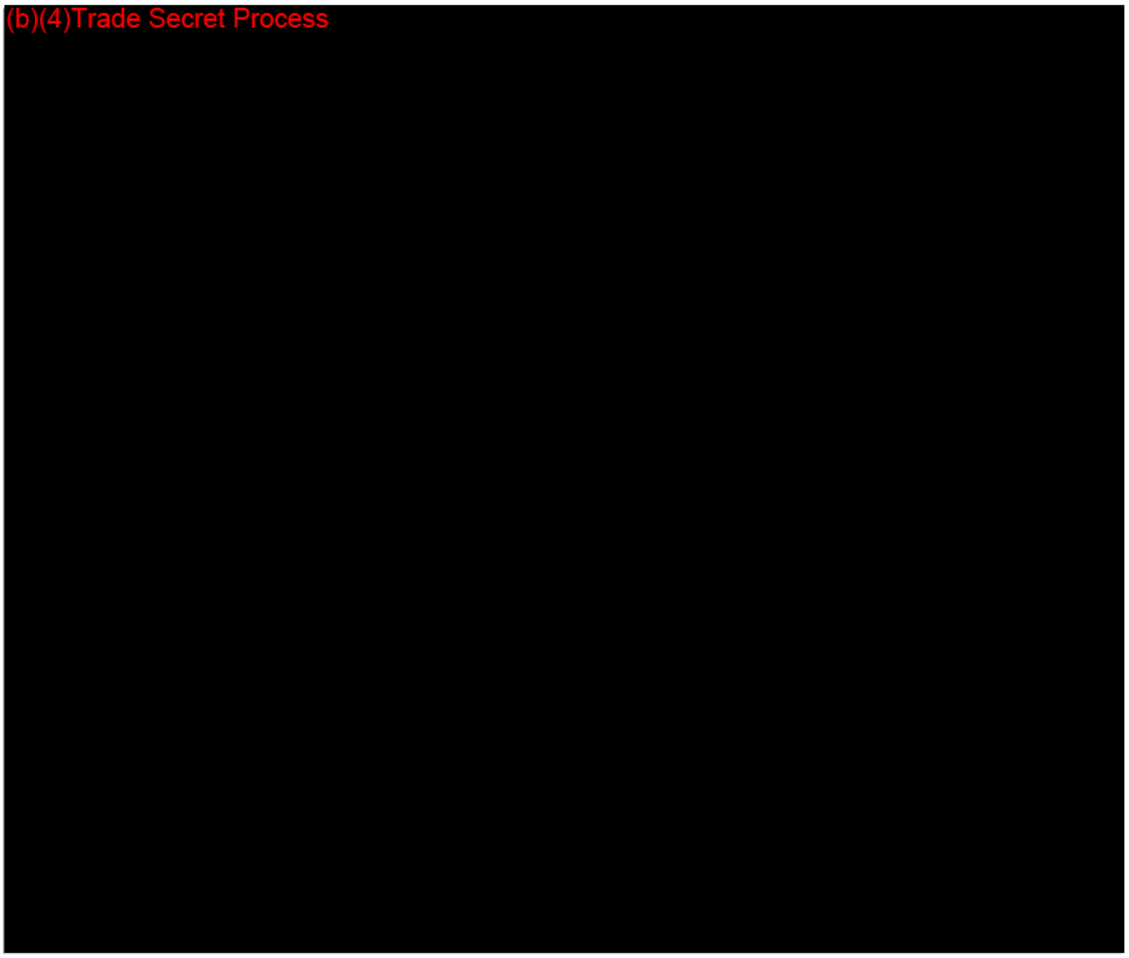
TITLE: Project Poole: Usability testing for the PICO Single Use Negative Pressure Wound Therapy System

PROTOCOL REF: W10414/P31

1. Background and Objectives

In order to ensure the PICO Single Use Negative Pressure Wound Therapy System Patient Manual will be useful and effective for the target audience, a representative sample of intended users will be asked to provide feedback on the content and format of the manual. This feedback will ensure the labeling is readable and easily understood and the instructions for operating PICO are effective for the target audience.

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

PROTOCOL CONTENTS

1. Background and Objectives.....1
2. Health and Safety.....3
3. Materials.....3
4. Equipment.....3
5. End Result of the Protocol.....3
6. Method.....3
7. Evaluation.....4
8. Fate of Material.....4

Appendix	Title	No. of pages
1	Patient Information testing questionnaire	4

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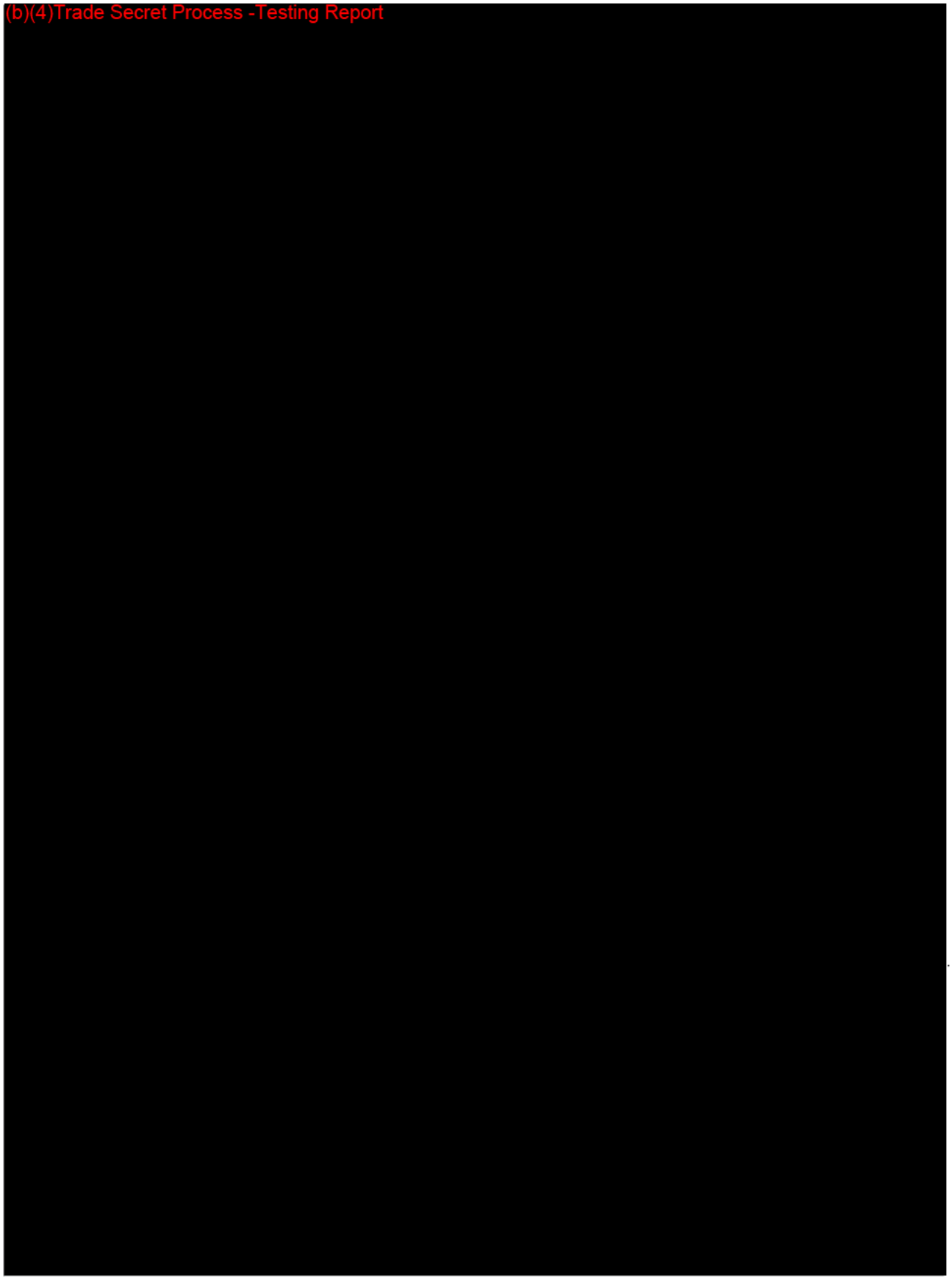
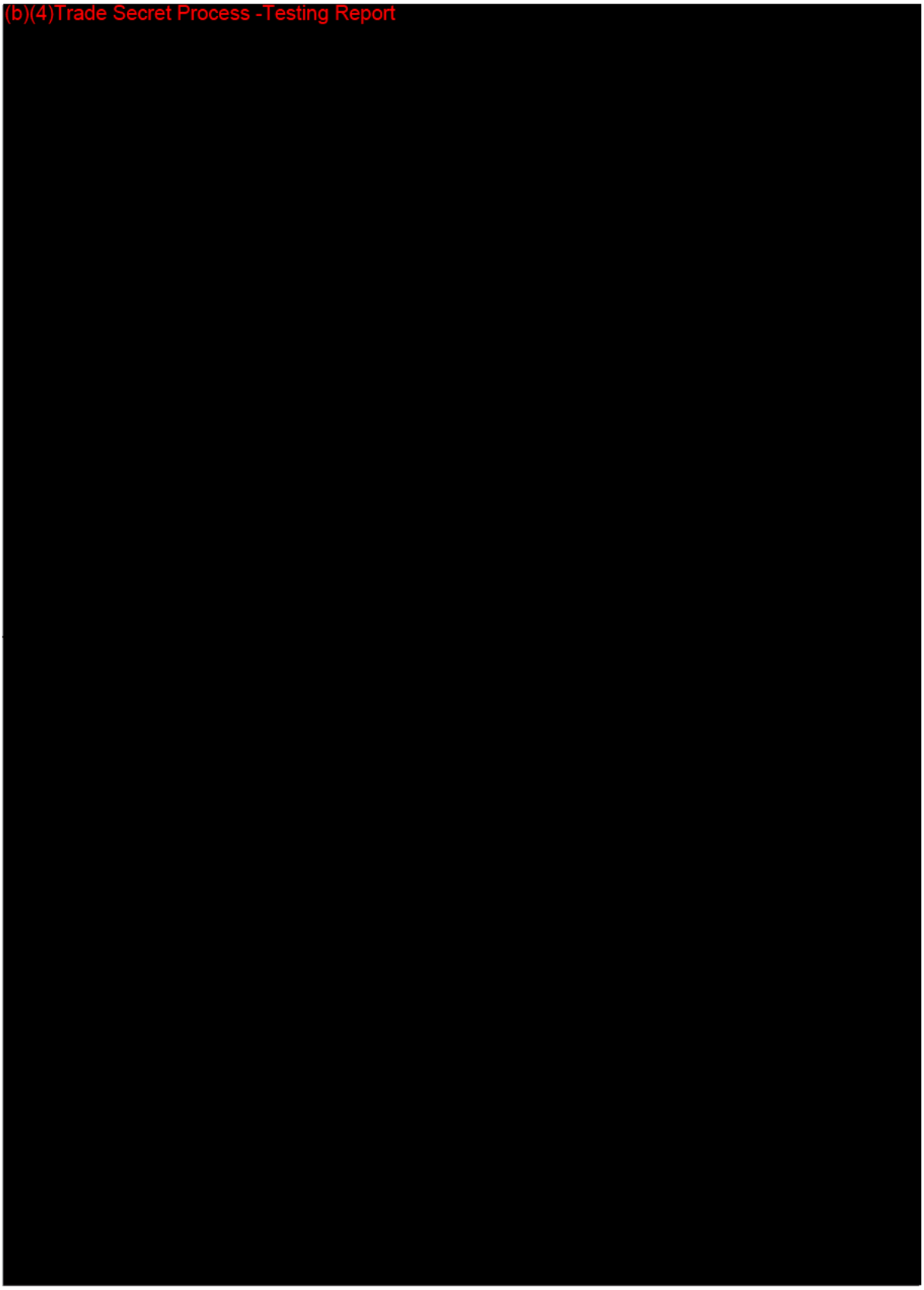
(b)(4)Trade Secret Process -Testing Report

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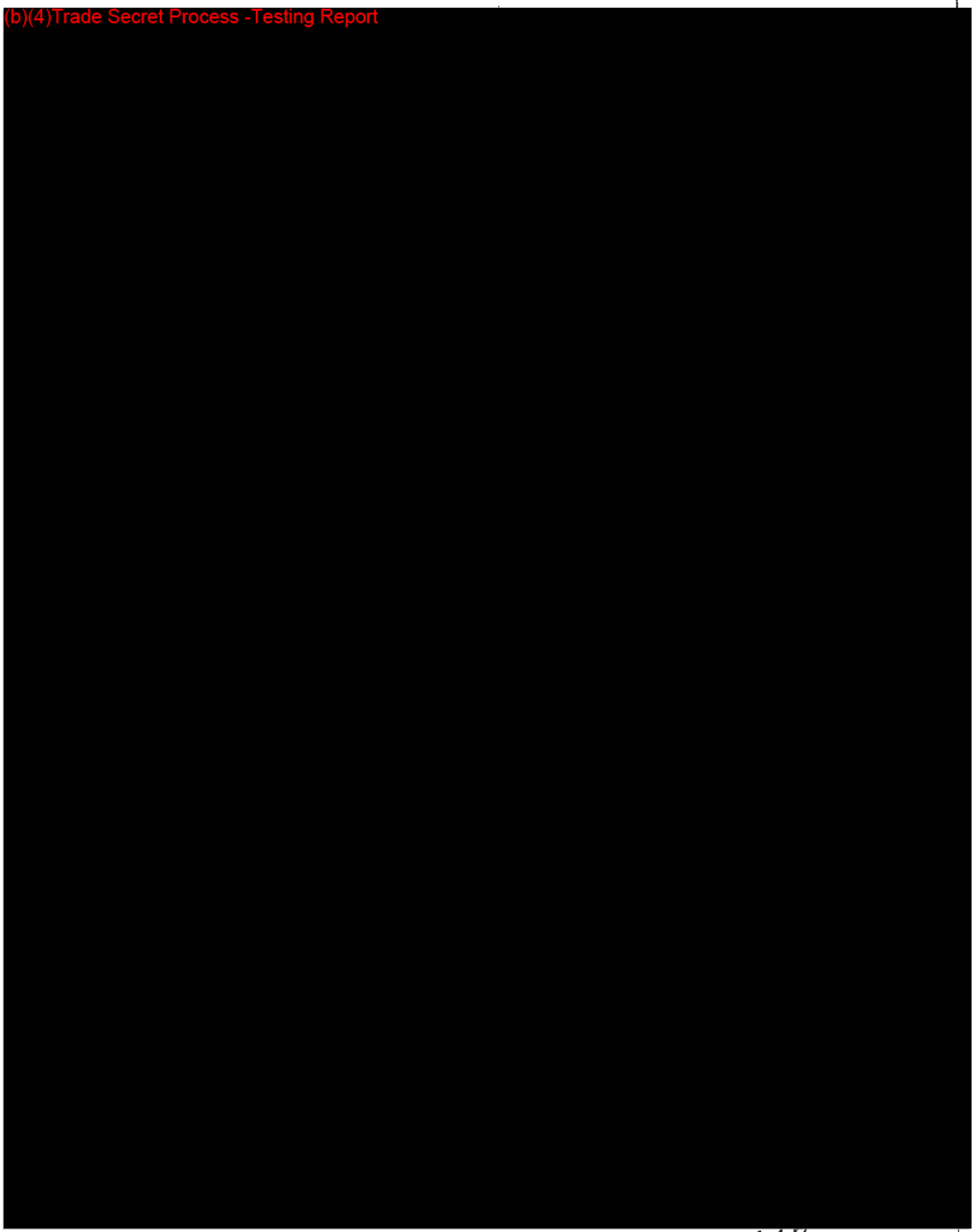

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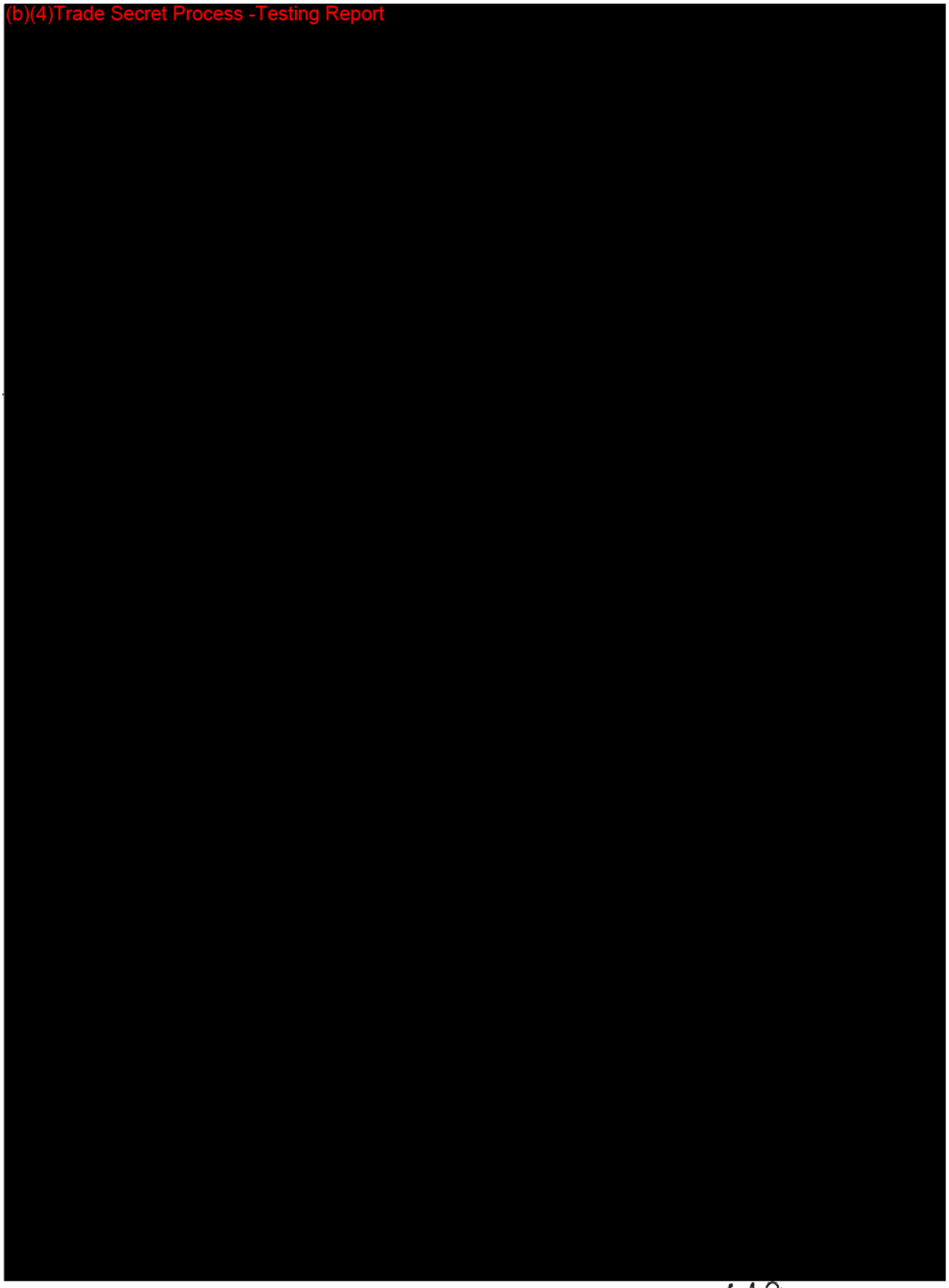

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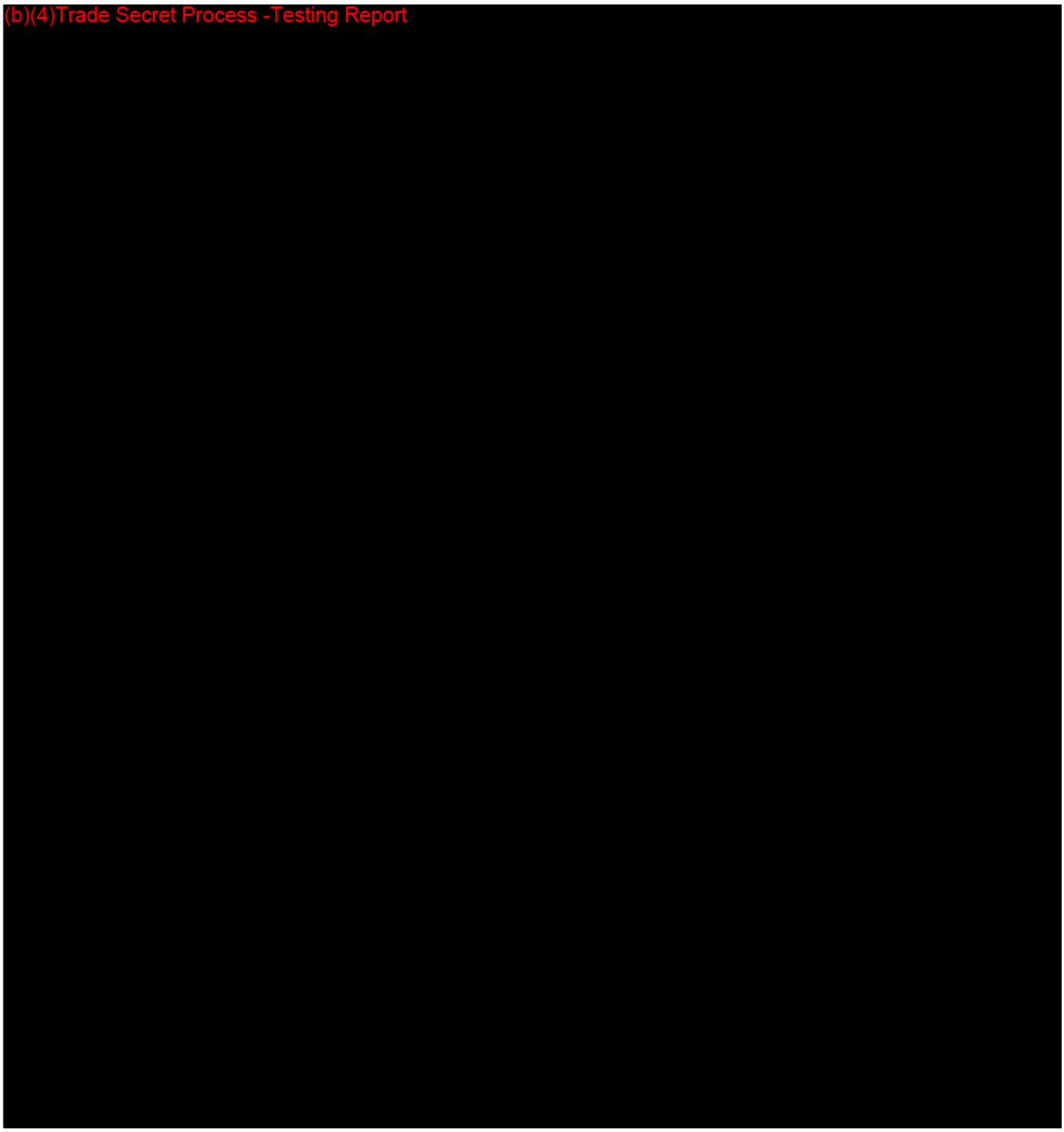

and 5 secondary fixation strips. The trays are manufactured from (b)(4)Trade Secret Process - (b)(4)Trade Secret Process -Testing Report and are sealed with a Tyvek lid. A third tray containing a non sterile pump, two lithium batteries and the Instructions for Use are placed into the carton; along with the two dressing trays. The tray containing the pump and batteries is manufactured from the same material as the dressing tray. The tray is contained within a printed cardboard sleeve to ensure the pump and batteries remain in place. Drawings of the dressing tray and pump tray are enclosed.

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(b)(4)Trade Secret Process -Design Drawings

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BIOCOMPATIBILITY

The biocompatibility of PICO Single Use Negative Pressure Wound Therapy System has been demonstrated through assessment according to ISO 10993-1: 2003 Biological Evaluation of Medical Devices, and appropriate *in vivo* and *in vitro* tests have been conducted using product that has been packaged and sterilised. These tests include cytotoxicity, sensitization and irritation and cover the PICO dressing and secondary fixation strips. These studies indicated that PICO Single Use Negative Pressure Wound Therapy System is safe for its intended use.

Test	Description of Method	Result
Cytotoxicity	**PICO Dressing** In order to determine the cytotoxic potential of the dressing, a Minimum Essential Medium (MEM) elution assay was conducted in accordance with ISO 10993-5.	N to 1:16, all non-cytotoxic (Grade 0)
	Secondary Fixation Strips Cytotoxicity testing has been performed on the secondary fixation strips, tested in accordance with ISO 10993-5. The test article extract was diluted in supplemented EMEM 1X and placed onto triplicate confluent monolayers of L-929 mouse fibroblast cells at the 100%, 50%, 25% and 5% solutions (v/v).	N to 1:16, all non-cytotoxic (Grade 0)

Sensitisation	**PICO Dressing** A Guinea Pig Maximisation Test was performed on the dressing in accordance with ISO 10993-10. **Secondary Fixation Strips** A guinea pig maximisation test was performed on the secondary fixation strips in accordance with ISO 10993-10.	Non-sensitising Non-sensitising
Irritation	**PICO Dressing** The dressing was evaluated for irritation in accordance with ISO 10993-10. **Secondary Fixation Strips** Irritation testing has been performed on the secondary fixation strips in accordance with ISO 10993-10.	PII SC = 0.0 PII SC = 0.1 Negligible irritant 0.9% NaCl extract: Primary Irritation Index: 0.11 Negligible

Additionally, the effects of the dressing wound contact layer have been assessed during a wound healing study on ALLEVYN Gentle Border dressings which have the same wound contact layer as the dressing included in the PICO Single Use Negative Pressure Wound Therapy System.

The results of the testing performed are described in the attached reports:

- PCS 208 Cytotoxicity Final Report
- PCS 209 Irritation Final Report
- PCS 210 Guinea Pig Maximisation Final Report
- Study No 68218 17 Day Wound Healing Study of ALLEVYN Gentle Border Dressings

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smith&nephew
ALLEVYN®
Wound Dressings

Good things happen when
patients feel better with ALLEVYN®

544

Living with a wound

We all know it isn't easy for patients. We know it's not easy for you.

Chronic wound fluid, and the constant risk of infection, can have a debilitating effect on everyday life.

ALLEVYN is designed to help patients through this difficult time, with its unique triple action fluid management, and sustained antimicrobial* action.

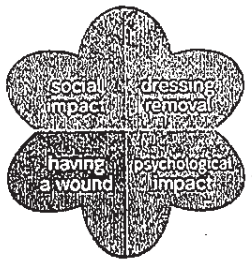
It's good that ALLEVYN minimises dressing changes, too.

Our aim is the same as yours: to improve patient quality-of-life and clinical outcomes.

If we can achieve that together, we'll also achieve something else: a reduction in the cost of chronic wounds to healthcare systems.

That should make everyone feel better.

Pain and exudate



* In-vitro

Triple-action technology

A moist wound healing environment is key to faster wound healing.[3] Whatever the wound or patient skin type ALLEVYN® triple-action technology will deliver active fluid management.

Triple-action technology is effective as it:

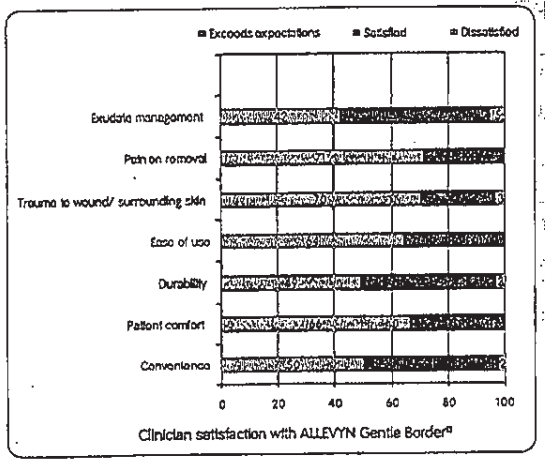
1. Absorbs wound bed fluid to cut maceration risk,[1] support peri-wound skin[2] and minimise exudate pooling thereby being able to leave the dressing in place longer.[2,3]
2. Sustains moist environment through rapid fluid uptake[4] to promote fast healing[4] and prevent leakage thereby helping the wound heal faster.[1]
3. Actively transpires excess fluid to remove bulk[3] and help reduce the need for dressing changes thereby freeing up nursing time.[2,3]

Gentle Border

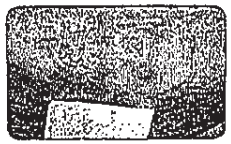
The ALLEVYN® Gentle Border range has a soft silicone gel adhesive for skin that's particularly fragile or sensitive, reducing patient anxiety without compromising care.

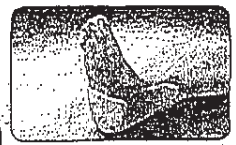
ALLEVYN Gentle Border
ALLEVYN Gentle Border Heel
NEW! ALLEVYN Gentle Border Sacrum
NEW! ALLEVYN Gentle Border 10x20cm

- Reduces trauma on removal for patients with fragile skin[8]
- Provide all the advantages of triple-action technology
- Showerproof dressing that can be lifted and repositioned[1]
- Provides comfort and protection to the wound[9]



Clinician satisfaction with ALLEVYN Gentle Border[8]


A thigh burn on a 91-year-old woman. ALLEVYN Gentle Border[17] helped decrease wound pain and pain at dressing change.


ALLEVYN Gentle Border Heel is a flat silicone gel adhesive dressing for use without secondary retention. Comfortable for every patient through universal fit.

Painful forearm abrasion at risk of infection due to gravel injuries[18]

The wound showed signs of healing in two days following the application of Ag Gentle Border

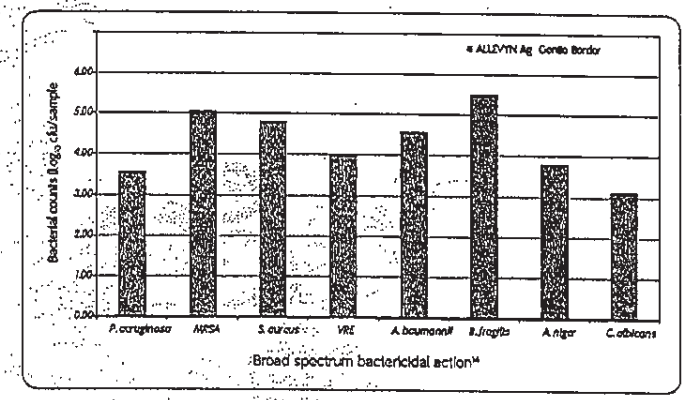
After 4 dressing changes, the wound showed 100% epithelialisation with a healthy peri wound area and no clinical signs of infection

* As demonstrated in vitro.

Ag Gentle Border

A silicone gel adhesive dressing containing silver sulfadiazine. Delivers sustained* antimicrobial protection and minimses pain on removal from patients with fragile skin.[10,13]

ALLEVYN® Ag Gentle Border
- Minimises pain and trauma for the patient at dressing change[10]
- Delivers broad spectrum antimicrobial* action to fight infection[9,14]
- Provides excellent exudate management and enduring patient comfort[9]
- A showerproof and convenient two in one solution for exuding wounds[4]



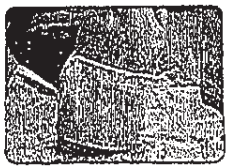
Broad spectrum bactericidal action[14]

The comfort of.
Gentle dressings

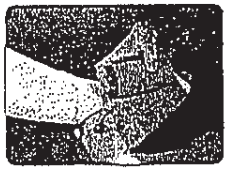
When a 'third hand' is needed, the ALLEVYN® Gentle range helps patients feel as comfortable as possible with a soft gel adhesive, but lends a helping hand for application on to various areas of the body.

ALLEVYN Gentle
ALLEVYN Non-Adhesive
ALLEVYN Heel

- Provide easier application and reduce trauma to skin on removal[2]
- Remain safely in place during your preparation and application of secondary retention
- Ideal for use under compression bandaging[28]

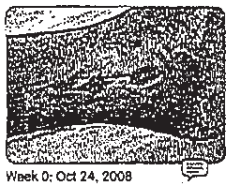


ALLEVYN Gentle stays in place on the foot of this diabetic patient, allowing the clinician to prepare retention bandaging.

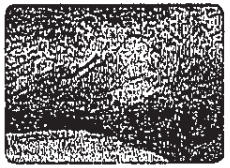


The PROFORE® bandaging system provides effective treatment for leg ulcers.

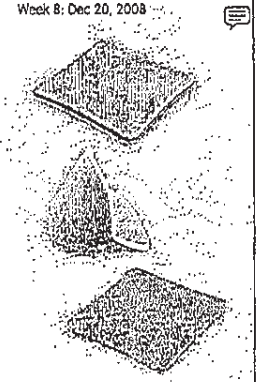
Improved Patient Concordance and Clinical Outcomes



Week 0: Oct 24, 2008



Week 8: Dec 20, 2008



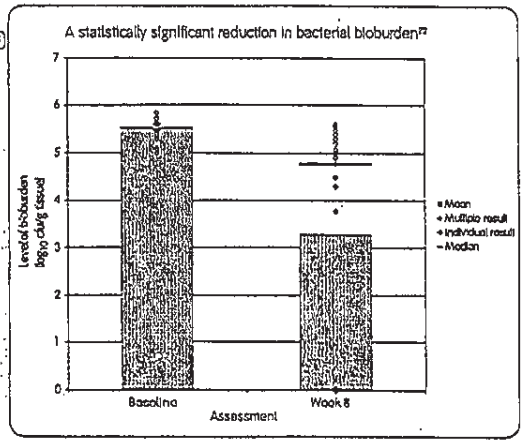
* As demonstrated in vitro
**ALLEVYN Ag Non Adhesive

Ag Gentle dressings

Designed with a soft gel adhesive for patients with fragile skin, ALLEVYN® Ag Gentle delivers sustained antimicrobial* protection combined with easier application and reduced trauma on removal.[13,21]

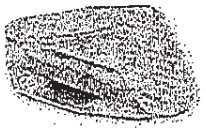
ALLEVYN Ag Gentle
ALLEVYN Ag Non-Adhesive
ALLEVYN Ag Heel

- Easier application with secondary retention, minimal trauma on removal[28]
- Effective antimicrobial* protection against a broad range of wound pathogens[8,29]
- Enduring patient comfort and excellent exudate management[21]
- Up to 7 day duration – no compromise on wear time[28]



Clinical trial results with ALLEVYN Ag** in hard to heal venous ulcers demonstrated:

- *A statistically significant reduction in bacterial bioburden.*
- *A statistically significant reduction in the percentage of patients with clinical signs of infection*
- *A significant decrease in wound pain*
- *A much higher wound closure rate than expected*[21]



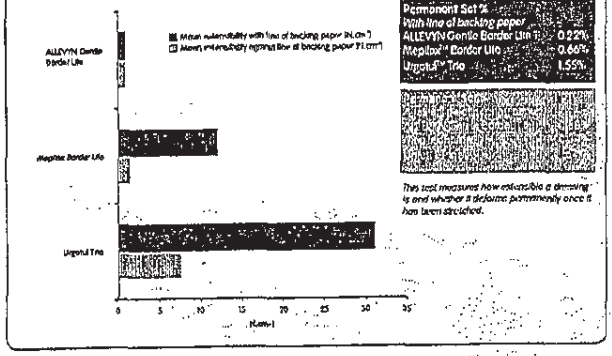
Gentle Border Lite

New ALLEVYN® Gentle Border Lite combines a lighter foam that is conformable[23] and comfortable to wear with the gentleness of a silicone adhesive for minimal pain on removal[10].

- Contains a thinner foam core
- Easily moulds to the contours of awkward body[9] areas
- Easy to apply
- Shower proof dressing[11]
- Ideal for patients with fragile skin[10] who have low to moderately exuding wounds

*ALLEVYN Gentle Border Lite dressings provides greater conformability**[23] – ensuring a more comfortable experience for patients and better wound coverage*

Extensibility and permanent set[23] of ALLEVYN Gentle Border Lite and competitor dressings

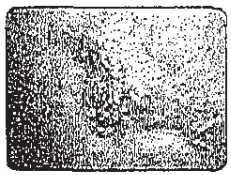


Permanent Set %	
With line of backing paper	
ALLEVYN Gentle Border Lite	0.22%
Mepilex® Border Lite	0.66%
Urgotul™ Tne	1.55%

This test measures how extensible a dressing is and whether it deforms permanently once it has been stretched.

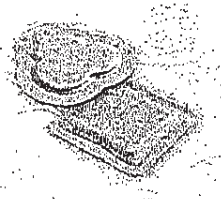
**In one direction

Wound before treatment with ALLEVYN Ag Adhesive[18]



Clinical trial findings with ALLEVYN Ag** across a variety of wound types showed:

"significant evidence of a reduction in the wound area", "the level of exudate" and "the percentage of patients presenting with clinical signs of infection"[23]



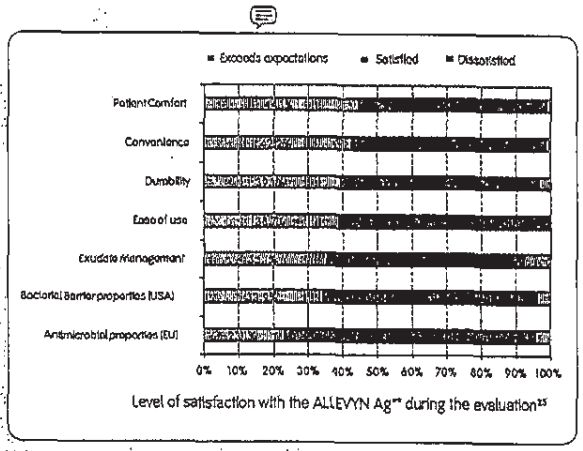
* As demonstrated in vitro
**ALLEVYN Ag Adhesive, Non Adhesive and Sacrum

Secure management of exudate and infection

ALLEVYN® Ag Adhesive and Sacrum provide sustained* silver protection with additional security of fixation for high friction areas or active patients[13]

ALLEVYN Ag Adhesive
ALLEVYN Ag Sacrum

- Sustained antimicrobial protection for up to 7 days[15]
- Excellent fluid management and reduced risk of maceration[12,24]
- Extensive wear time and reduced need for dressing changes[12,9]



Level of satisfaction with the ALLEVYN Ag** during the evaluation[23]

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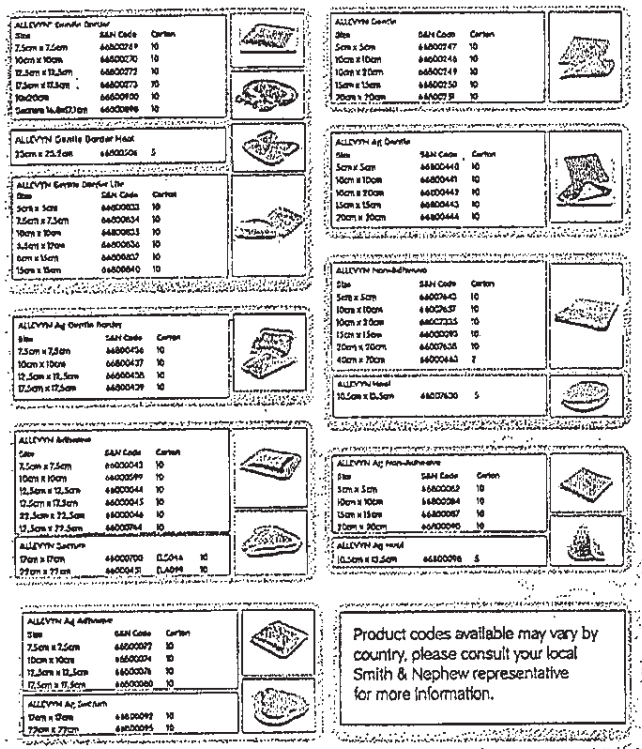
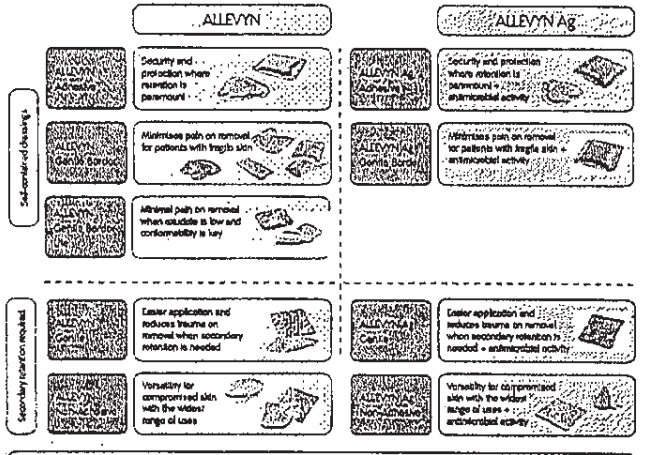


Product codes available may vary by country, please consult your local Smith & Nephew representative for more information.

The ALLEVYN® range



Your nurse or carer has decided that you need the best possible care and ALLEVYN will help your wound to heal so you can get on with your life.[4] ALLEVYN will require changing when exudate is within 0.5cm of the edge of the pad:

Wound Management
Smith & Nephew
Medical Ltd
101 Hessle Road
Hull HU3 2BN
T 44 (0) 1482 225181
F 44 (0) 1482326328

www.smith-nephew.com/wound
www.allevyn.com

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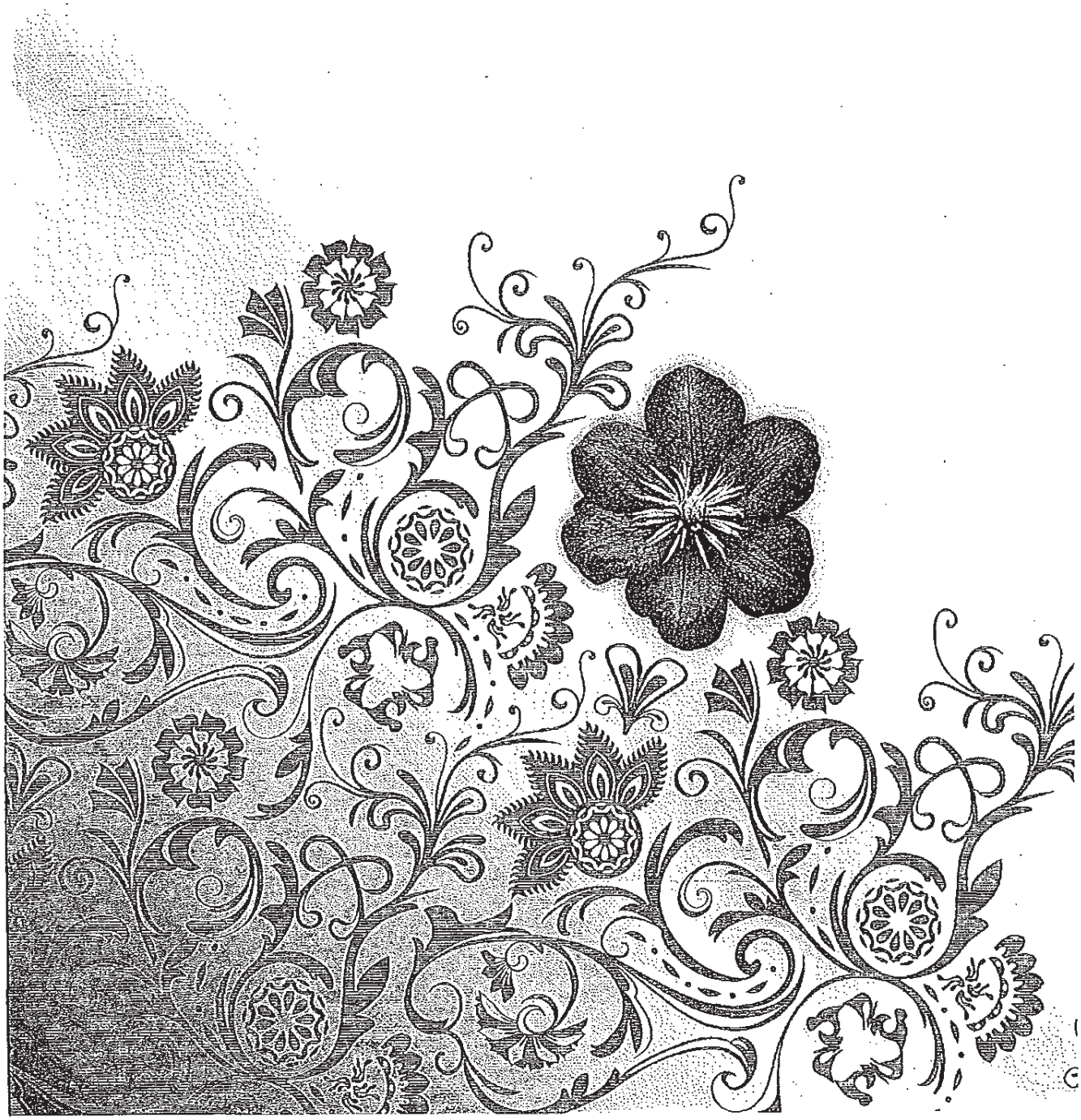
Tissue pattern © Oak Ting Wong Flower Image © Hanna Karpova



TITLE:	POOLE PUMP DFMEA
PROJECT	BRAVE POOLE PUMP DEVELOPMENT (055)
DOCUMENT NUMBER:	DAL-055-10-0000
REVISION	C

APPROVALS

NAME	ROLE	SIGNATURE	DATE
Andrew Mattson	Systems Engineer, Flextronics	On file in Agile	On file in Agile
Pankaj Satasiya	Project Manager, Flextronics	On file in Agile	On file in Agile
Carlos Arroyo	Quality Assurance, Flextronics	On file in Agile	On file in Agile
Chris Fryer	Project Manager, Smith & Nephew Advanced Wound Management	On file in Agile	On file in Agile
Neal Patrick	Quality Assurance, Smith & Nephew Advanced Wound Management	On file in Agile	On file in Agile

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PERFORMANCE TESTING - BENCH

The software validation testing addresses all of the electronic functions required to operate the device. In addition, the following laboratory tests have been performed.

1. **Dressing Filter Bacterial Efficiency**

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[redacted]

2. **Bacterial Barrier**

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3. Bacteria Retention Testing

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4. Wound Model Testing

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5. **Wound Model Testing with Wound Fillers**

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[redacted]

6. **7 Day Life Cycle of the Pump**

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7. **Waterproofness, Absorbency & Moisture Vapor Permeability (MVP)Testing**

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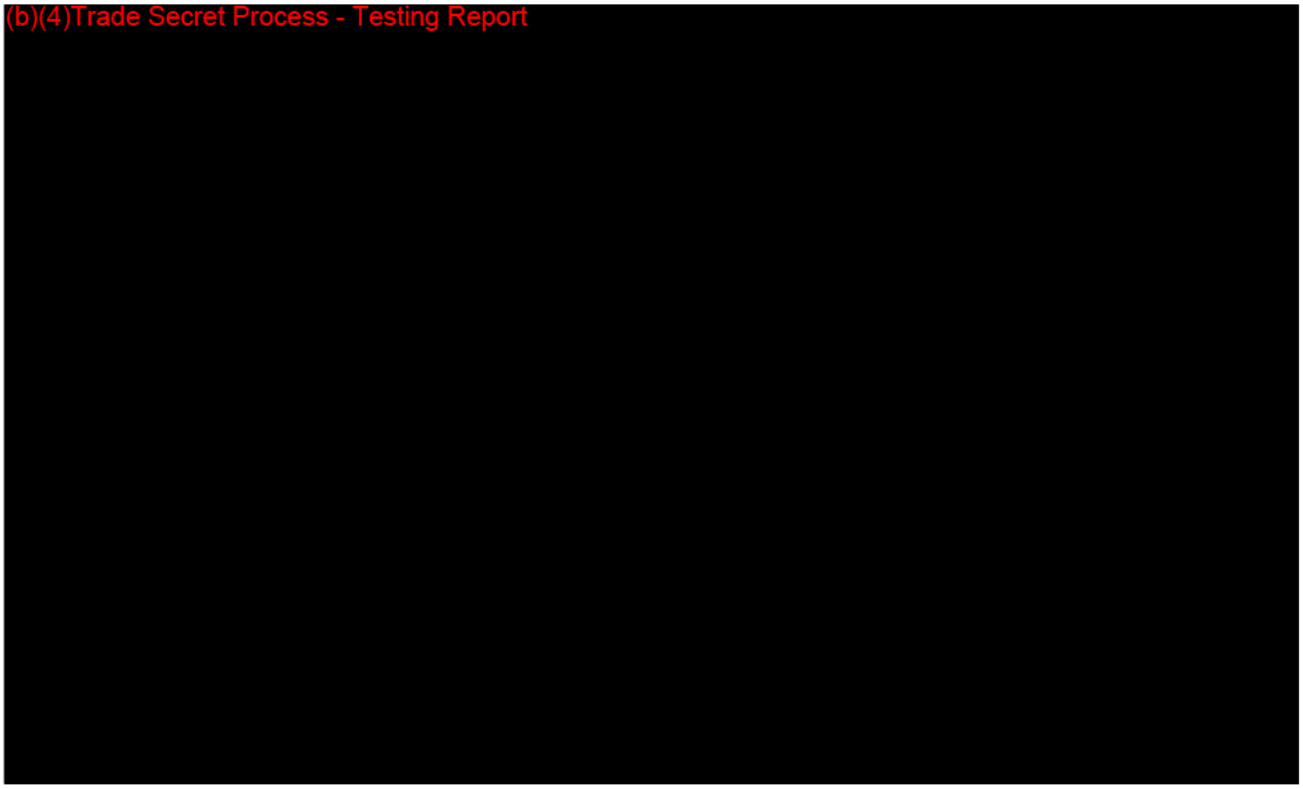
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PERFORMANCE TESTING – CLINICAL

A clinical trial has been performed to evaluate the functionality and performance characteristics only of PICO Single Use Negative Pressure Wound Therapy. The trial was performed at 2 study centers in South Africa. The trial was a prospective, non-comparative, multi-centre study and included the following wound types:

- Surgical incisions
- Skin grafts
- Low to moderately exuding trauma wounds

The primary objective of the clinical trial was to assess overall clinician acceptability and to assess the following aspects of the functional performance:

- Ease of application and removal
- Dressing wear time
- Battery life
- Exudate management

(b)(4)Trade Secret Process - Testing Report

Note: Reference to "Negative Pressure Enhanced Dressing" is made within the clinical trial report. This was a description used in the clinical trial documentation. All references made to "Negative Pressure Enhanced Dressing" are referring to PICO Single Use Negative Pressure Wound Therapy System.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name — Kelley Burridge, PhD

Subject: 510(k) Number — K111702/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

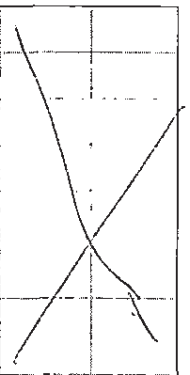
☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)		
Infant (29 days -< 2 years old)		
Child (2 years -< 12 years old)		
Adolescent (12 years -< 18 years old)		
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	✓



Regulation Number	Class*	Product Code
21 CFR 878.4780	II	OMP

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause — (Branch Chief) — PRSB — (Branch Code) — 12/15/2011 (Date)

Final Review: — (Division Director) — 12/15/2011 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K111170/S002

Date: Dec. 15, 2011
To: The Record
From: Kelley Burridge, Ph. D.
Branch: Plastic and Reconstructive Surgery
Division: Surgical, Orthopedic and Restorative Devices
Office: Device Evaluation

12/15/11

510(k) Holder: Smith & Nephew, Inc.
Establishment Registration Number: 3006760724
Device Name: PICO Single Use Negative Pressure Wound Therapy System
Contact: Terry McMahon, Director of Regulatory Affairs and Quality Assurance
Phone: (727) 392-1261
Fax: (727) 399-3468
Email: terry.mcmahon@smith-nephew.com

I. Purpose of Submission

The 510(k) holder would like to introduce PICO Single Use Negative Pressure Wound Therapy System into interstate commerce as a prescription device.

II. Document History

K11170/S002 (dated 12/12/11 and received in ODE 12/14/11) was assigned to me on 12/14/11 with a branch due date of 12/15/11.

K11170/S001 (dated 9/20/11 and received in ODE 9/21/11) was assigned to me on 9/23/11 with a branch due date of 10/21/11. This device was discussed at a telephone conference as part of I110698 on 9/7/11.

(b) (5)

[redacted]

III. Recommendation

The reviewer recommends that the device is substantially equivalent.

Regulation Number: 21 CFR §878. 4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP

IV. Indications for Use

(b)(4)Trade Secret Process [redacted]

For models 66800862, 66800863, 66800865, and 66800866:

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

For models 66800864, 66800867, 66800868, and 66800869:

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low levels of exudate and infectious materials.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns

- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

V. Labeling

(b)(4)Trade Secret Process

[redacted]

VI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:

(b)(4)Trade Secret Process

[redacted]

4. Explain how new characteristics could or could not affect safety or effectiveness:

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[redacted]

(b)(4)Trade Secret Process

5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

(b)(4)Trade Secret Process

7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

(b)(4)Trade Secret Process

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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VII. Response to FDA Request for Additional Information

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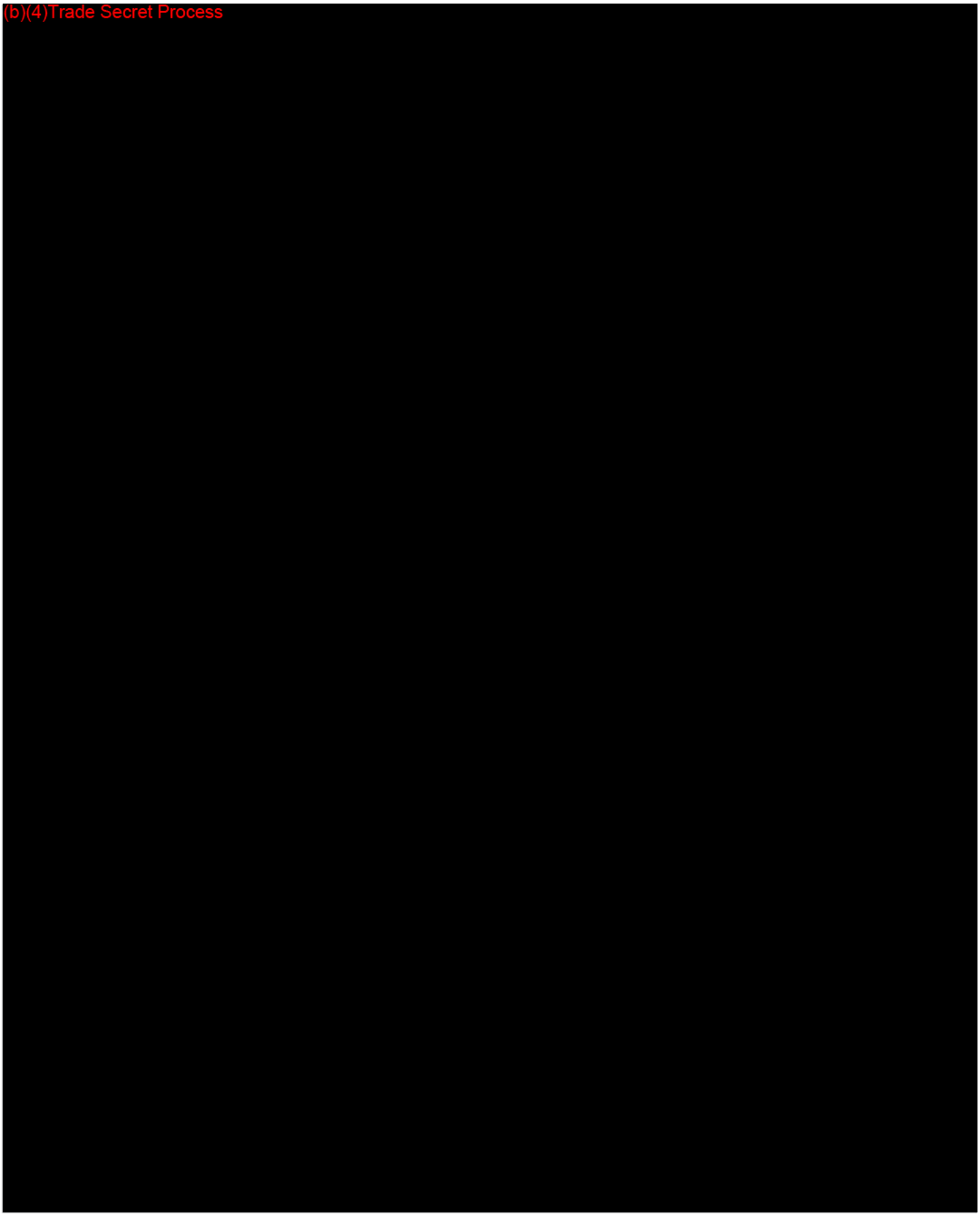

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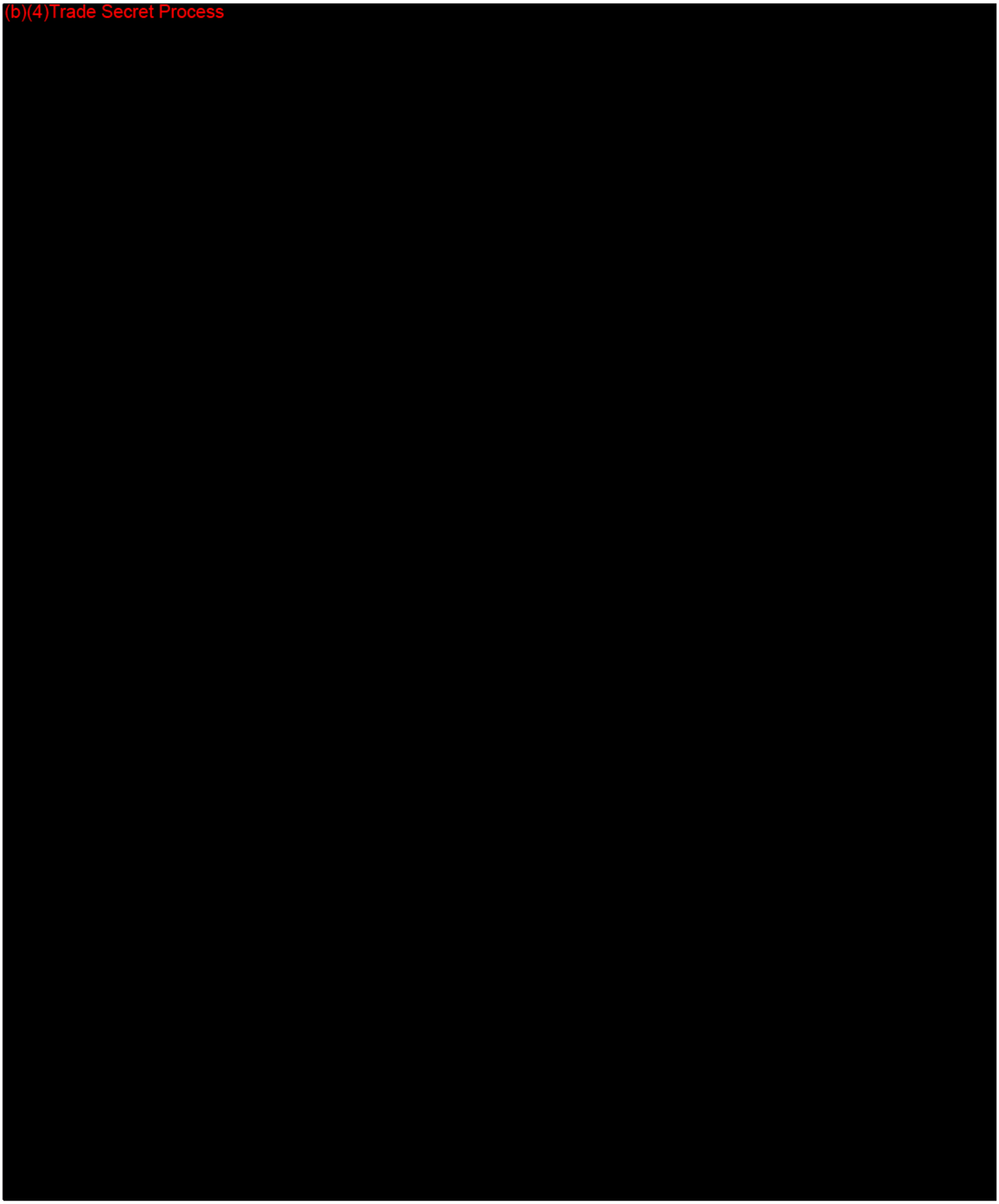

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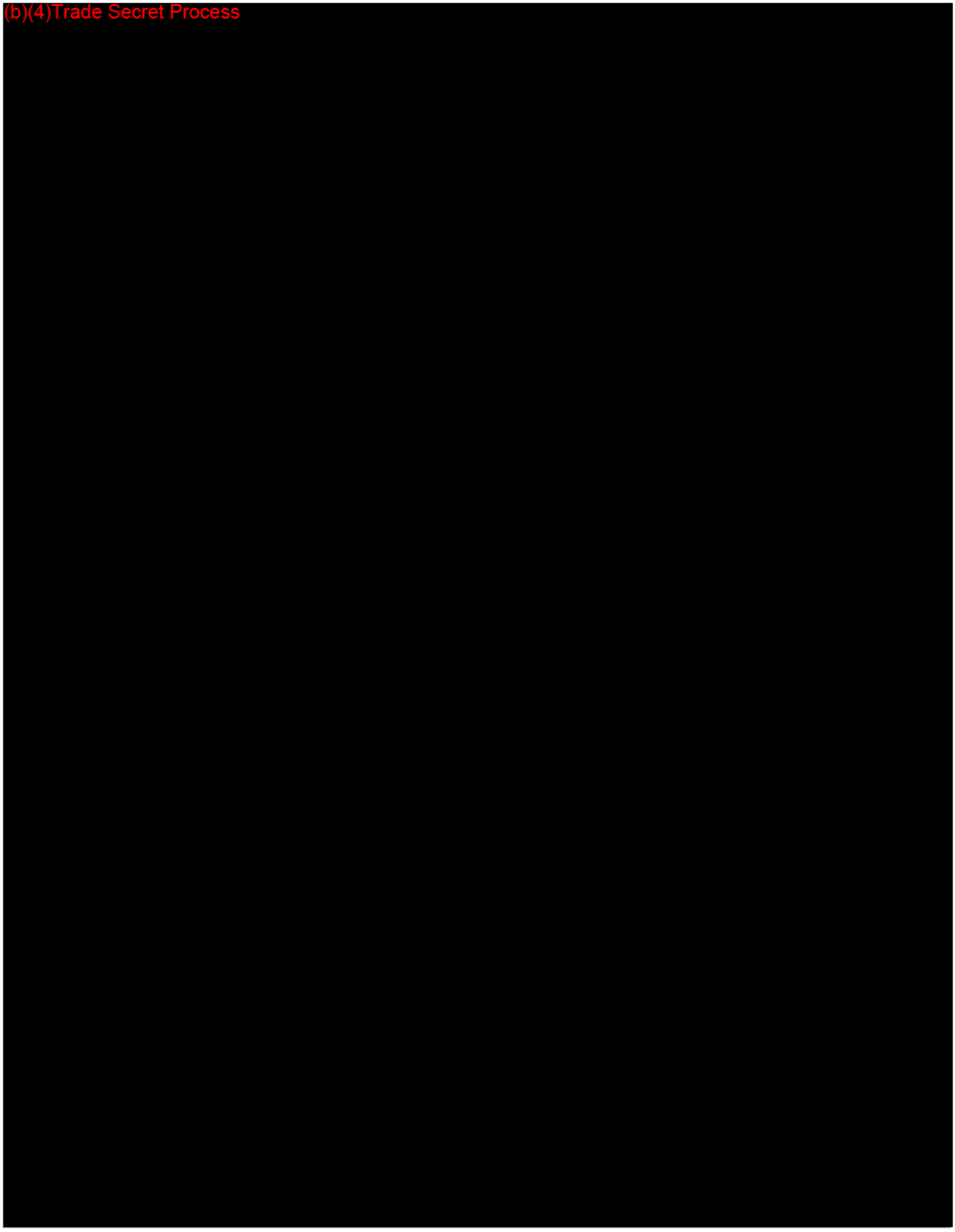

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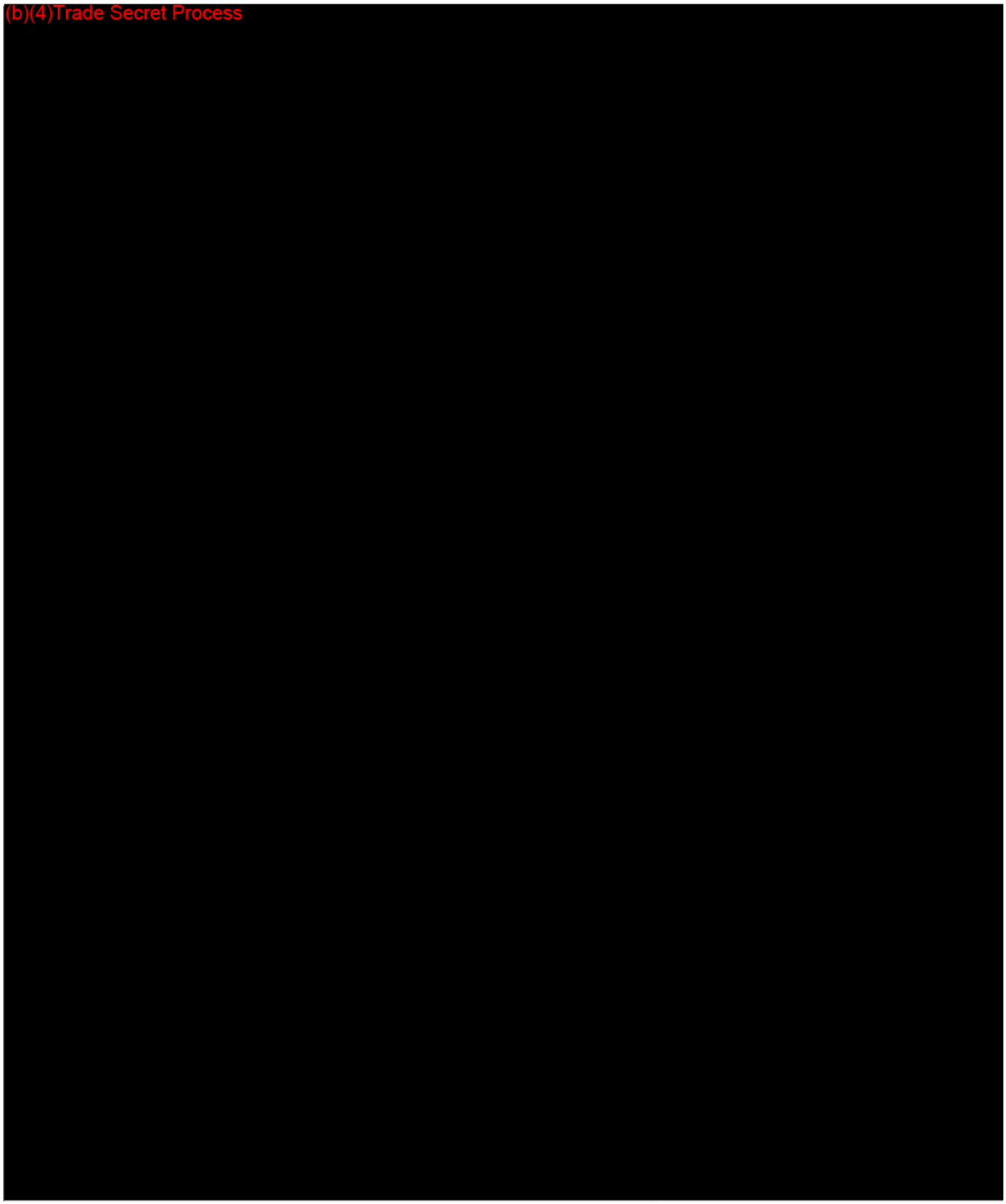
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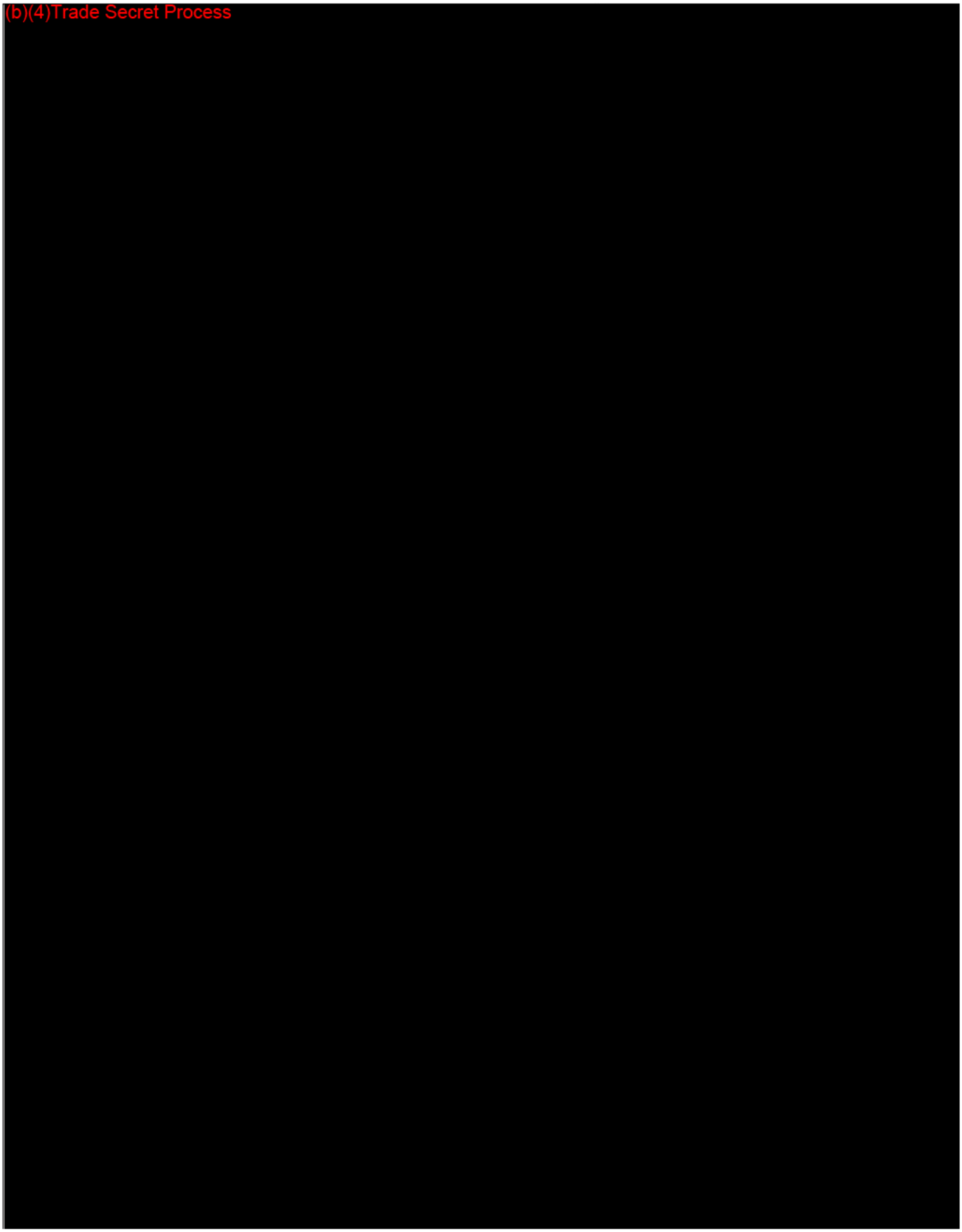

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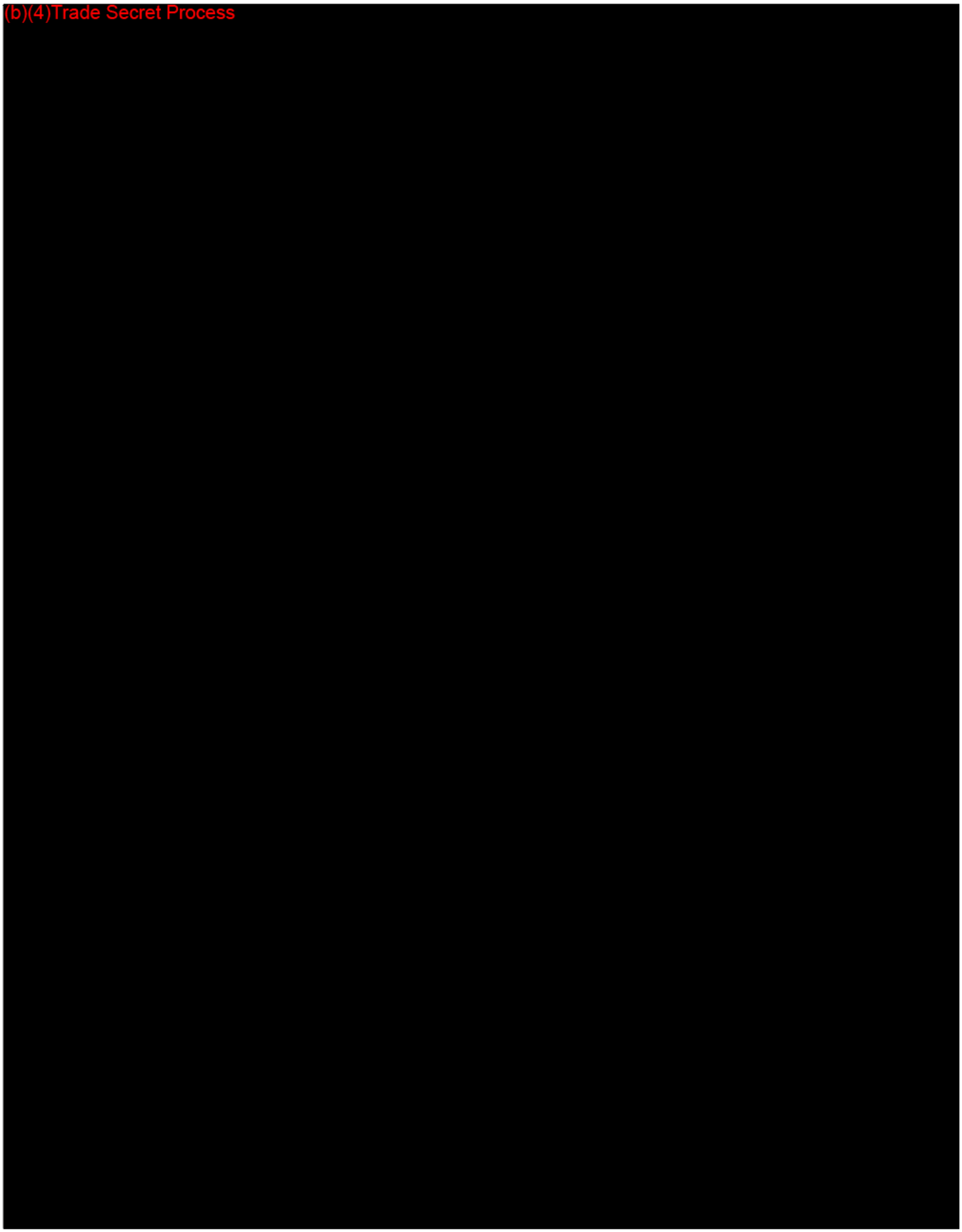

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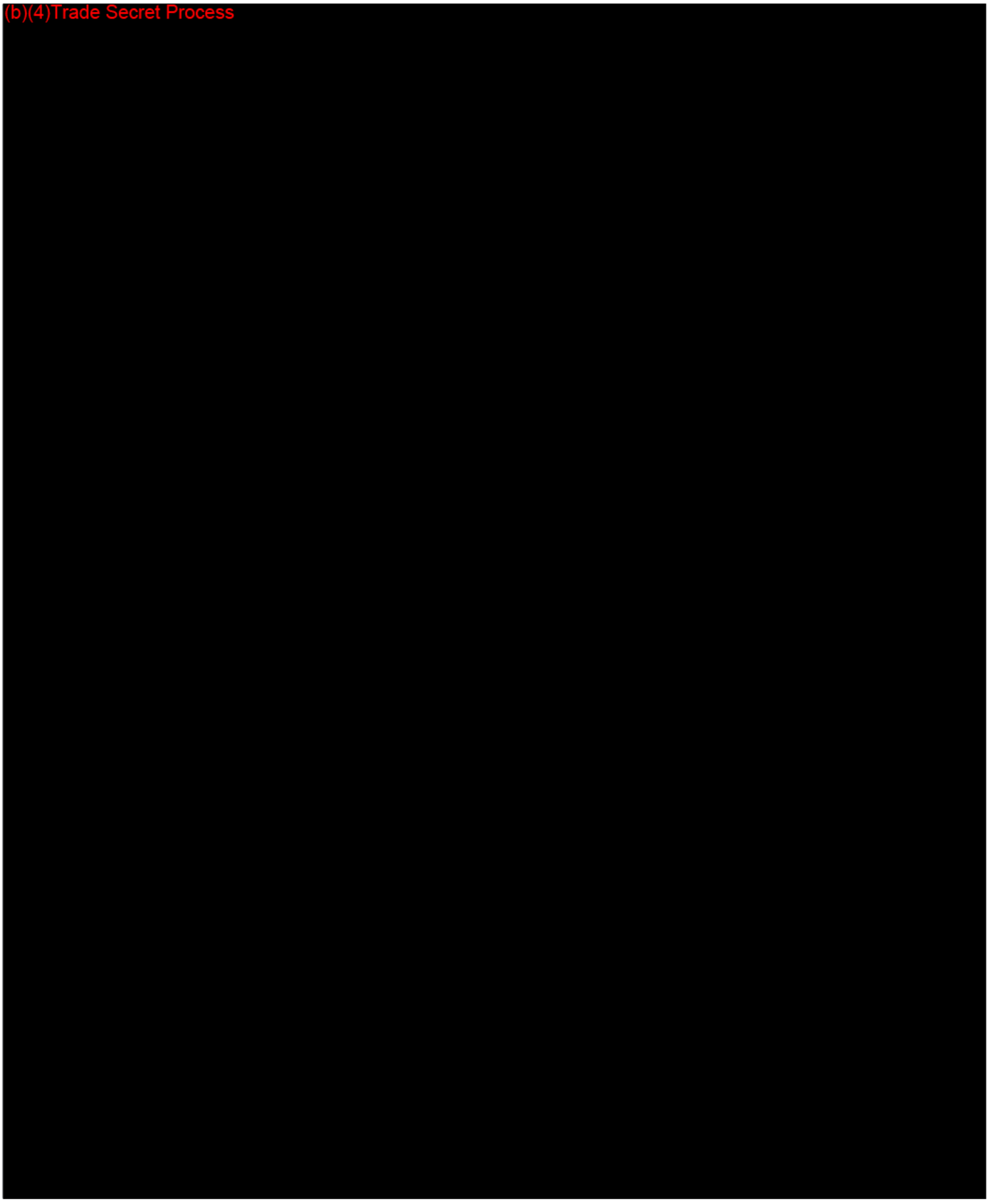

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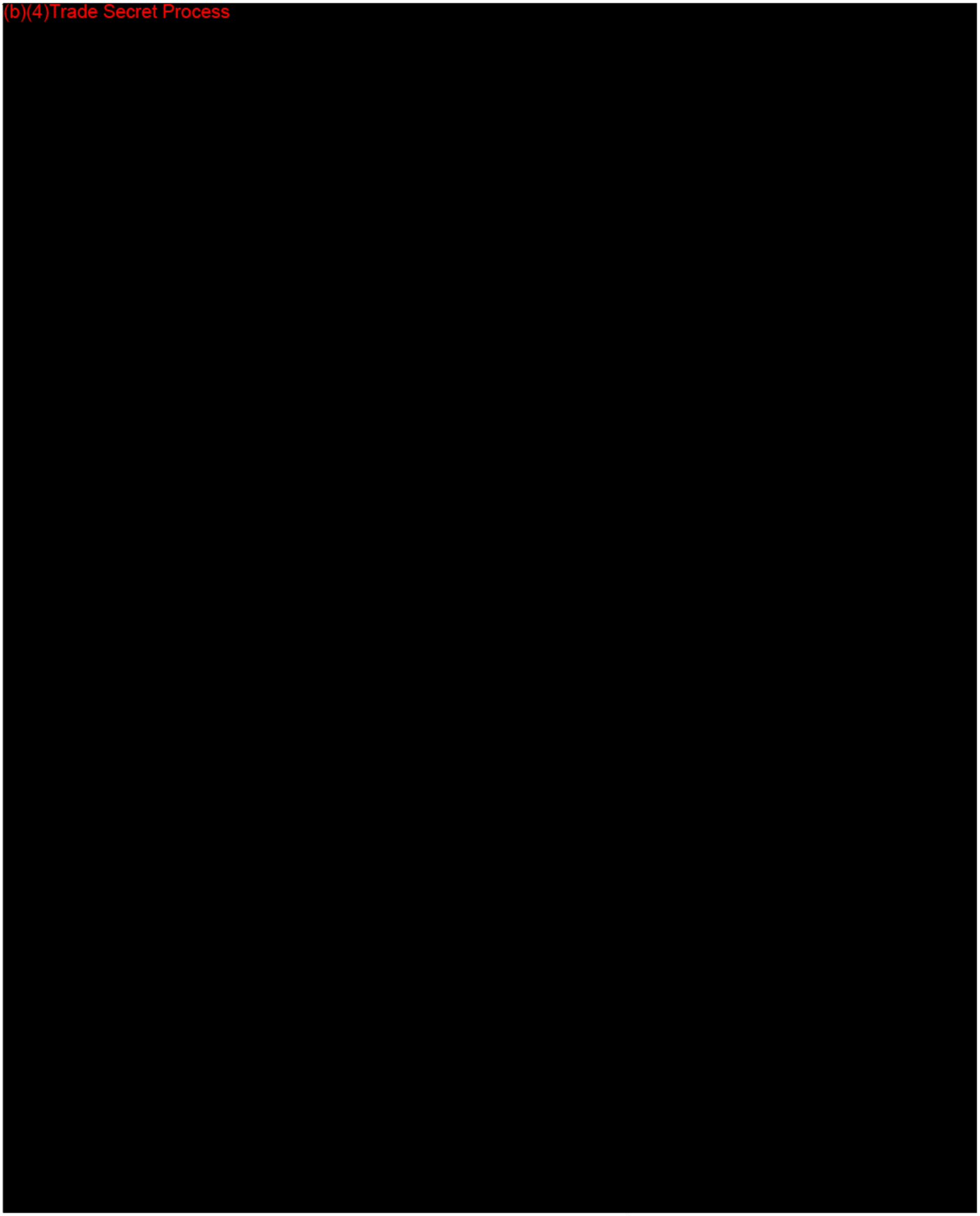

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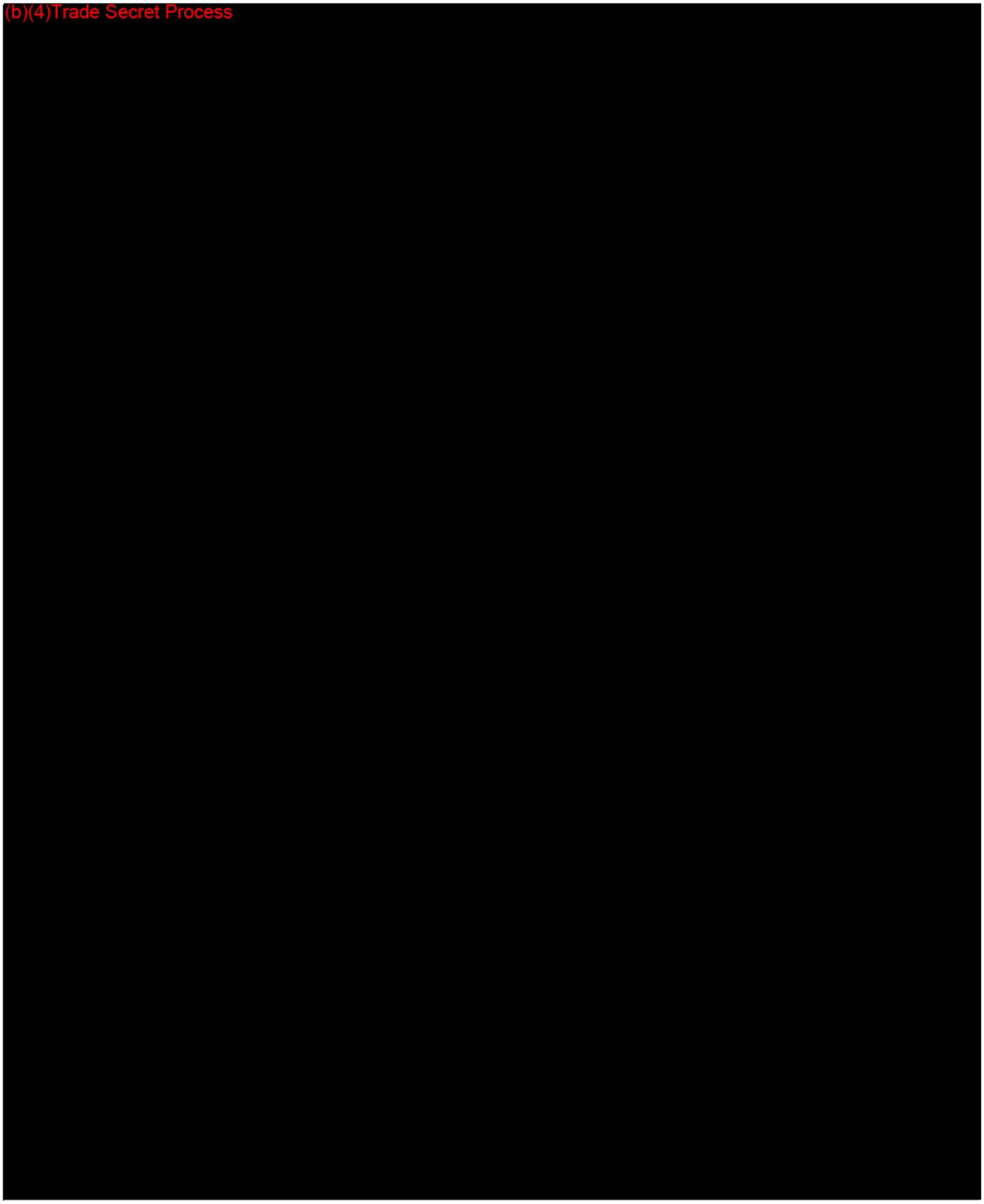

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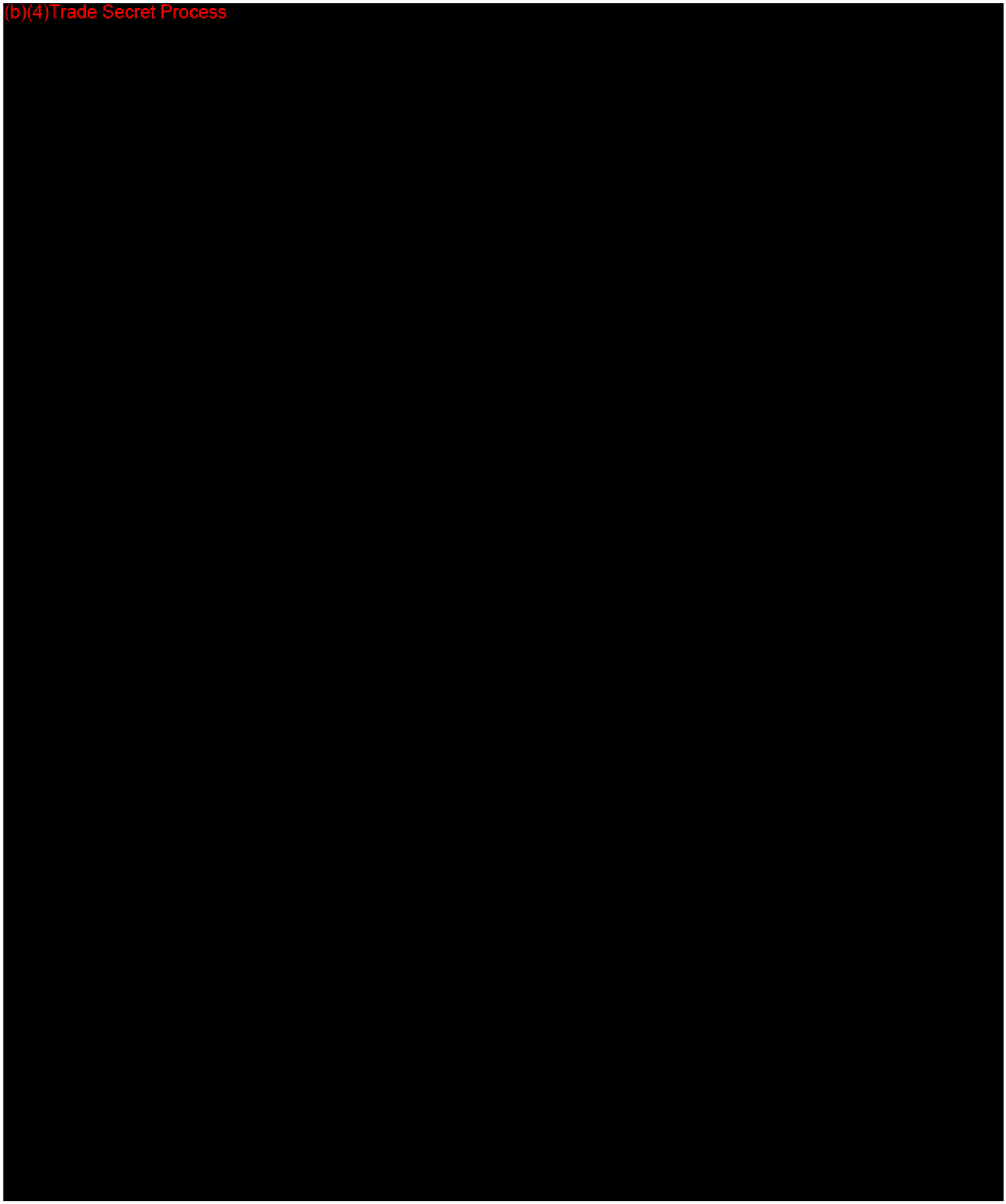

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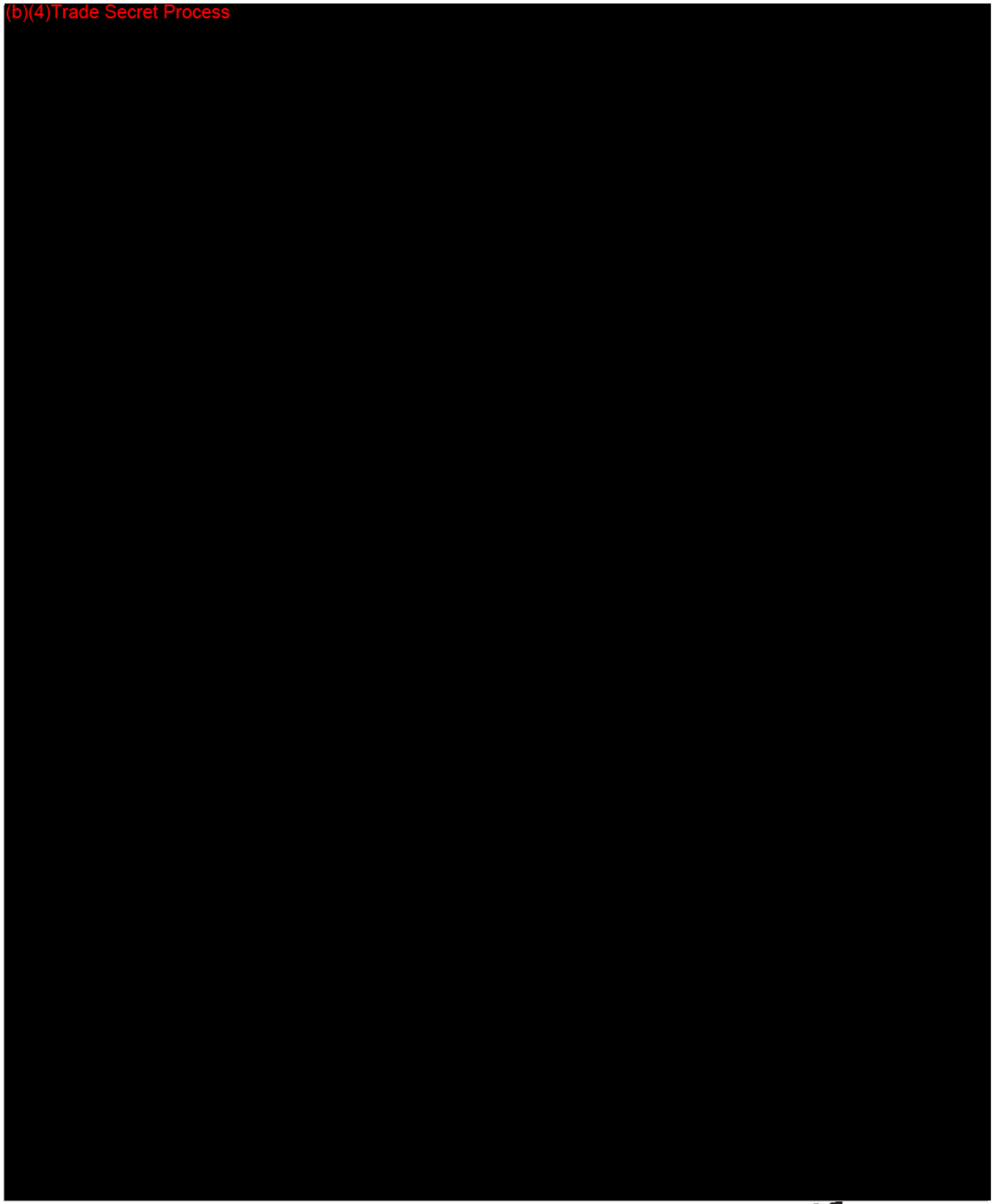

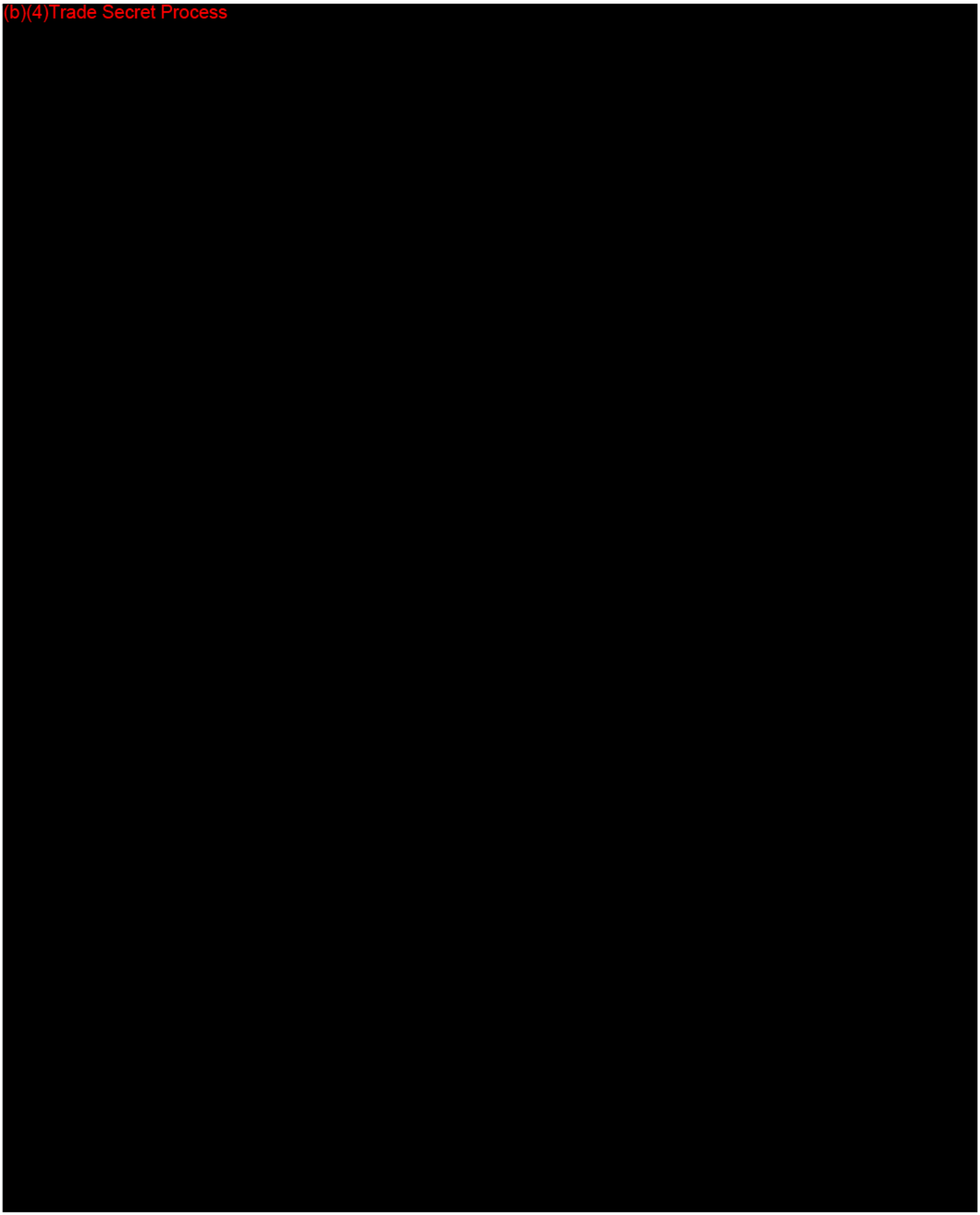
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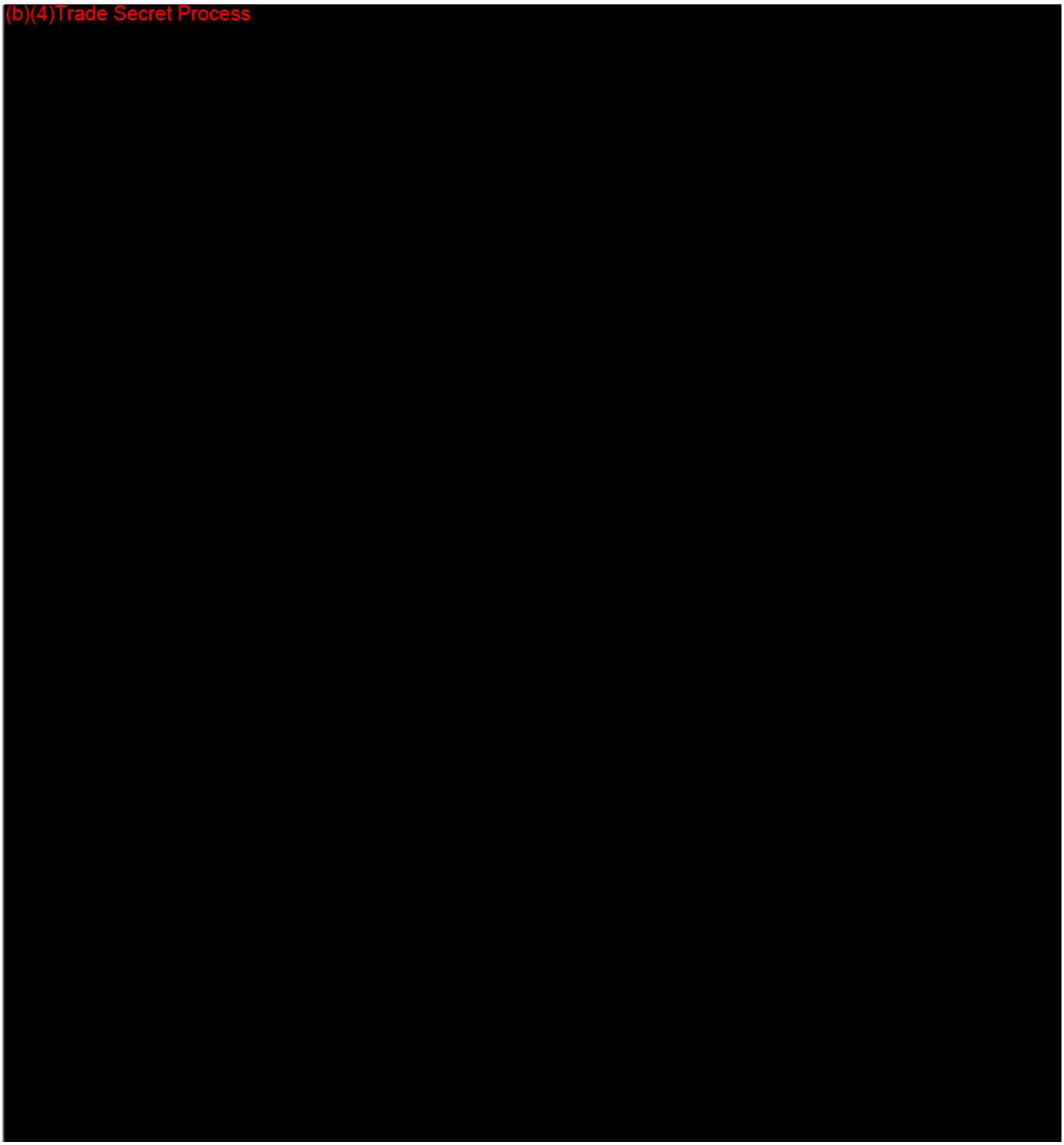
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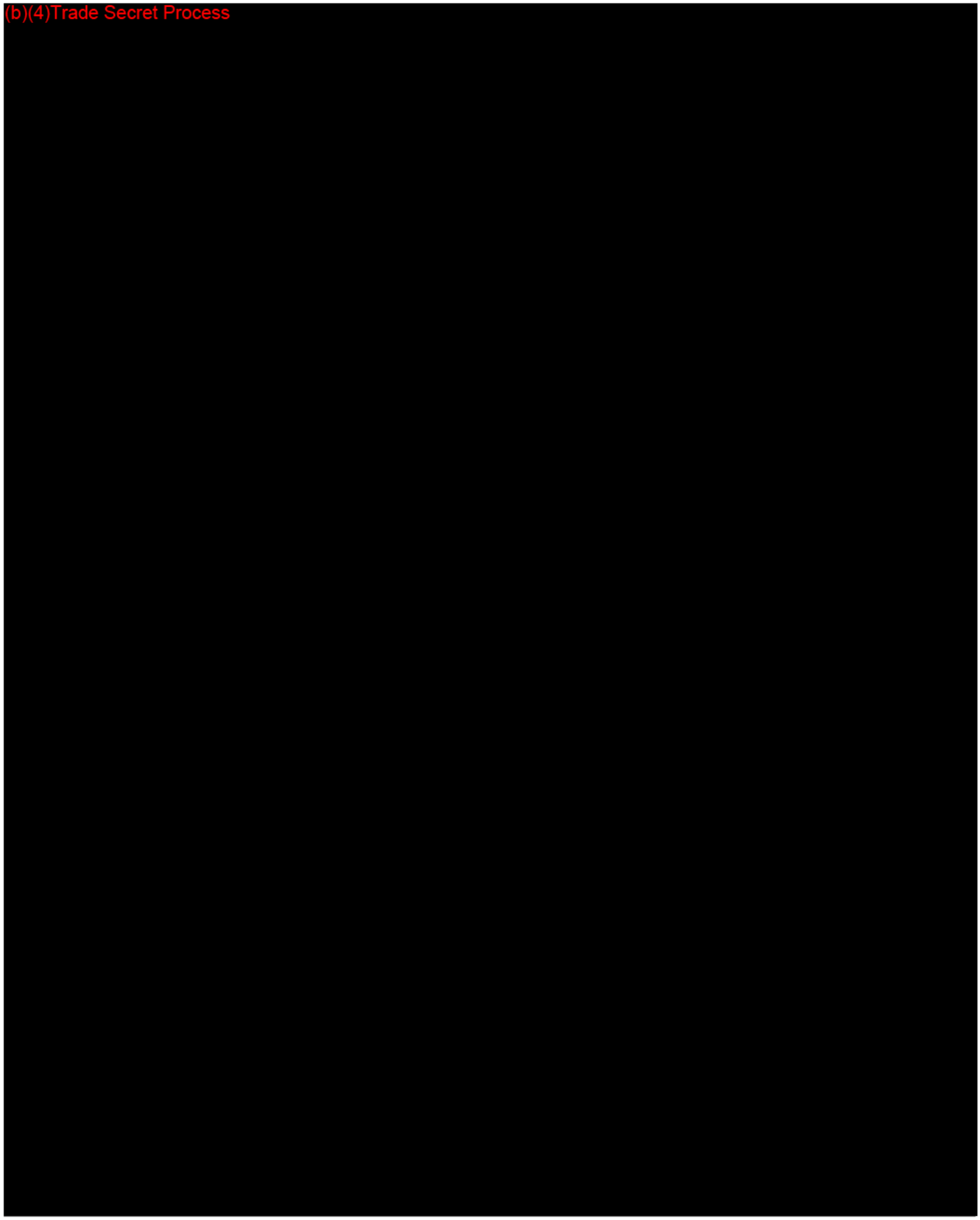

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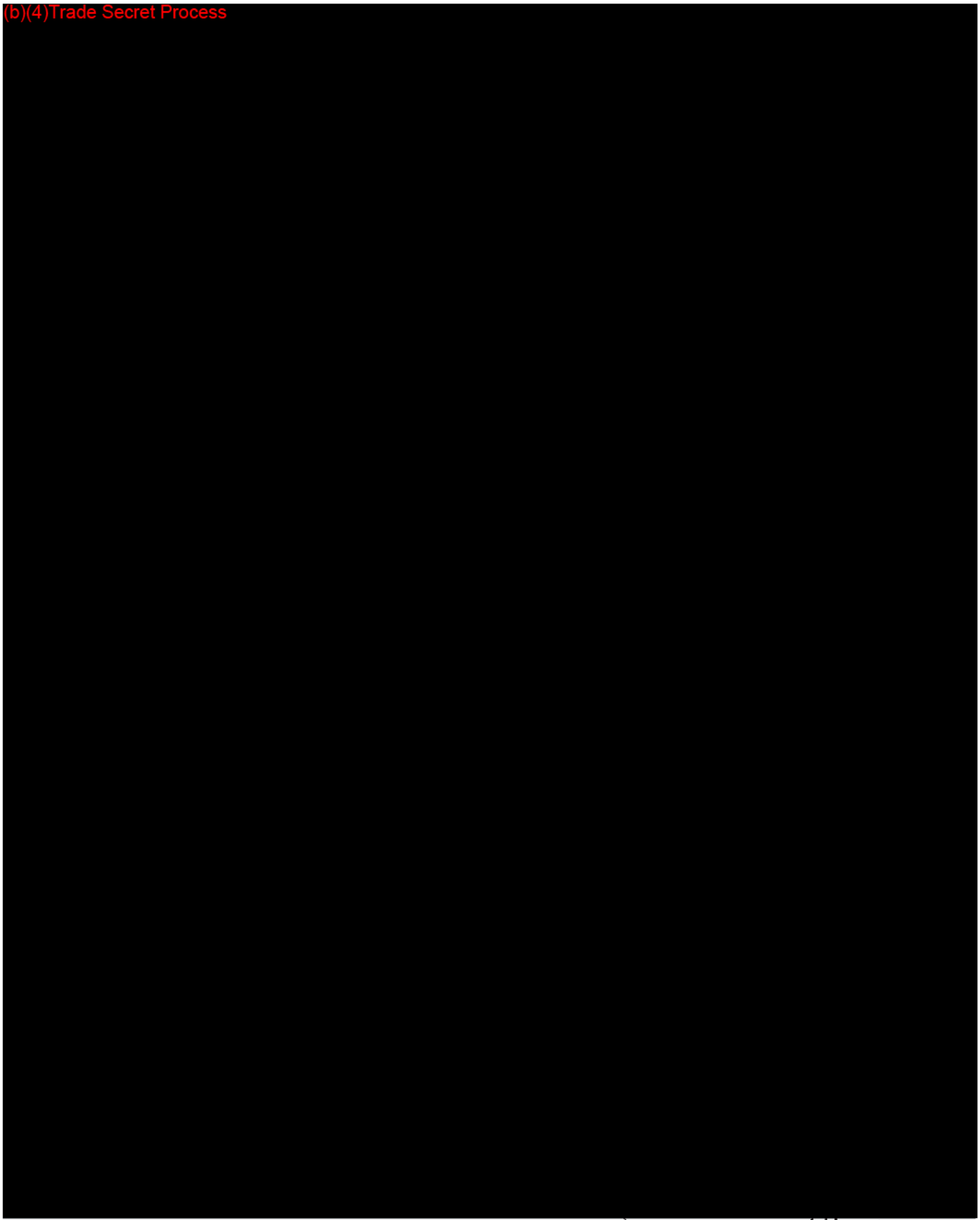

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VIII. Contact History

Note: Terry McMahon contacted the lead reviewer by telephone on a regular basis to check on the status of this file.

Date	Type – Topic
12/14/2011 - 12/15/2011	Telephone – Series of calls with Terry McMahon, Jane Hare, and Liam Phelan of Smith and Nephew and Kelley Burridge of FDA regarding ability of dressings to manage moderate exudate levels.
12/10/2011	Email – Kelley Burridge emailed sponsor regarding outstanding issues.
12/5/2011	Email – Jeffrey Silberberg emailed sponsor regarding EMC testing.
11/27/2011- 11/30/2011	Emails – Responses to questions and additional testing provided by sponsor.
11/22/2011	Telephone – Phone call between Terry McMahon, Jane Hare, and Chris Fryer of Smith and Nephew and Kelley Burridge and Jeffrey Silberberg of FDA. Additional EMC testing recommended to address outstanding issue of interference. Capacity table will be modified.
10/27/2011	Emails- Sponsor accidentally omitted the response to deficiency 3 from Supplement 1. Sent via email on 10/27/11.
9/13/2011	Emails-EMC deficiencies.
9/7/2011	Telephone-Phone conversation between Terry McMahon, Liam Phelan, Jane Hare, Laura Reynolds, Robin Martin, and Chris Fryer of Smith & Nephew and David Krause, Suzanne Schwartz, and Kelley Burridge of FDA regarding outstanding issues as part of I110698.
8/2/2011	Emails-Software deficiencies.
8/1/2011	Telephone-Phone conversation between Terry McMahon and Liam Phelan of Smith & Nephew and Kelley Burridge of FDA regarding AI letter.

Kelley Burridge

Kelley Burridge, Ph.D.
Scientific Reviewer, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

12/15/11
Date

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David Krause I concur E SE Dec. 15, 2011

David Krause, Ph.D. Date
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

Reference List

1. Lebleu, N., C. Roques, P. Aimar, and C. Causserand. 2009. Role of the cell-wall structure in the retention of bacteria by microfiltration membranes. Journal of Membrane Science 326: 178-185 ISI:000261906700023.
2. Moues, C. M., F. Heule, and S. E. R. Hovius. 2011. A review of topical negative pressure therapy in wound healing: sufficient evidence? American Journal of Surgery 201: 544-556 ISI:000289311700022.

Wound Management
Smith & Nephew, Inc.
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Suite 110
St. Petersburg, FL 33716

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F 727 392-6914 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com

We are smith&nephew

December 15, 2011

Kelley Burridge, Ph. D.
Scientific Reviewer
CDRH/ODE/DSORD/PRSB
Food and Drug Administration
White Oak Bldg 66 (WO66) Rm G425
10903 New Hampshire Ave
Silver Spring, MD 20993

RE: Additional Information for 510(k) #K111170

Dear Dr. Burridge:

(b)(4)Trade Secret Process

[redacted]

Sincerely,

Terry C. McMahon
Director of Regulatory Affairs
and Quality, N.A.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111170

Device Name: PICO Single Use Negative Pressure Wound Therapy System

Indications for Use:

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Product Codes: 66800862, 66800863,66800865 and 66800866 are indicated for use on low and moderately exuding wounds.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111170

Device Name: PICO Single Use Negative Pressure Wound Therapy System

Indications for Use:

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low levels of exudate and infectious materials.

Product Codes: 66800864, 66800867,66800868 and 66800869 are indicated for use on low exuding wounds,

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

PICO Single Use Negative Pressure Wound Therapy System

1. **Submitter:** Smith & Nephew, Inc.
   970 Lake Carillon Drive, Suite 110
   St. Petersburg, FL 33716

2. **Contact:** Terry McMahon
   Director of Regulatory Affairs & Quality, North America
   727-399-3785
   Email: terry.mcmahon@smith-nephew.com

3. **Device name:** PICO Single Use Negative Pressure Wound Therapy System
   Common name: Negative Pressure Wound Therapy powered suction pump
   Classification name: Powered suction pump (21 CFR 878.4780)
   Product Classification/Code: Class II, OMP

4. **Date summary prepared:** December 15, 2011

5. **Predicate Device Information:**
   NPD 1000 Negative Pressure Wound Therapy System (K080275)
   Kalypto Medical
   6393 Oakgreen Avenue
   Hastings, MN 55033

   Renasys Go (K083375)
   Smith & Nephew Inc,
   St. Petesburg, FL

Prevena Incision Management System (K100821)
KCI USA, INC.
6203 Farinon Dr.
San Antonio, TX 78249

6. **Device Description:**

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable suction device consisting of a electric motor driven, twin-diaphragm, vacuum pump connected to a super-absorbent, gentle adhesive dressing. The pump is supplied non-sterile and single use, the dressing and secondary fixations strips are supplied sterile and single use. The dressing is applied to the wound and secondary fixation strips are placed over the outside edges to help hold the dressing in place. When the suction pump is turned on, air is pulled out of the dressing creating negative pressure and drawing excess fluid from the wound into the dressing. The pump is battery operated and is supplied with two AA lithium batteries which provide up to 168 hours (7 days) of battery life depending upon leak rate. The batteries can be replaced if required. The pump is designed to stop working after 168 hours (7 days) of use and will not re-start after this time, even with new batteries. Negative pressure will not be applied at this point. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. A carry bag is not provided with the system however will be available to order separately.

7. Intended Use

7a. Low and moderately exuding wounds

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Product Codes: 66800862, 66800863, 66800865 and 66800866 are indicated for use on low and moderately exuding wounds.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

7b. Low exuding wounds

PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low levels of exudate and infectious materials.

Product Codes: 66800864, 66800867, 66800868 and 66800869 are indicated for use on low exuding wounds,

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

8. **Summary of Non-Clinical Testing**

The biocompatibility of the PICO Single Use Negative Pressure Wound Therapy System has been demonstrated through assessment according to ISO 10993-1: 2003 and appropriate *in vivo* and *in vitro* tests have been conducted using product that has been packaged and sterilised. These tests include cytotoxicity, sensitization and irritation and cover the PICO dressing and secondary fixation strips. These studies indicated that the PICO Single Use Negative Pressure Wound Therapy System is safe for its intended use.

Test	Description of Method	Result
Cytotoxicity	**PICO Dressing** In order to determine the cytotoxic potential of the dressing, a Minimum Essential Medium (MEM) elution assay was conducted in accordance with ISO 10993-5. **Secondary Fixation Strips** Cytotoxicity testing has been performed on the secondary fixation strips, tested in accordance with ISO 10993-5. The test article extract was diluted in supplemented EMEM 1X and placed onto triplicate confluent monolayers of L-929 mouse fibroblast cells at the 100%, 50%, 25% and 5% solutions (v/v).	N to 1:16, all non-cytotoxic (Grade 0) N to 1:16, all non-cytotoxic (Grade 0)
Sensitisation	**PICO Dressing** A Guinea Pig Maximisation Test was performed on the dressing in accordance with ISO 10993-10. **Secondary Fixation Strips** A guinea pig maximisation test was performed on the secondary fixation strips in accordance with ISO 10993-10.	Non-sensitising Non-sensitising
Irritation	**PICO Dressing** The dressing was evaluated for irritation in accordance with ISO 10993-10. **Secondary Fixation Strips** Irritation testing has been performed on the secondary fixation strips in accordance with ISO 10993-10.	PII SC = 0.0 PII SC = 0.1 Negligible irritant 0.9% NaCl extract: Primary Irritation Index: 0.11 (Negligible)

Additionally, the effects of the dressing wound contact layer have been assessed during a wound healing study on ALLEVYN Gentle Border dressings, report reference which have the same wound contact layer as the dressing included in the PICO Single Use Negative Pressure Wound Therapy System.

Testing has been completed in accordance with IEC / UL 60601-1; General Requirements for Safety of Electrical Medical Equipment and IEC 60601-1-2; Electromagnetic Safety Requirements For Electrical Medical Equipment. Software validation has been completed in accordance with IEC 62304 Software for Medical Devices.

9. **Conclusions Drawn**

Based on results of testing performed the subject device is substantially equivalent to the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275), Renasys Go (K083375) and Prevena Incision Management System (K100821).

PICO has similar design characteristics and provides similar functions to NPD 1000 Negative Pressure Wound Therapy System (K080275), Renasys Go (K083375) and Prevena Incision Management System (K100821). The intended use, indications and instructions for use for the subject and predicate devices are similar.

PICO does not raise any new issues of safety and effectiveness.

Burridge, Kelley

From: Burridge, Kelley
Sent: Saturday, December 10, 2011 3:01 PM
To: 'McMahon, Terry'; 'Hare, Jane N'
Cc: Krause, David
Subject: RE: Feedback on Proposed Responses to Questions on K111170

Dear Mr. McMahon and Ms. Hare,

(b)(4)Trade Secret Process

[redacted]

Sincerely,

Kelley Burridge

From: McMahon, Terry [mailto:terry.mcmahon@smith-nephew.com]
Sent: Friday, December 09, 2011 1:16 PM
To: Burridge, Kelley
Cc: Krause, David
Subject: RE: Feedback on Proposed Responses to Questions on K111170
Importance: High

Dr. Burridge,

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Thank you in advance for your cooperation.

Regards,

Terry C. McMahon
Director, Regulatory Affairs
and Quality - North America

Smith & Nephew Wound Management
St. Petersburg, Florida, USA
Direct Phone: (727) 399-8785
Cell: (727) 644-7162
Direct Fax: (727) 329-5613

e-mail: terry.mcmahon@smith-nephew.com

Burridge, Kelley

From: McMahon, Terry [terry.mcmahon@smith-nephew.com]
Sent: Monday, December 05, 2011 5:40 PM
To: Burridge, Kelley
Cc: Krause, David
Subject: RE: Additional Information Request - 510(k) #K111170

Dear Dr. Burridge,

(b)(4)Trade Secret Process

[redacted]

Sincerely,

Terry C. McMahon
Director, Regulatory Affairs
and Quality - North America

Smith & Nephew Wound Management
St. Petersburg, Florida, USA
Direct Phone: (727) 399-3785
Cell: (727) 644-7162
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e-mail: terry.mcmahon@smith-nephew.com

Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Monday, December 05, 2011 5:12 PM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry
Subject: RE: K111170 PICO Single Use Negative Pressure Wound Therapy System - (b)(4)Trade Secret Process

Dear Dr Silberberg,

(b)(4)Trade Secret Process

Kind regards,

Jane

smith&nephew
Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|
jane.hare@smith-nephew.com|
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M +44 7778321678
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From: Silberberg, Jeffrey L. [mailto:Jeffrey.Silberberg@fda.hhs.gov]
Sent: 05 December 2011 06:55
To: Hare, Jane N
Cc: Burridge, Kelley; McMahon, Terry
Subject: RE: K111170 PICO Single Use Negative Pressure Wound Therapy System - (b)(4)Trade Secret Process

Jane,

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

[redacted]

Jeff

Jeffrey L. Silberberg
Senior Electronics Engineer
FDA Center for Devices and Radiological Health
Building 62, Room 4216
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 1-301-796-2584
FAX: 1-301-796-9931
e-mail: jeffrey.silberberg@fda.hhs.gov

From: Hare, Jane N [mailto:jane.hare@smith-nephew.com]
Sent: Wednesday, November 30, 2011 4:32 AM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry
Subject: K111170 PICO Single Use Negative Pressure Wound Therapy System - Final Report of additional ESD/EMI testing

Dear Dr Silberberg,

(b)(4)Trade Secret Process

[redacted]

Kind regards,

Jane

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[redacted]

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Burridge, Kelley

From: Silberberg, Jeffrey L.
Sent: Monday, December 05, 2011 1:55 AM
To: Hare, Jane N
Cc: Burridge, Kelley; McMahon, Terry
Subject: RE: K111170 PICO Single Use Negative Pressure Wound Therapy System - (b)(4)Trade Secret (b)(4)Trade Secret Process

Jane,

(b)(4)Trade Secret Process

[redacted]

Jeff

Jeffrey L. Silberberg
Senior Electronics Engineer
FDA Center for Devices and Radiological Health
Building 62, Room 4216
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 1-301-796-2584
FAX: 1-301-796-9931
e-mail: jeffrey.silberberg@fda.hhs.gov

From: Hare, Jane N [mailto:jane.hare@smith-nephew.com]
Sent: Wednesday, November 30, 2011 4:32 AM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry
Subject: K111170 PICO Single Use Negative Pressure Wound Therapy System - (b)(4)Trade Secret Process (b)(4)Trade Secret

Dear Dr Silberberg,

(b)(4)Trade Secret Process

[redacted]

Kind regards,

Jane

51

smith&nephew

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[redacted]

Burridge, Kelley

From: McMahon, Terry [terry.mcmahon@smith-nephew.com]
Sent: Wednesday, November 30, 2011 5:51 PM
To: Burridge, Kelley
Cc: Hare, Jane N
Subject: RE: Additional Information for K111170 - PICO
Importance: High

Dear Dr. Burridge,

(b)(4)Trade Secret Process

[redacted]

Regards,

Terry C. McMahon
Director, Regulatory Affairs
and Quality - North America

Smith & Nephew Wound Management
St. Petersburg, Florida, USA
Direct Phone: (727) 399-3785
Cell: (727) 644-7162
Direct Fax: (727) 329-5613

e-mail: terry.mcmahon@smith-nephew.com

Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Wednesday, November 30, 2011 4:32 AM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry
Subject: K111170 PICO Single Use Negative Pressure Wound Therapy System - (b)(4)Trade Secret Process (b)(4)Trade Secret Process
Attachments: EM11056026 Report.pdf

Dear Dr Silberberg,

(b)(4)Trade Secret Process

Kind regards,

Jane

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Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|
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Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Tuesday, November 29, 2011 2:32 PM
To: Burridge, Kelley
Cc: Silberberg, Jeffrey L.; McMahon, Terry
Subject: K111170 PICO Single Use Negative Pressure Wound Therapy System

Dear Dr Burridge

(b)(4)Trade Secret Process

[redacted]

Kind regards,

Jane

smith&nephew

Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|

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[redacted]

Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Monday, November 28, 2011 2:42 PM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry; Fryer, Chris
Subject: K111170 PICO Single Use Negative Pressure Wound Therapy System
Importance: High
Attachments: (b)(4)Trade Secret Process [redacted]

Dear Jeff

(b)(4)Trade Secret Process [redacted]

Kind regards,

smith&nephew

Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|

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(b)(4)Trade Secret Process [redacted]

Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Sunday, November 27, 2011 11:50 AM
To: Burridge, Kelley
Cc: McMahon, Terry
Subject: K111170 - PICO Single Use Negative Pressure Wound Therapy System (E-mail: 2 of 2)
Attachments (b)(4)Trade Secret Process

Dear Dr Burridge,

(b)(4)Trade Secret Process

Kind regards

smith&nephew

Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|

jane.hare@smith-nephew.com|

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(b)(4)Trade Secret Process

Burridge, Kelley

From: Hare, Jane N [jane.hare@smith-nephew.com]
Sent: Sunday, November 27, 2011 11:39 AM
To: Burridge, Kelley
Cc: McMahon, Terry
Subject: K111170 - PICO Single Use Negative Pressure Wound Therapy System (E-mail 1 of 2)
Attachments: (b)(4)Trade Secret Process

Dear Dr Burridge

(b)(4)Trade Secret Process

Kind regards

smith&nephew

Jane Hare | Director of Regulatory Affairs | Advanced Wound Management, Healthcare Systems - Regulatory Affairs|

jane.hare@smith-nephew.com|

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(b)(4)Trade Secret Process

[redacted]

Burridge, Kelley

From: Silberberg, Jeffrey L.
Sent: Tuesday, November 22, 2011 5:54 PM
To: Fryer, Chris
Cc: Burridge, Kelley; McMahon, Terry; Hare, Jane N
Subject: RE: PICO

Chris,

(b)(4)Trade Secret Process [redacted]

Thanks.

Jeff

Jeffrey L. Silberberg
Senior Electronics Engineer
FDA Center for Devices and Radiological Health
Building 62, Room 4216
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 1-301-796-2584
FAX: 1-301-796-9931
e-mail: jeffrey.silberberg@fda.hhs.gov

From: Fryer, Chris [mailto:Chris.Fryer@smith-nephew.com]
Sent: Tuesday, November 22, 2011 5:32 PM
To: Silberberg, Jeffrey L.
Cc: Burridge, Kelley; McMahon, Terry; Hare, Jane N
Subject: PICO

Dear Jeff

(b)(4)Trade Secret Process [redacted]

Kind Regards
Chris Fryer
Chris Fryer
Project Manager - Advanced Wound Care
D 44(0) 1482 673 722
M 44(0) 7852 977 438

61

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(b)(4)Trade Secret Process

[redacted]

Burridge, Kelley

From: Burridge, Kelley
Sent: Tuesday, November 22, 2011 5:01 PM
To: 'McMahon, Terry'
Cc: 'Fryer, Chris'; 'Hare, Jane N'
Subject: RE: Contact Info

Terry,

(b)(4)Trade Secret Process [redacted]

Best Regards,
Kelley

From: McMahon, Terry [mailto:terry.mcmahon@smith-nephew.com]
Sent: Tuesday, November 22, 2011 4:07 PM
To: Burridge, Kelley
Cc: Fryer, Chris; Hare, Jane N
Subject: Contact Info

Kelley,

(b)(4)Trade Secret Process [redacted]

Thanks,
Terry

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Burridge, Kelley

From: McMahon, Terry [terry.mcmahon@smith-nephew.com]
Sent: Tuesday, November 22, 2011 11:55 AM
To: Burridge, Kelley
Subject: Fw: Call with Smith and Nephew- Dial-in instructions

Kelley,

(b)(4)Trade Secret Process

[redacted]

Terry

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----- Original Message -----
From: McMahon, Terry
To: 'kelley.burridge@fda.hhs.gov' <kelley.burridge@fda.hhs.gov>
Sent: Mon Nov 21 14:31:28 2011
Subject: Call with Smith and Nephew- Dial-in instructions

Kelley,

(b)(4)Trade Secret Process

[redacted]

Terry

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64

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kelley Barridge, PhD

Subject: 510(k) Number K111170/S1

To: The Record

Please list CTS decision code AI

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

~~x Hold (Additional Information or Telephone Hold)~~ 11/18/11

x Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

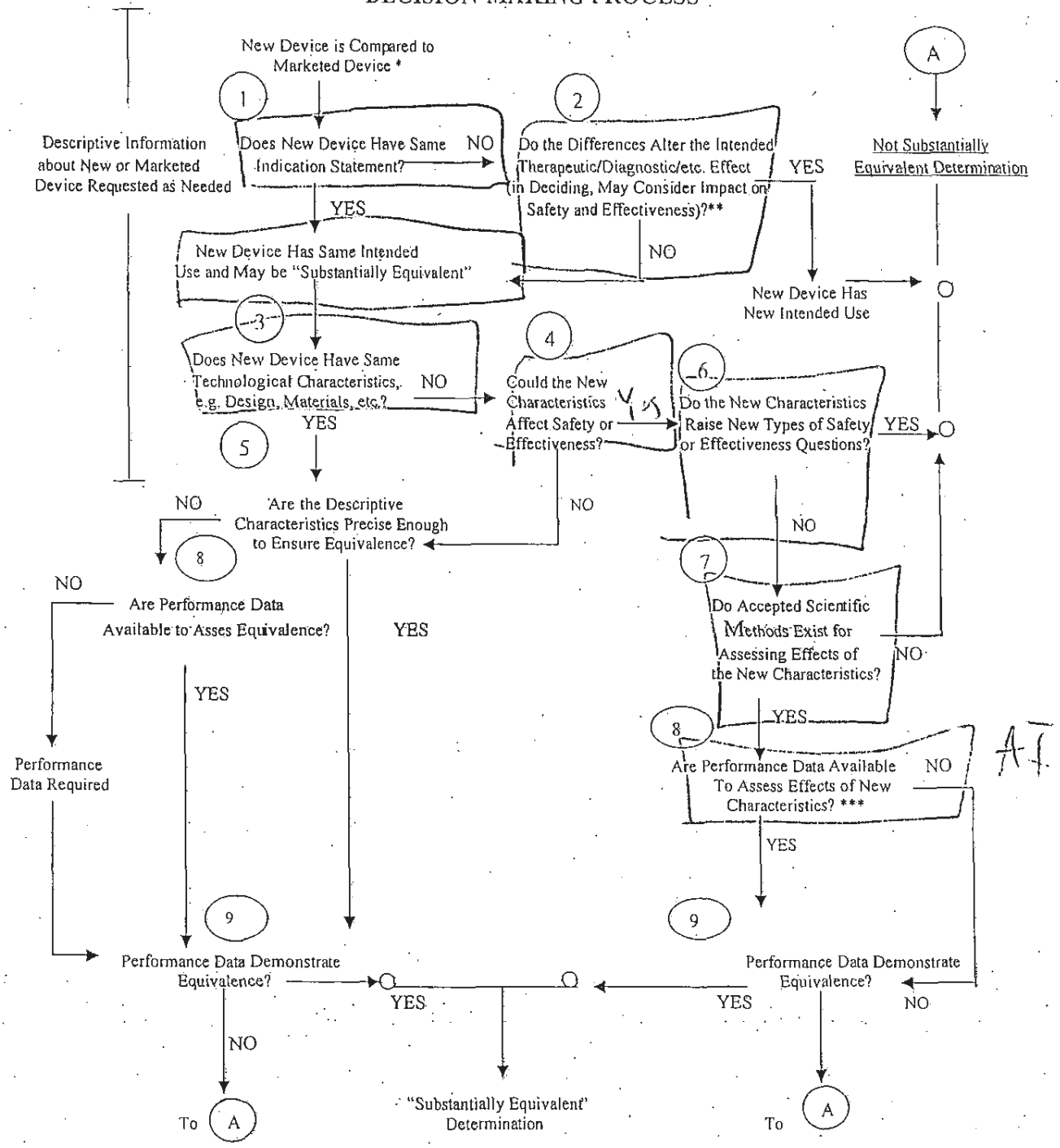
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause (Branch Chief) PRSB (Branch Code) NOV. 16 2011 (Date)

Final Review: David Krause (Division Director) 11/16/2011 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K111170/S001

Date: Nov. 18, 2011
To: The Record
From: Kelley Burridge, Ph. D.
Branch: Plastic and Reconstructive Surgery
Division: Surgical, Orthopedic and Restorative Devices
Office: Device Evaluation

510(k) Holder: Smith & Nephew, Inc.
Establishment Registration Number: 3006760724
Device Name: PICO Single Use Negative Pressure Wound Therapy System
Contact: Terry McMahon, Director of Regulatory Affairs and Quality Assurance
Phone: (727) 392-1261
Fax: (727) 399-3468
Email: terry.mcmahon@smith-nephew.com

I. Purpose of Submission

The 510(k) holder would like to introduce PICO Single Use Negative Pressure Wound Therapy System into interstate commerce as a prescription device.

II. Document History

K11170/S001 (dated 9/20/11 and received in ODE 9/21/11) was assigned to me on 9/23/11 with a branch due date of 10/21/11. This device was discussed at a telephone conference as part of I110698 on 9/7/11.

(b) (5)

[redacted]

III. Recommendation

The reviewer requests additional information as described below.

Regulation Number: 21 CFR §878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP

V. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription)	Section 6		
Truthful and Accuracy Statement	Section 8		
510(k) Summary or 510(k) Statement	Supplement 1 pg 1390		
Standards Form			X

The sponsor will be asked to revise the 510(k) Summary to include all information required by 21 CFR §807.92.

VII. Additional Predicate Device Added (Supplement 1)

K100821 Prevena Incision Management System, KCI, 21 CFR §878.4780, OMP, powered suction pump

Indications for Use
The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Device Description
The Prevena Incision Management System consists of a single use, sterile dressing that is applied over the closed wound, in a simple peel and place process. The dressing contains a polyurethane-coated polyester fabric with 0.019% silver (K061615), polyurethane film with acrylic adhesive to provide adhesion of the dressing to the skin surrounding the closure (K811291), a polyurethane foam bolster (K063692), and a polyurethane shell (K02211) that covers the foam bolster and polyester fabric. The only change to bolster is a change in colorant from black to violet 23 (21 CFR 73.3107). Negative pressure is provided to the dressing via a negative pressure therapy unit preset to deliver negative pressure at -125 mmHg. Wound fluids are collected in a sterile, disposable 45 mL canister. The device is intended to be applied to the wound site immediately after surgery, and continue for a minimum of 2 days up to a maximum of 7 days, depending on the surgeon's preference.

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[redacted]

VIII. **Labeling** (Section 15, Supplement 1 pg 7)

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Warnings

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Precautions

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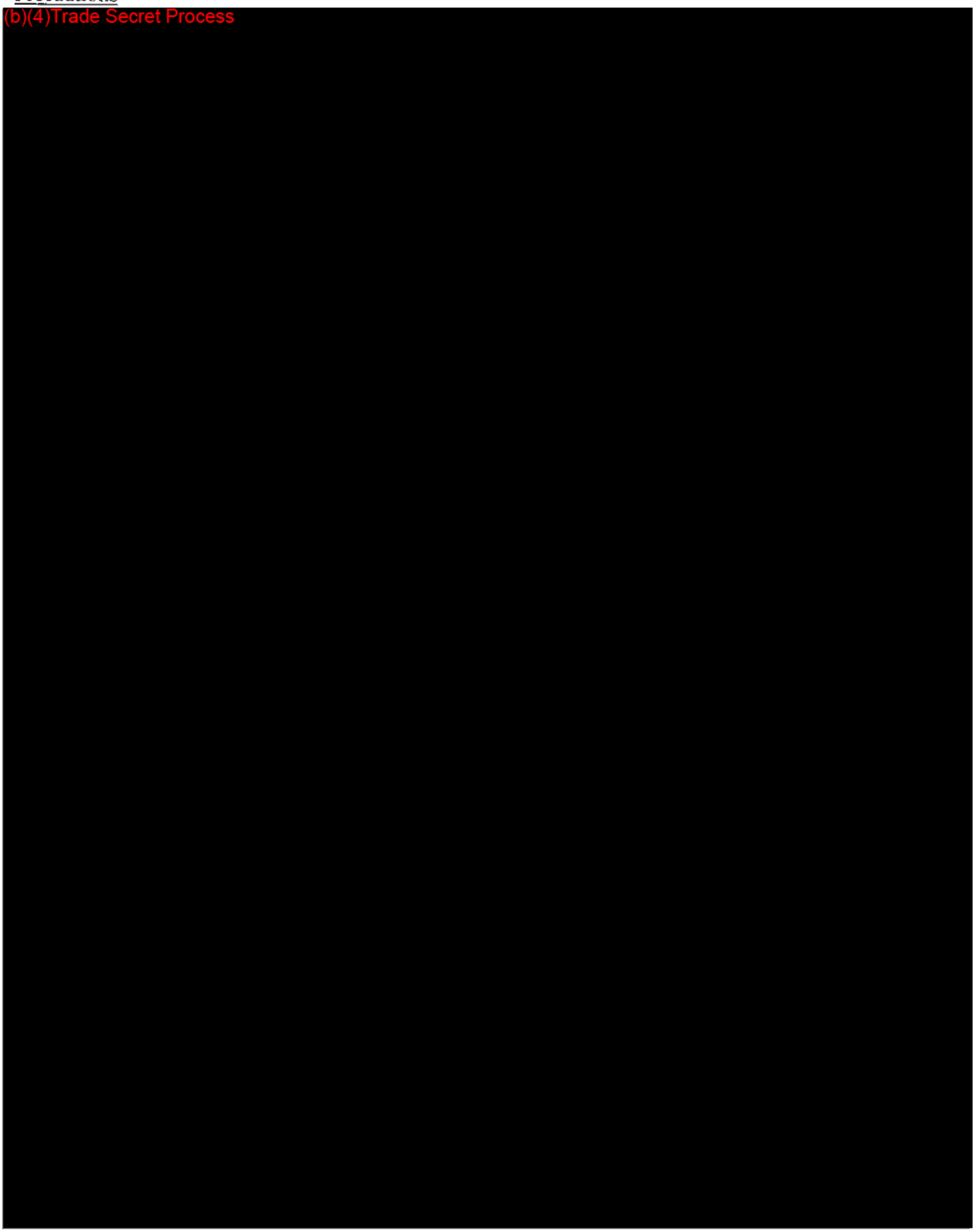

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Possible adverse events

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[redacted]

Instructions for Use

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[redacted]

IX. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	X		If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:

(b)(4)Trade Secret Process

[redacted]

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2. Explain why there is or is not a new effect or safety or effectiveness issue:

(b)(4)Trade Secret Process

3. Describe the new technological characteristics:

(b)(4)Trade Secret Process

4. Explain how new characteristics could or could not affect safety or effectiveness:

(b)(4)Trade Secret Process

5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

(b)(4)Trade Secret Process

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

X. Response to FDA Request for Additional Information

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[redacted]

Clinical Study (Supplement 1 pg 27-70)

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(b)(4)Trade Secret Process

[redacted]

Post Market Information outside the US (Supplement 1 pg 71-72)

(b)(4)Trade Secret Process

[redacted]

In Vitro Testing

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The sponsor's response is adequate.

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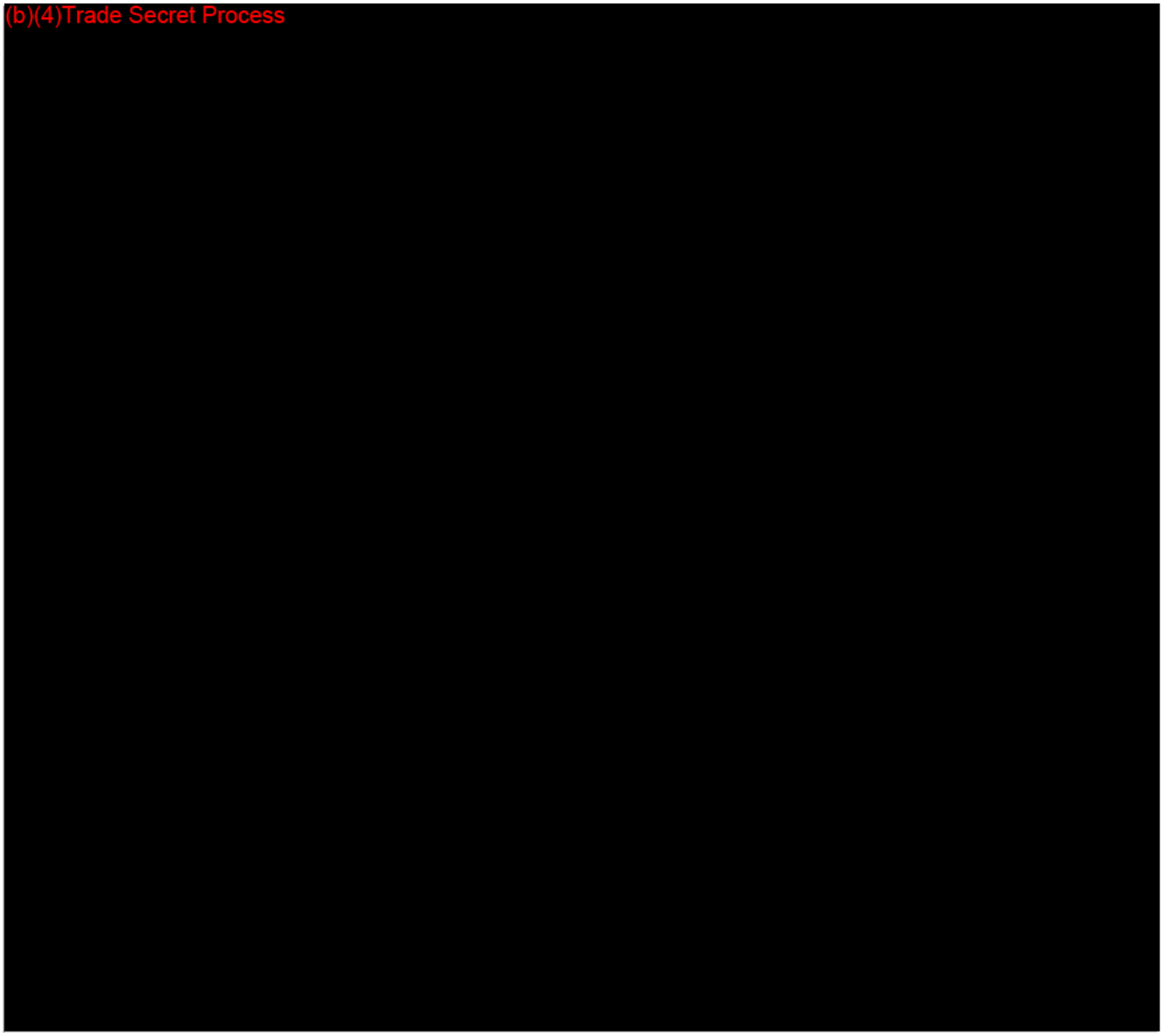

The sponsor's response is adequate.

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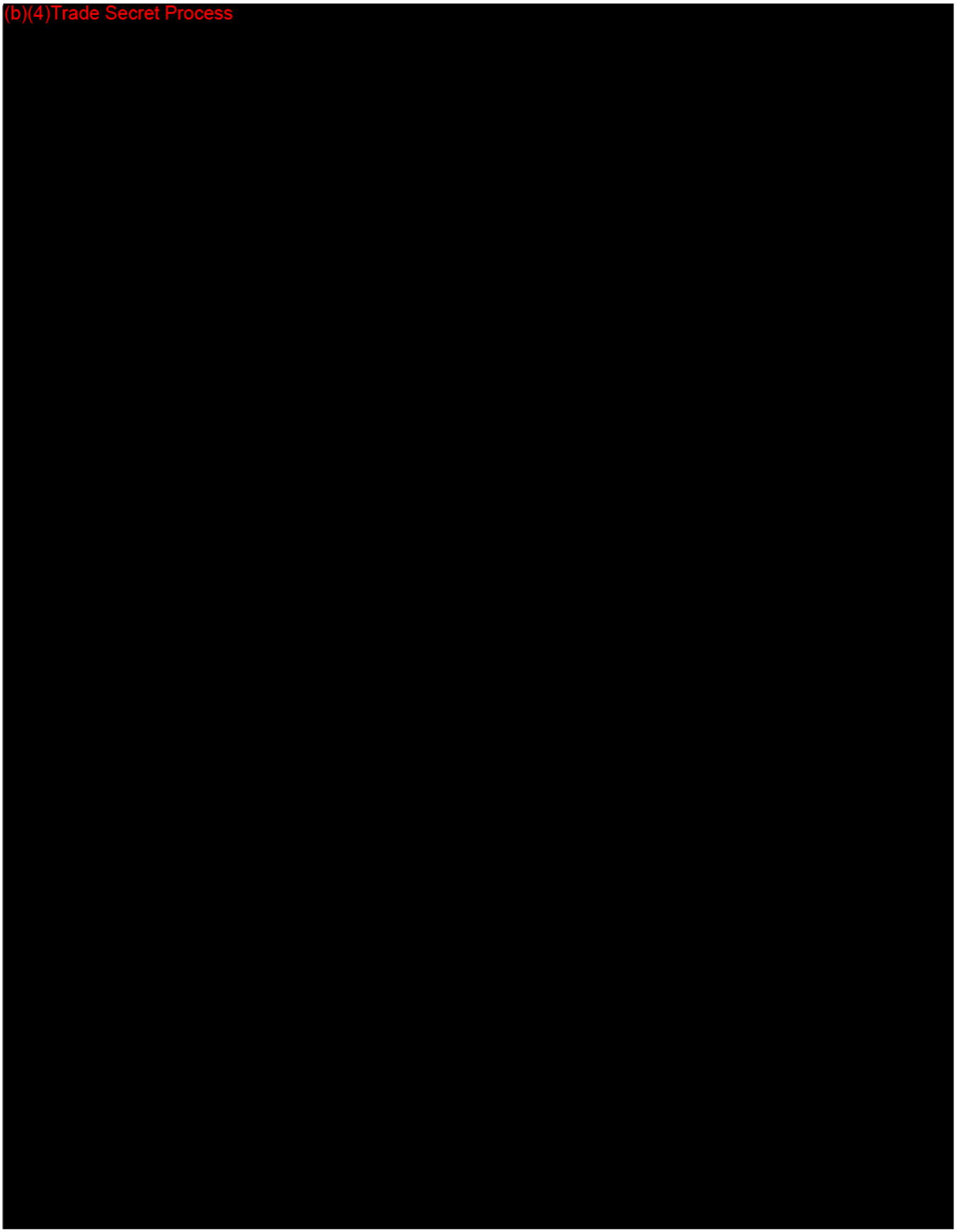

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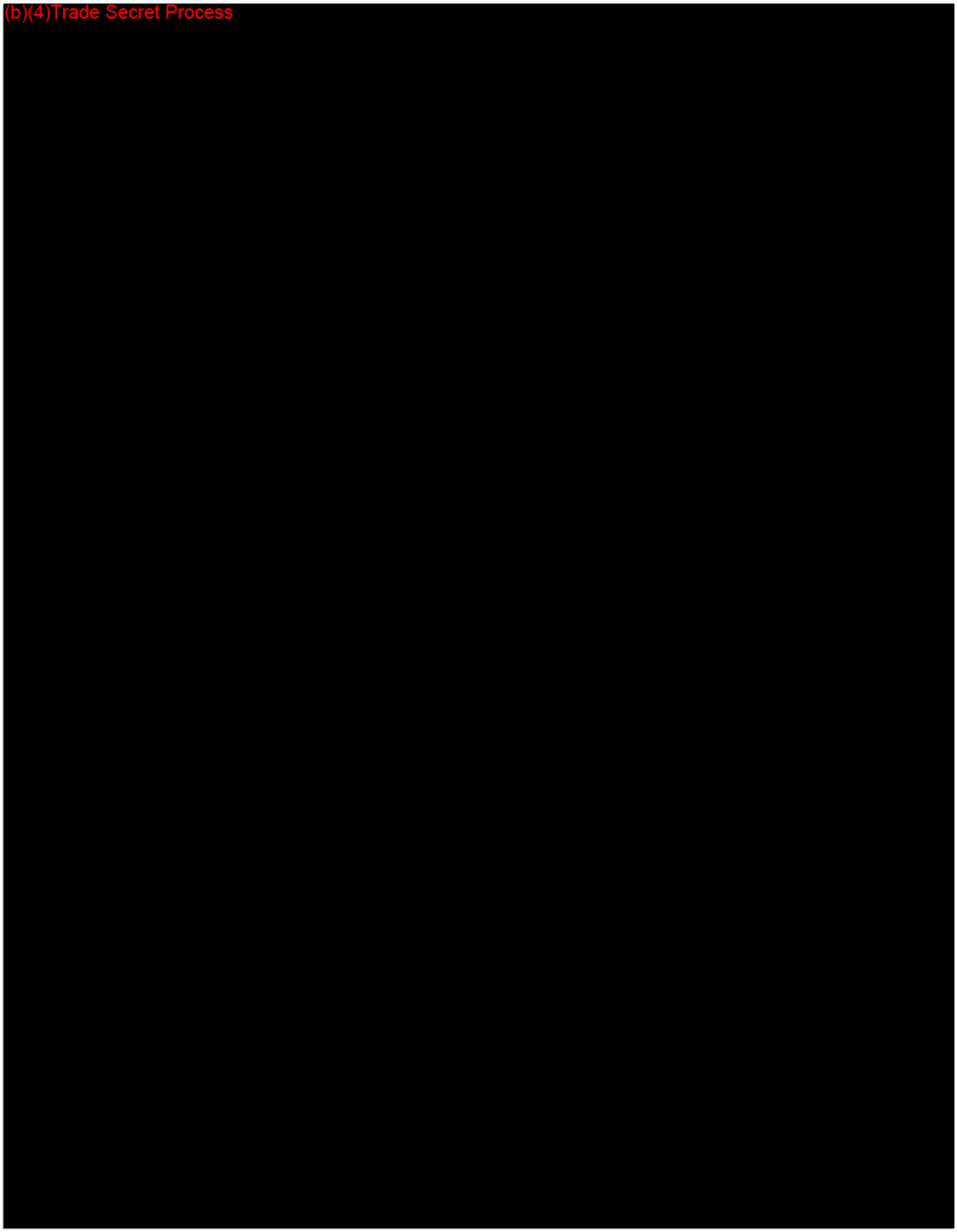
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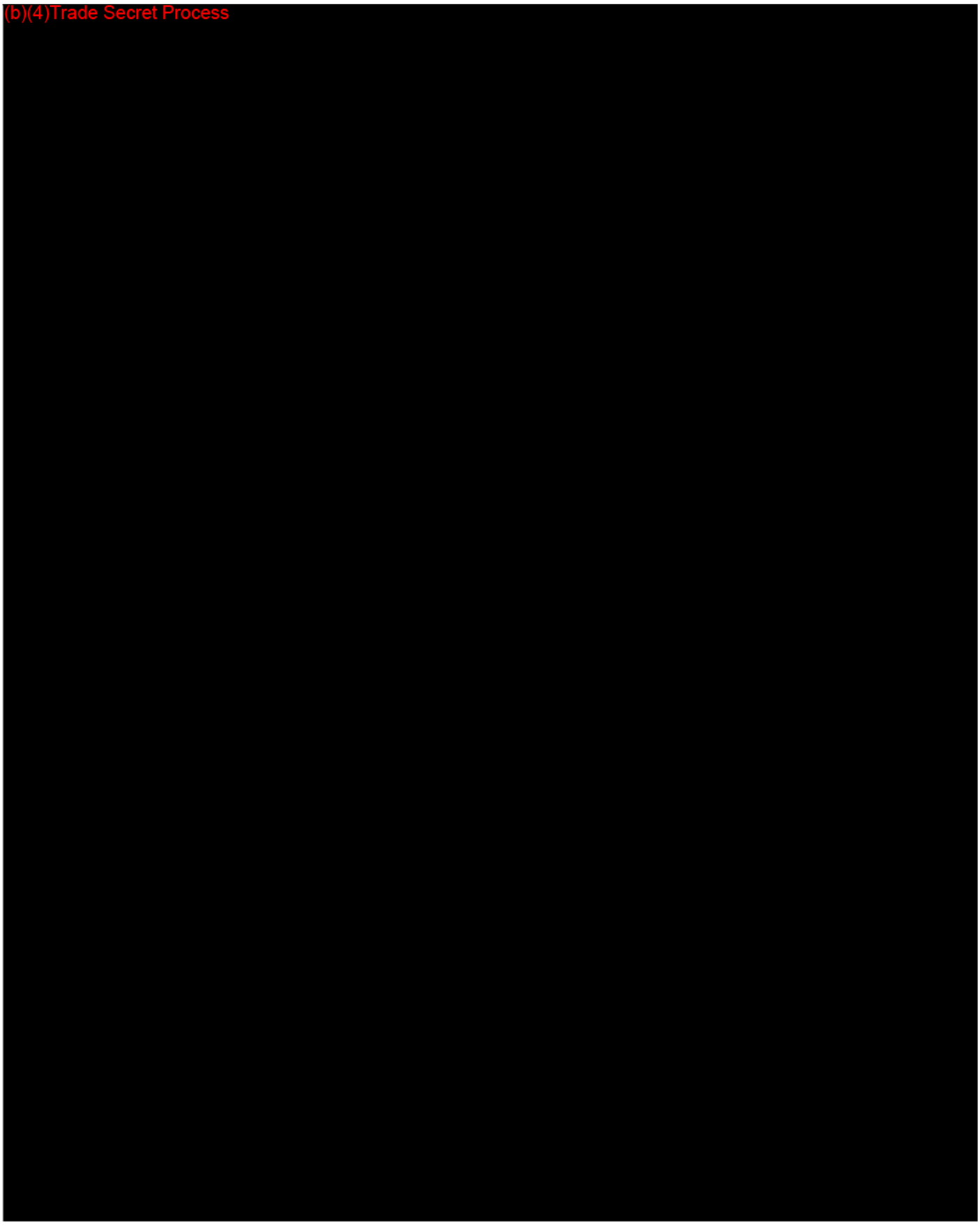

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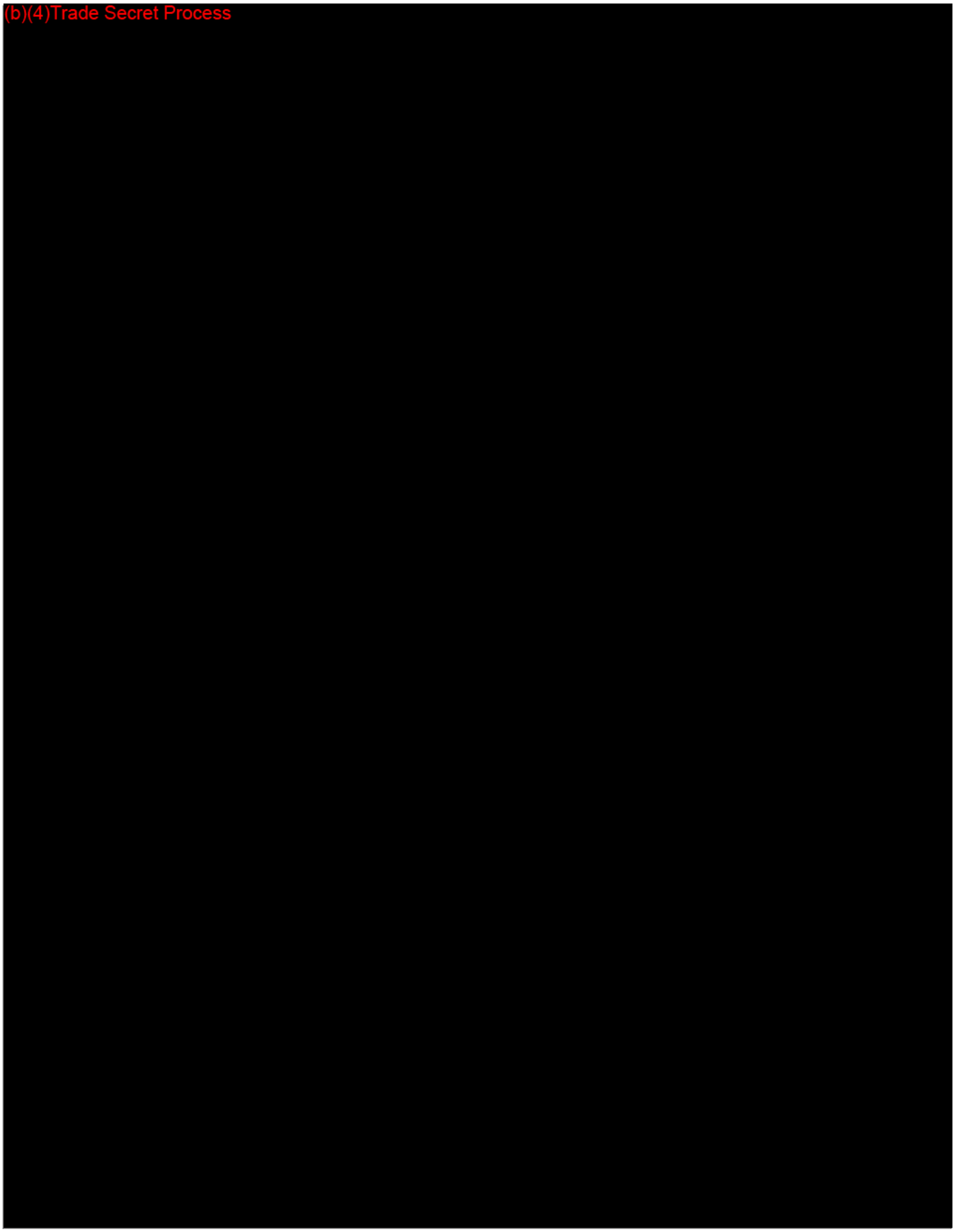

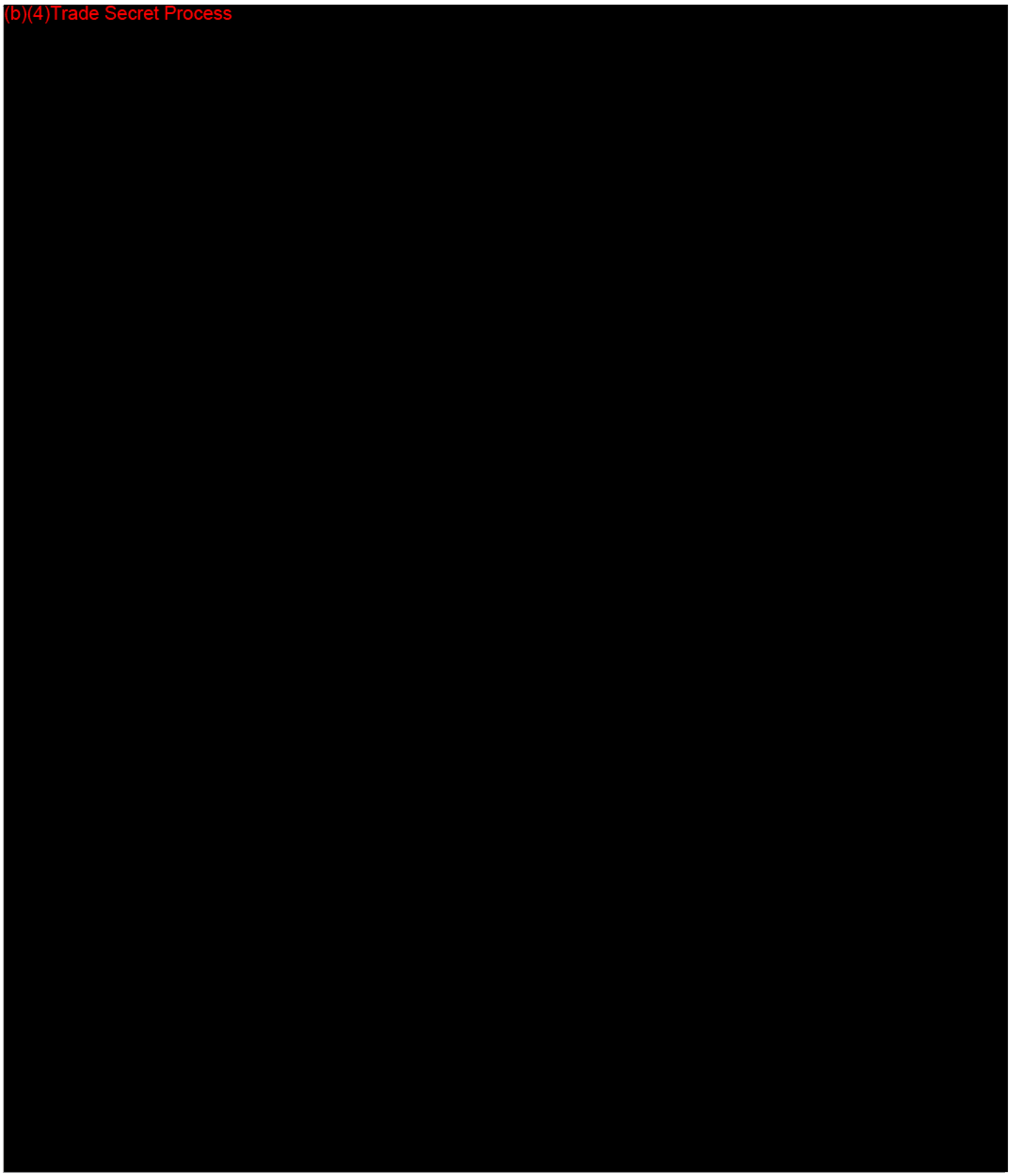
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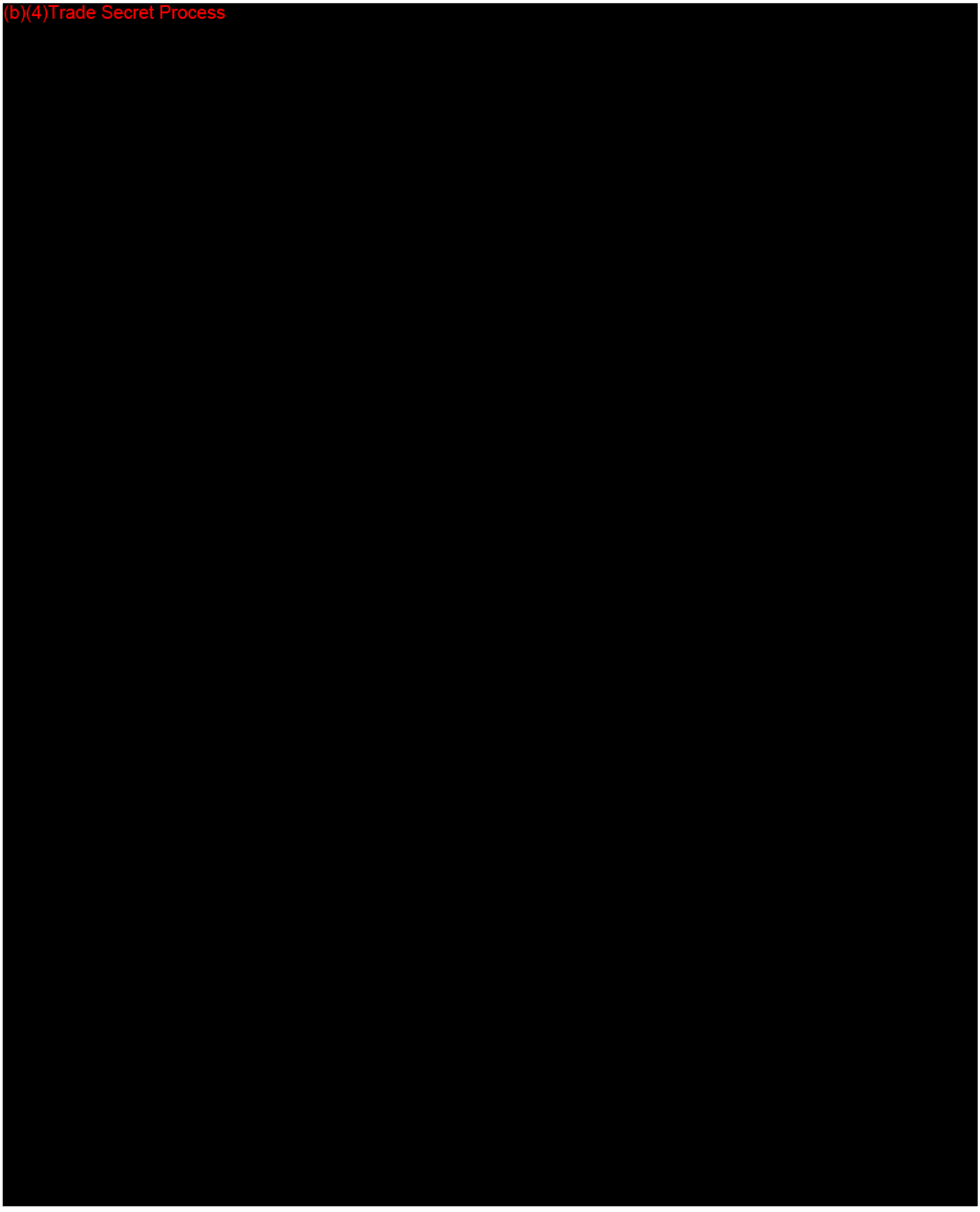

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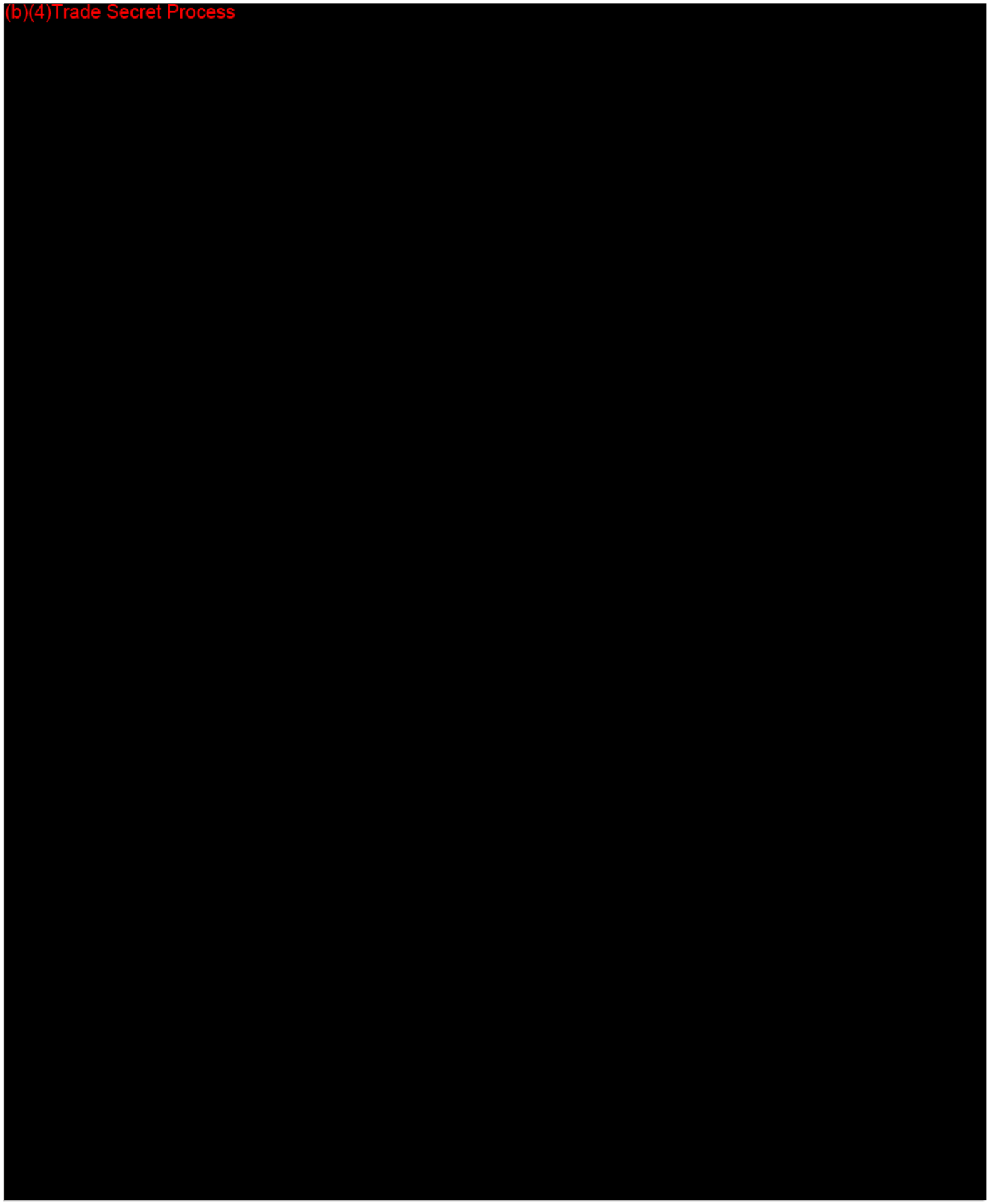

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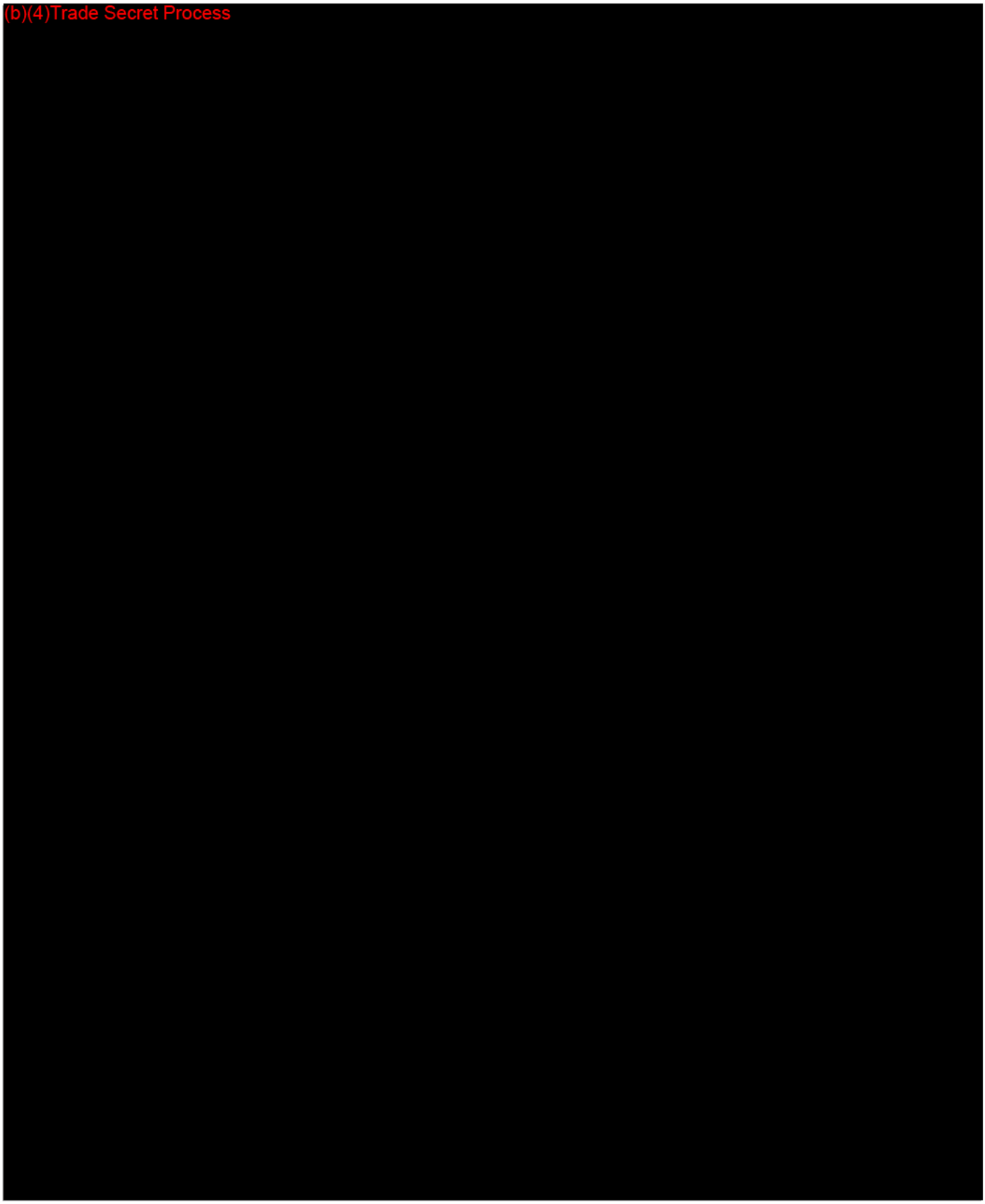

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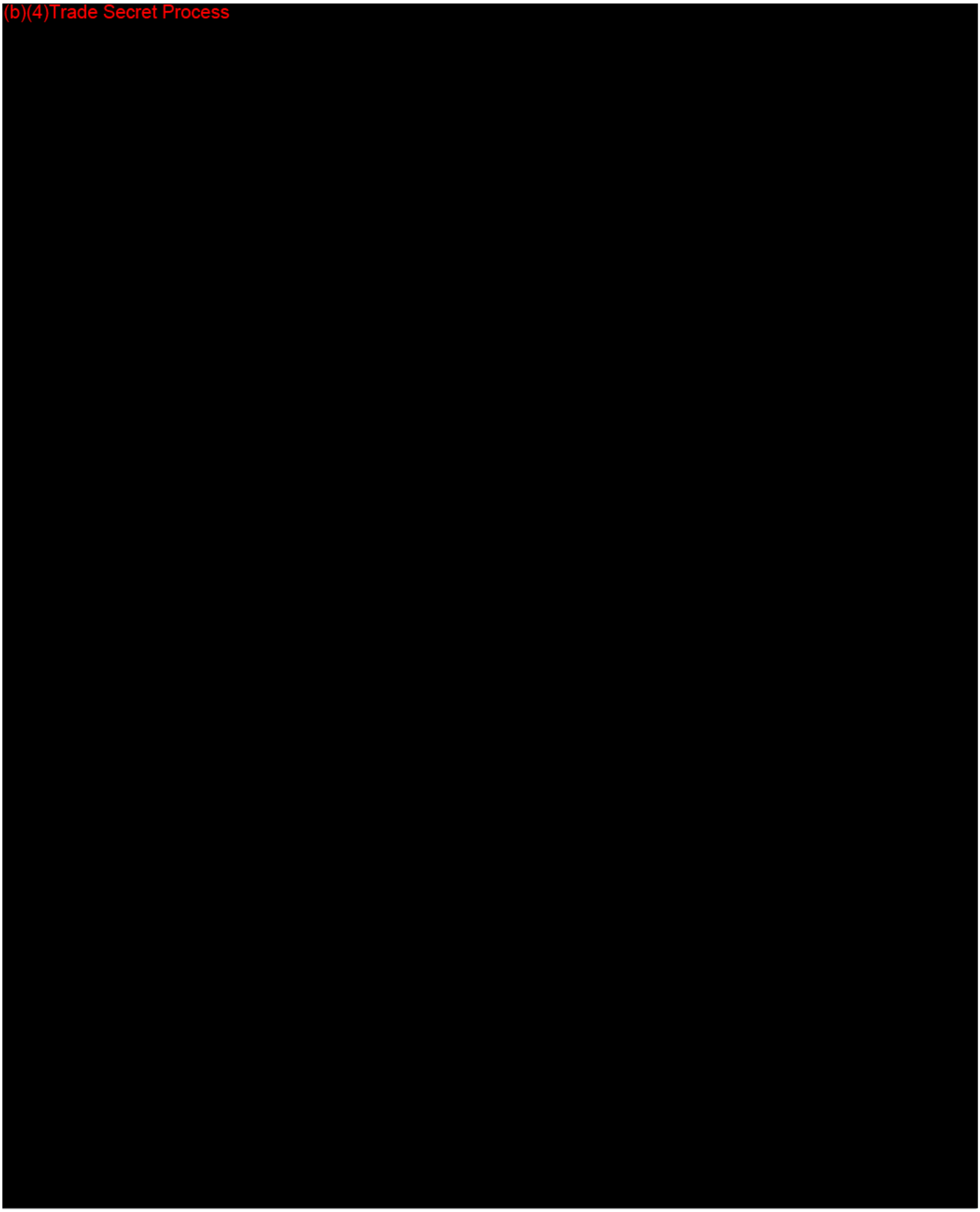

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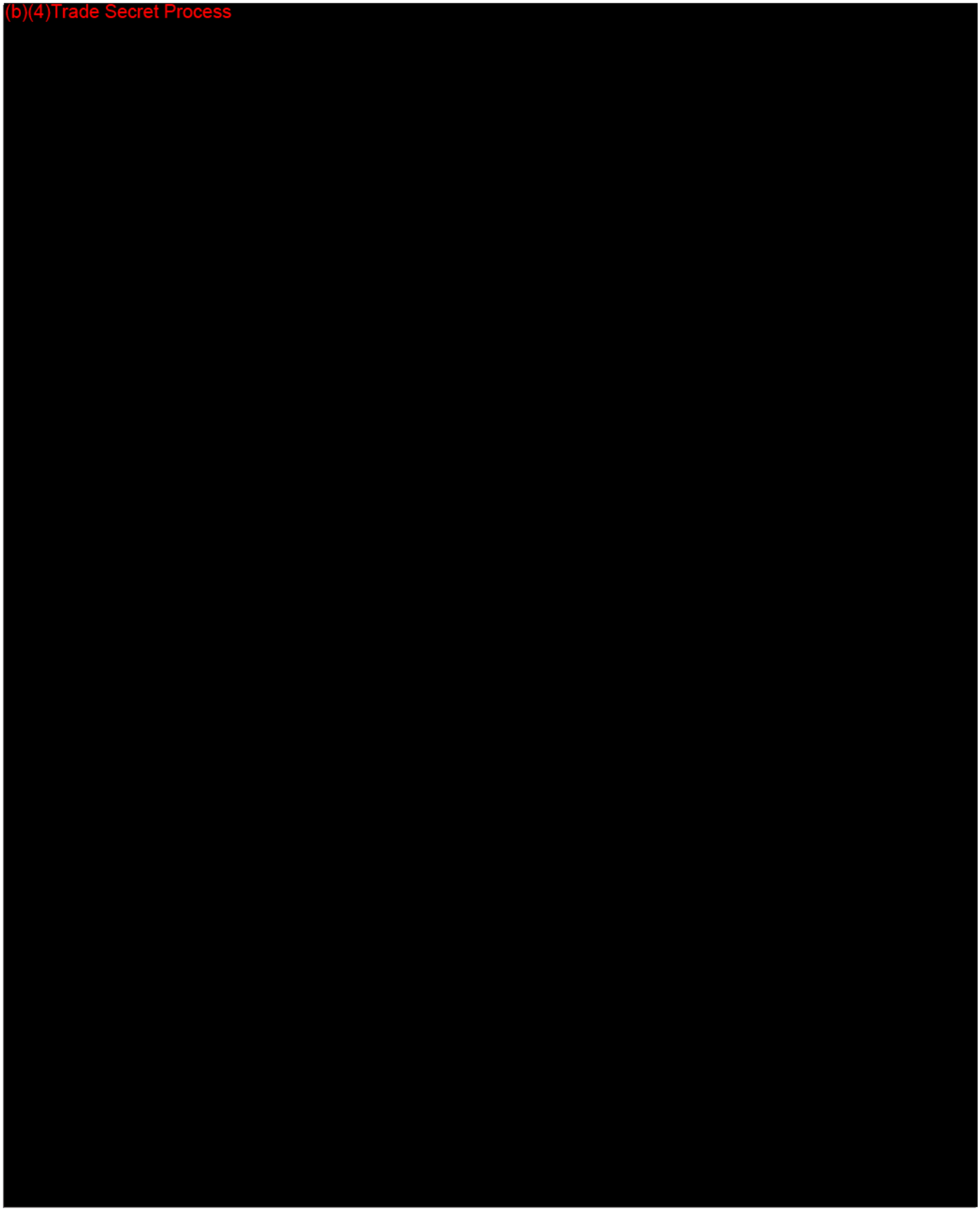

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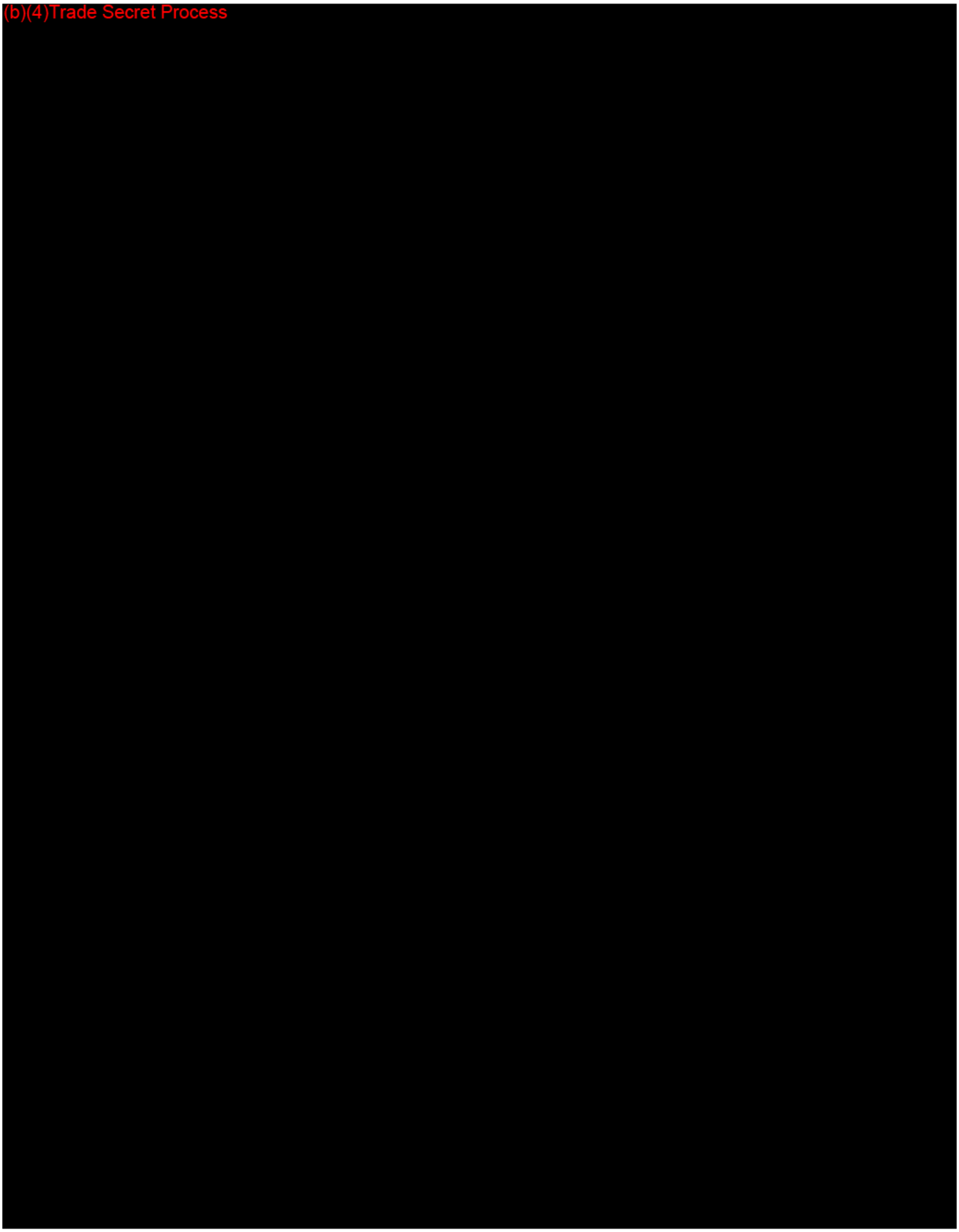

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The sponsor's response is adequate.

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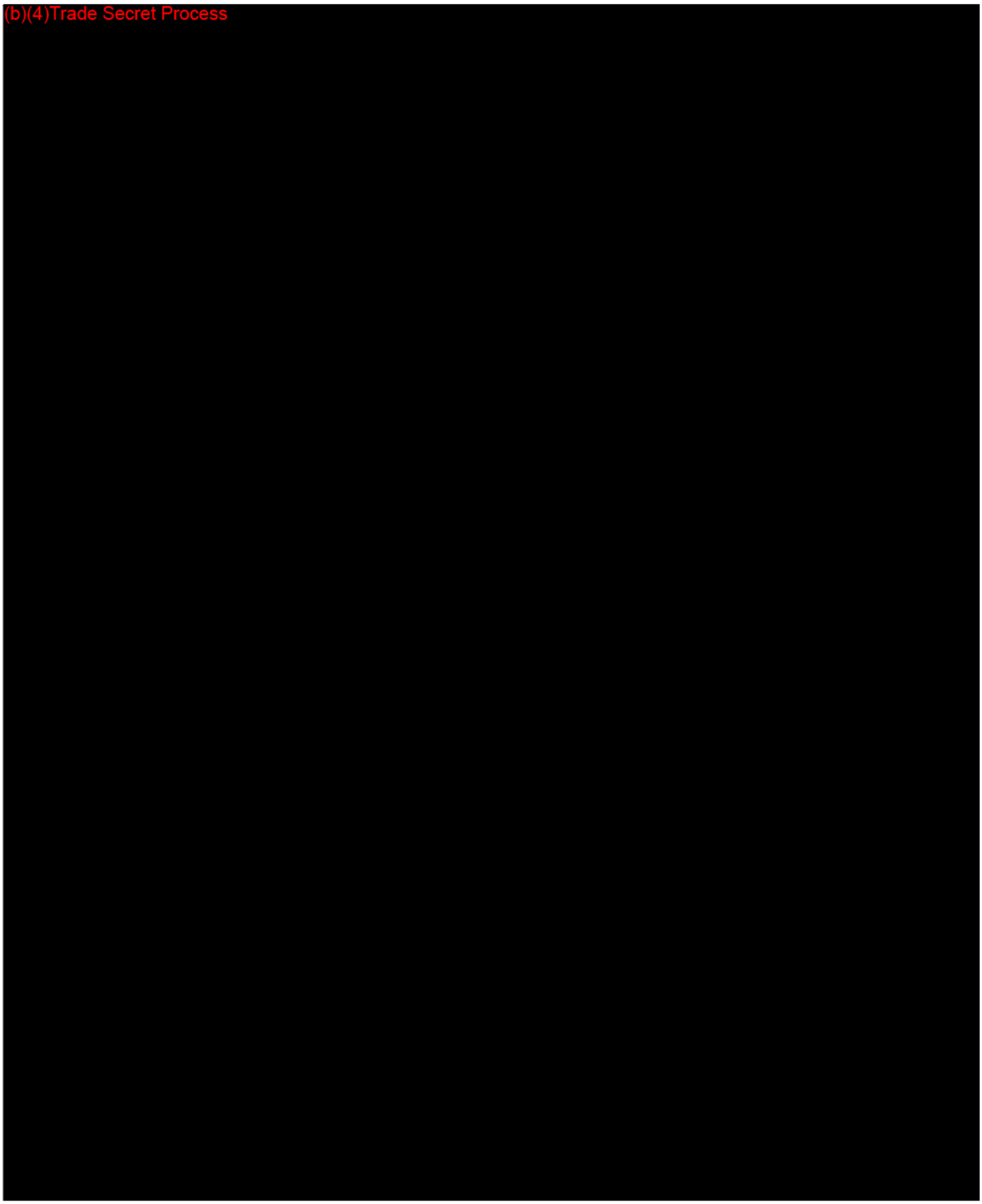

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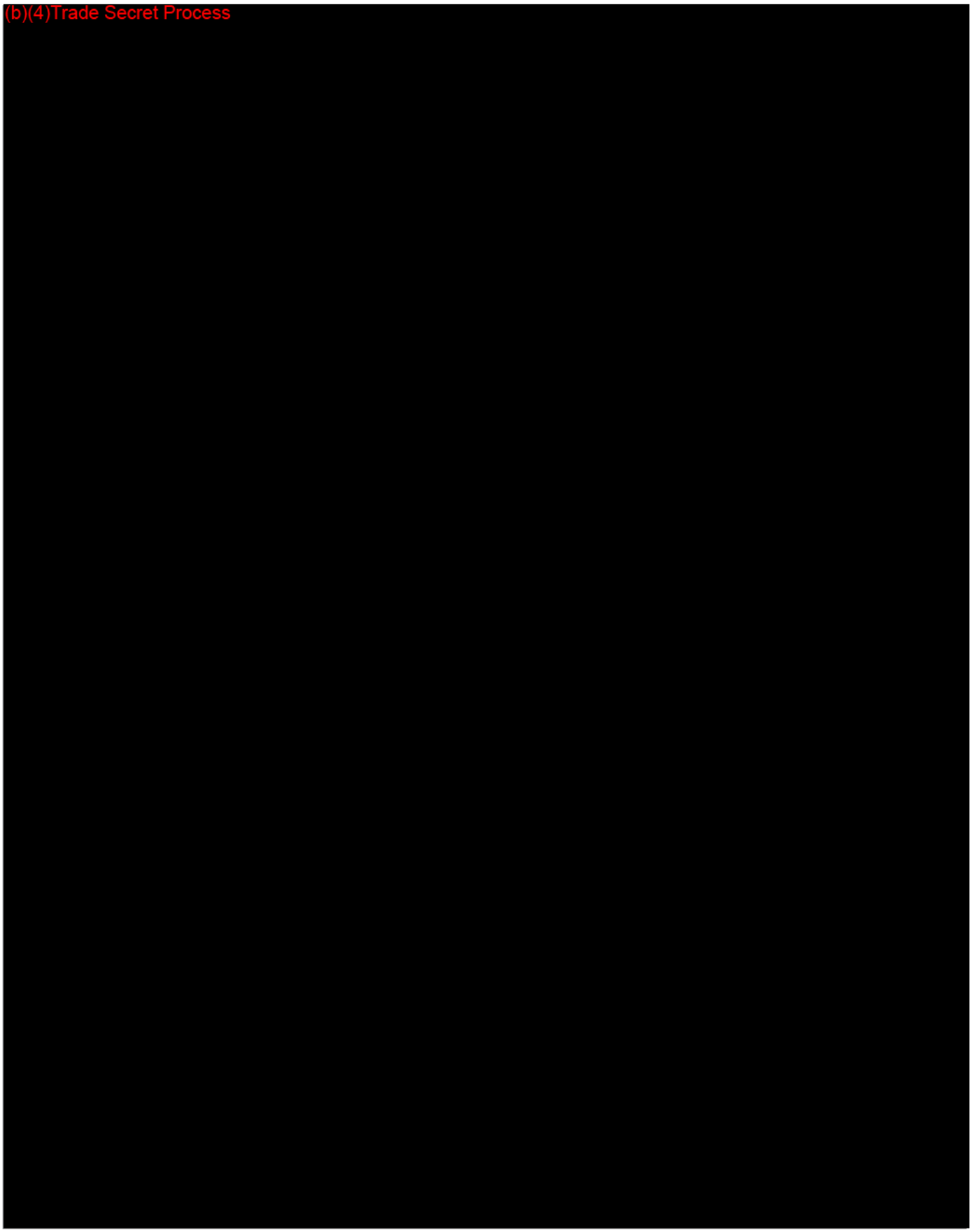

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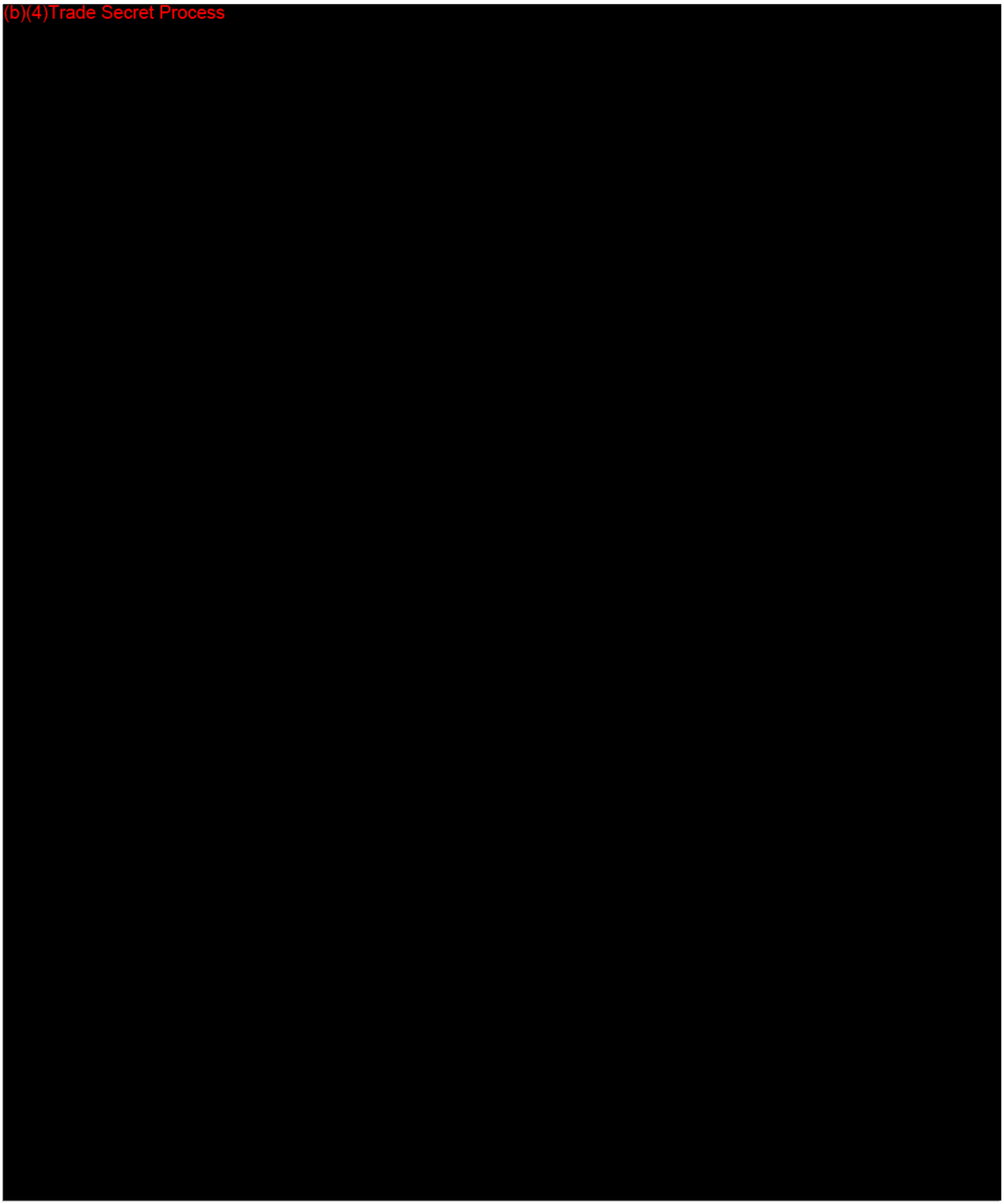

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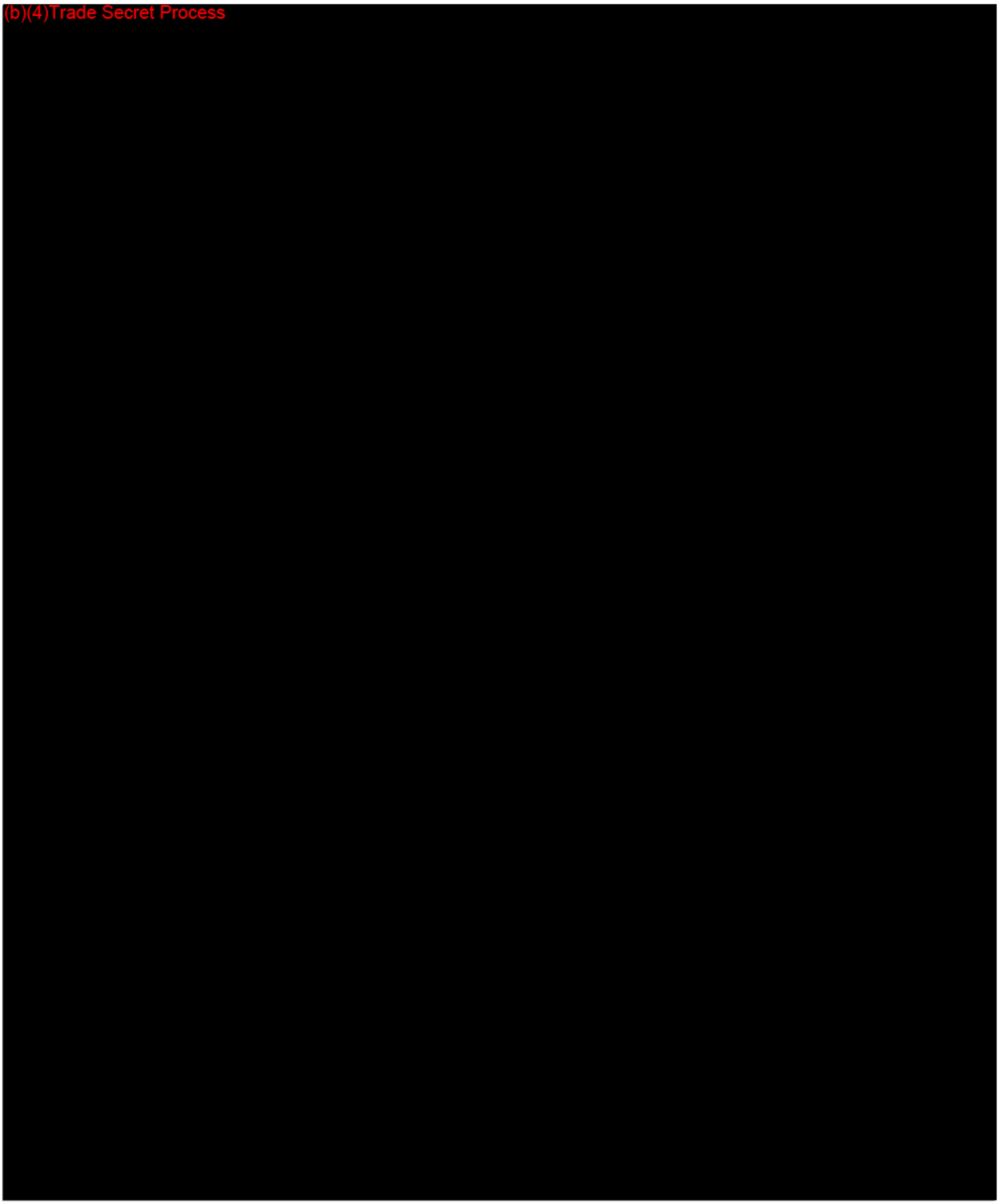

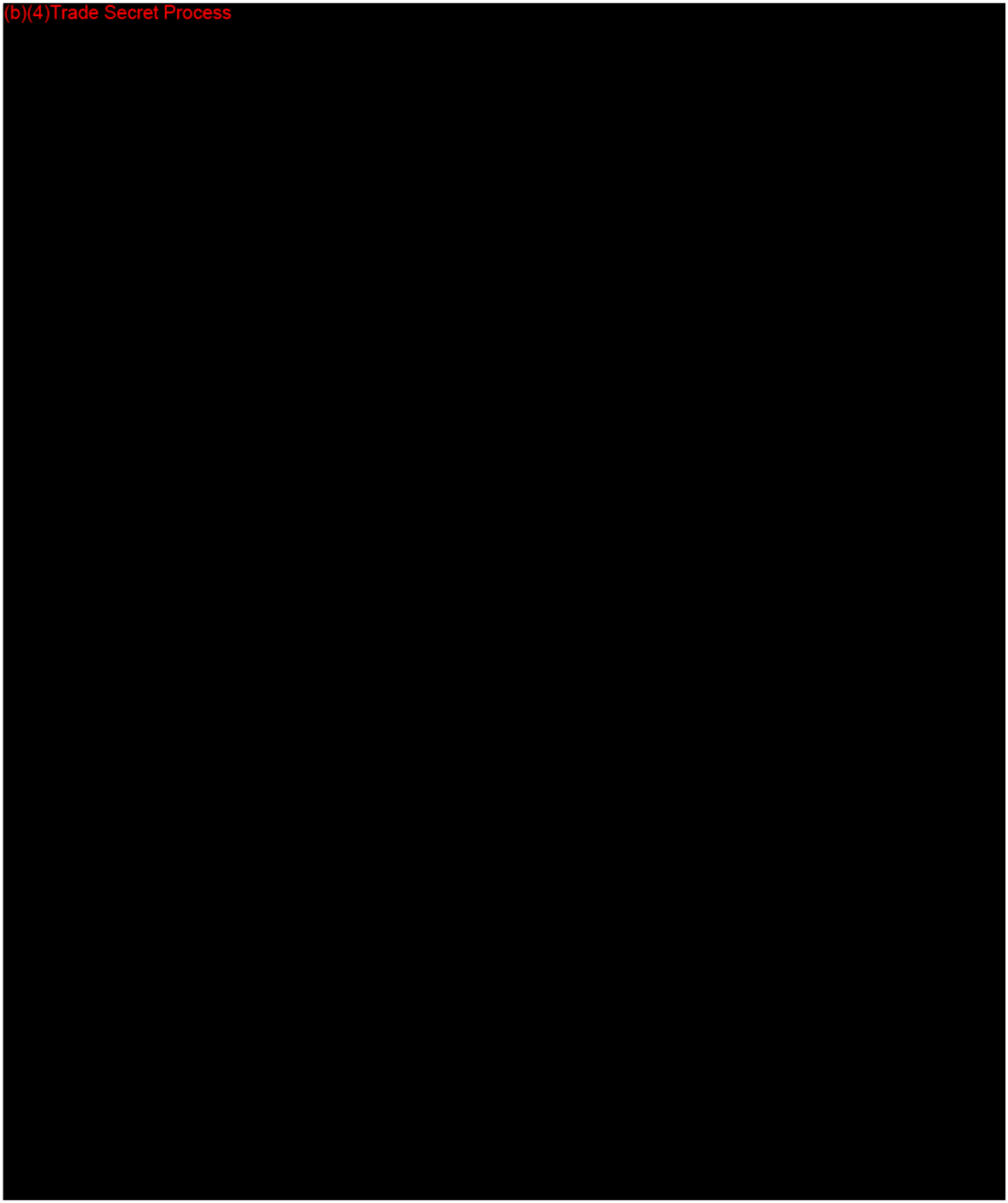
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The sponsor's response is adequate.

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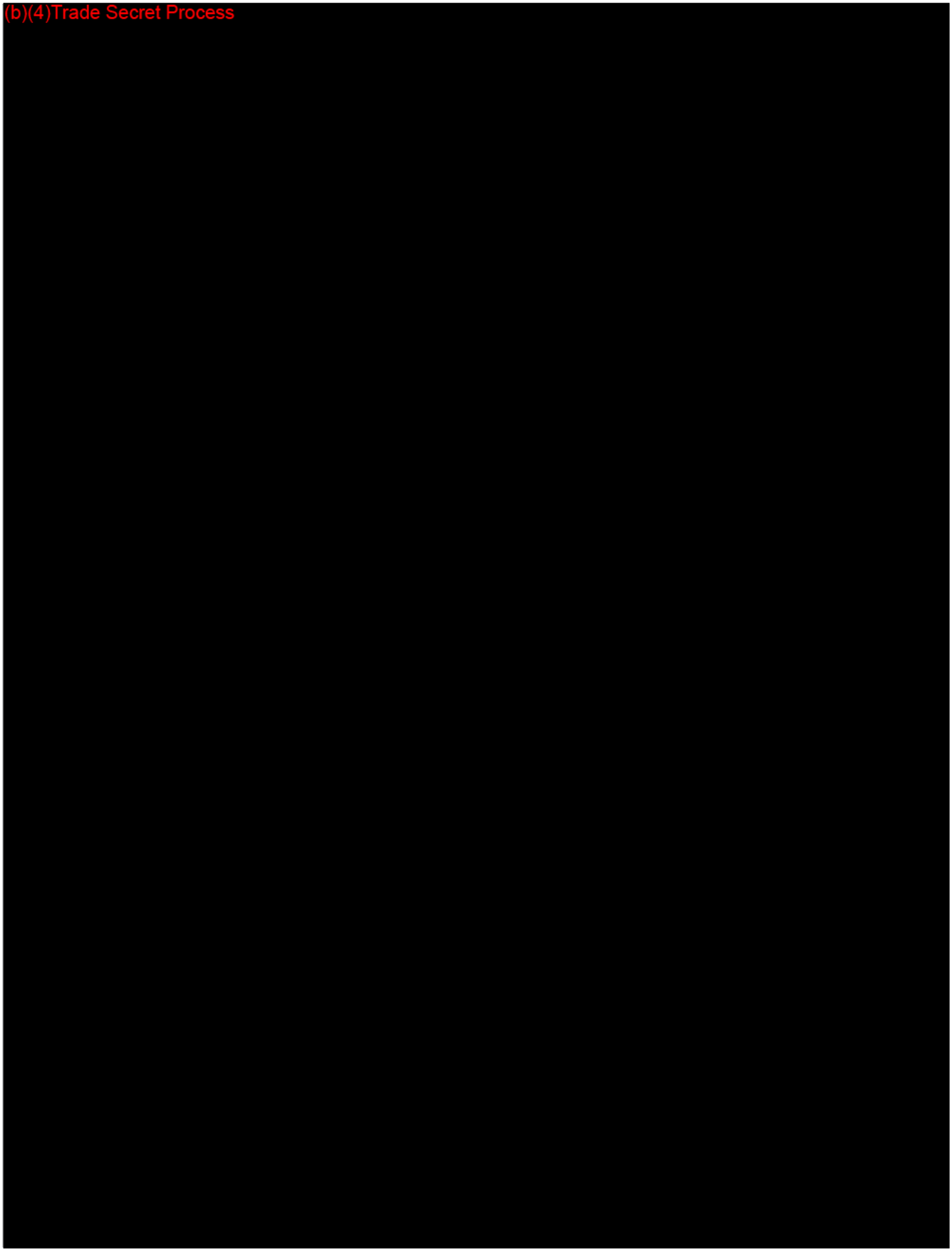

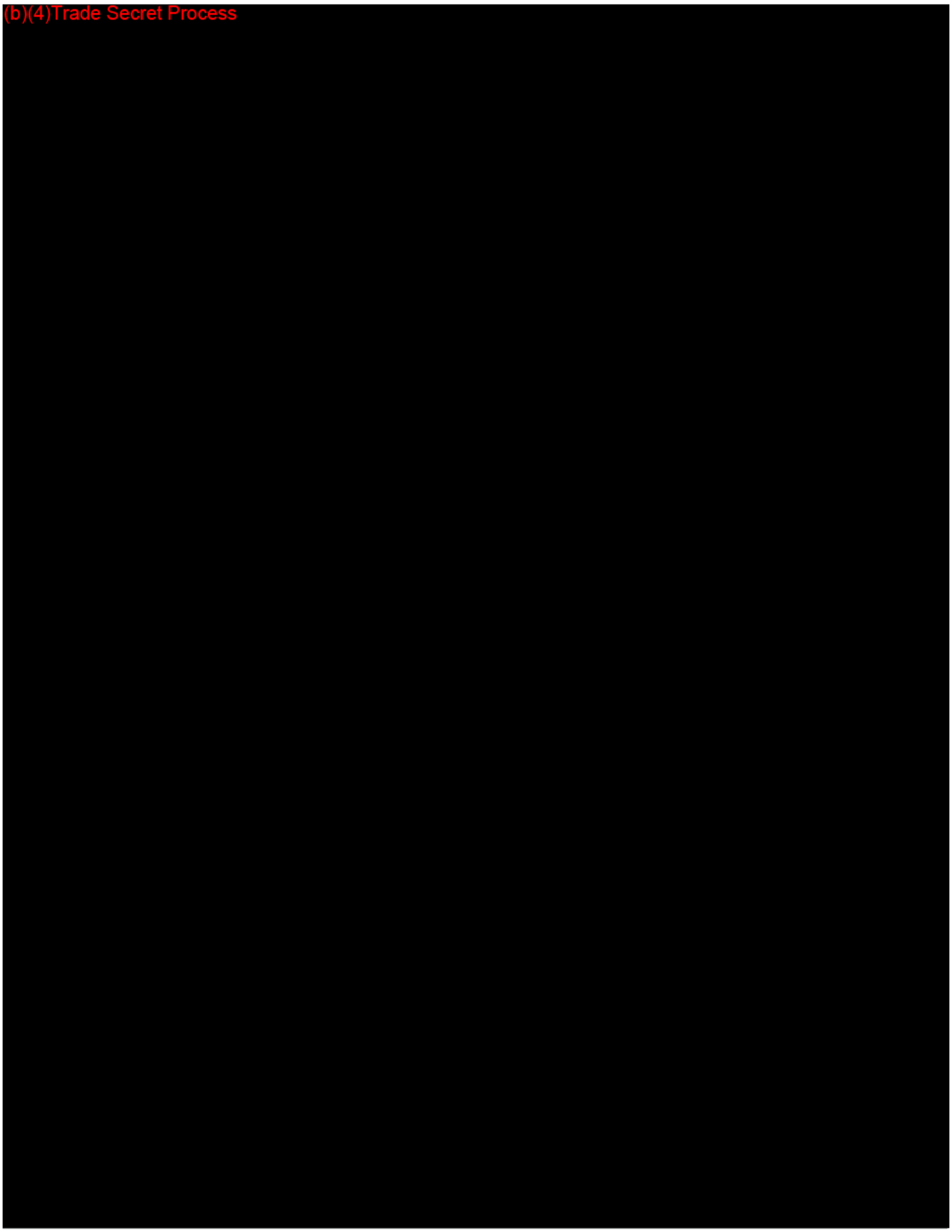
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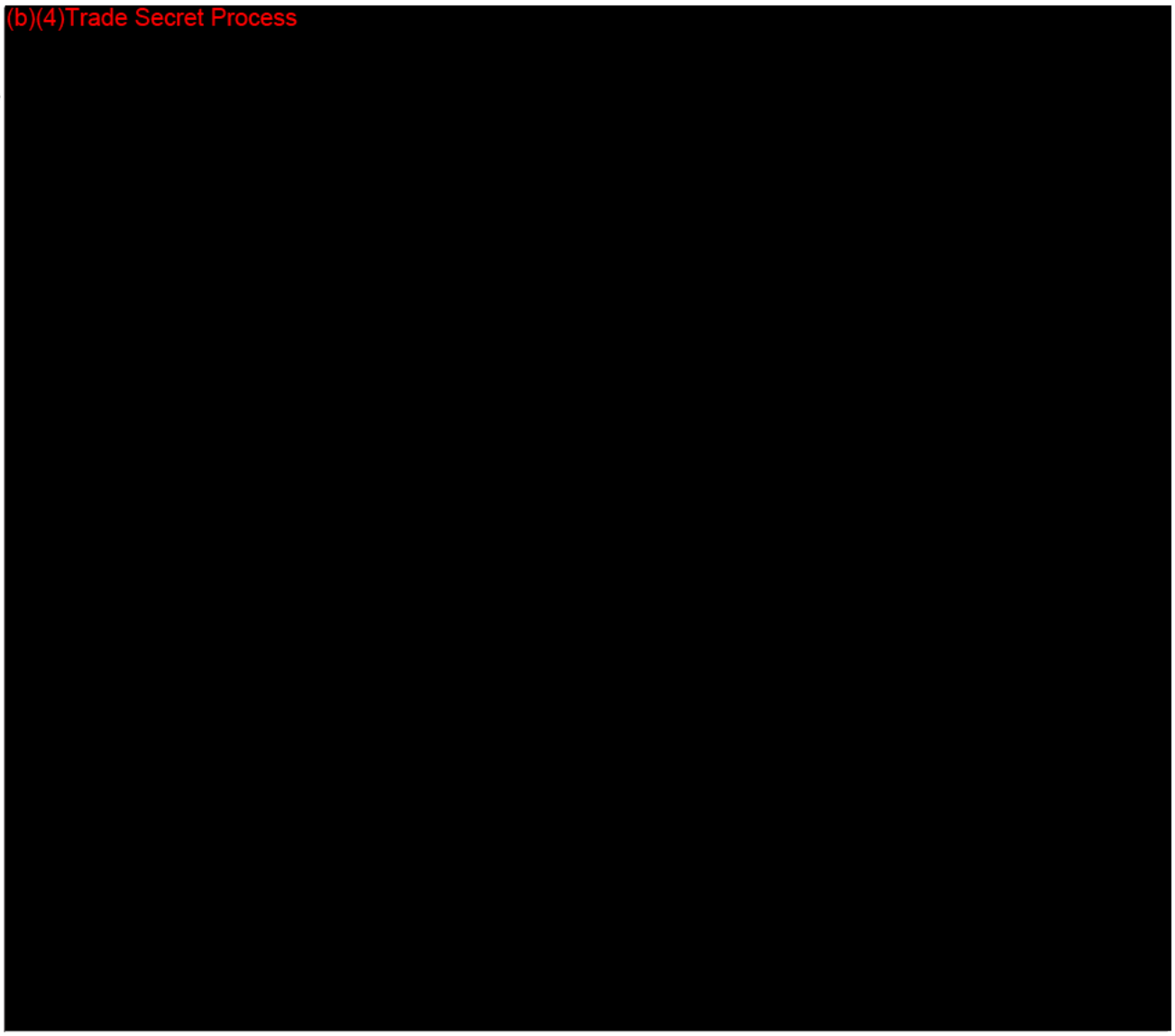

The sponsor's response is adequate.

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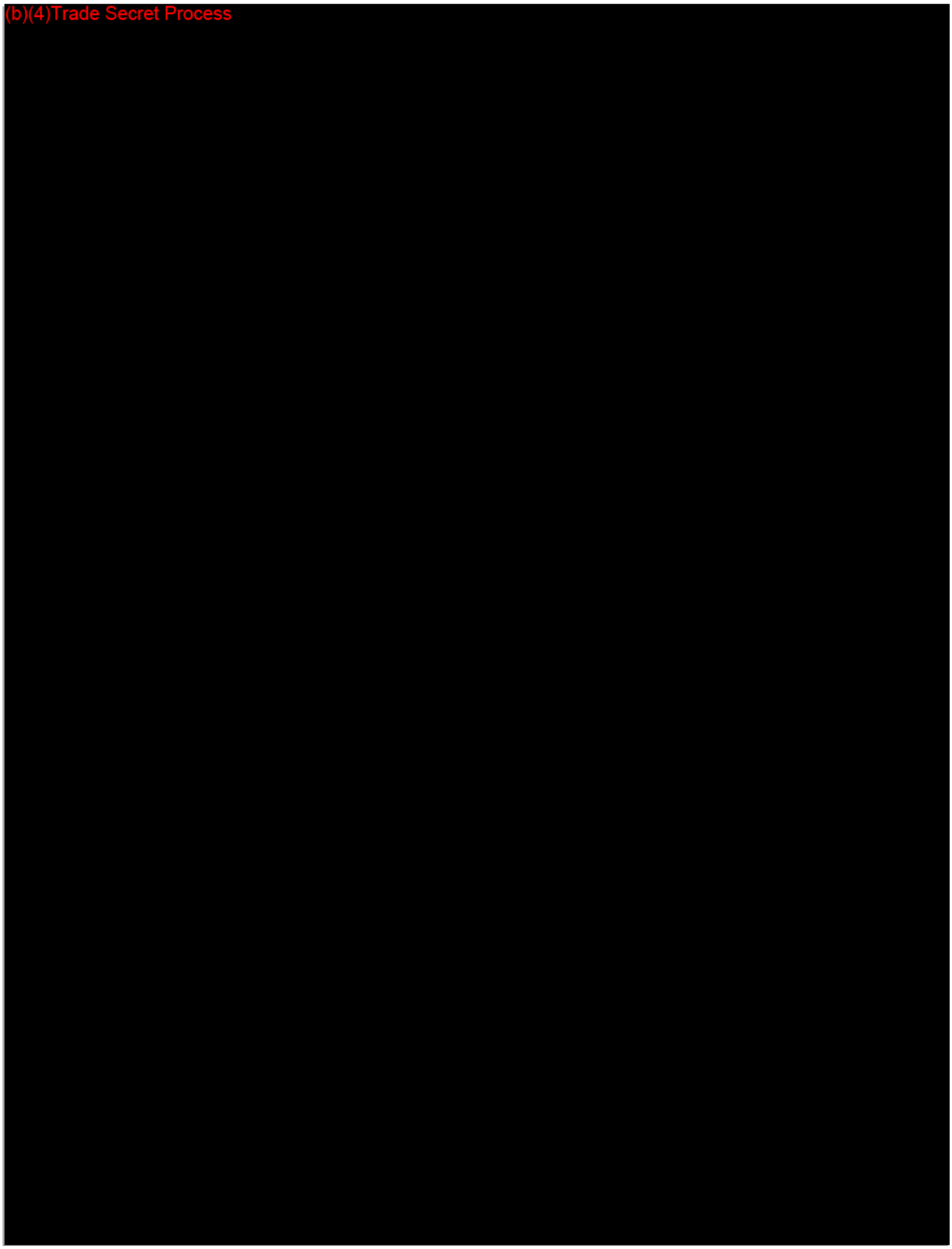

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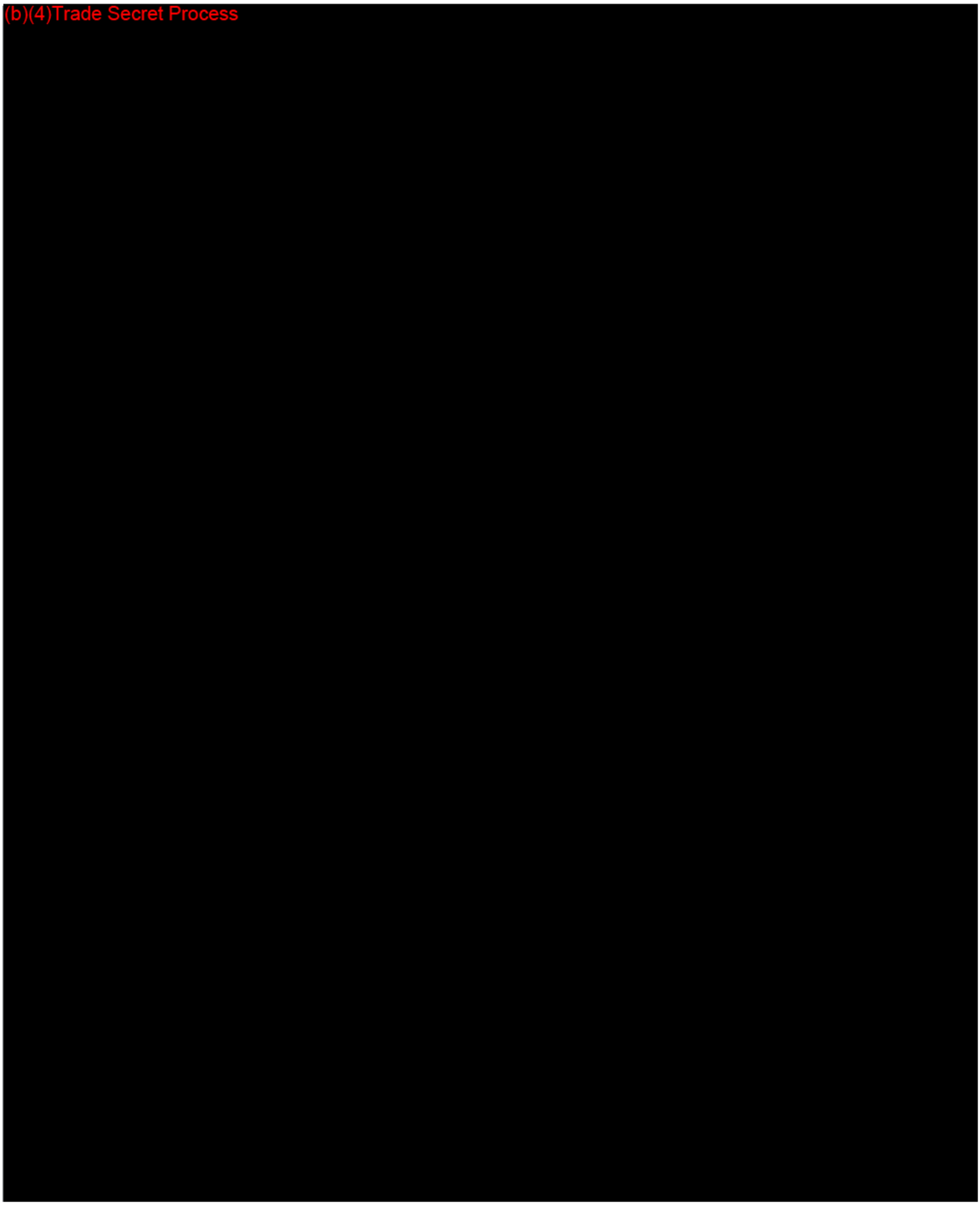

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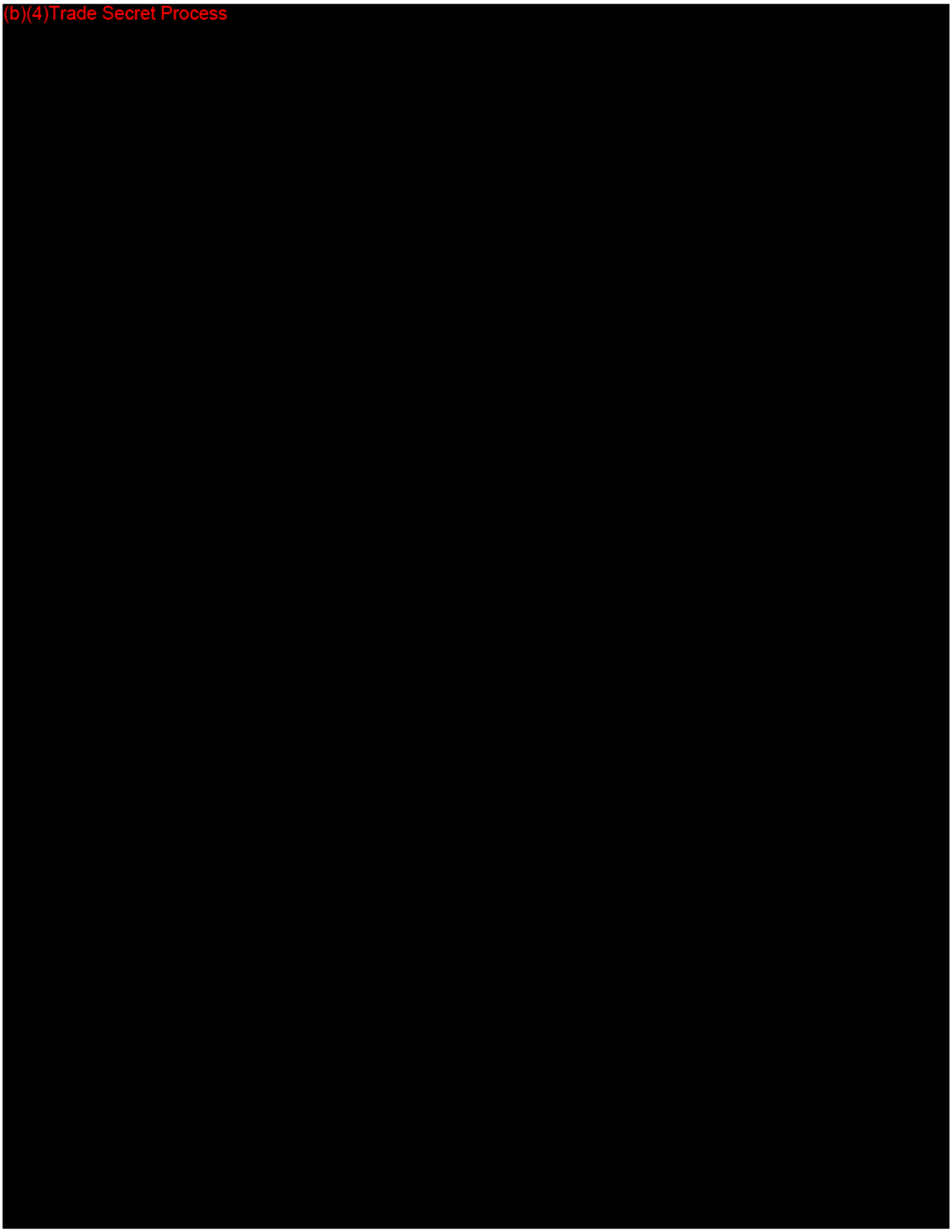

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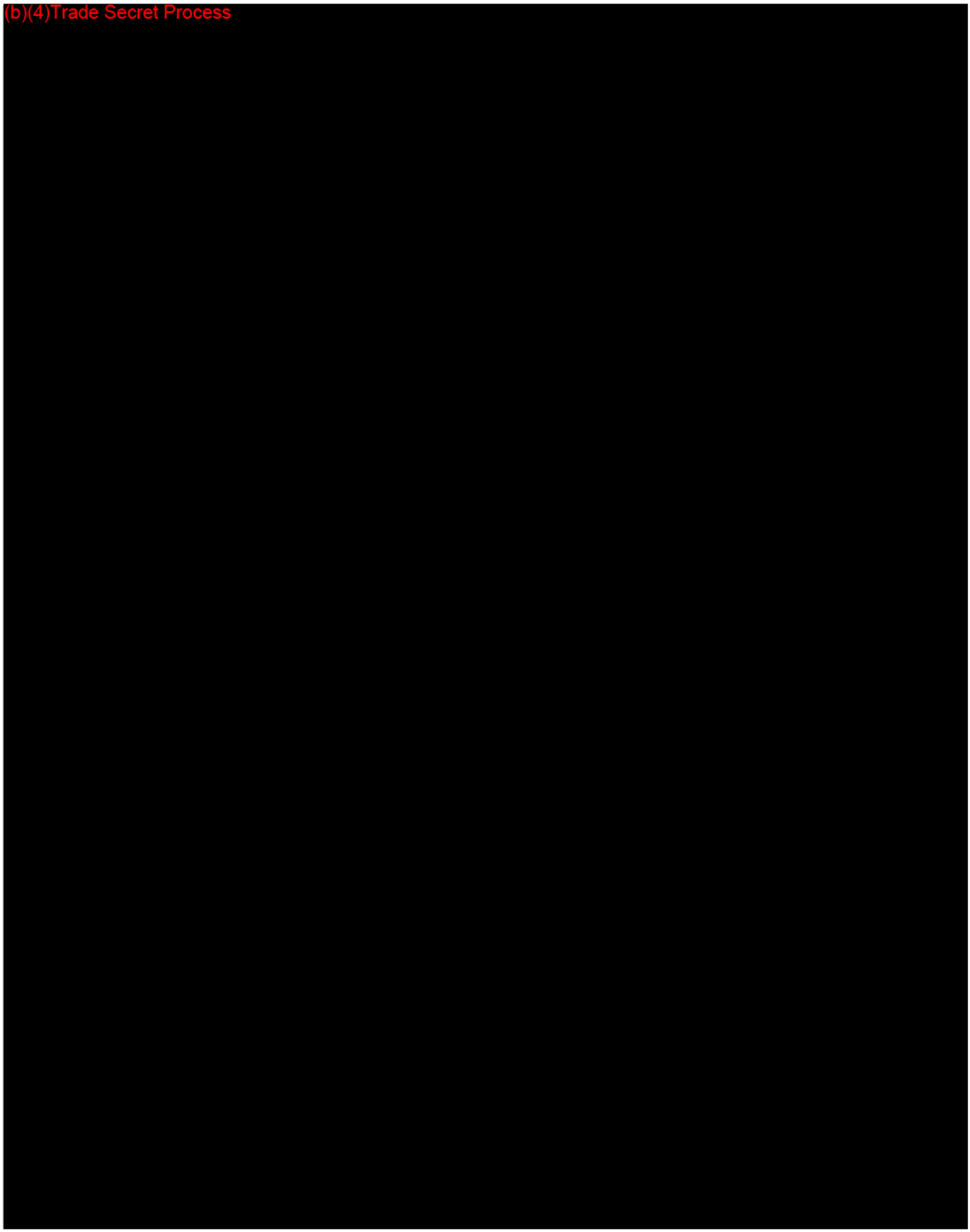

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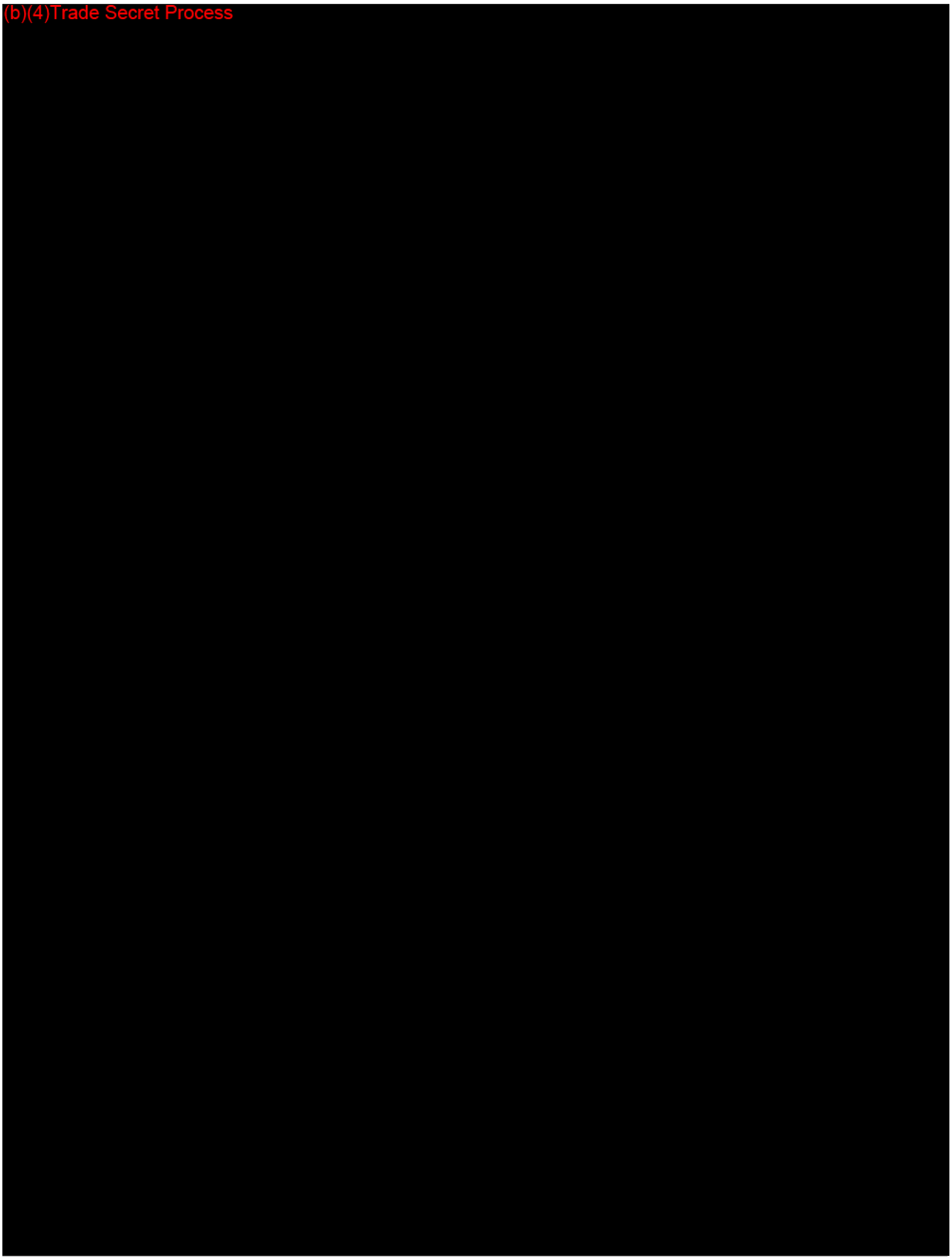

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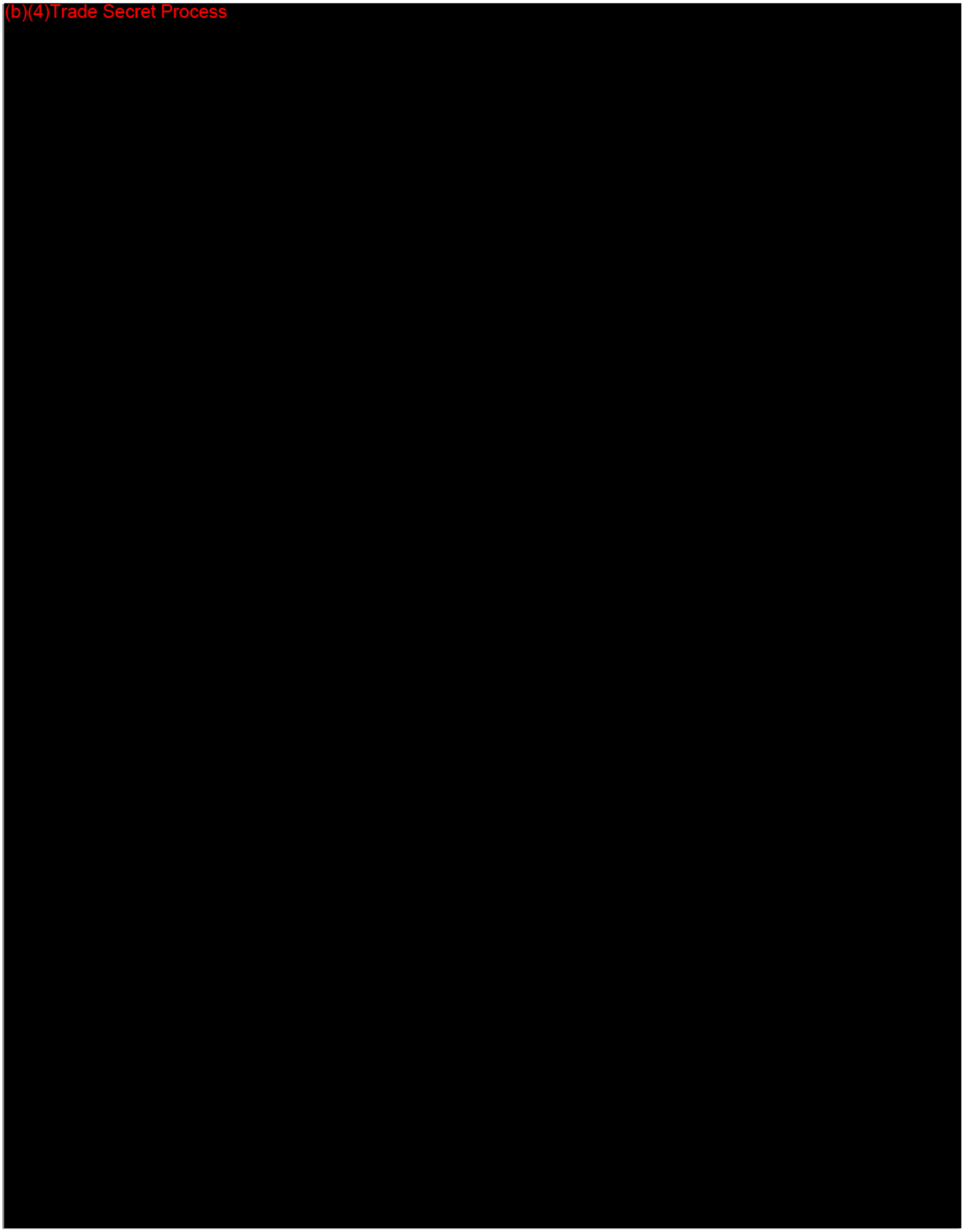

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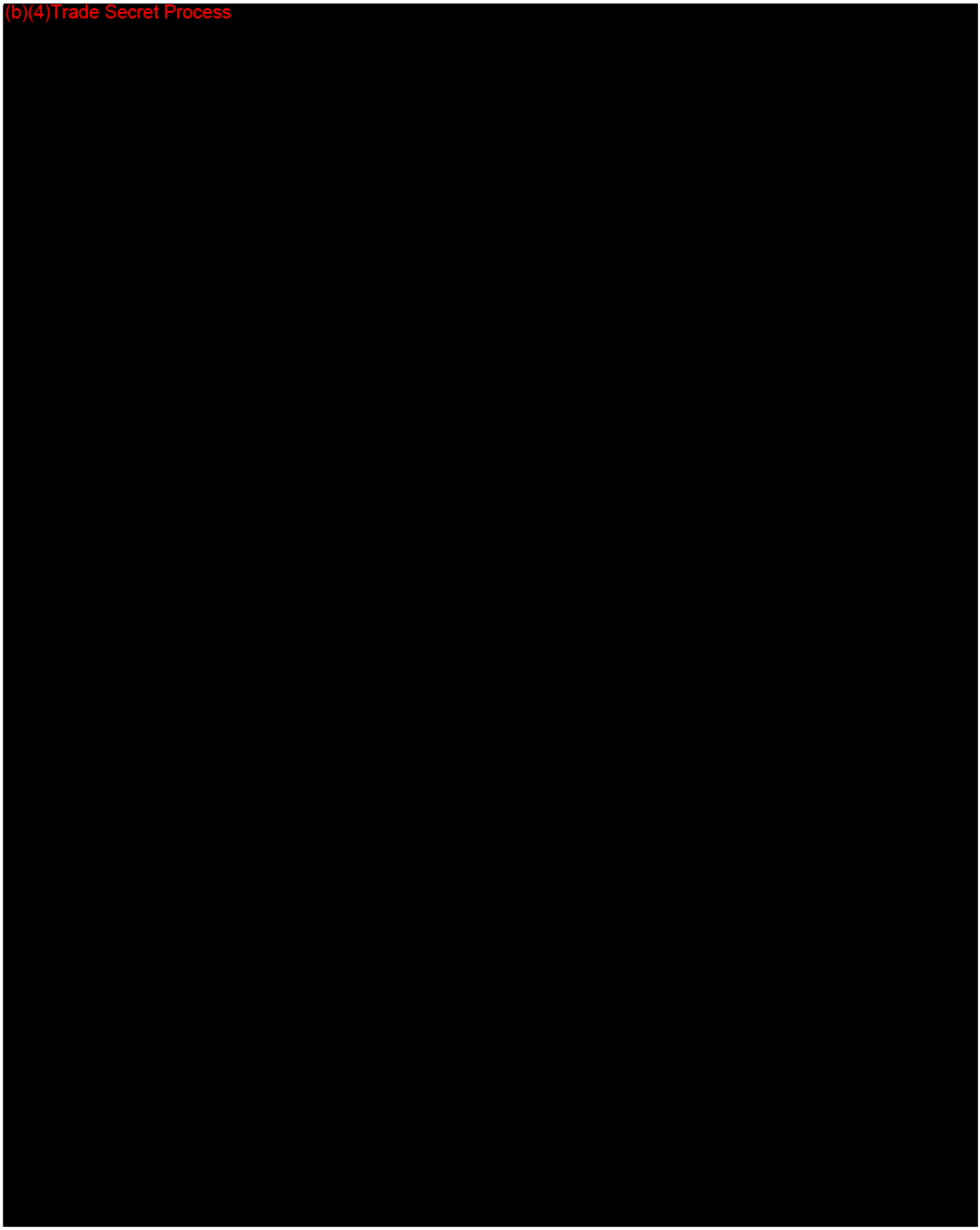

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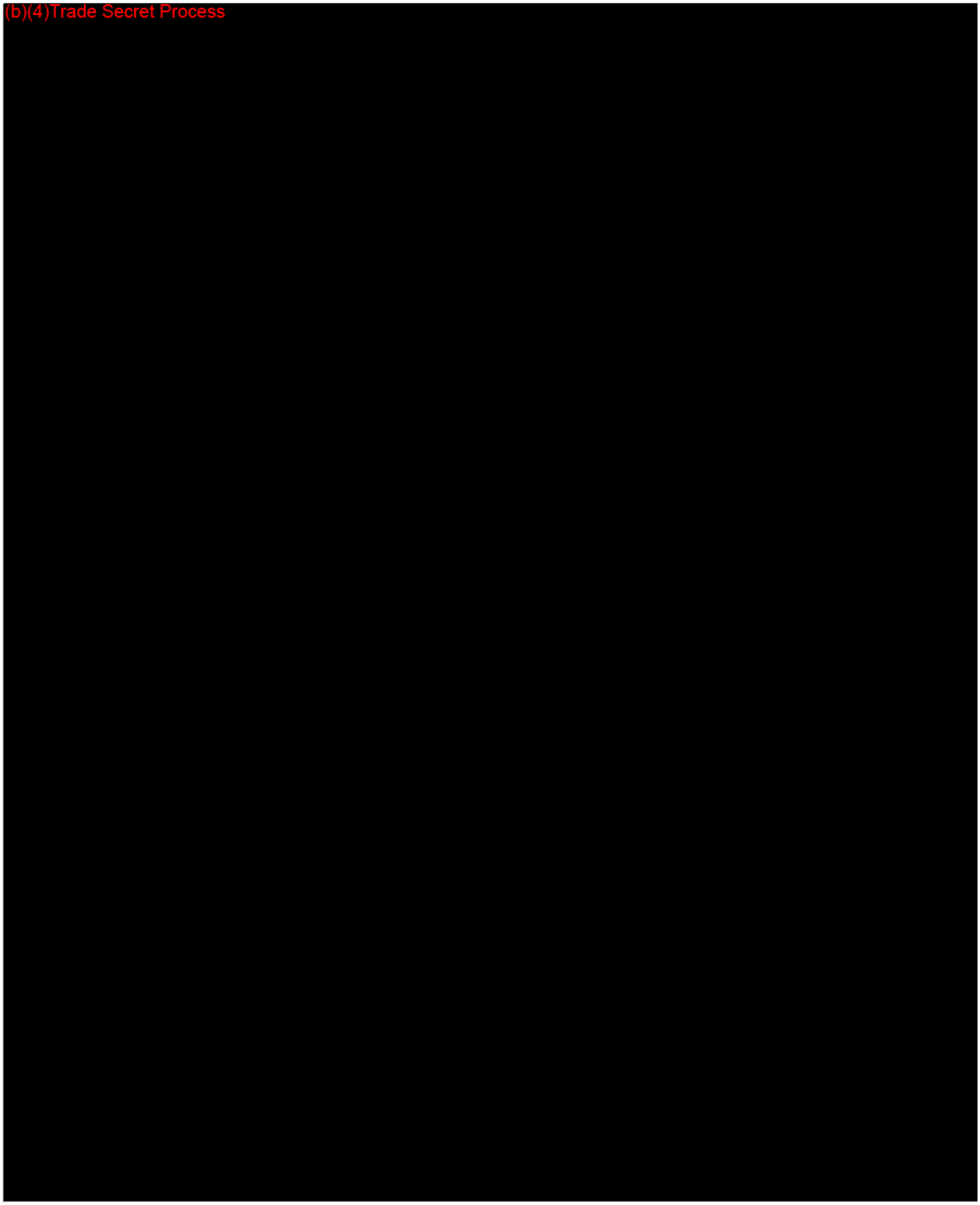

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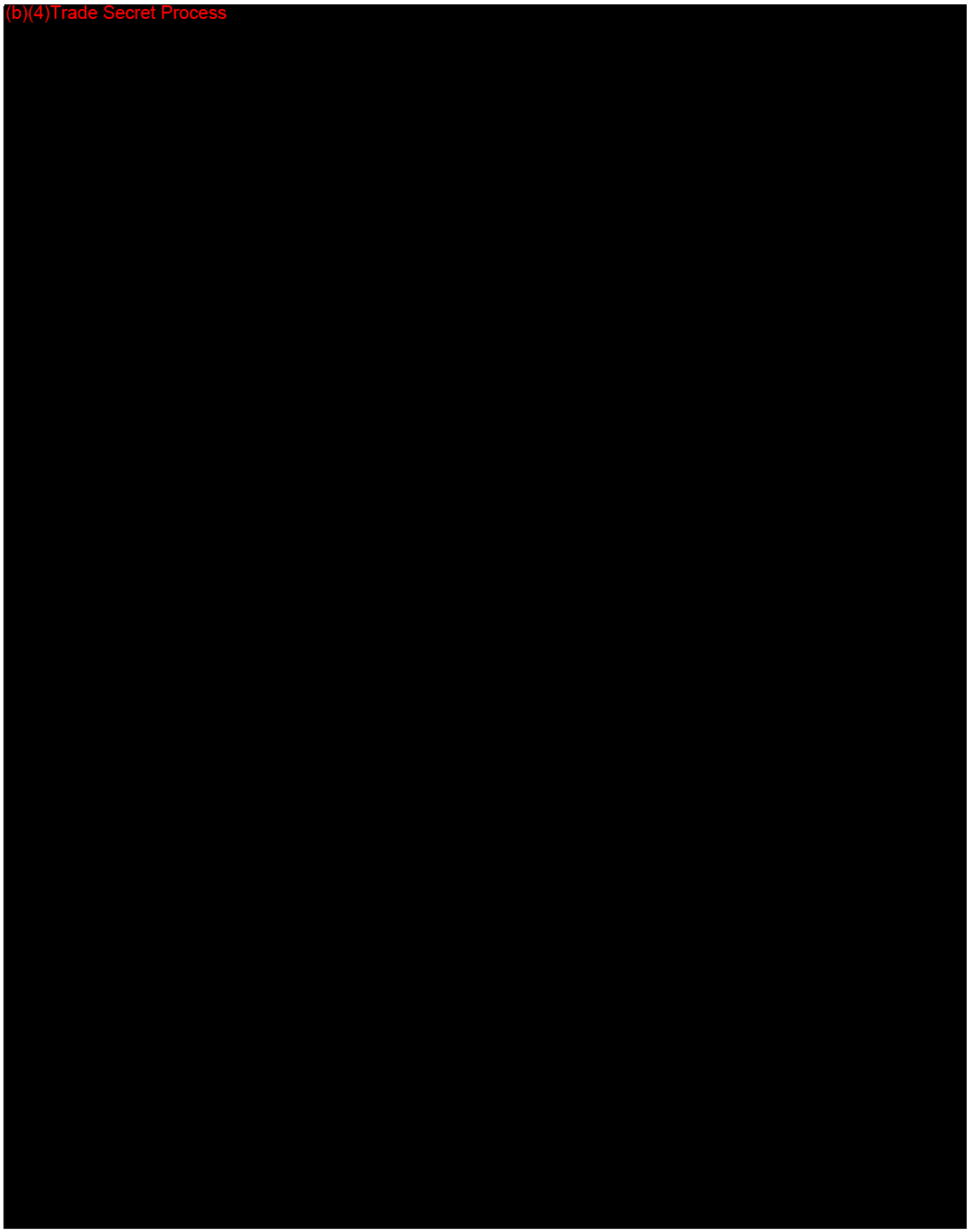

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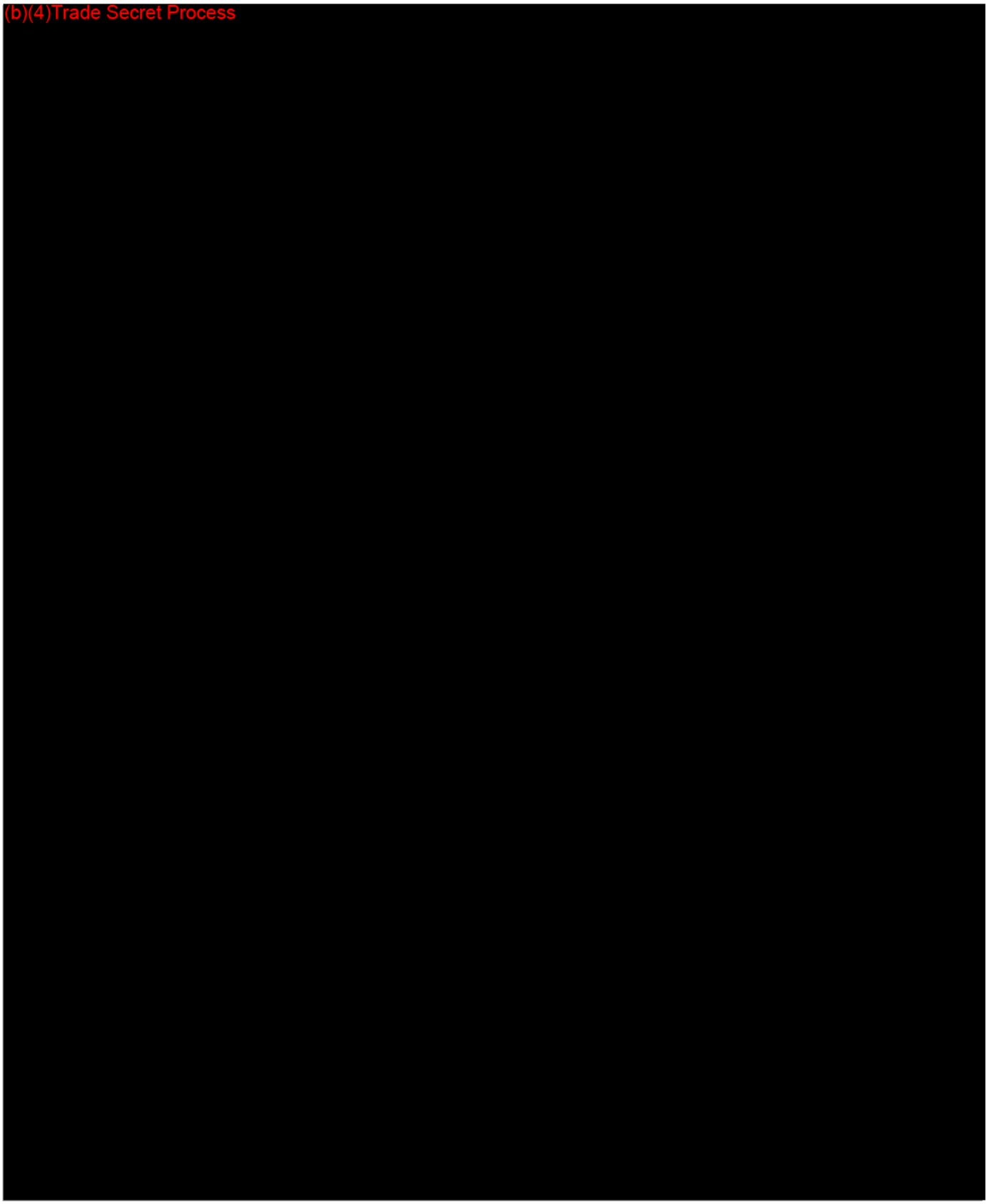

Kelley Burridge

11/18/11

Kelley Burridge, Ph.D.
Scientific Reviewer, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

Date

David Krause

11/18/2011

David Krause, Ph.D.
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

Date

Reference List

1. Lebleu, N., C. Roques, P. Aimar, and C. Causserand. 2009. Role of the cell-wall structure in the retention of bacteria by microfiltration membranes. Journal of Membrane Science 326: 178-185 ISI:000261906700023.
2. Moues, C. M., F. Heule, and S. E. R. Hovius. 2011. A review of topical negative pressure therapy in wound healing: sufficient evidence? American Journal of Surgery 201: 544-556 ISI:000289311700022.

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Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following issues:

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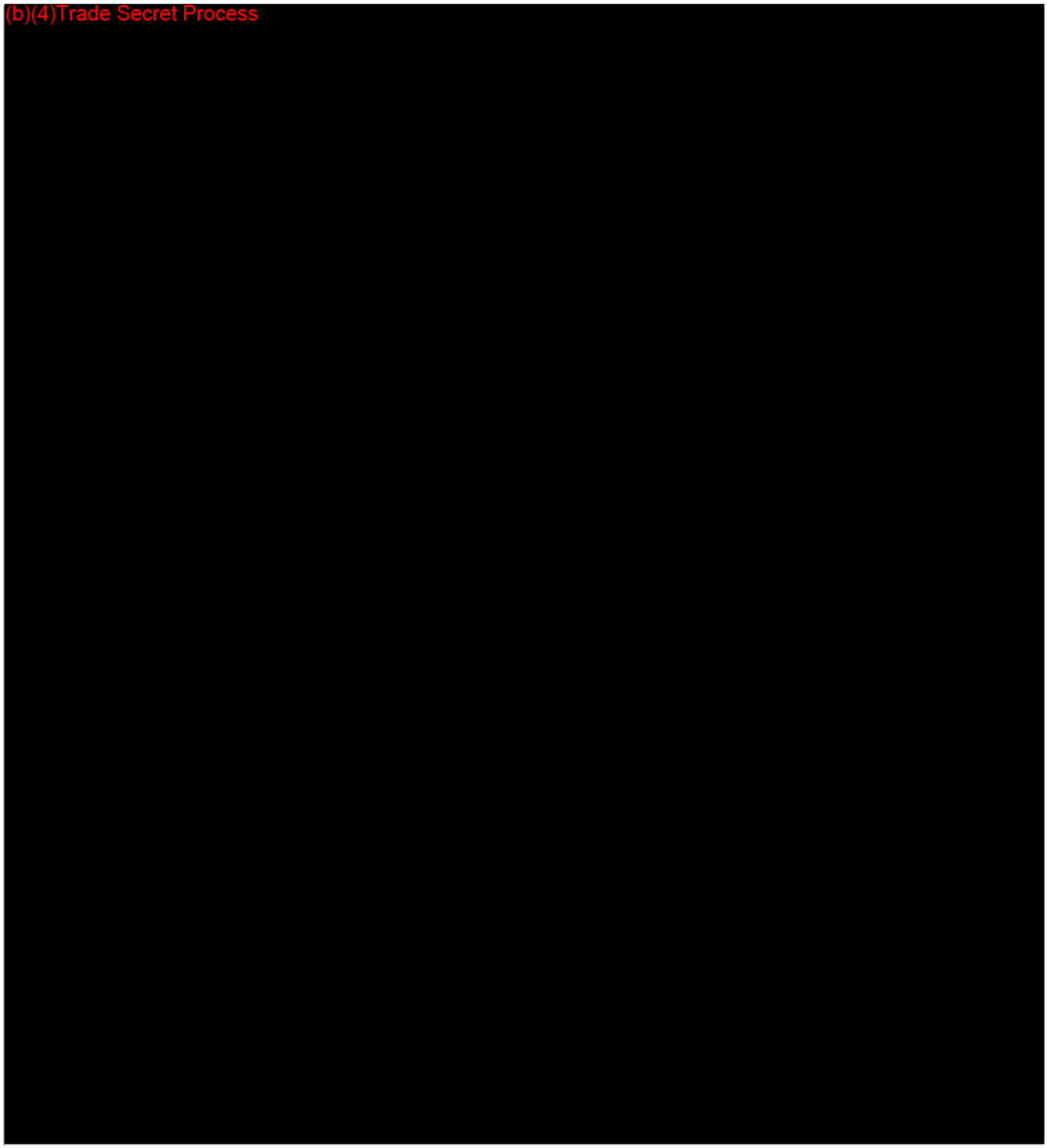

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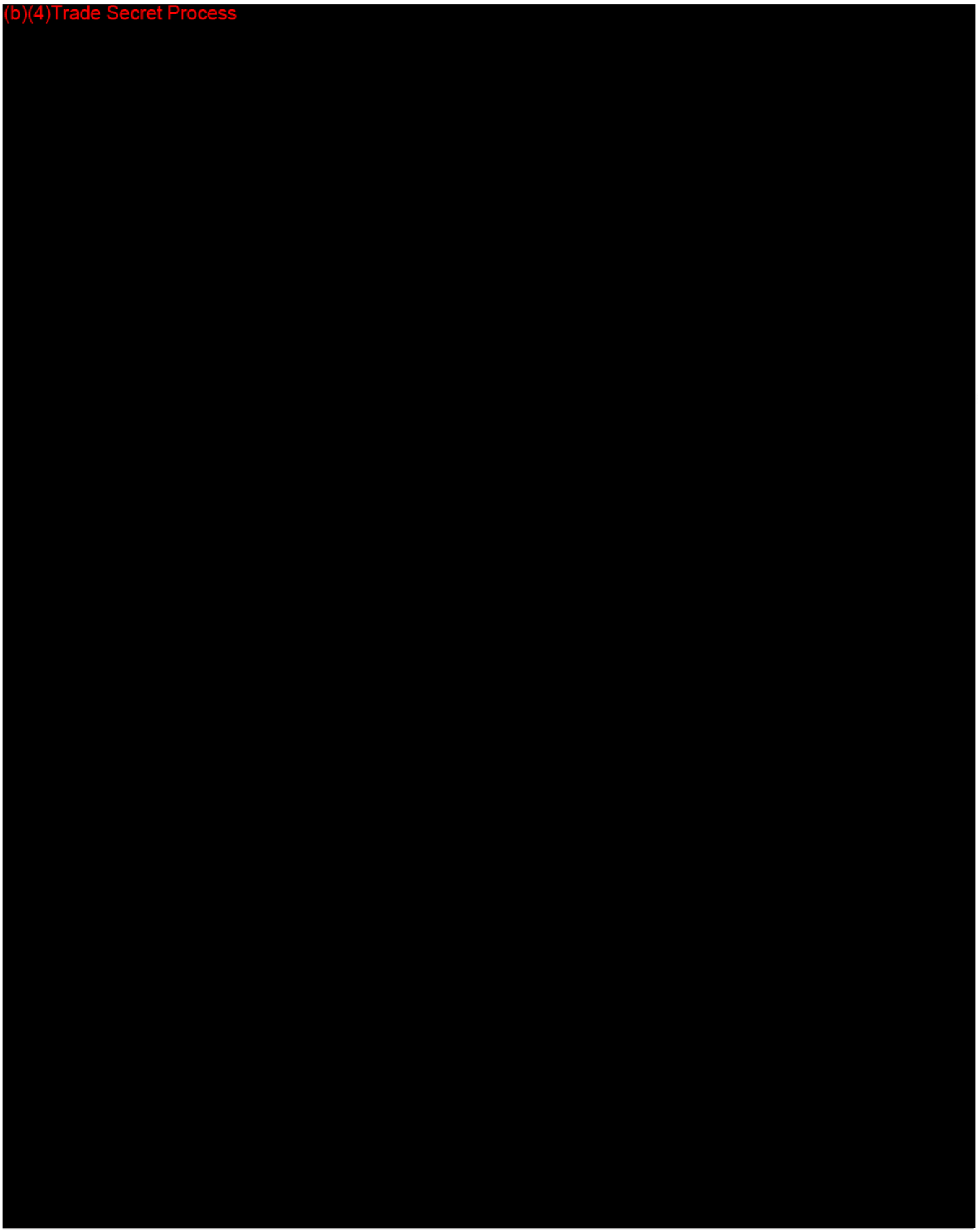

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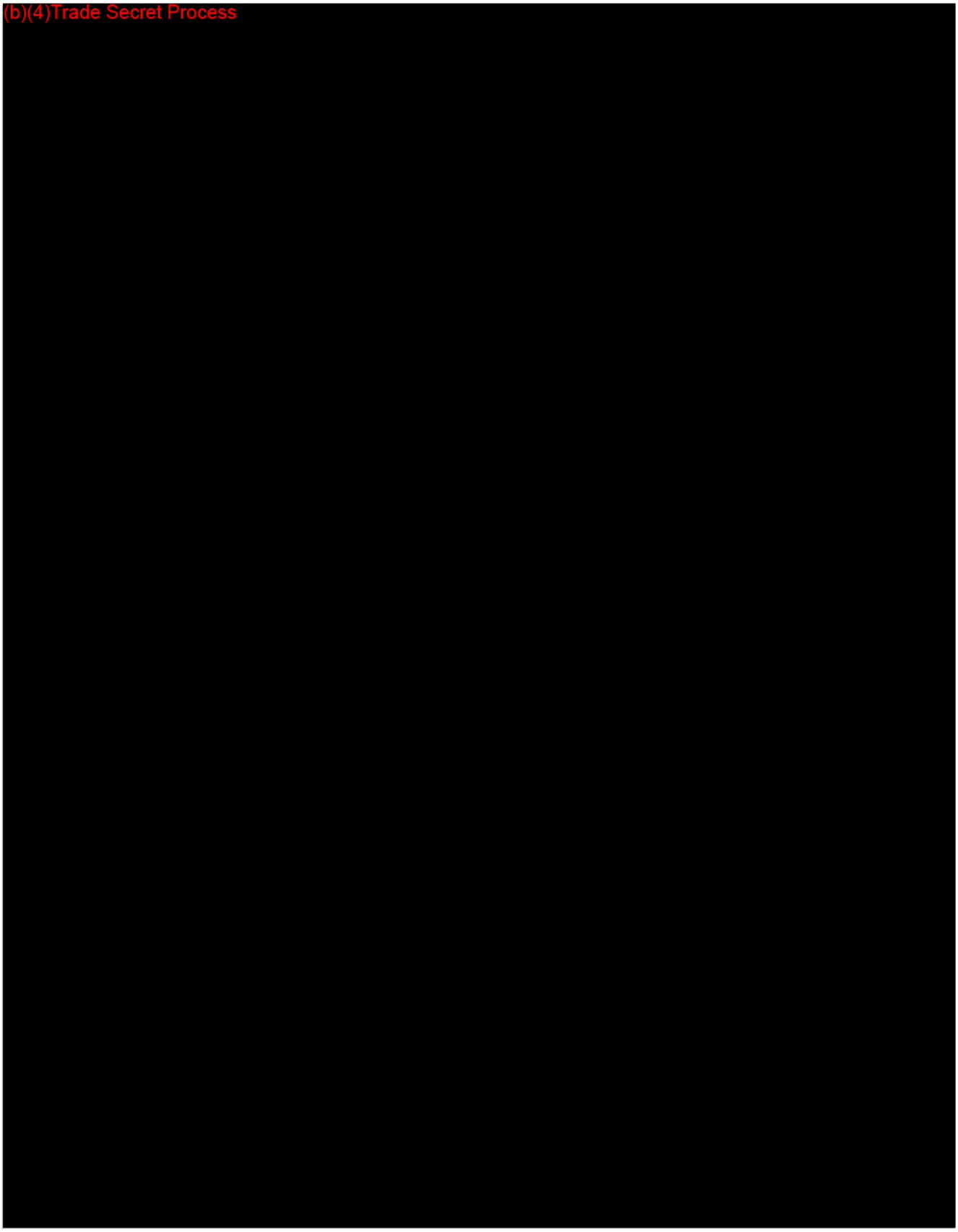

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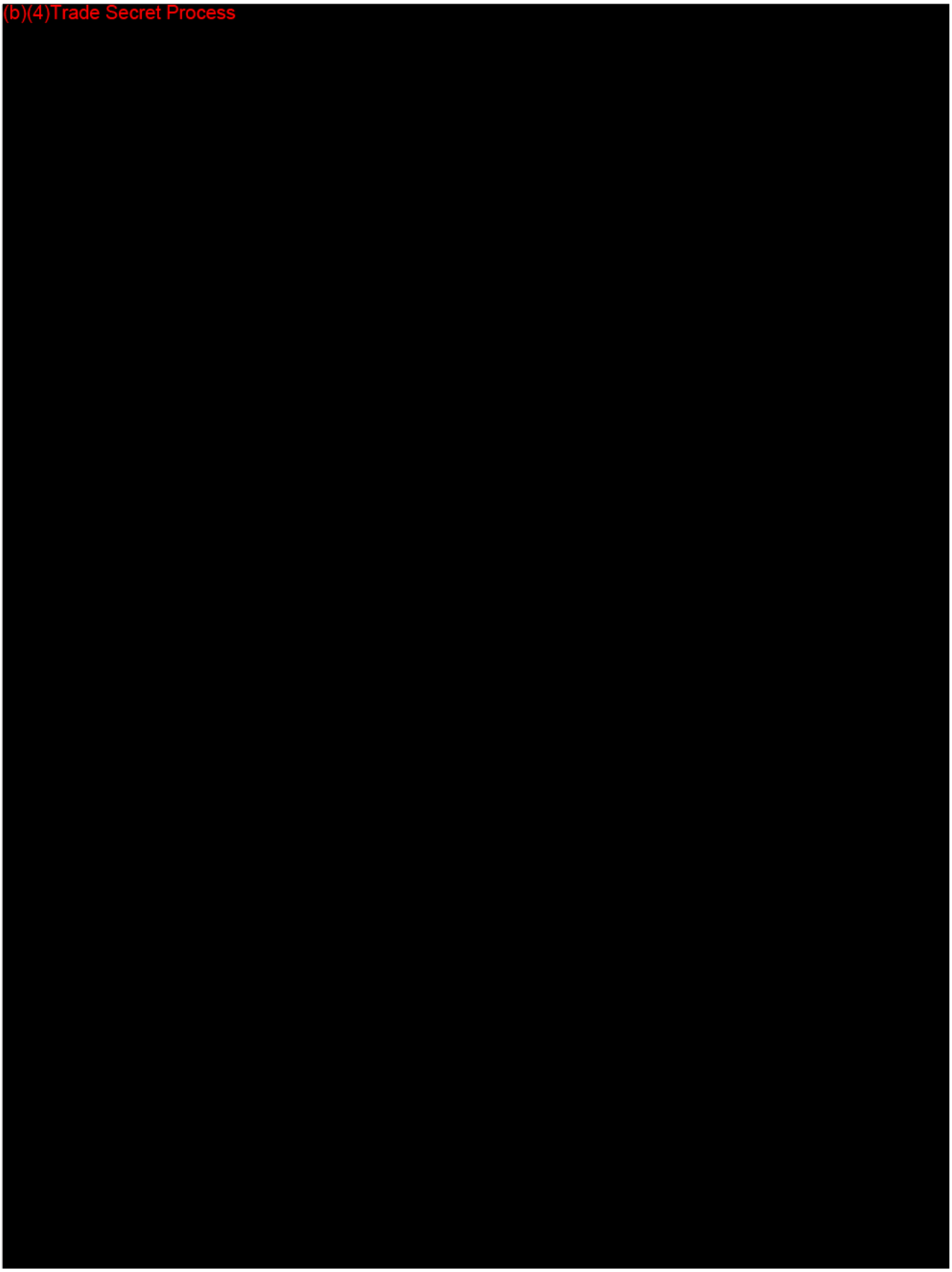

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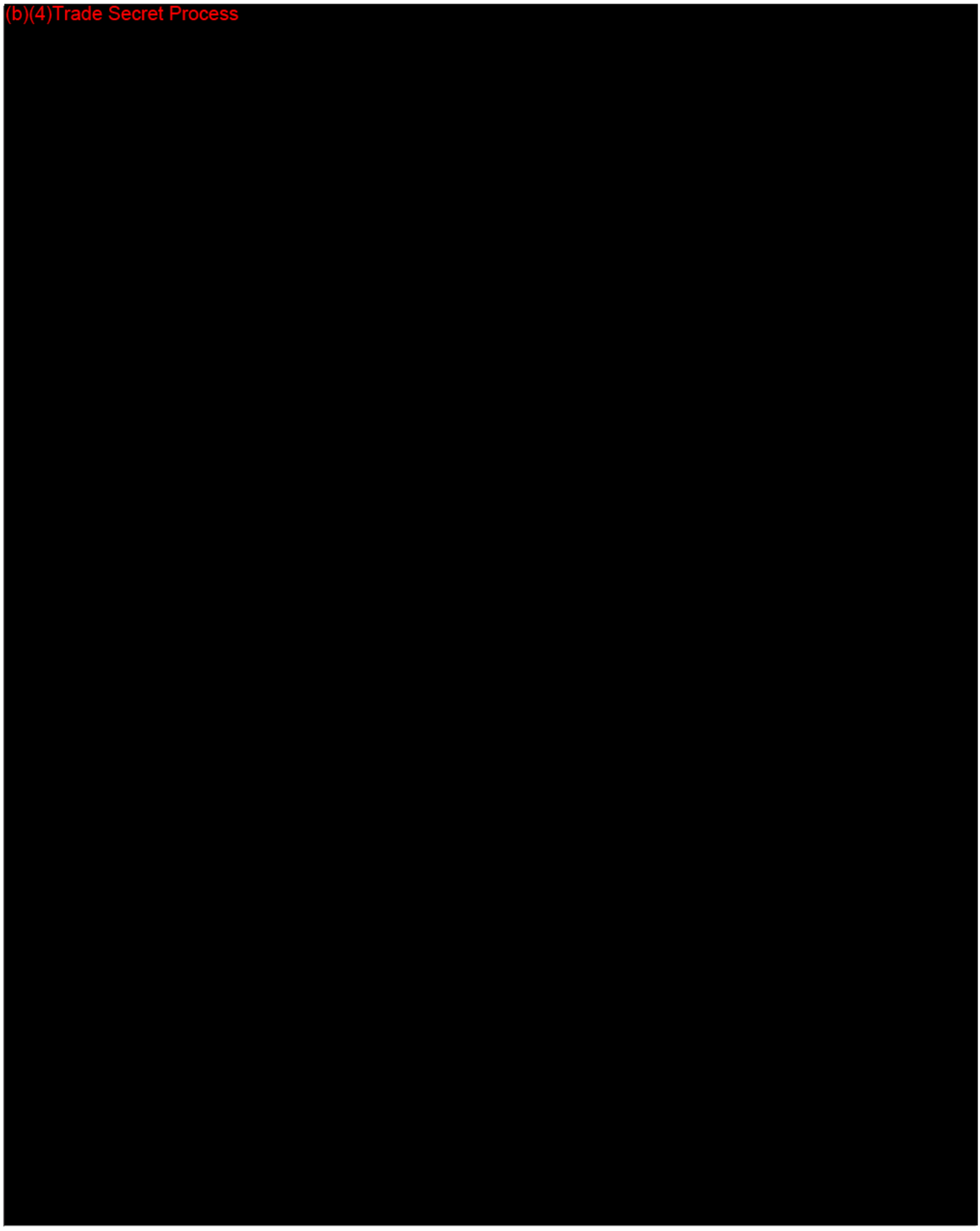

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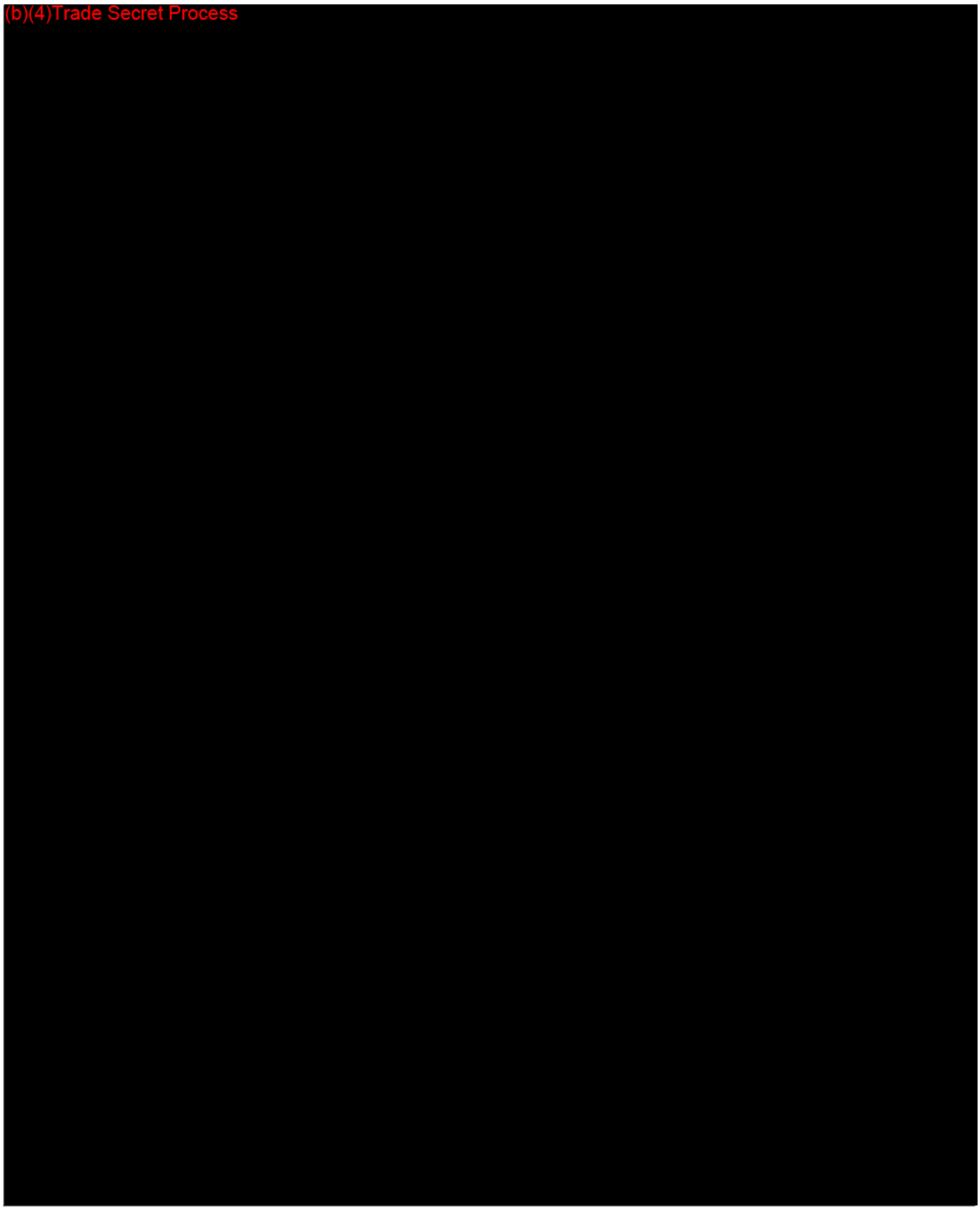

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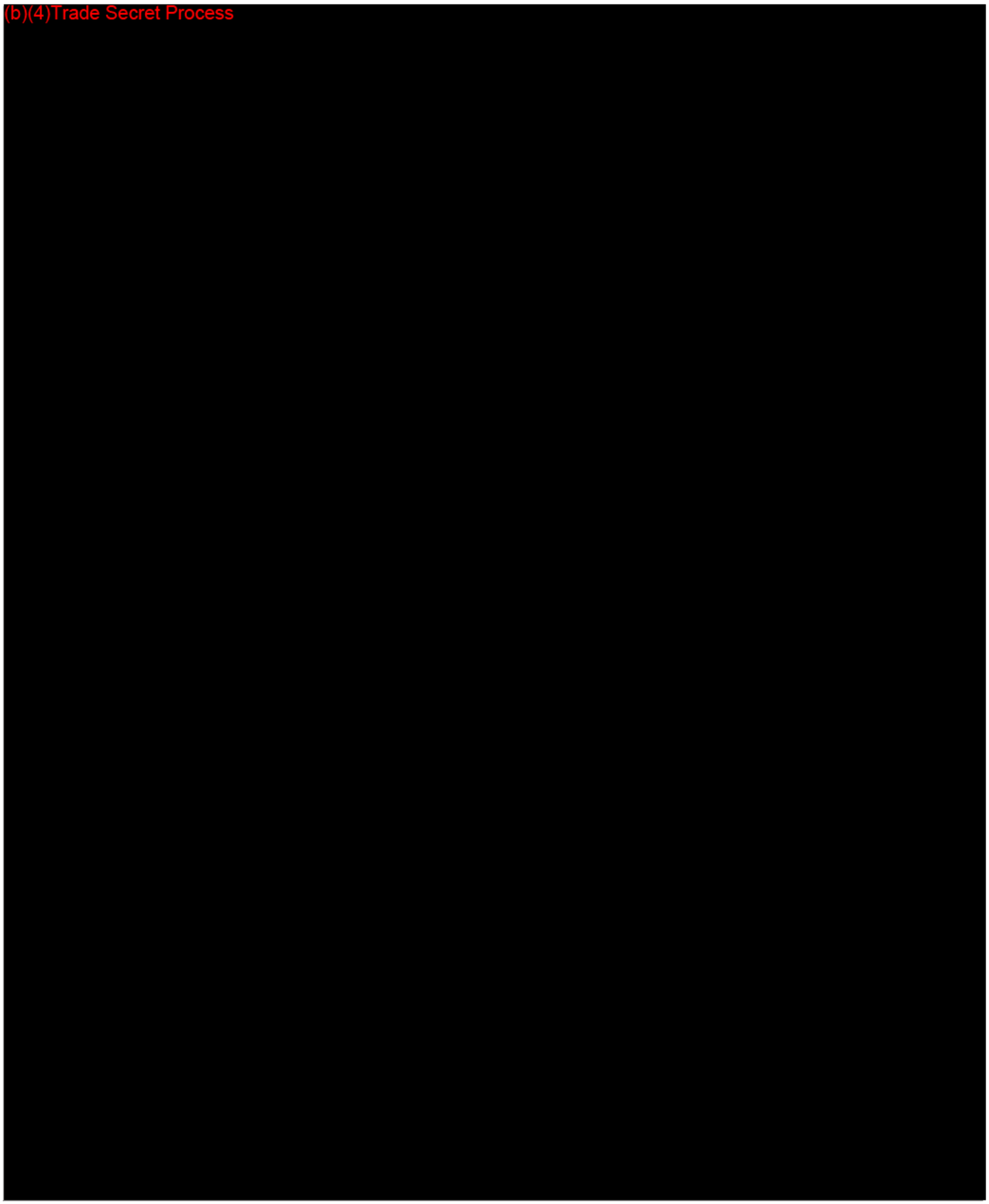


(b)(4)Trade Secret Process

[redacted]

Sincerely yours,

David Krause, Ph. D.
Branch Chief
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and
Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Office of Device Evaluation
Division of Surgical, Orthopedic and Restorative Devices
Plastic and Reconstructive Surgery Branch

K111170/S001
Clinical Consulting Review Memorandum

Date: November 2nd, 2011

To: Kelley Burridge, PhD
Scientific Reviewer
CDRH/ODE/DSORD/PRSB

CC: David Krause, PhD - Branch Chief Plastic and Reconstructive Surgery
"The Record"

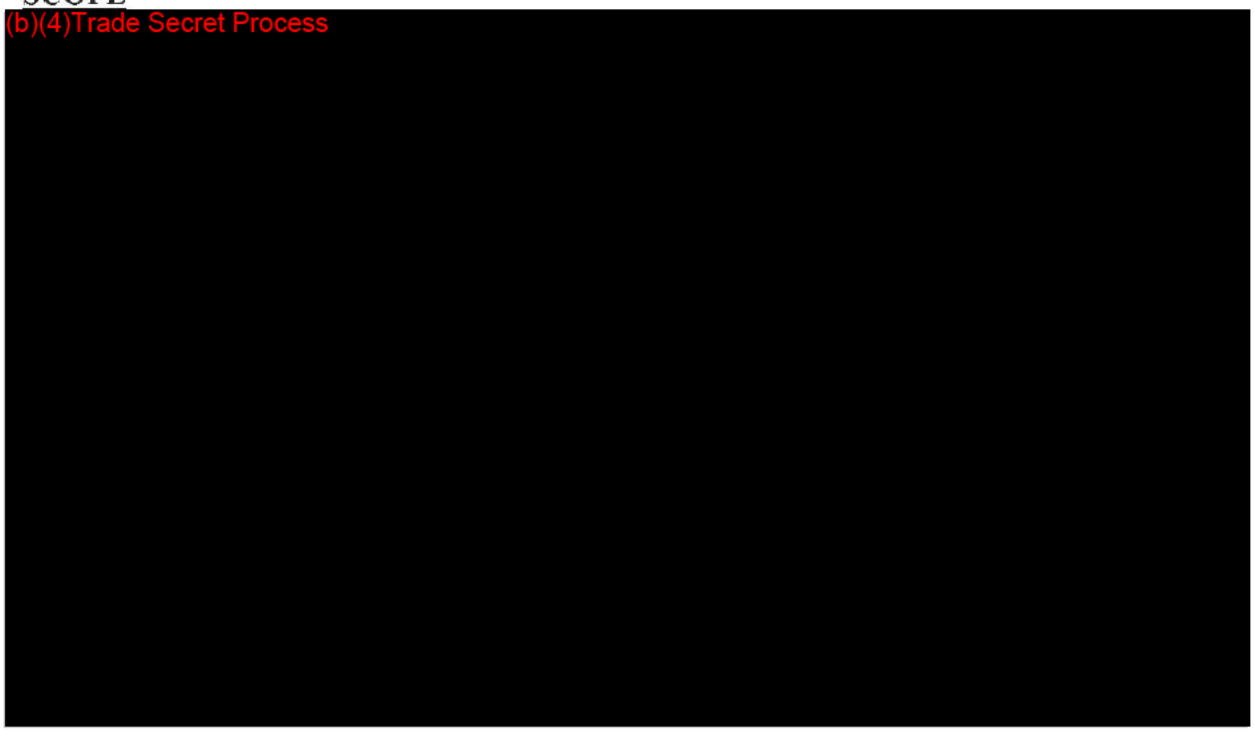
From: Suzanne Schwartz, MD
Clinical Reviewer
CDRH/ODE/DSORD/PRSB

Device Name: Pico Single Use NPWT System

Sponsor: Smith and Nephew

SCOPE

(b)(4)Trade Secret Process



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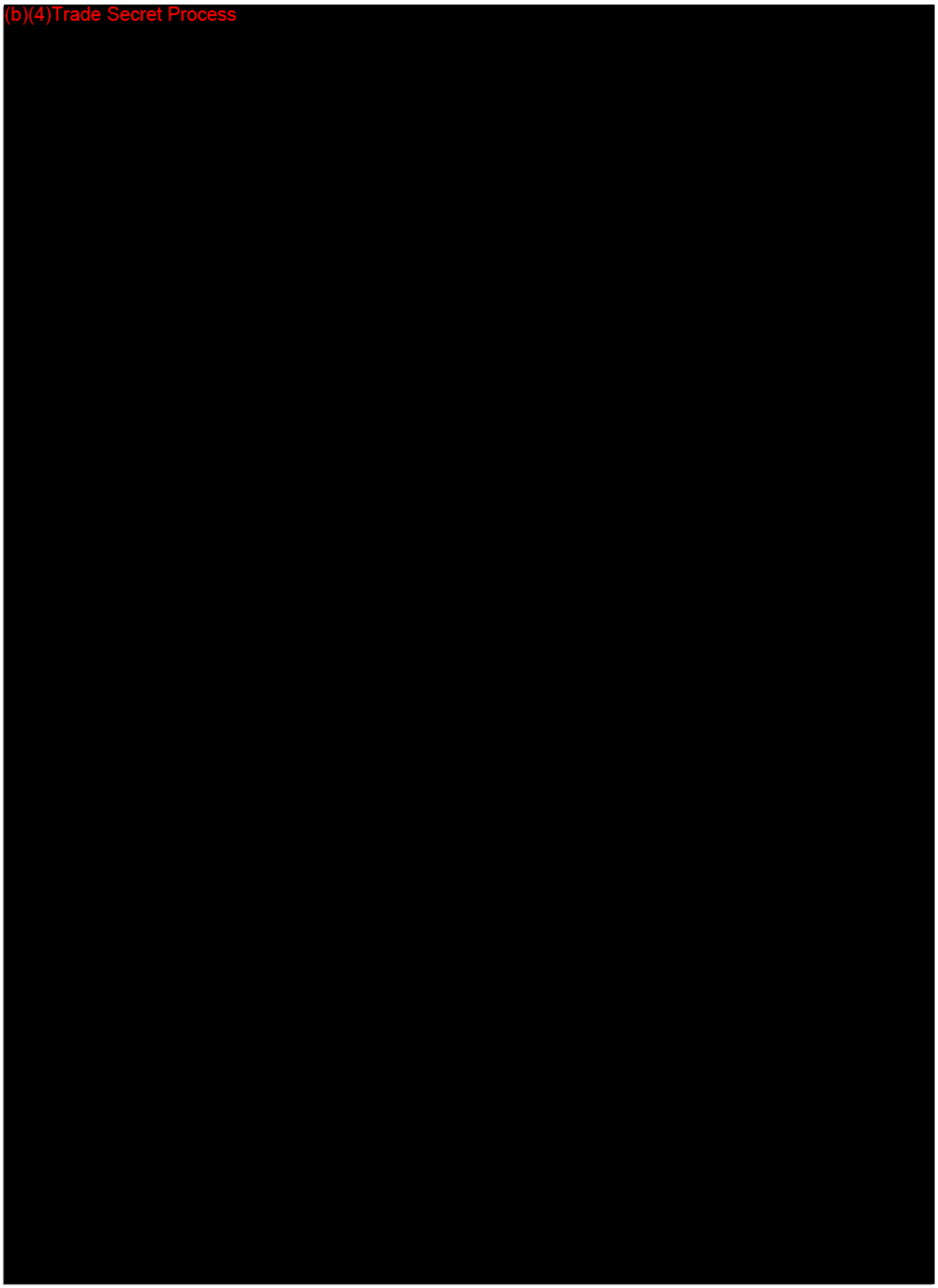

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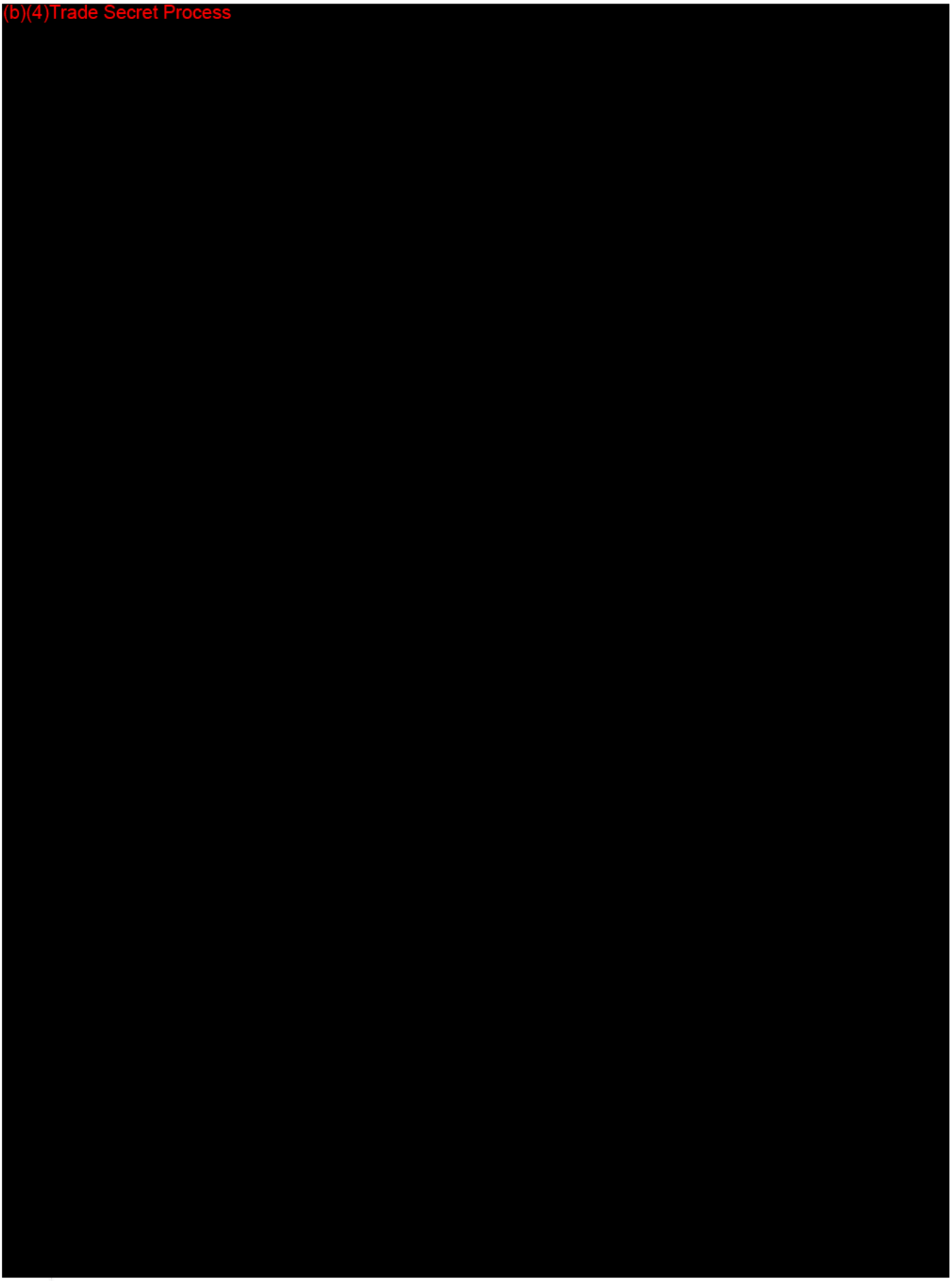

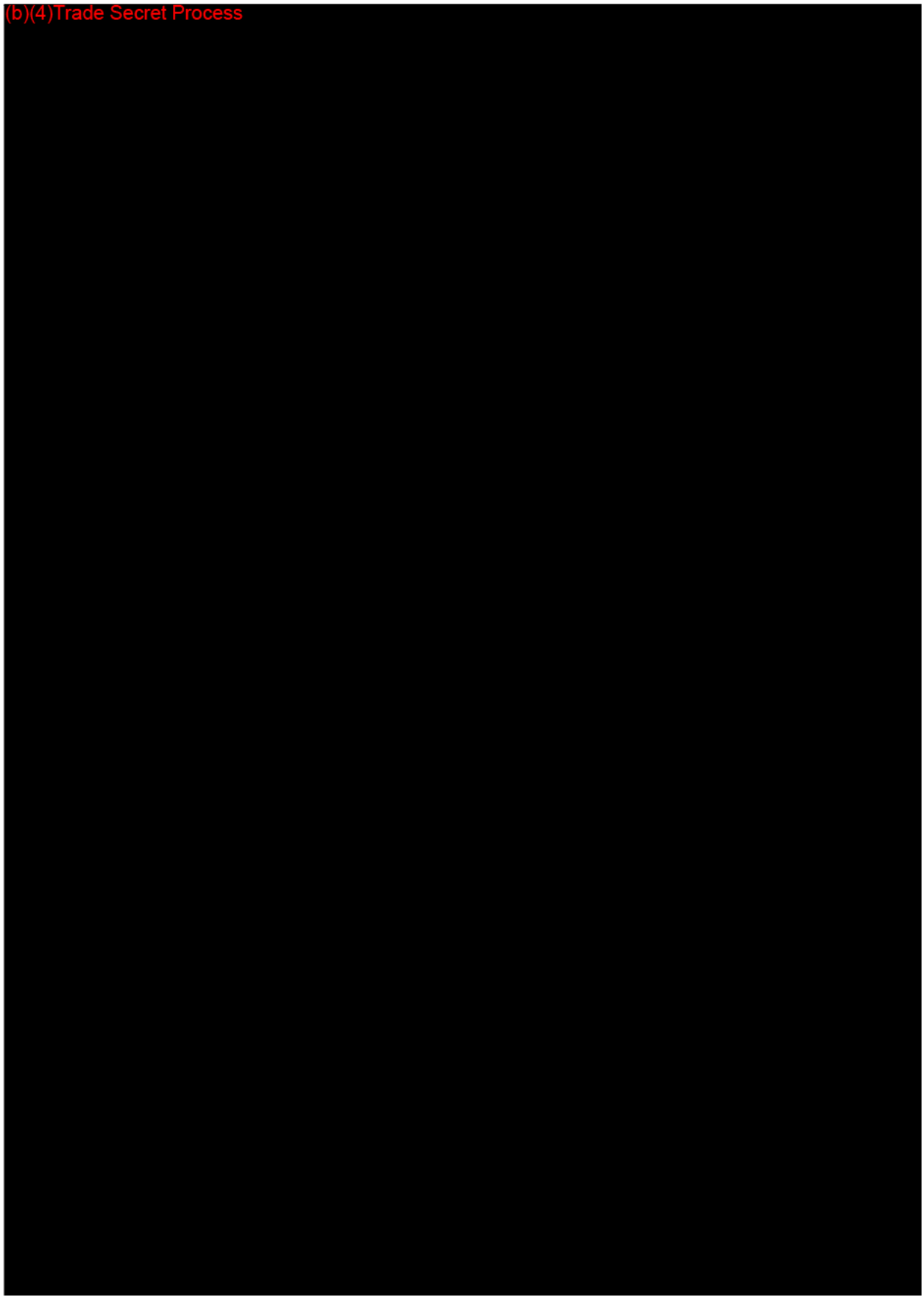
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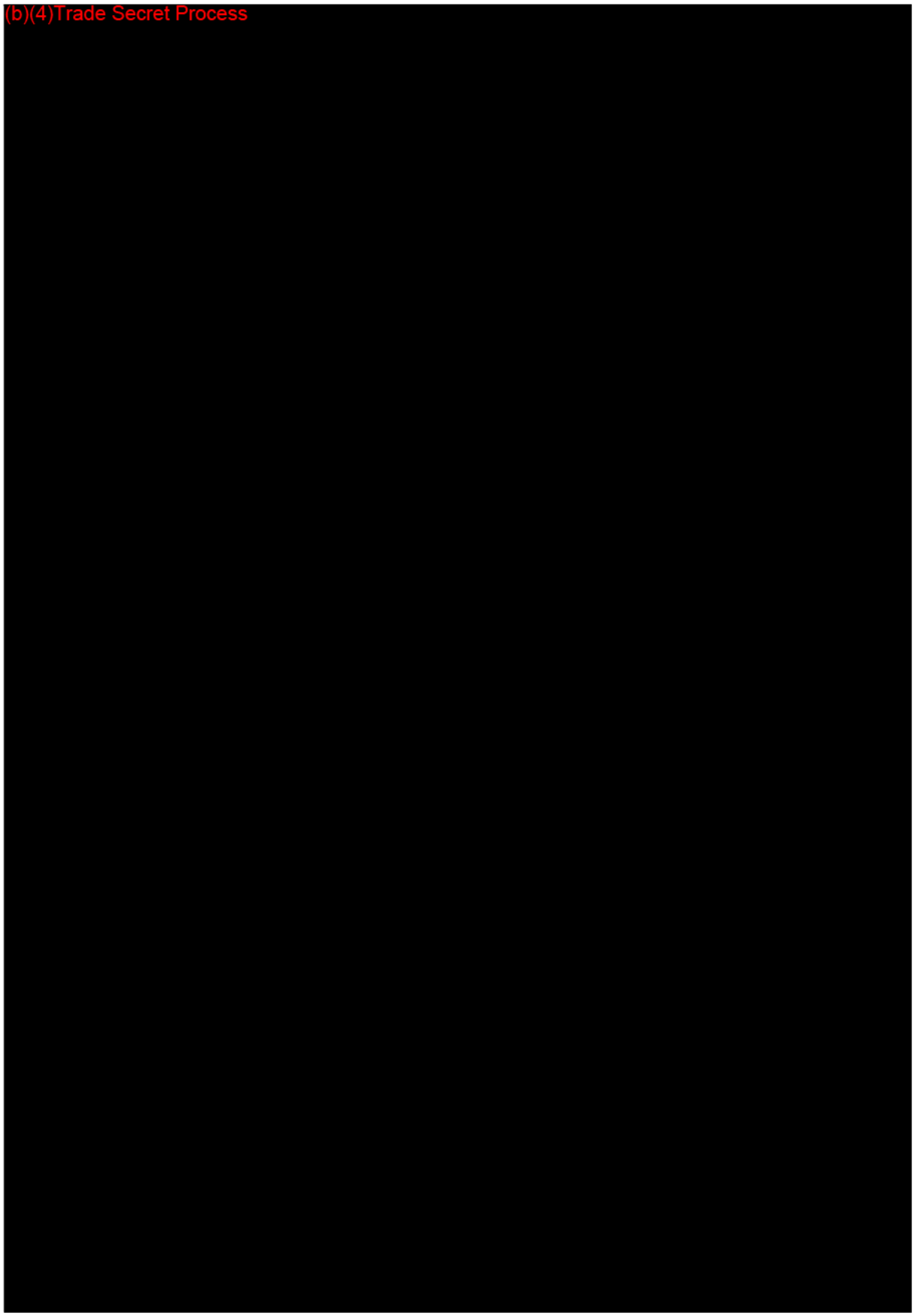

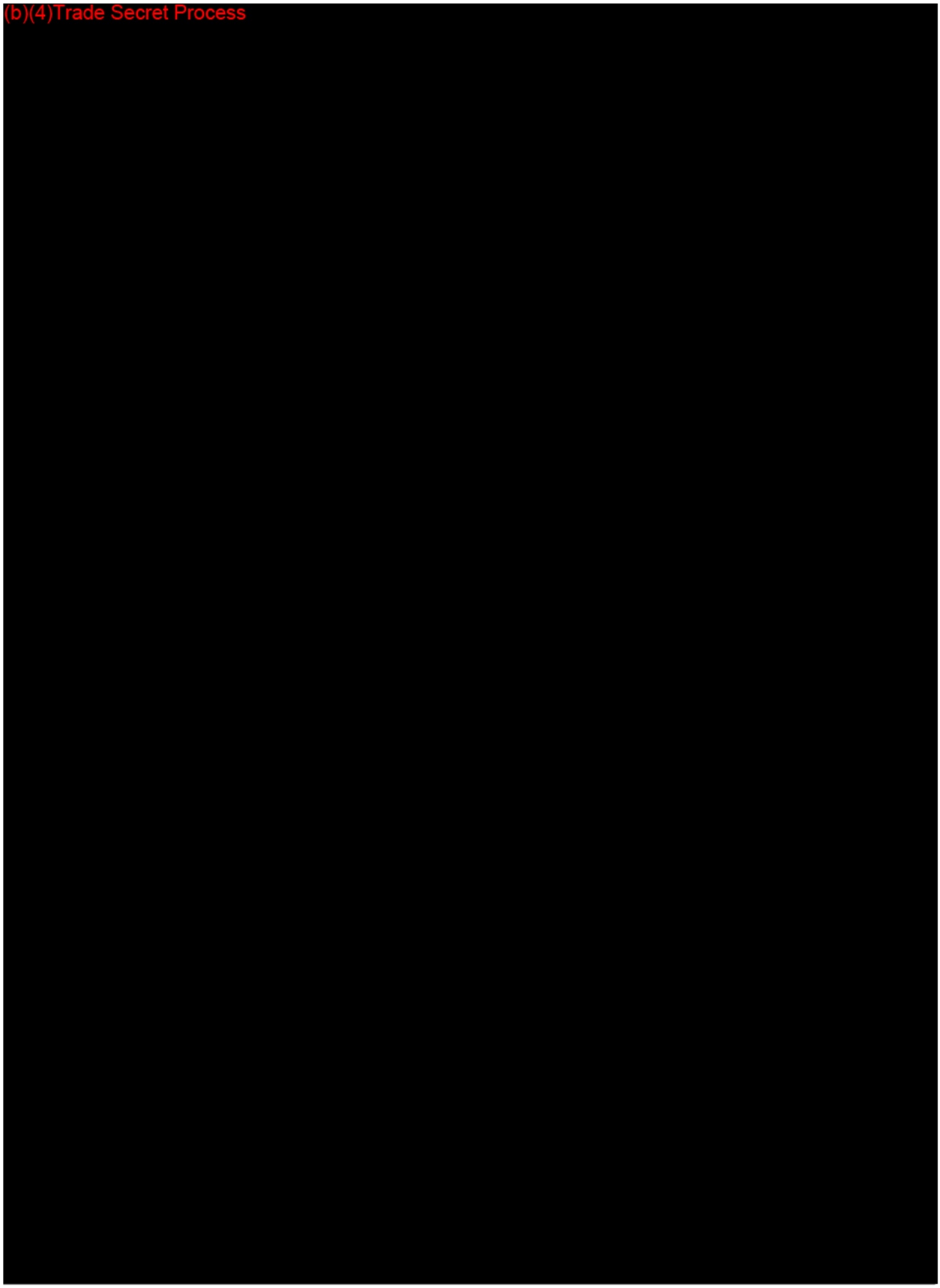
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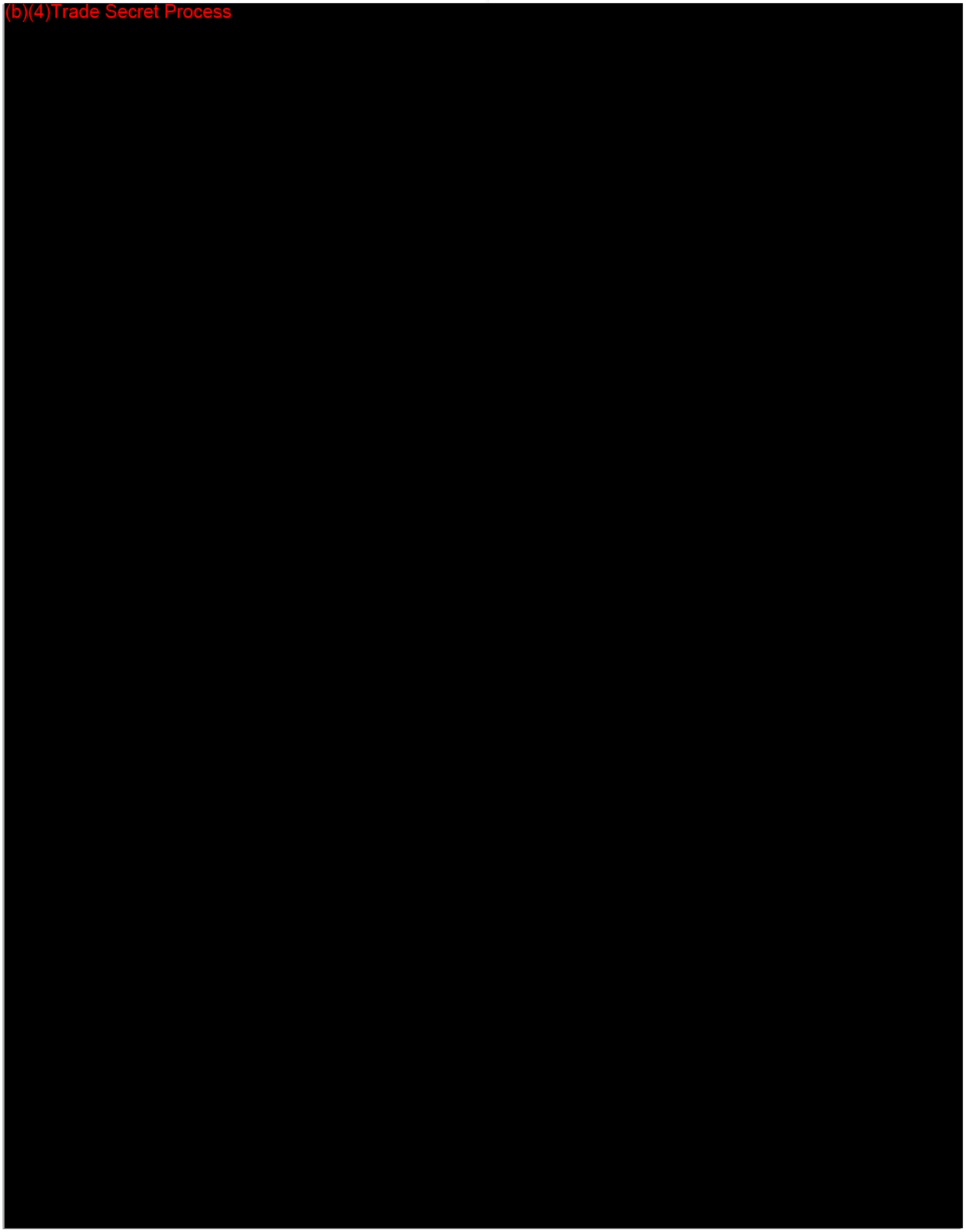

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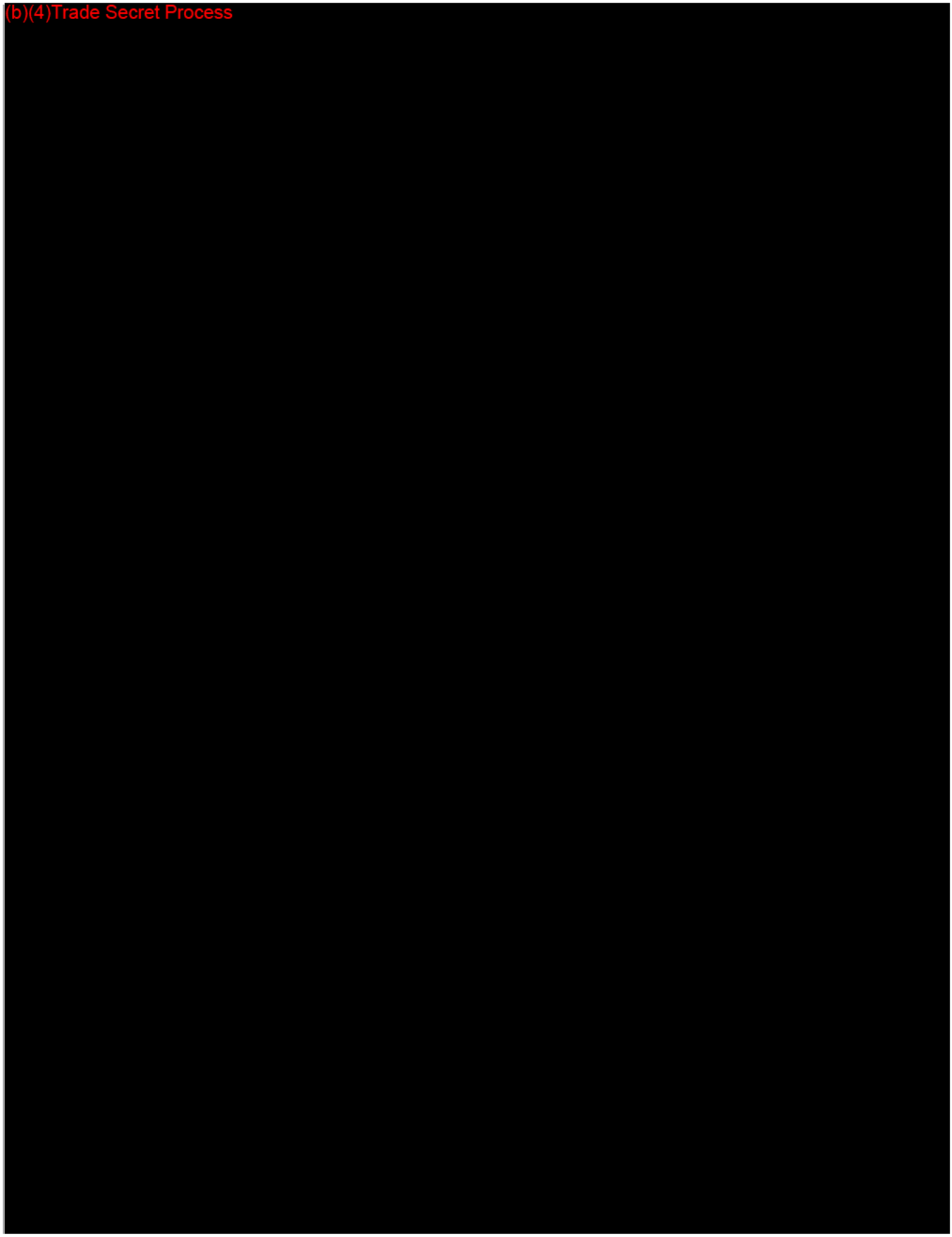

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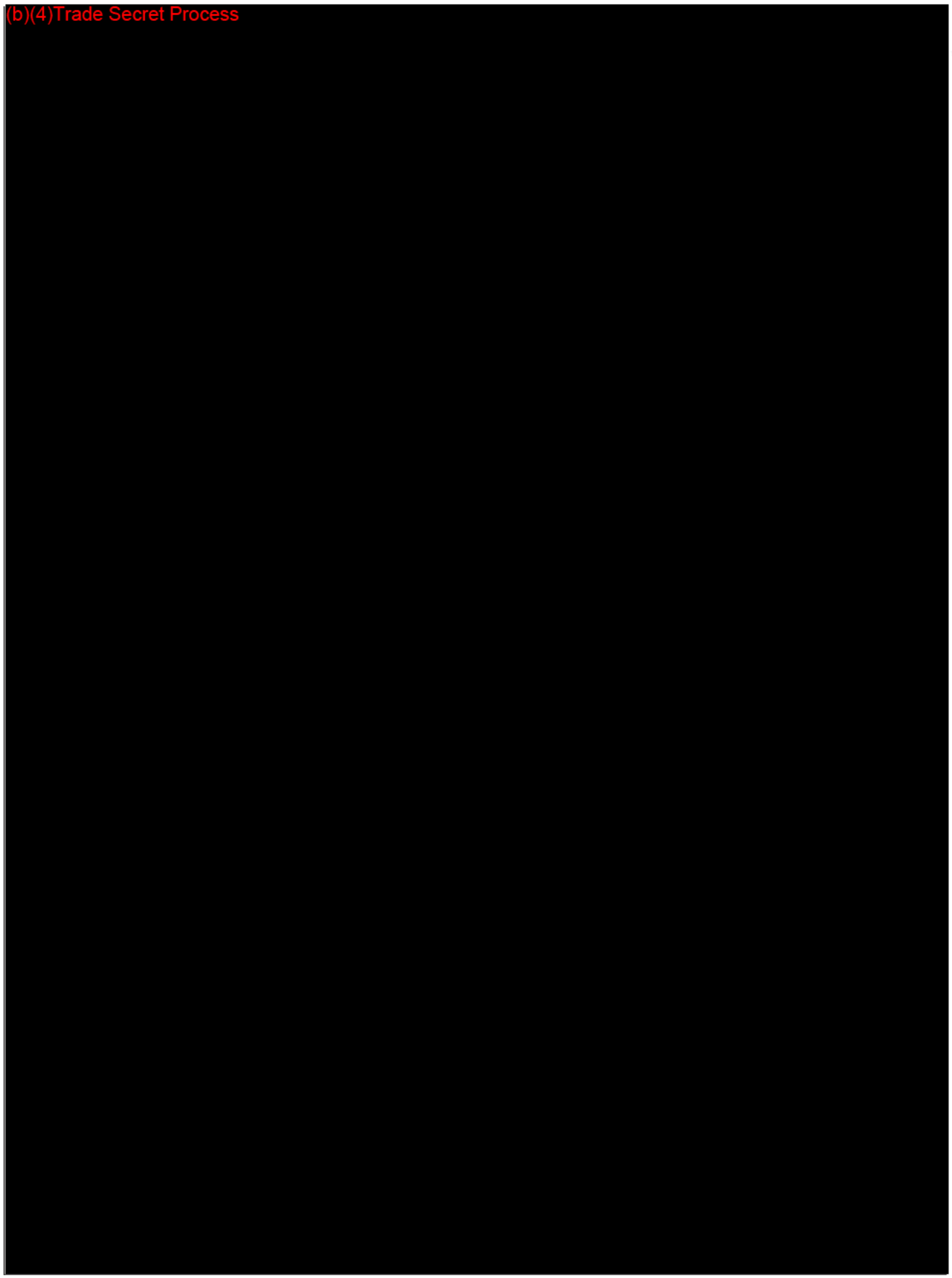

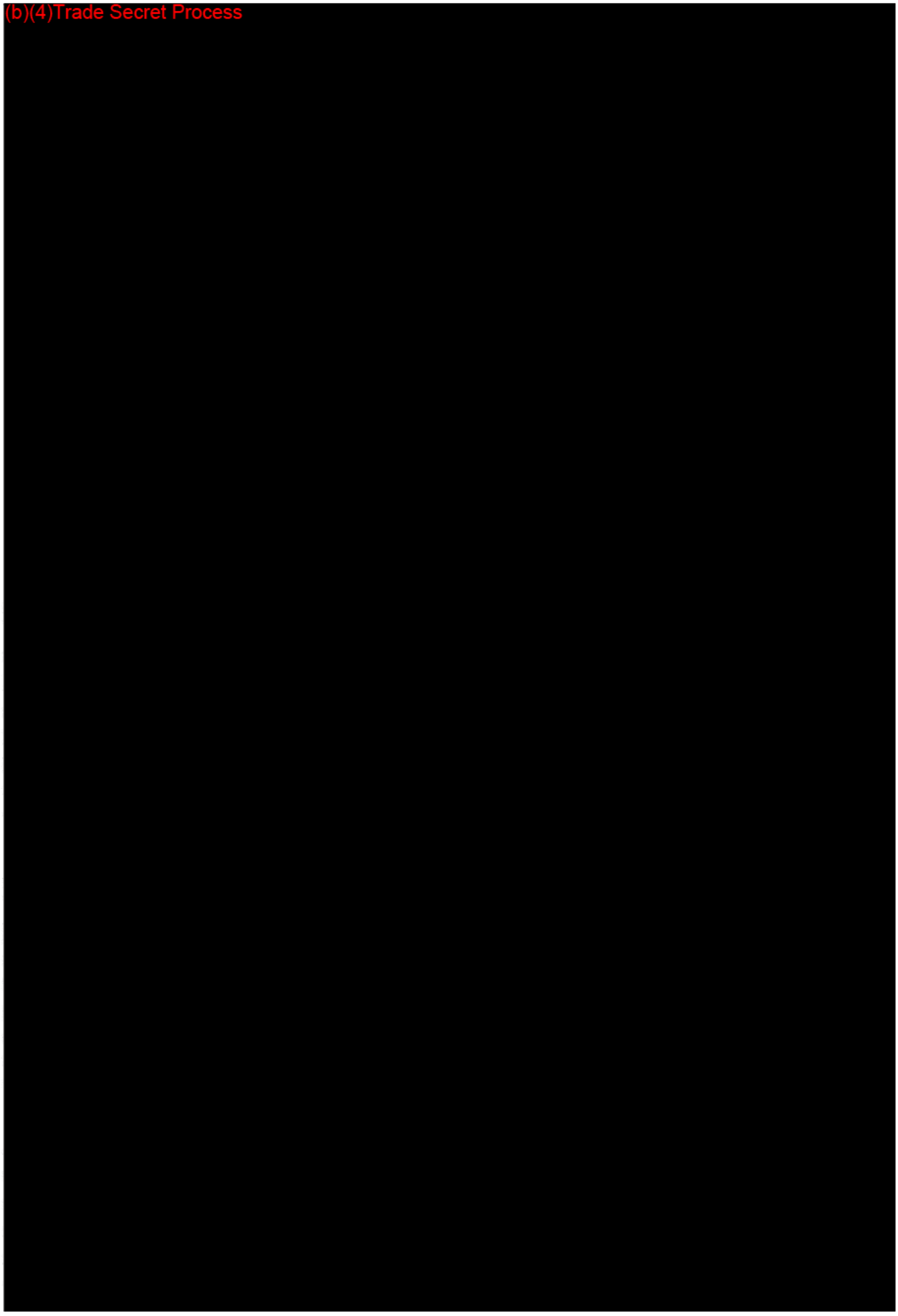
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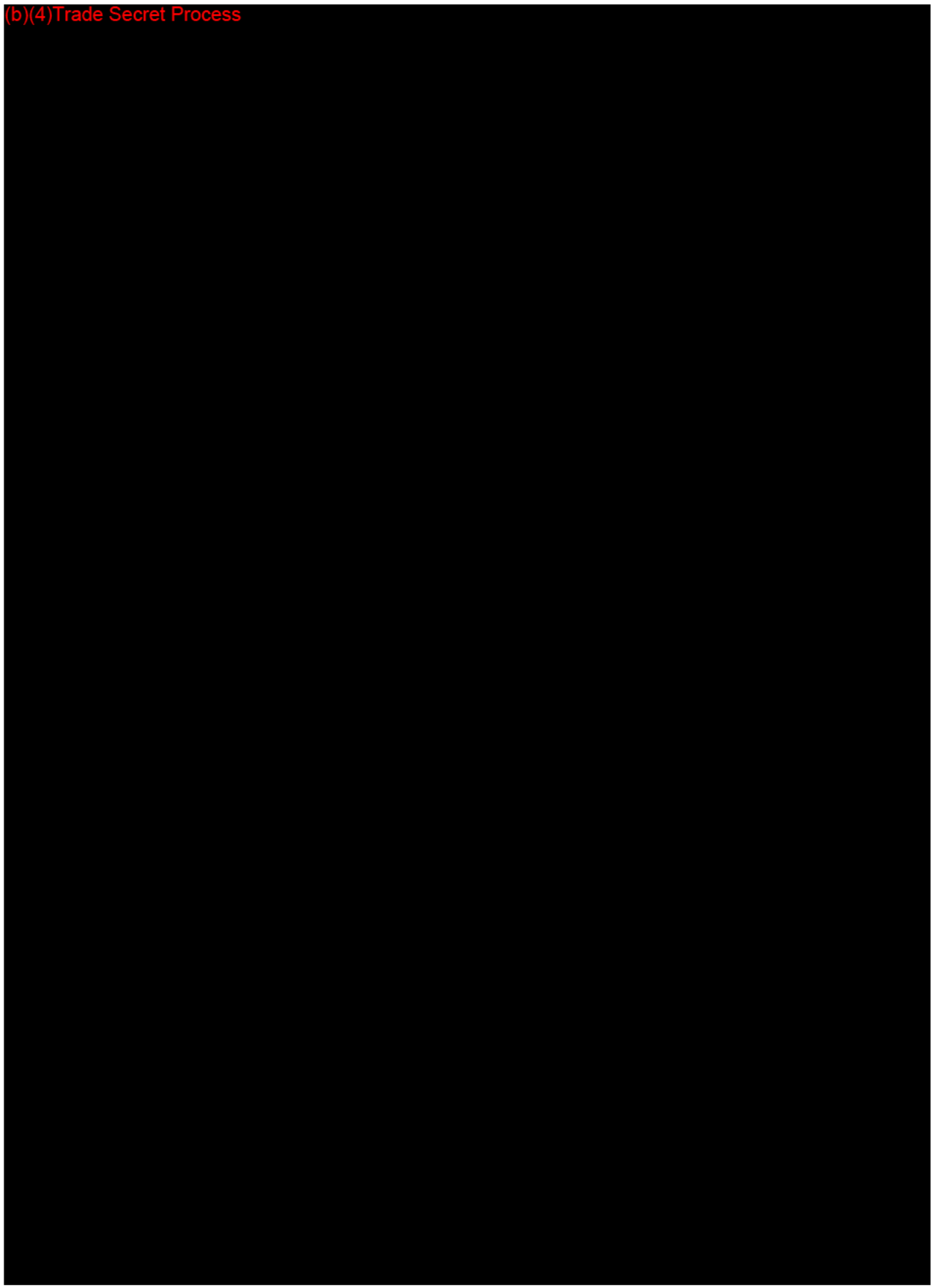

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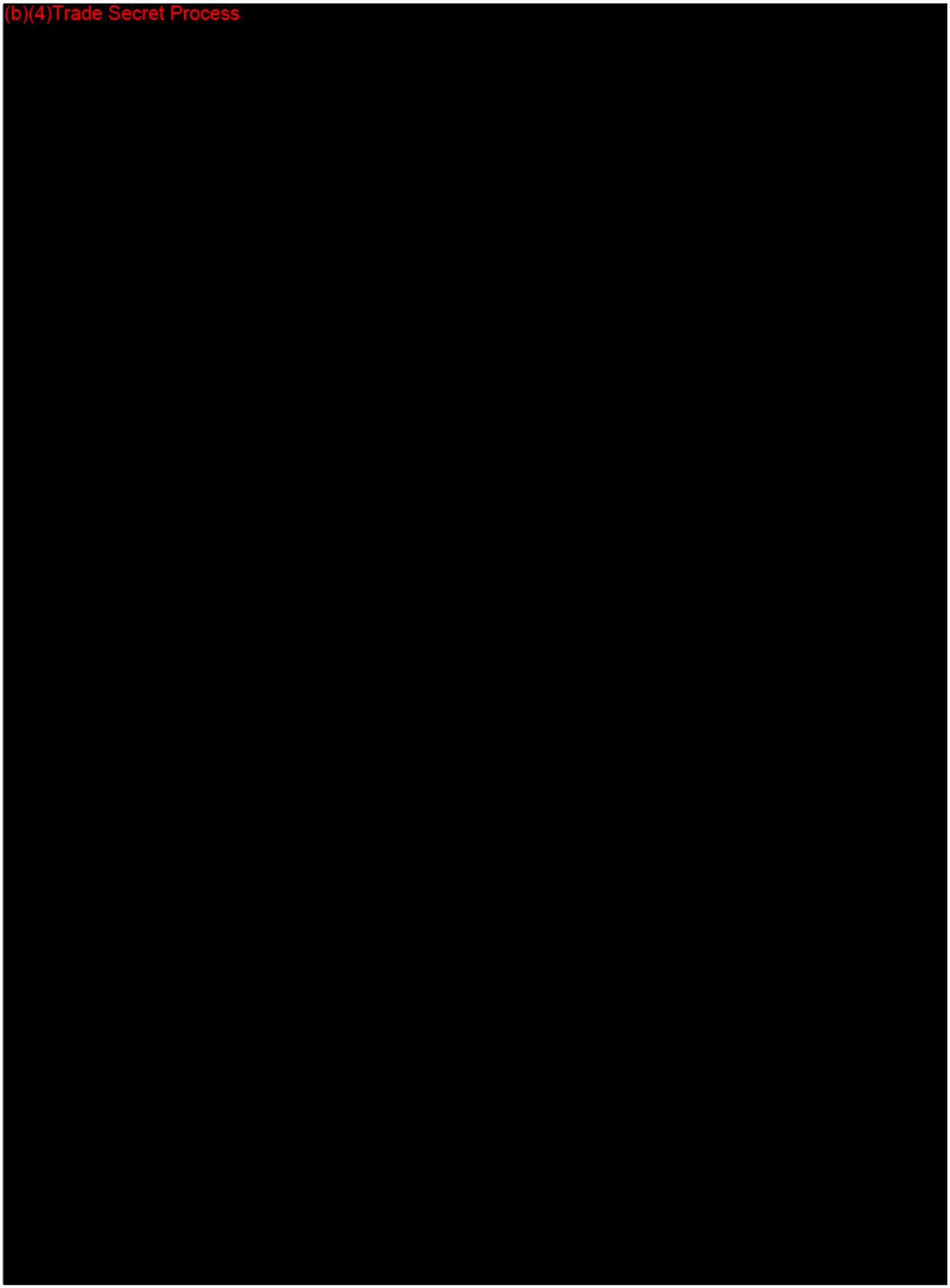

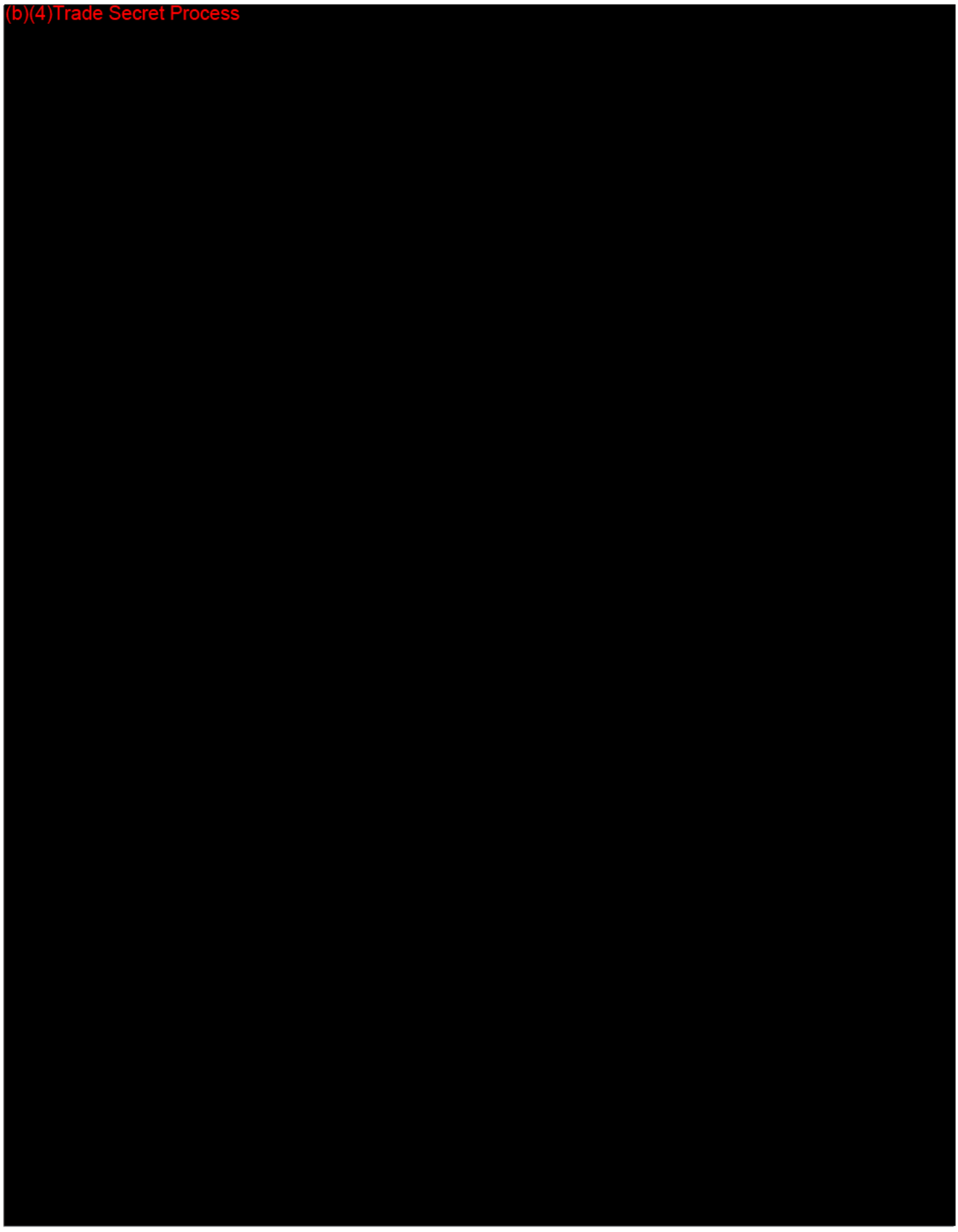
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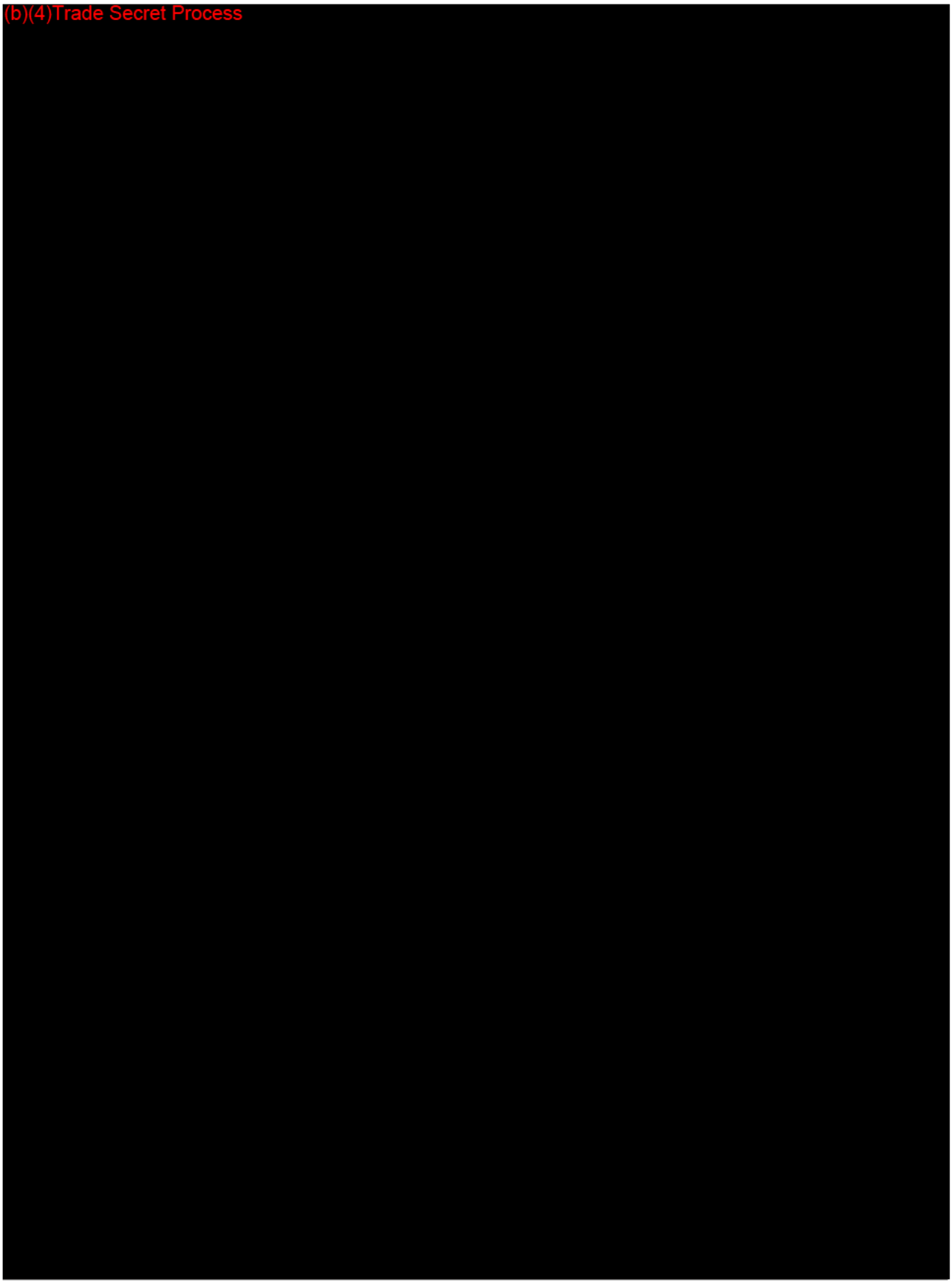

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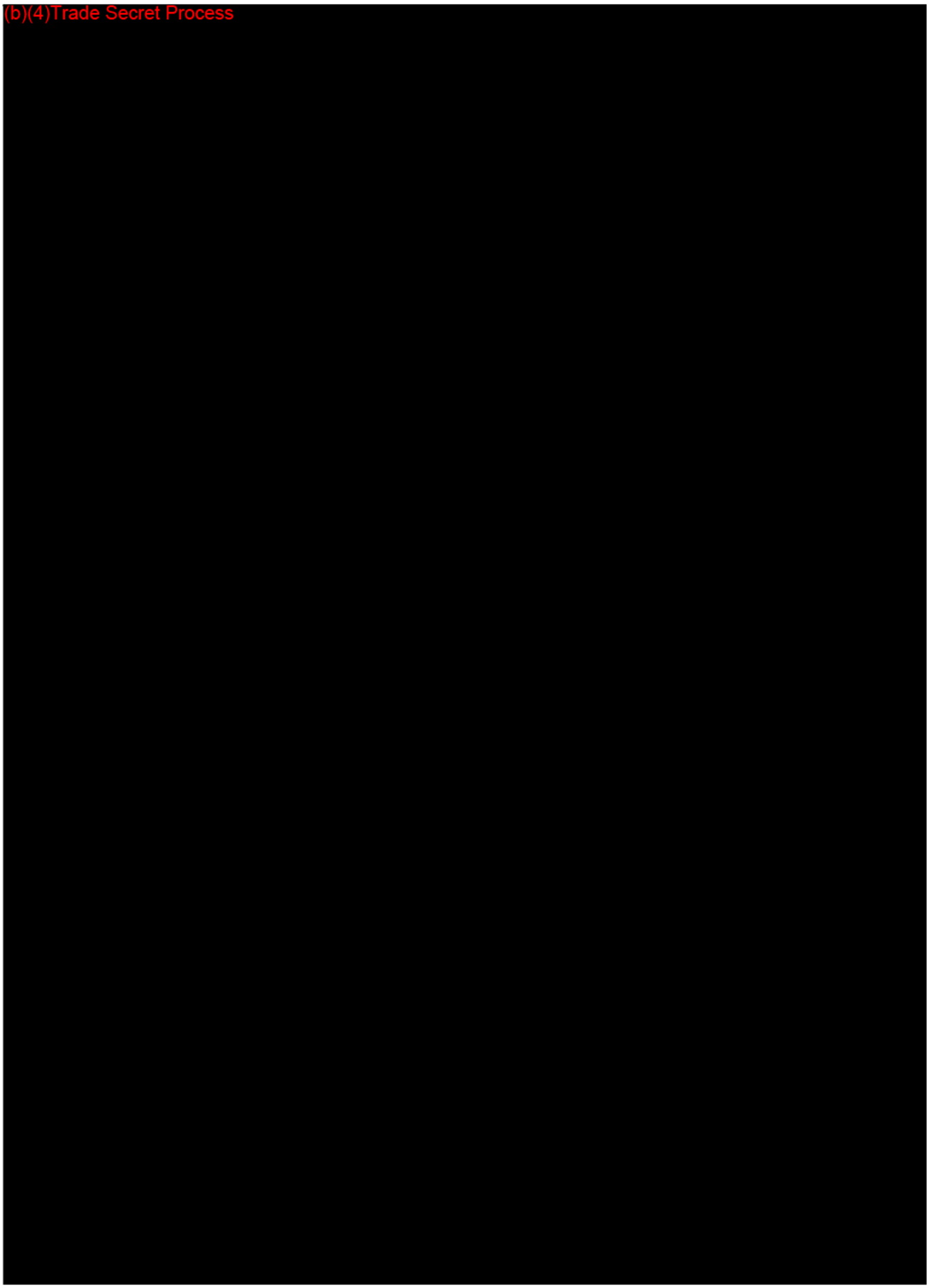

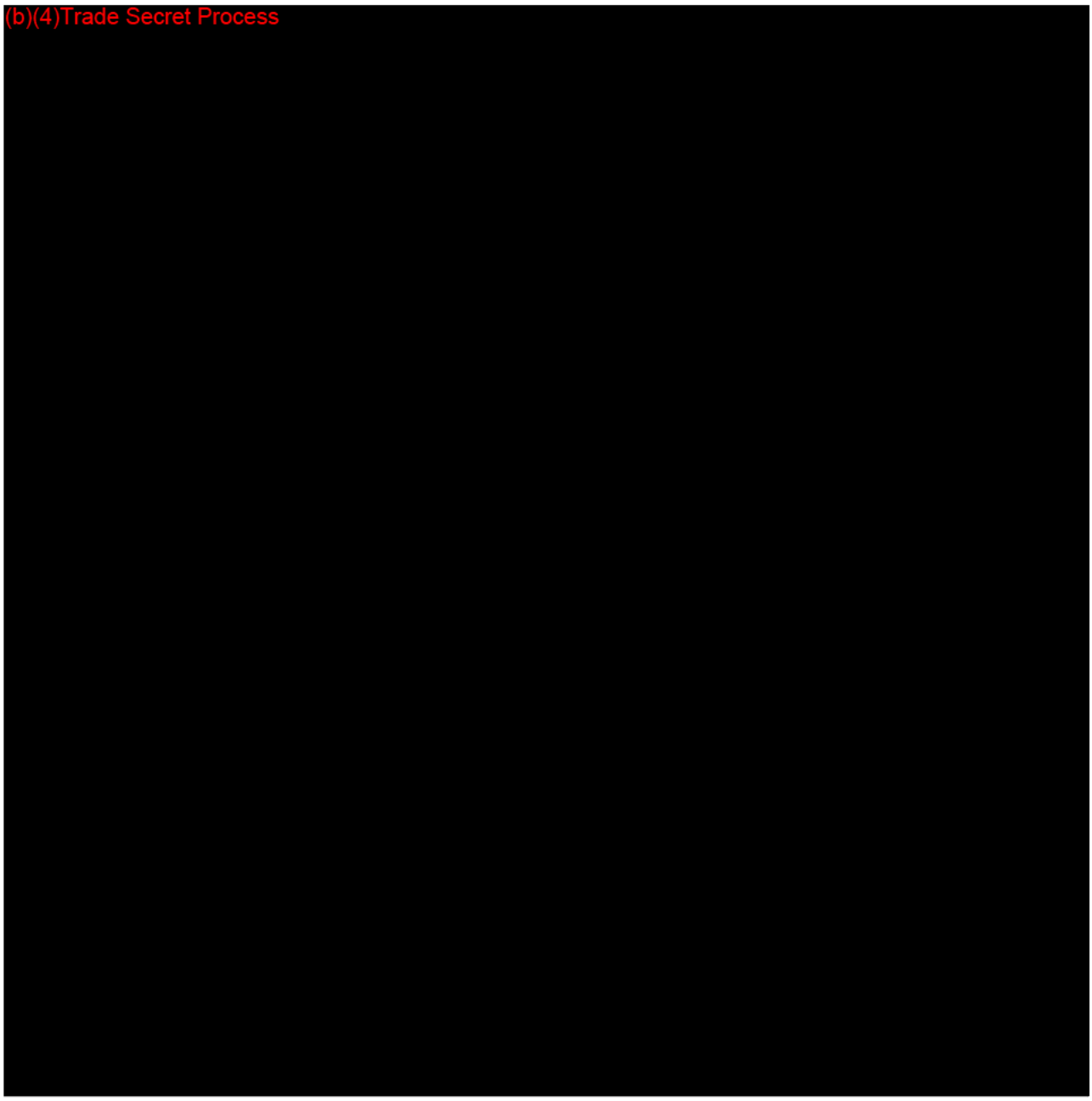
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 18, 2011

From Senior Electronics Engineer (Jeffrey L. Silberberg), CDRH/OSEL/DESE

Subject Review of electrical safety and EMC AI responses in K111170/S001 – Smith & Nephew PICO negative pressure wound therapy system

To Kelley Burridge, CDRH\ODE\DSORD\PRSB

CC Director, Division of Electrical and Software Engineering (Alford R. Taylor, Jr.,), CDRH/OSEL

(b)(4)Trade Secret Process

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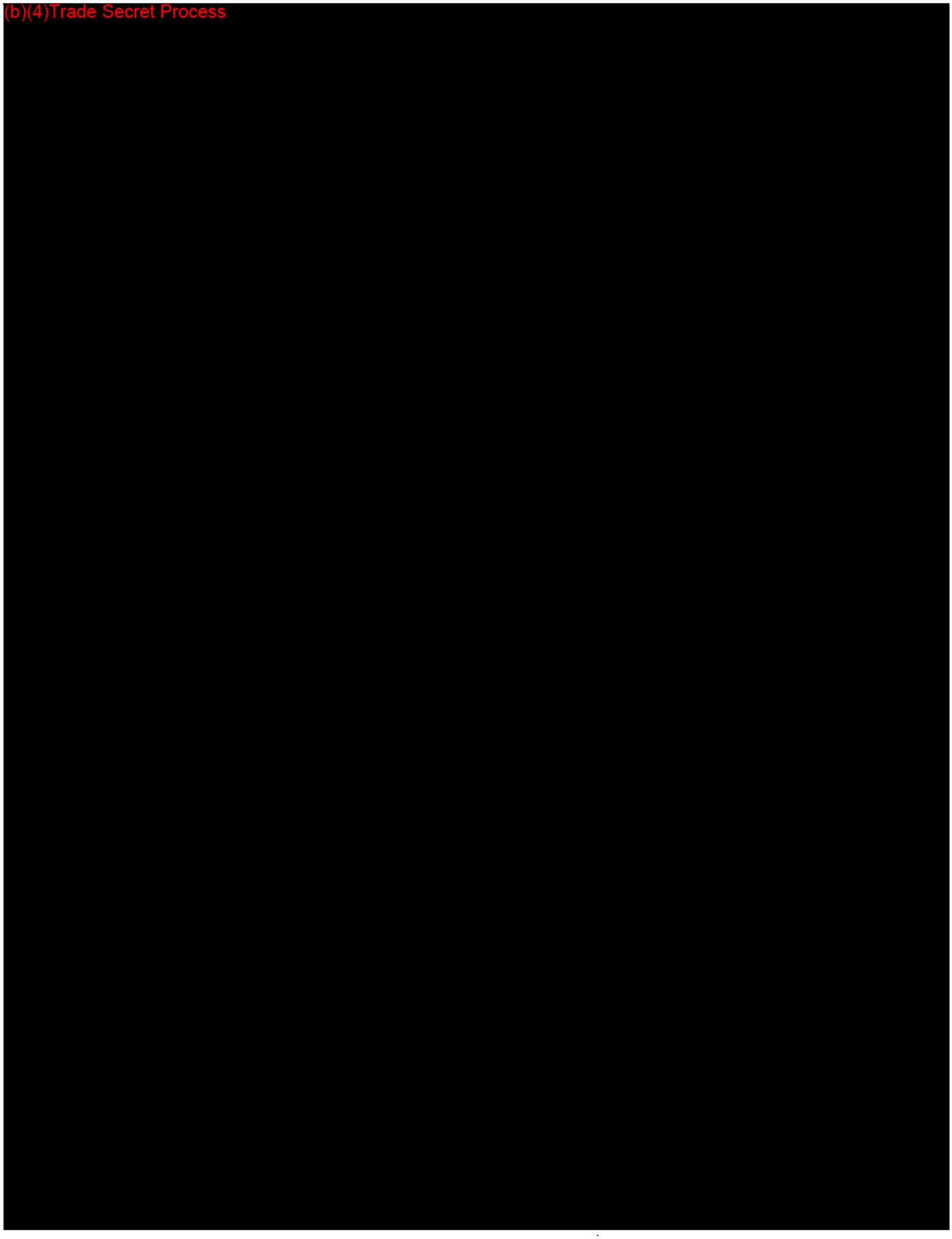
(b)(4)Trade Secret Process



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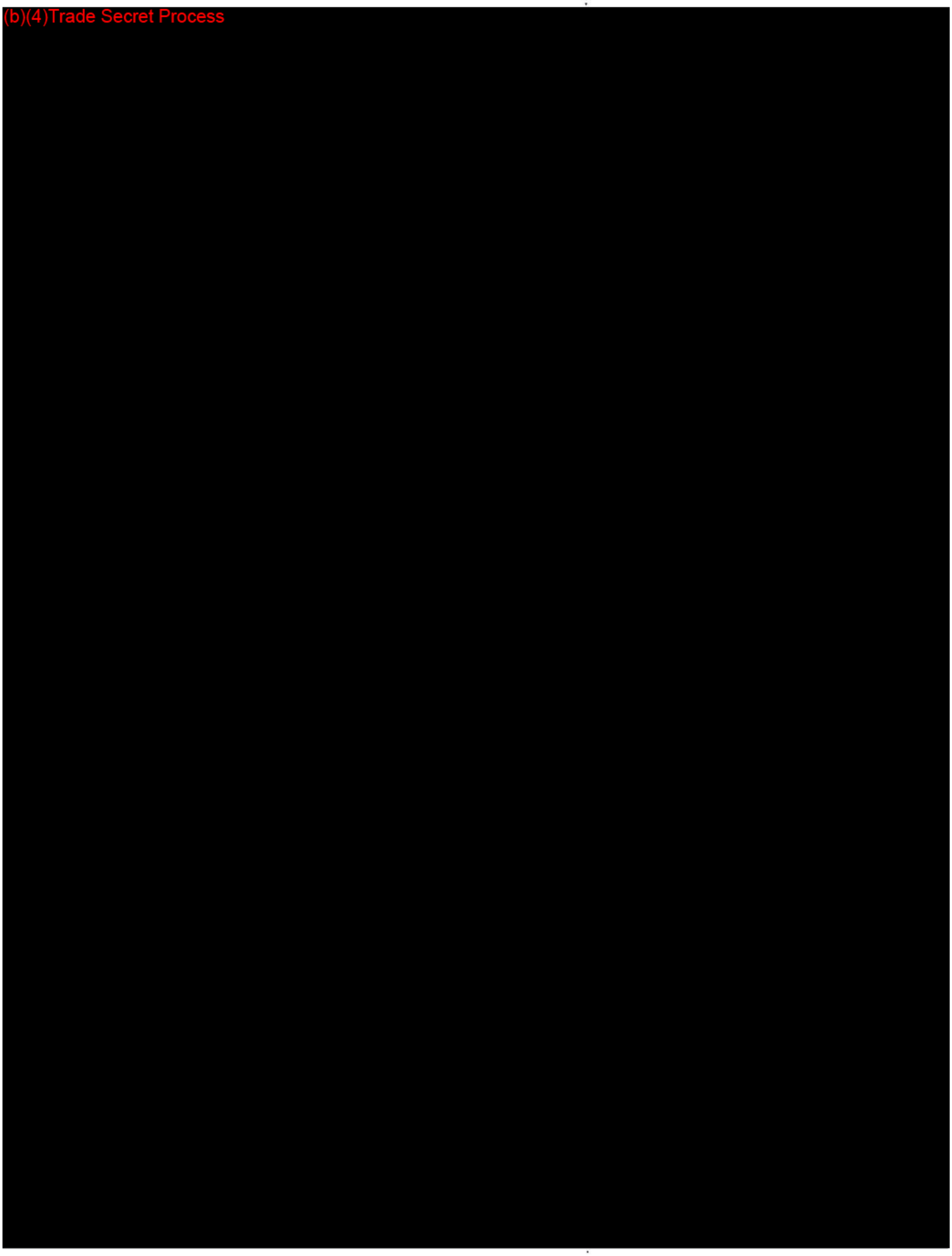
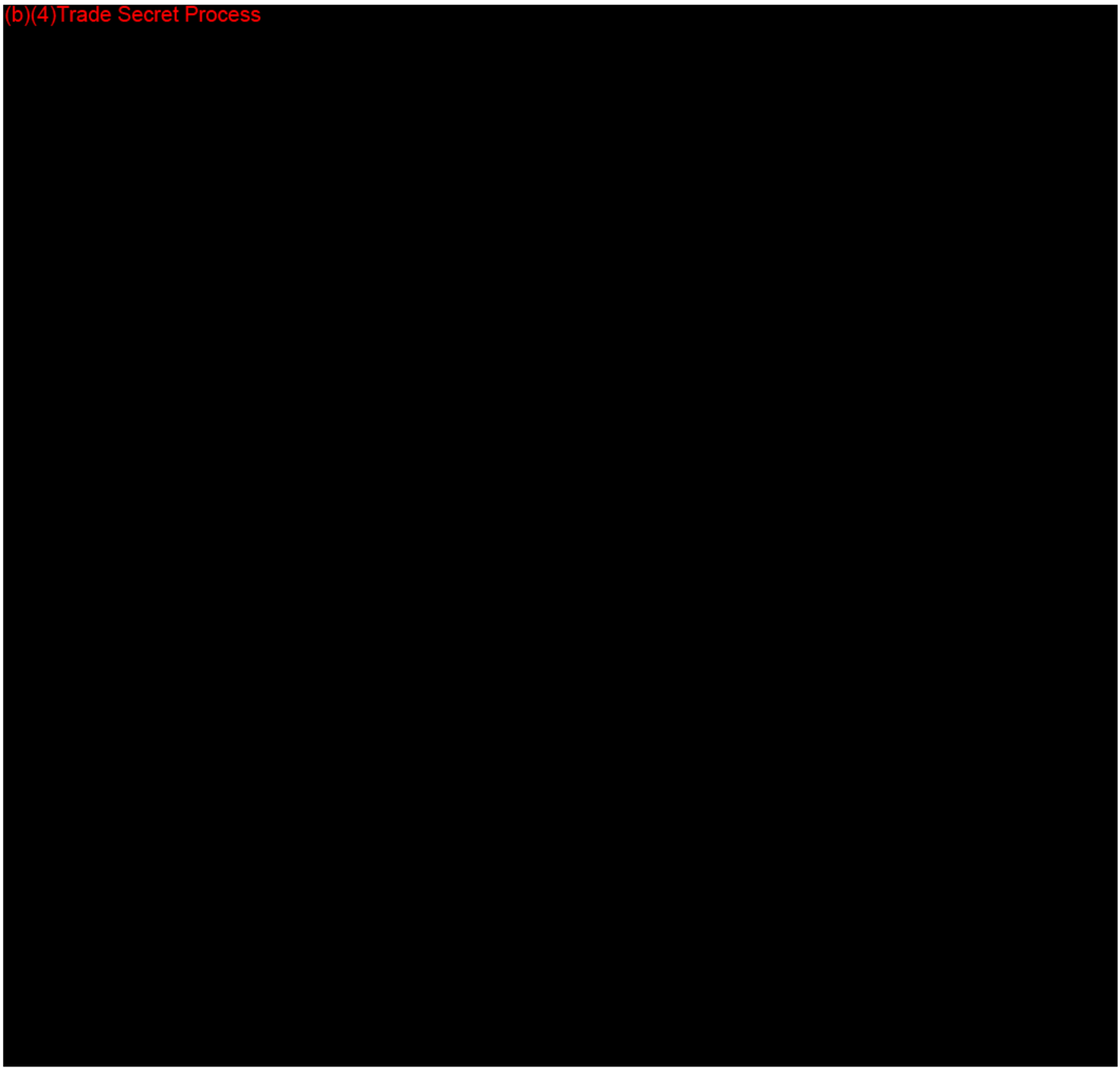
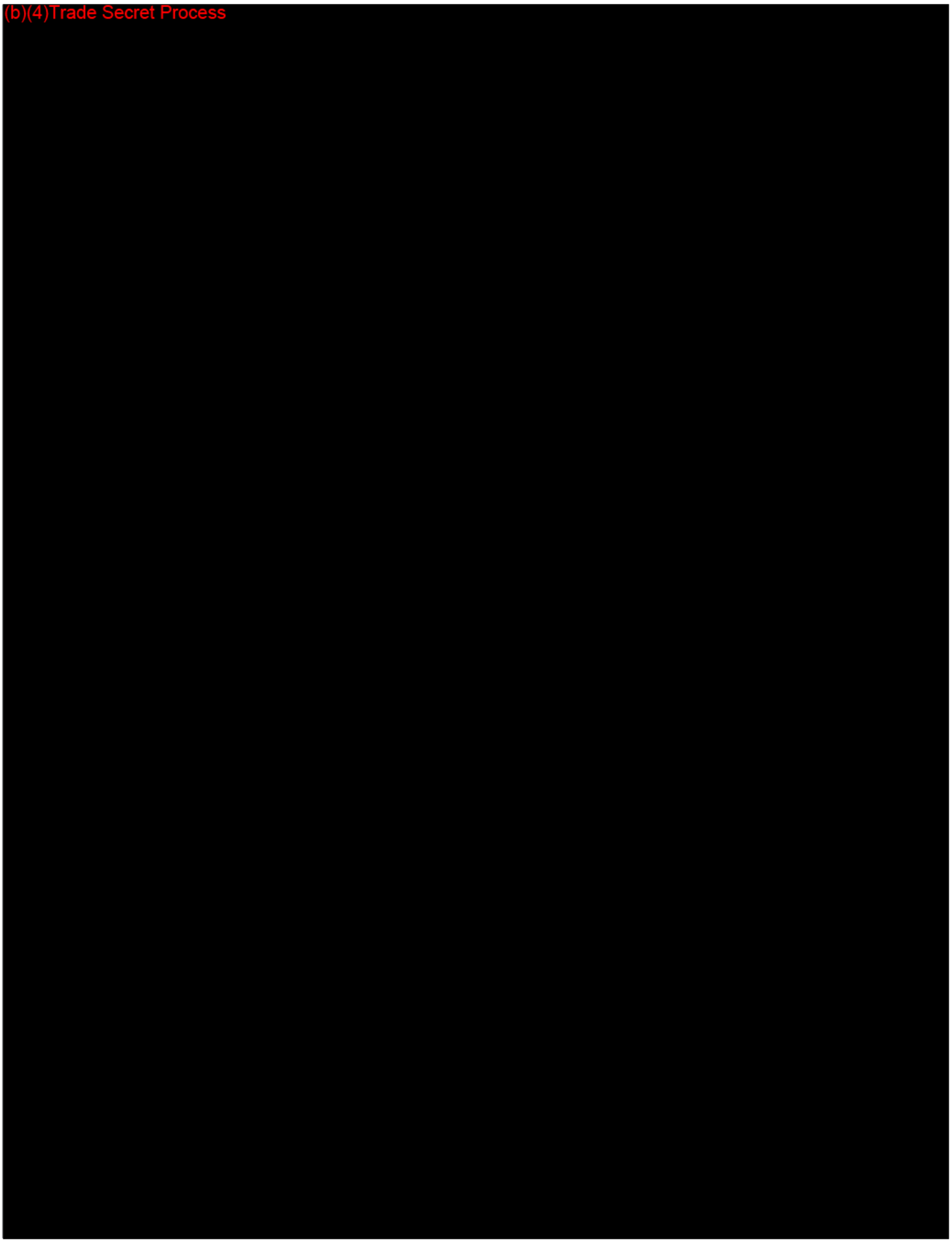



(b)(4)Trade Secret Process

(b)(4)Trade Secret Process - Design Drawings

(b)(4)Trade Secret Process - Design Drawings

(b)(4)Trade Secret Process



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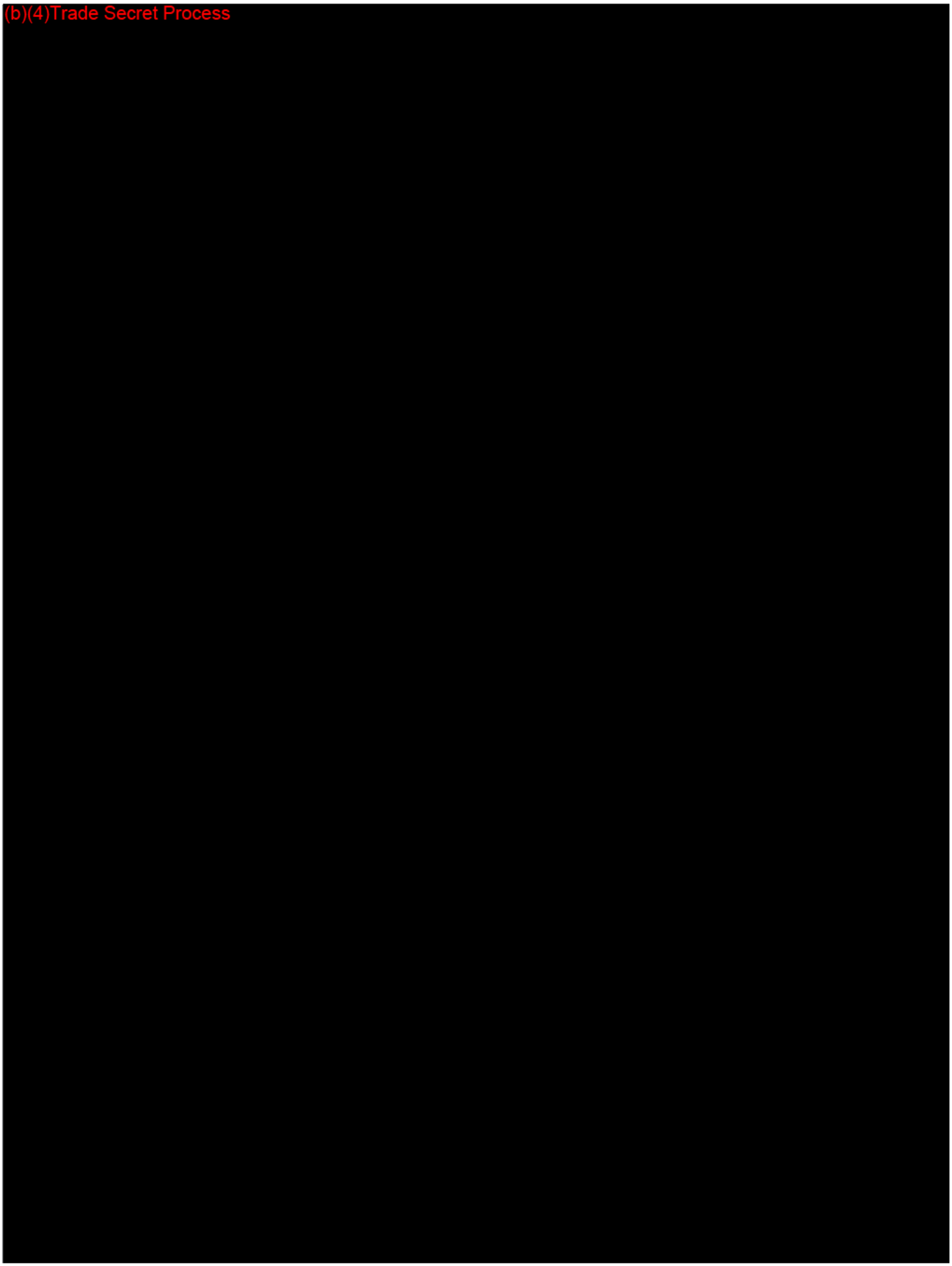

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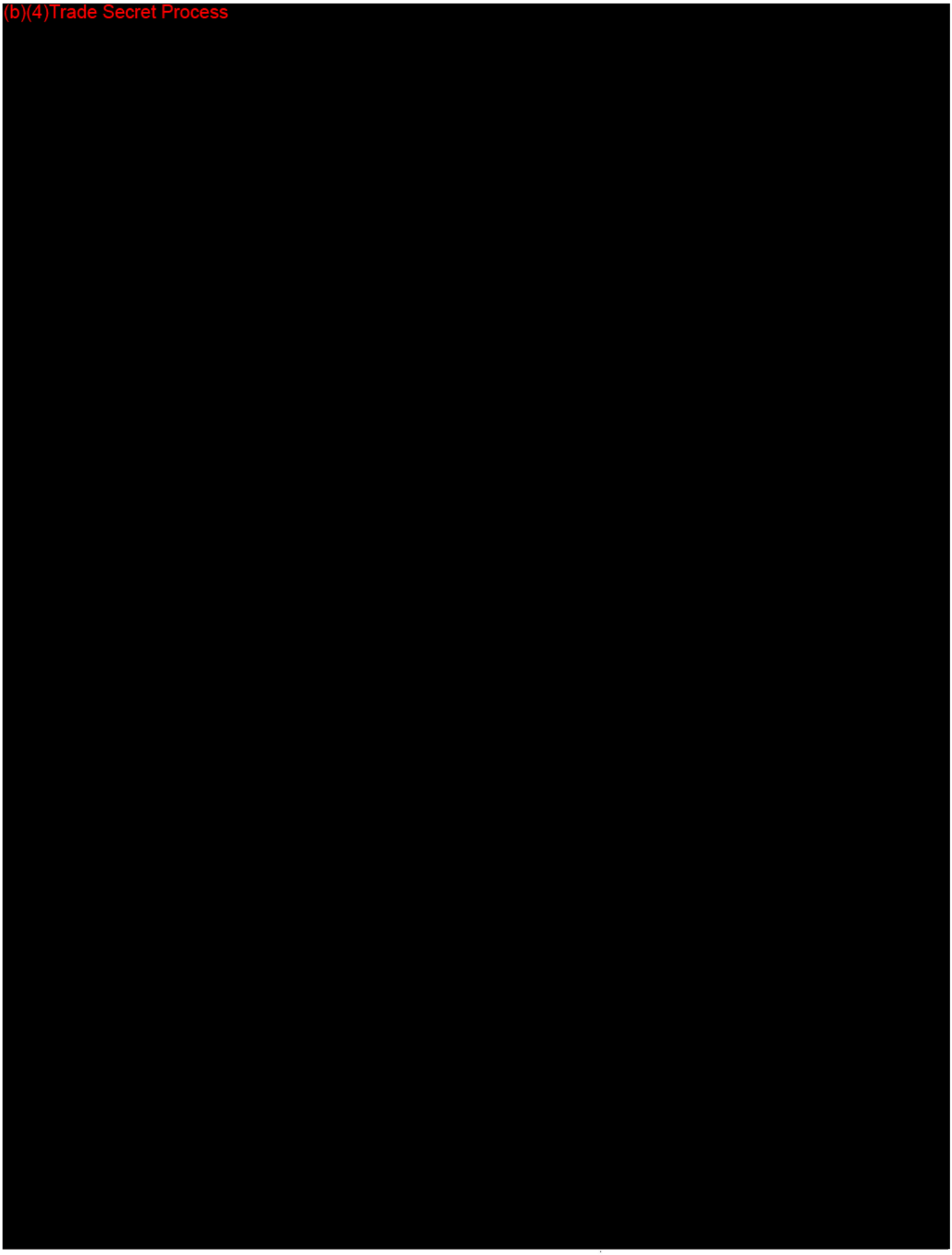


(b)(4)Trade Secret Process

[redacted]

Jeffrey L. Silberberg Senior Electronics Engineer DESE/OSEL/CDRH	Date	Alford R. Taylor, Jr. Director, Division of Electrical and Software Engineering, OSEL/DESE	Date

(b)(4)Trade Secret Process - Software Specs

(b)(4)Trade Secret Process - Software Specs

(b)(4)Trade Secret Process - Software Specs

(b)(4)Trade Secret Process - Software Specs

(b)(4)Trade Secret Process - Software Specs

Burridge, Kelley

From: McMahon, Terry [terry.mcmahon@smith-nephew.com]
Sent: Thursday, October 27, 2011 11:40 AM
To: Burridge, Kelley
Subject: (b)(4)Trade Secret Process
Importance: High
Attachments: (b)(4)Trade Secret Process

Dear Dr. Burridge,

(b)(4)Trade Secret Process

Regards,

Terry C. McMahon
Director, Regulatory Affairs
and Quality - North America

Smith & Nephew Wound Management
St. Petersburg, Florida, USA
Direct Phone: (727) 399-3785
Cell: (727) 644-7162
Direct Fax: (727) 329-5613

e-mail: terry.mcmahon@smith-nephew.com

167

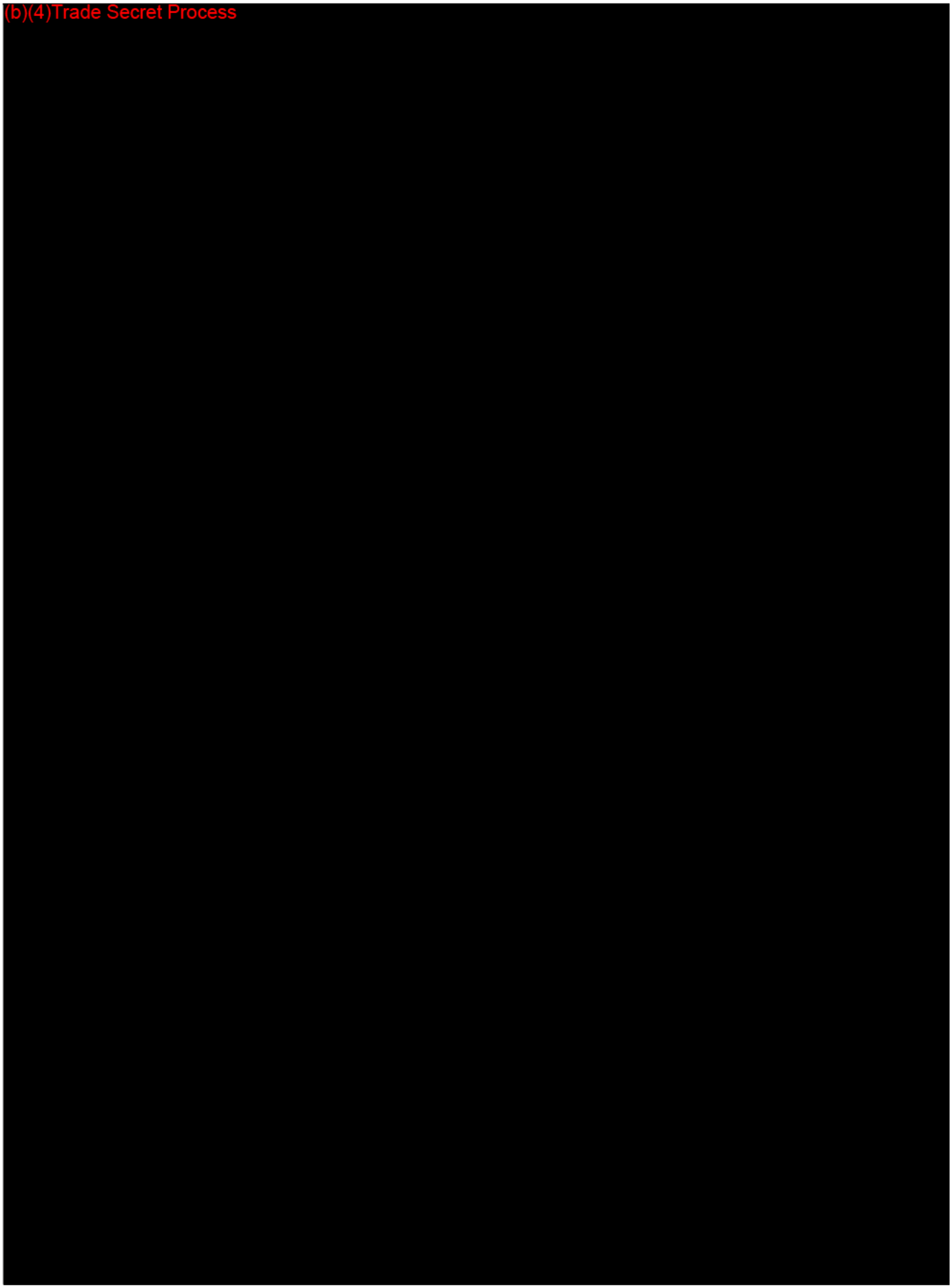
Burridge, Kelley

From: Burridge, Kelley
Sent: Tuesday, September 13, 2011 12:18 PM
To: 'McMahon, Terry'
Cc: 'Reynolds, Laura (Regulatory)'
Subject: (b)(4)Trade Secret Process

Dear Mr. McMahon,

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process



Best Regards,
Kelley Burridge

From: McMahon, Terry [mailto:terry.mcmahon@smith-nephew.com]
Sent: Monday, September 12, 2011 12:16 PM
To: Burridge, Kelley
Cc: Reynolds, Laura (Regulatory)
Subject: [redacted] (b)(4)Trade Secret Process
Importance: High

Dear Dr. Burridge,

(b)(4)Trade Secret Process

[redacted]

Thanks again for your direction and assistance.

Regards,

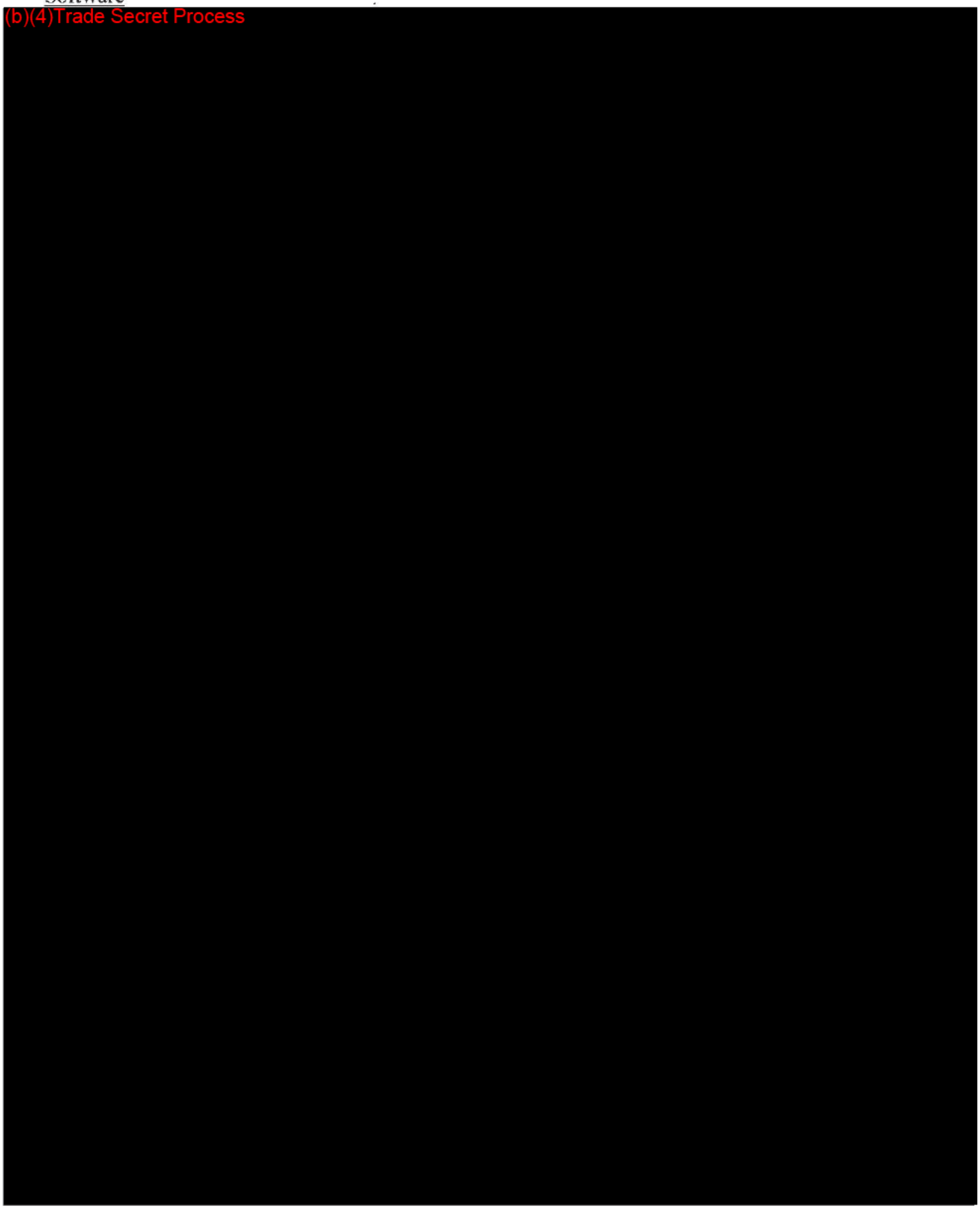
Terry C. McMahon
Director, Regulatory Affairs
and Quality - North America

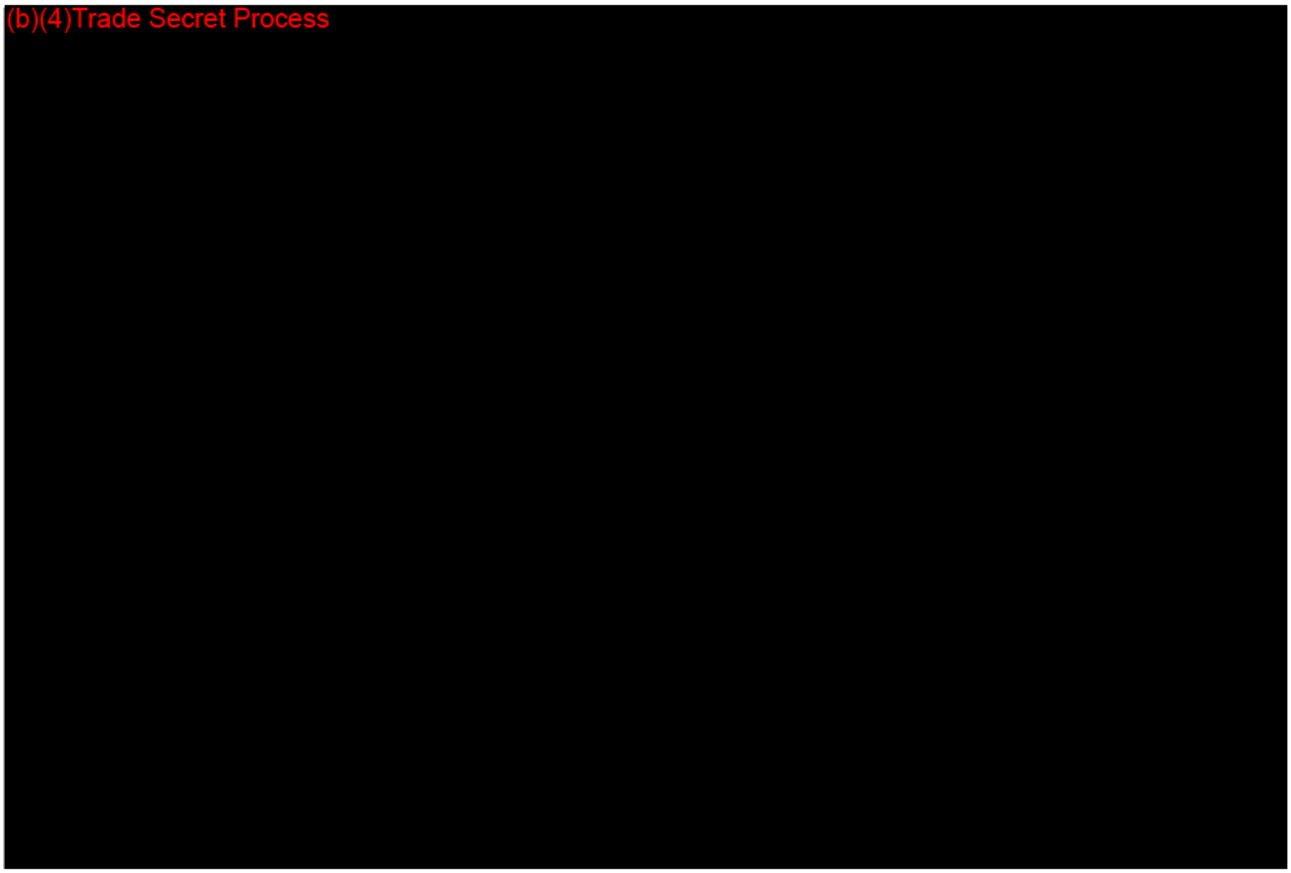
Smith & Nephew Wound Management
St. Petersburg, Florida, USA
Direct Phone: (727) 399-3785
Cell: (727) 644-7162
Direct Fax: (727) 329-5613

e-mail: terry.mcmahon@smith-nephew.com

Software

(b)(4)Trade Secret Process

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Burridge, Kelley

From: McMahon, Terry [terry.mcmahon@smith-nephew.com]
Sent: Thursday, August 04, 2011 1:05 PM
To: Burridge, Kelley
Subject: (b)(4)Trade Secret Process [redacted]

Thank you.

Sincerely,
Terry McMahon

This electronic transmission is strictly confidential to Smith & Nephew and intended solely for the addressee. It may contain information, which is covered by legal, professional, or other privilege. If you are not the intended addressee, or someone authorized by the intended addressee to receive transmissions on the behalf of the addressee, you must not retain, disclose in any form, copy or take any action in reliance on this transmission. If you have received this transmission in error, please notify us as soon as possible and destroy this message.

From: Burridge, Kelley <Kelley.Burridge@fda.hhs.gov>
To: McMahon, Terry
Cc: Reynolds, Laura (Regulatory)
Sent: Thu Aug 04 08:29:03 2011
Subject: (b)(4)Trade Secret Process [redacted]

Dear Mr. McMahon,

(b)(4)Trade Secret Process [redacted]

Best Regards,
Kelley Burridge

From: McMahon, Terry [mailto:terry.mcmahon@smith-nephew.com]
Sent: Tuesday, August 02, 2011 11:09 AM
To: Burridge, Kelley
Cc: Reynolds, Laura (Regulatory)
Subject: (b)(4)Trade Secret Process [redacted]
Importance: High

Dr. Burridge,

(b)(4)Trade Secret Process [redacted]

Sincerely,
Terry McMahon

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From: Reynolds, Laura (Regulatory)
To: McMahon, Terry
Sent: Tue Aug 02 08:14:27 2011
Subject: (b)(4)Trade Secret Process

Hi Terry

(b)(4)Trade Secret Process

Many thanks,
Laura

(b)(4)Trade Secret Process

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kelley Burridge, Ph.D.

Subject: 510(k) Number K111770

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA – Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 =<= 21, No special considerations compared to adults => 21 years old) Nanotechnology Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact-QC.	
Regulation Number	Class*	Product Code	

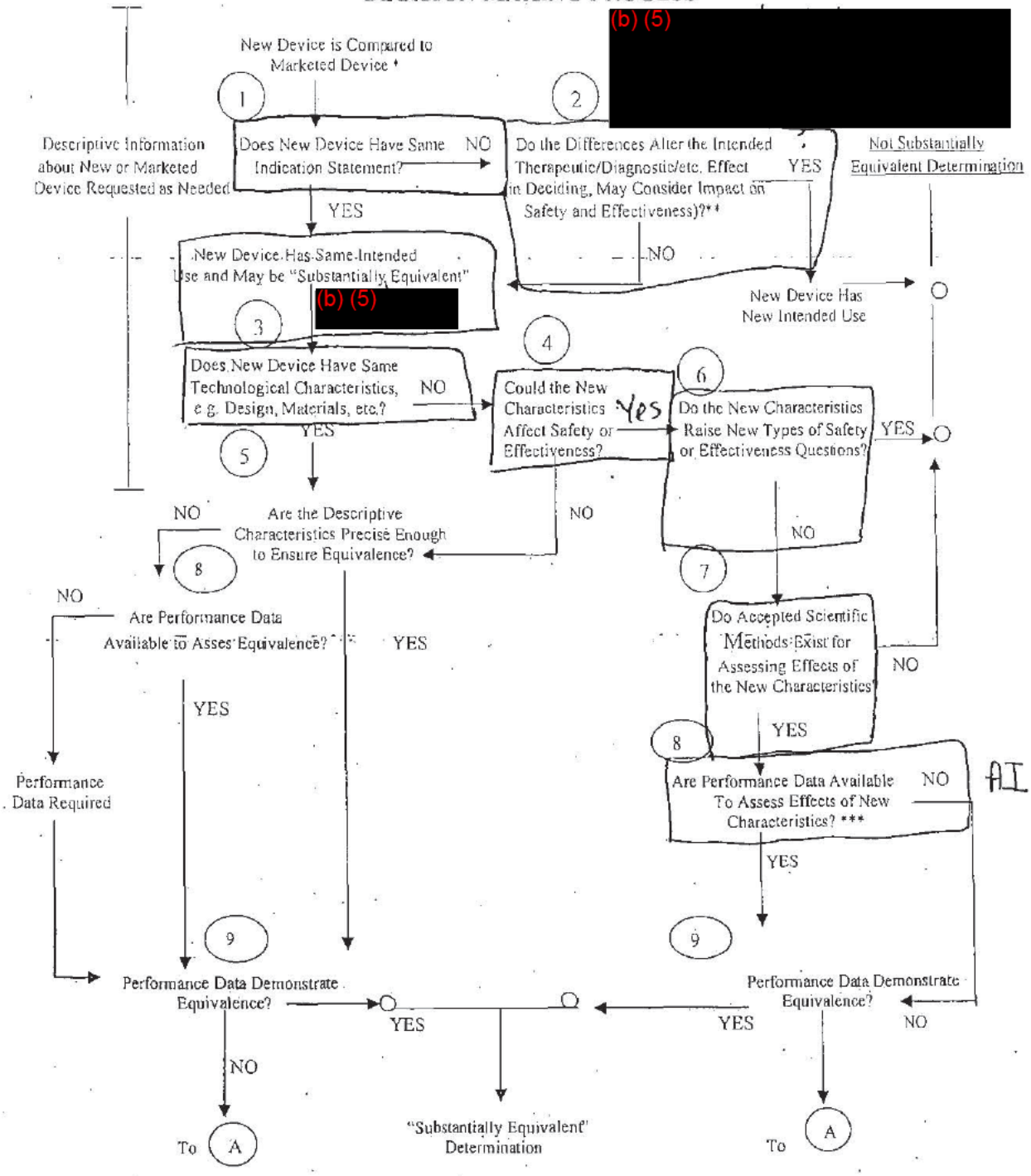
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krone (Branch Chief) PRSB (Branch Code) July 25, 2011 (Date)

Final Review: for David Krone (Division Director) July 25, 2011 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K111170

Date: July 25, 2011
To: The Record
From: Kelley Burridge, Ph. D.
Branch: Plastic and Reconstructive Surgery
Division: Surgical, Orthopedic and Restorative Devices
Office: Device Evaluation

510(k) Holder: Smith & Nephew, Inc.
Establishment Registration Number: 3006760724
Device Name: PICO Single Use Negative Pressure Wound Therapy System
Contact: Terry McMahon, Director of Regulatory Affairs and Quality Assurance
Phone: (727) 392-1261
Fax: (727) 399-3468
Email: terry.mcmahon@smith-nephew.com

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I. Purpose of Submission

The 510(k) holder would like to introduce PICO Single Use Negative Pressure Wound Therapy System into interstate commerce as a prescription device.

II. Document History

K111170 (dated 4/21/11 and received in ODE 4/26/11) was assigned to me on 4/29/11 with a branch due date of 6/10/11. A citizen's petition from Kalypto Medical was received on 6/10/11.

The lead and clinical reviewers discussed at length the various features of this device along with their clinical implications. Dr. David Krause (Branch Chief, PRSB) was briefed on this device by the lead and clinical reviewers.

The review team consisted of:

Lead: Kelley Burridge, PhD
Clinical: Suzanne Schwartz, MD
EMC: Jeffrey Silberberg
Software: Dillip Emmanuel

III. Recommendation

The reviewer requests additional information as described below.

Regulation Number: 21 CFR §878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP

IV. Document Summary

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process

[redacted]

V. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription)	Section 6		
Truthful and Accuracy Statement	Section 8		
510(k) Summary or 510(k) Statement	Section 7		
Standards Form			X

(b)(4)Trade Secret Process

[redacted]

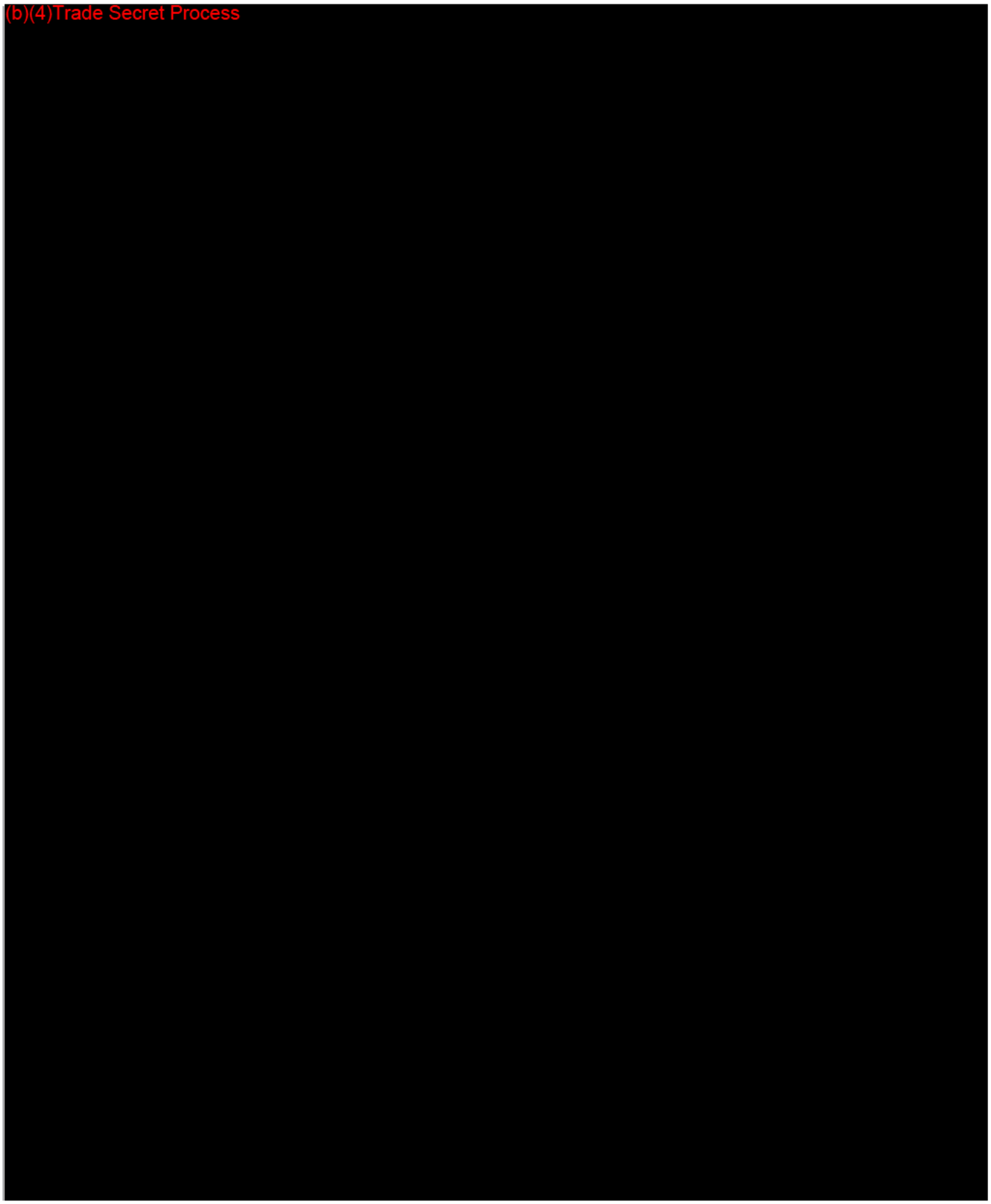
VI. Device Description (Sections 13 and 12)

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process



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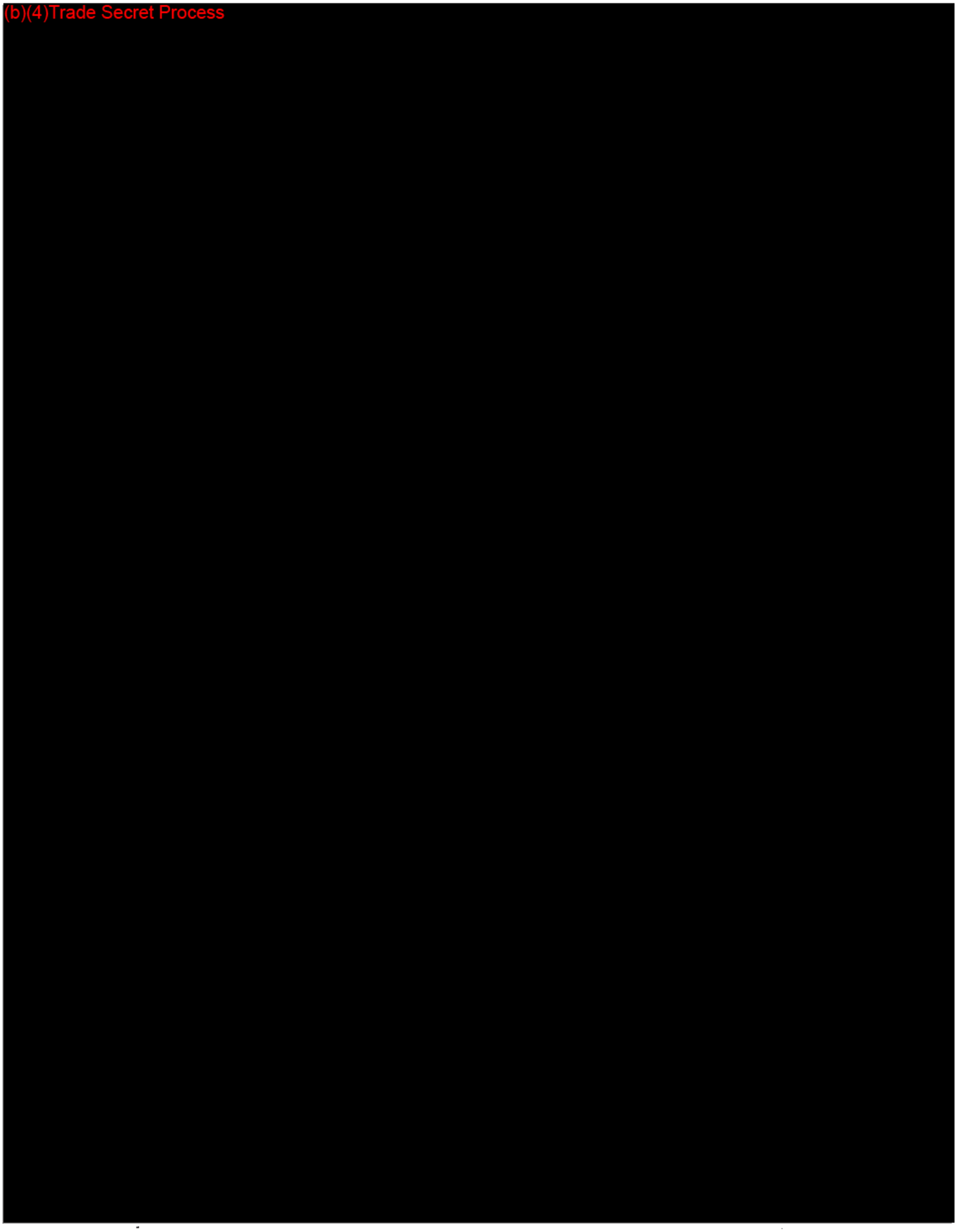

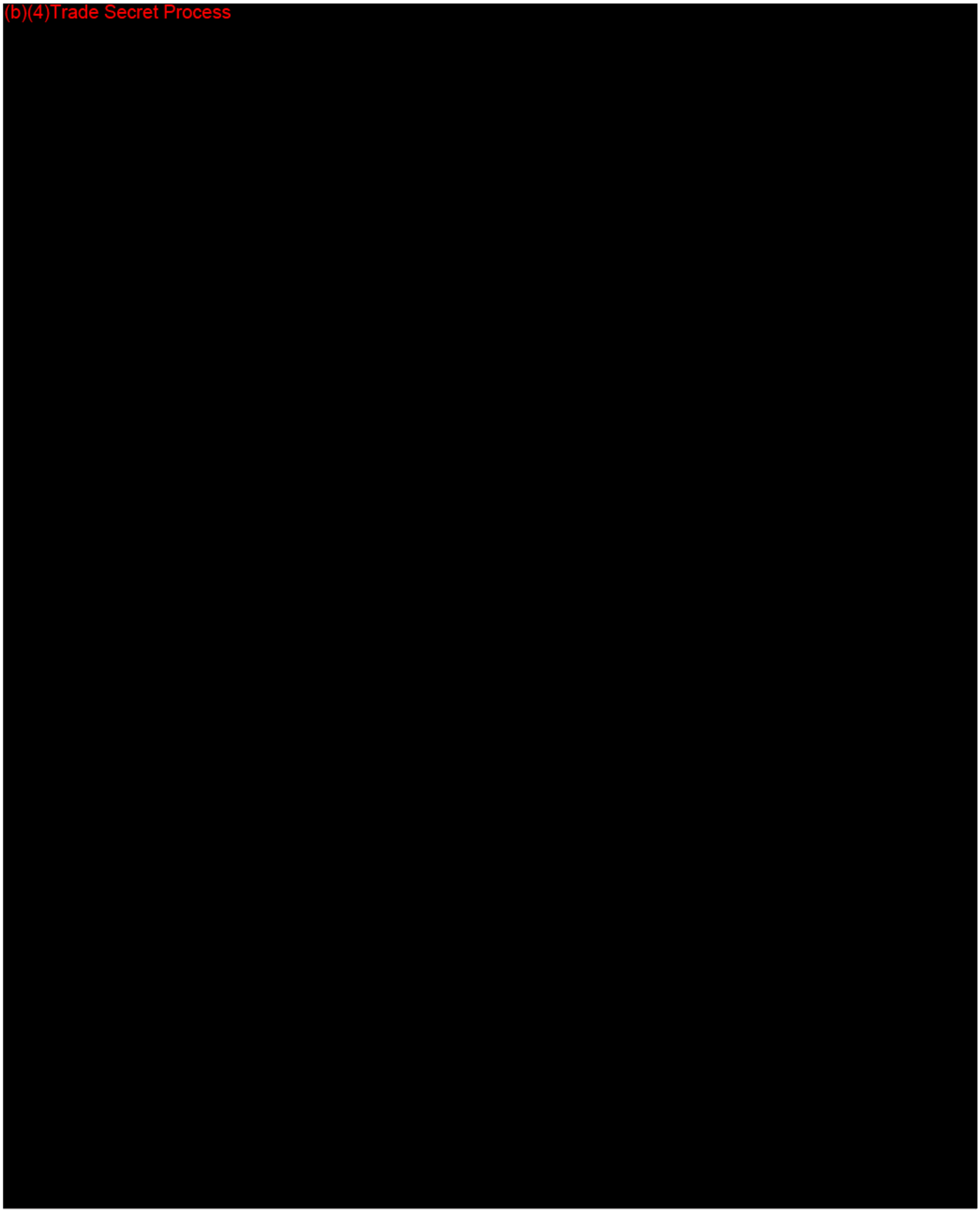
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(b)(4)Trade Secret Process

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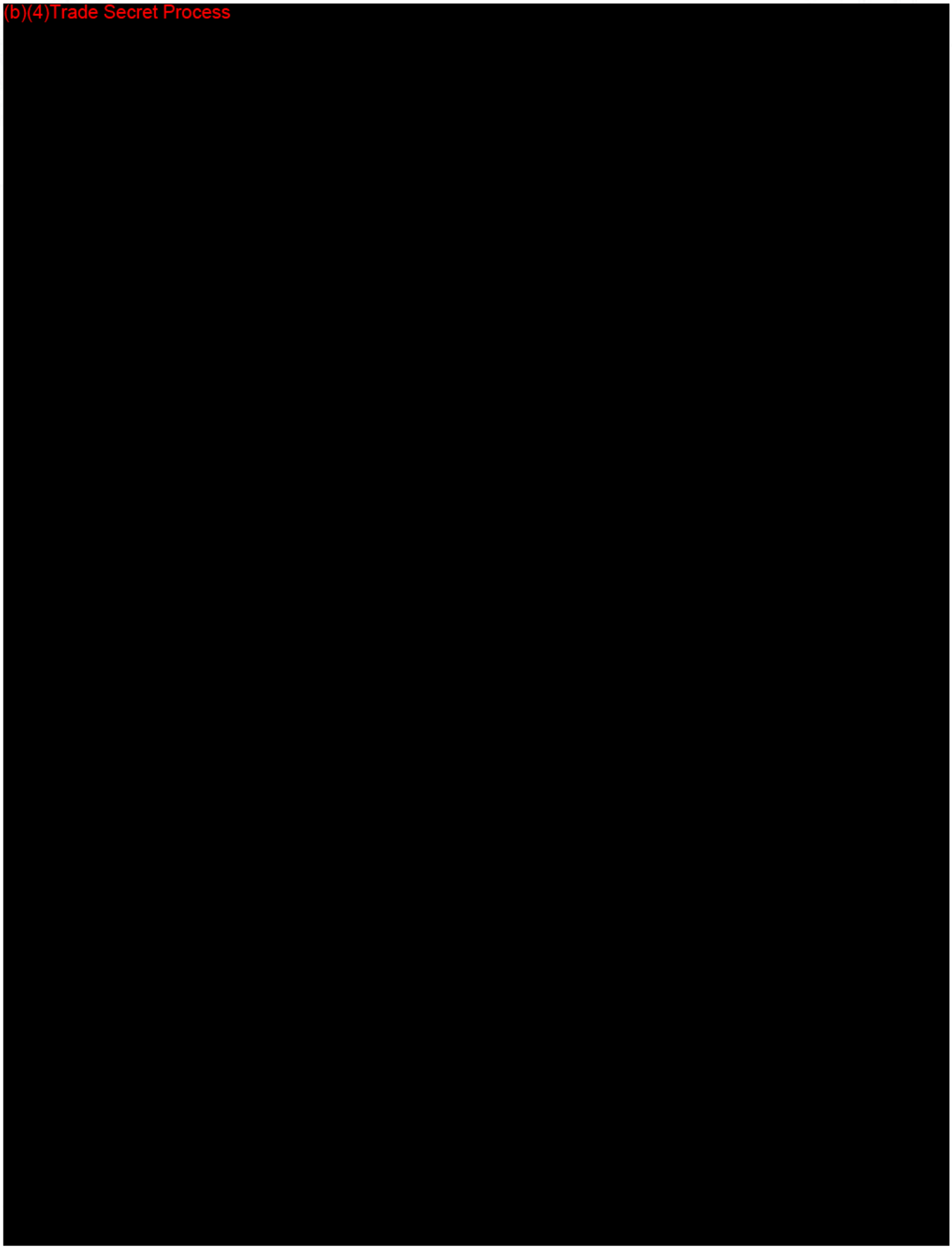

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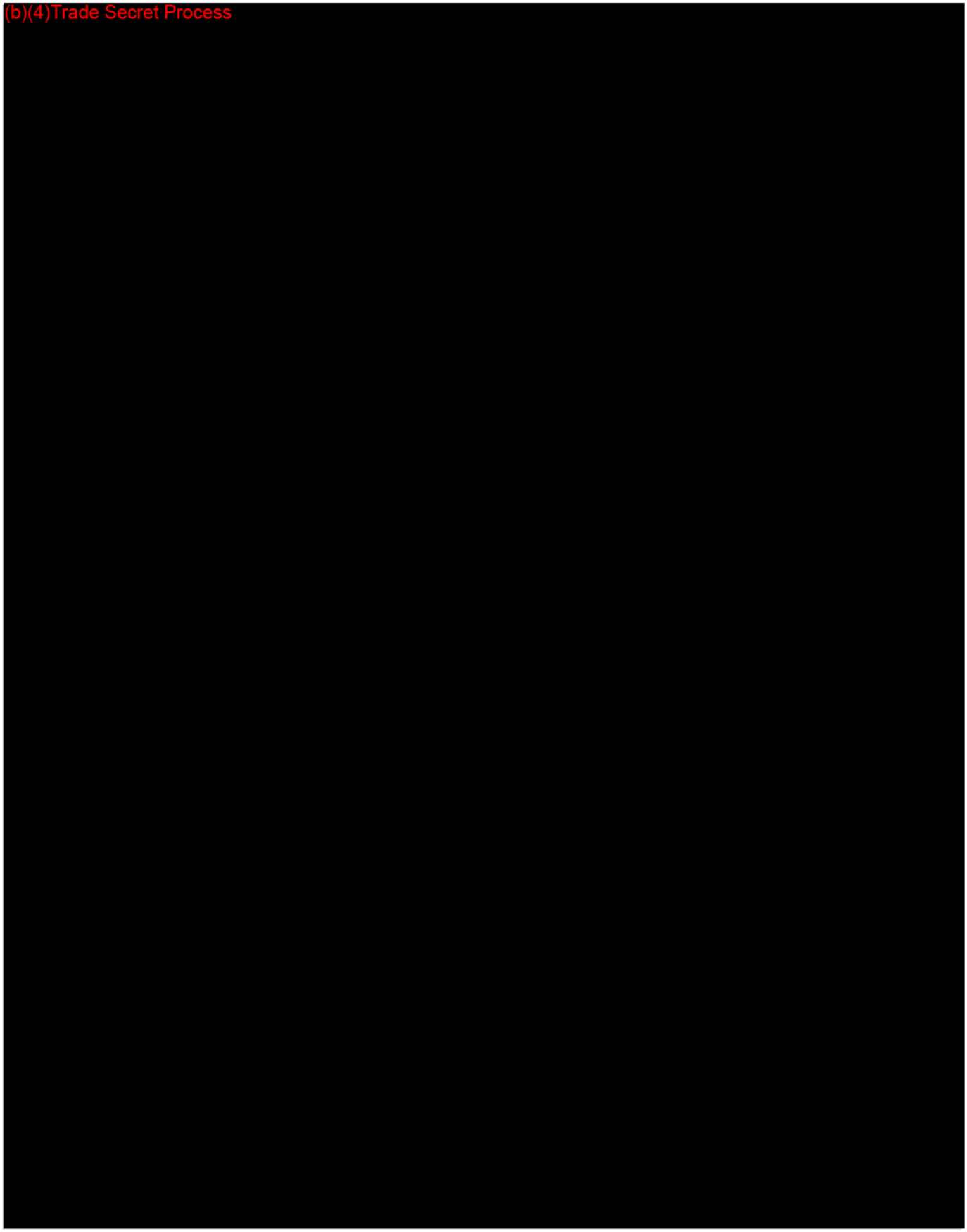

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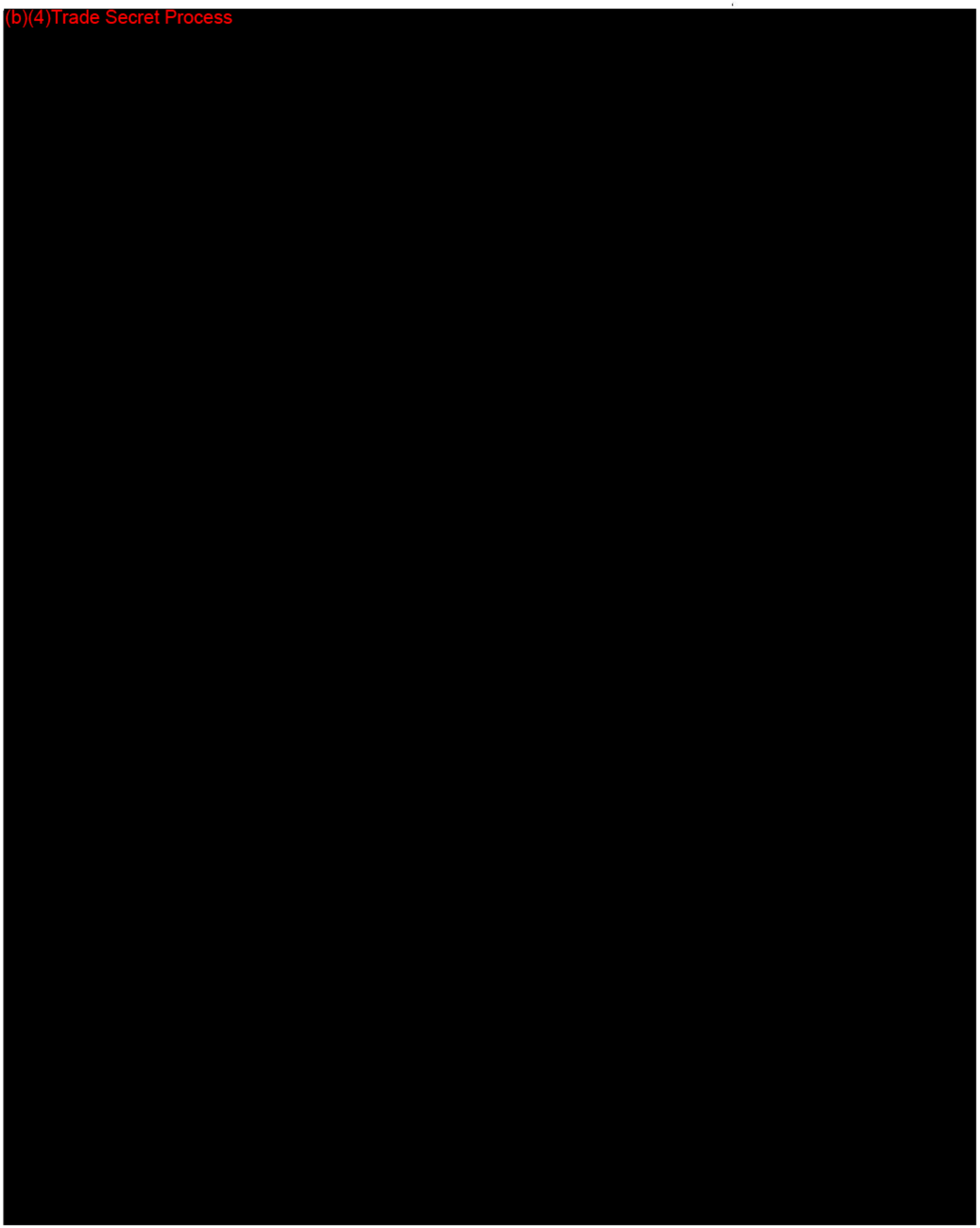

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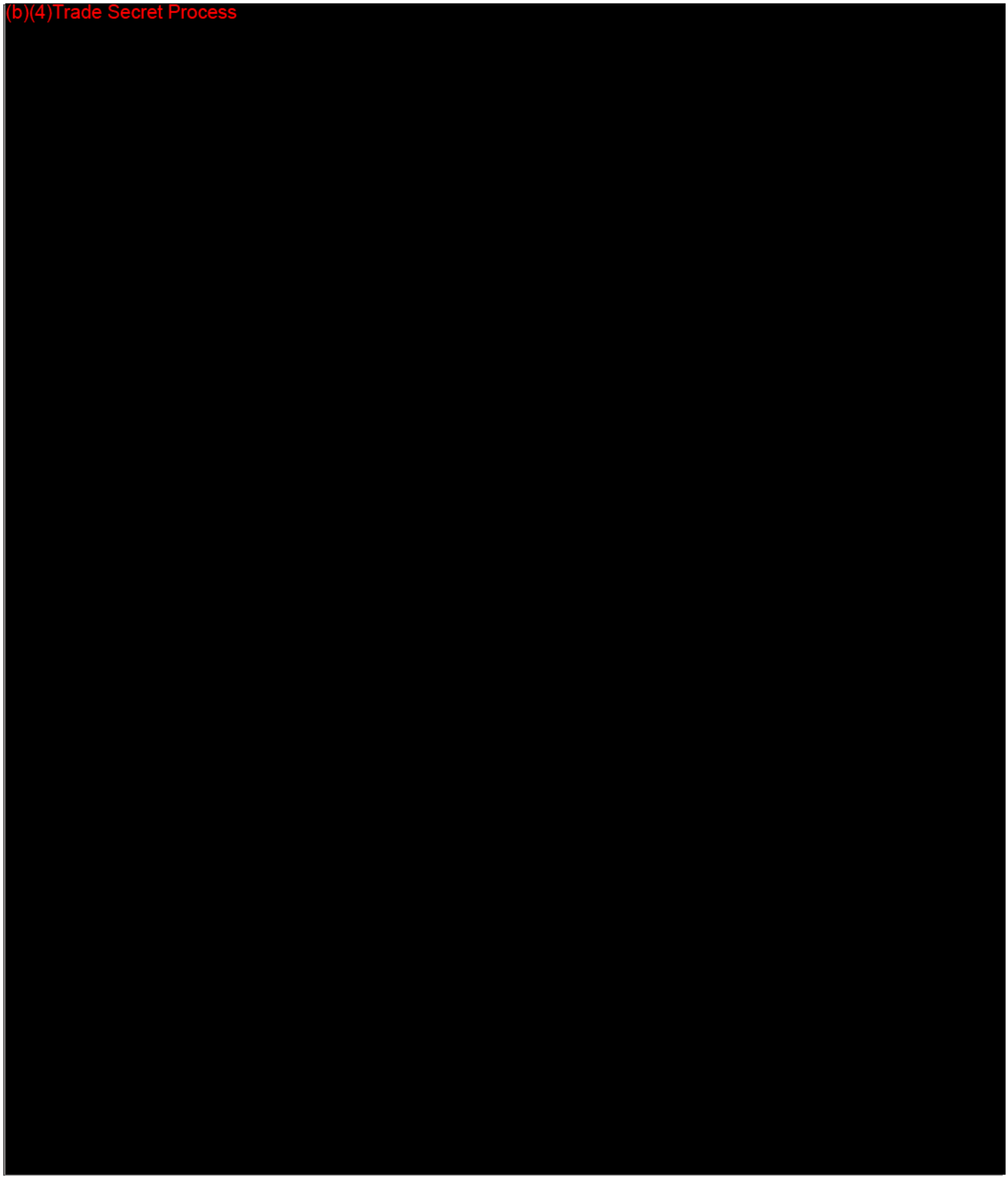

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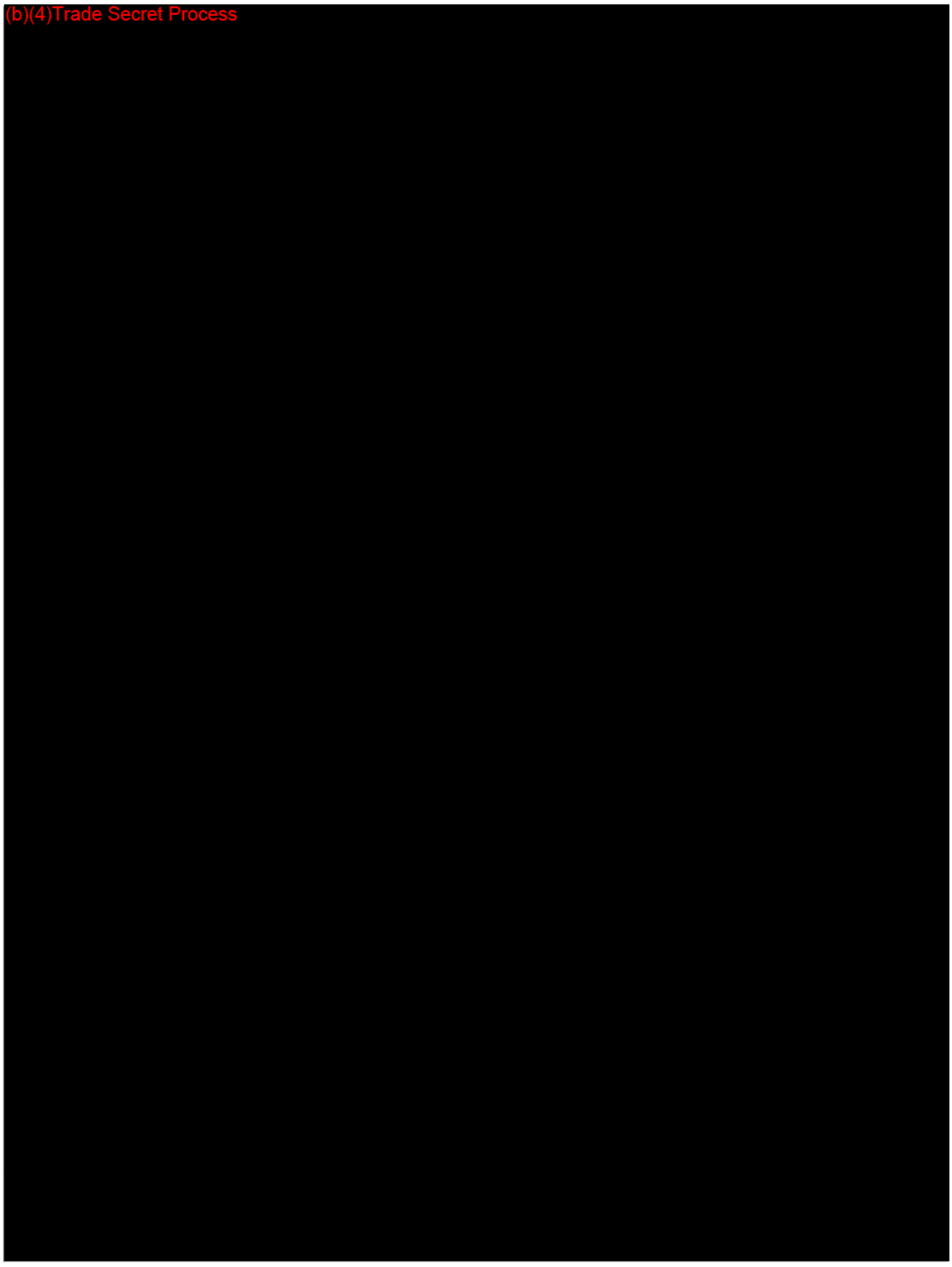

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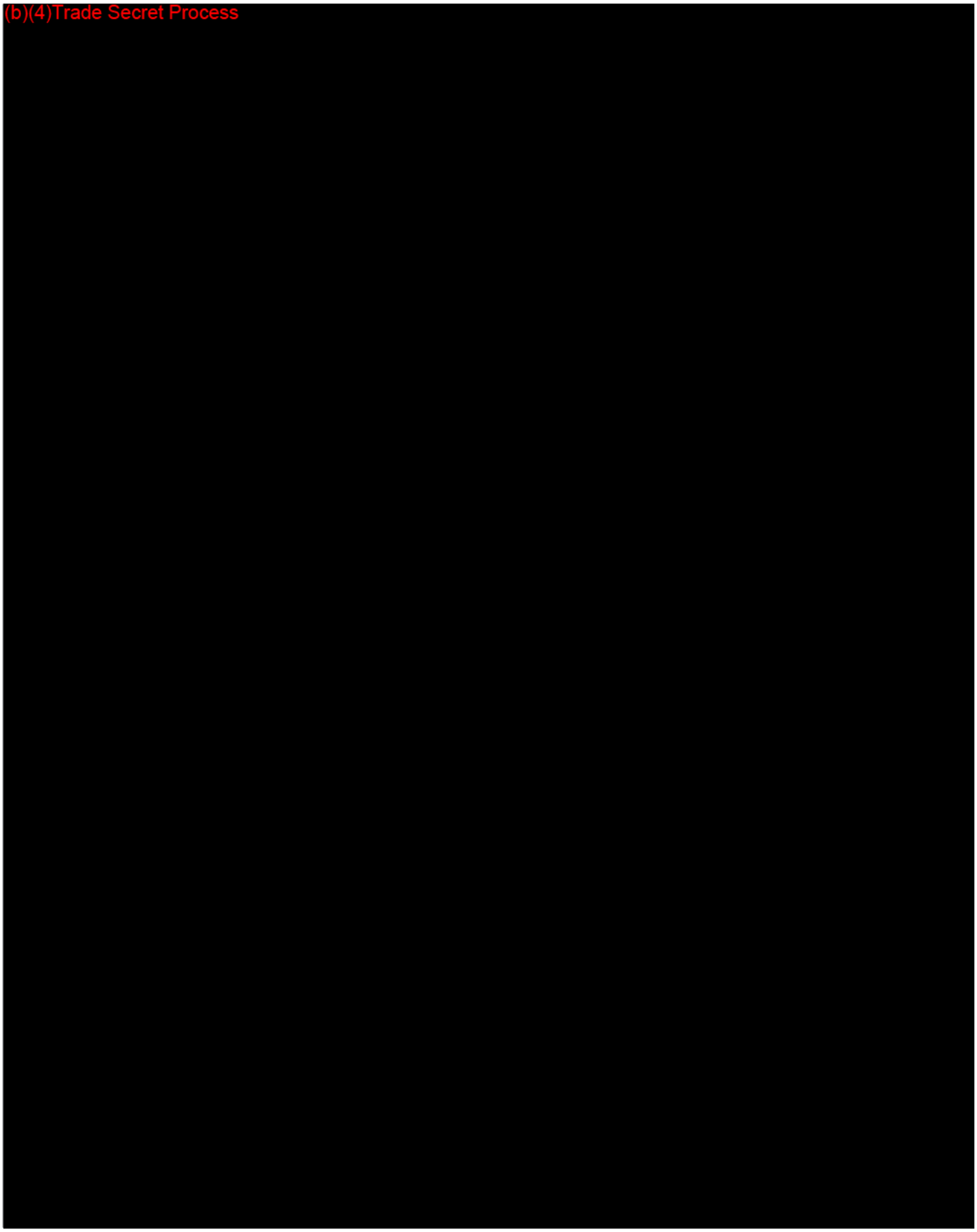

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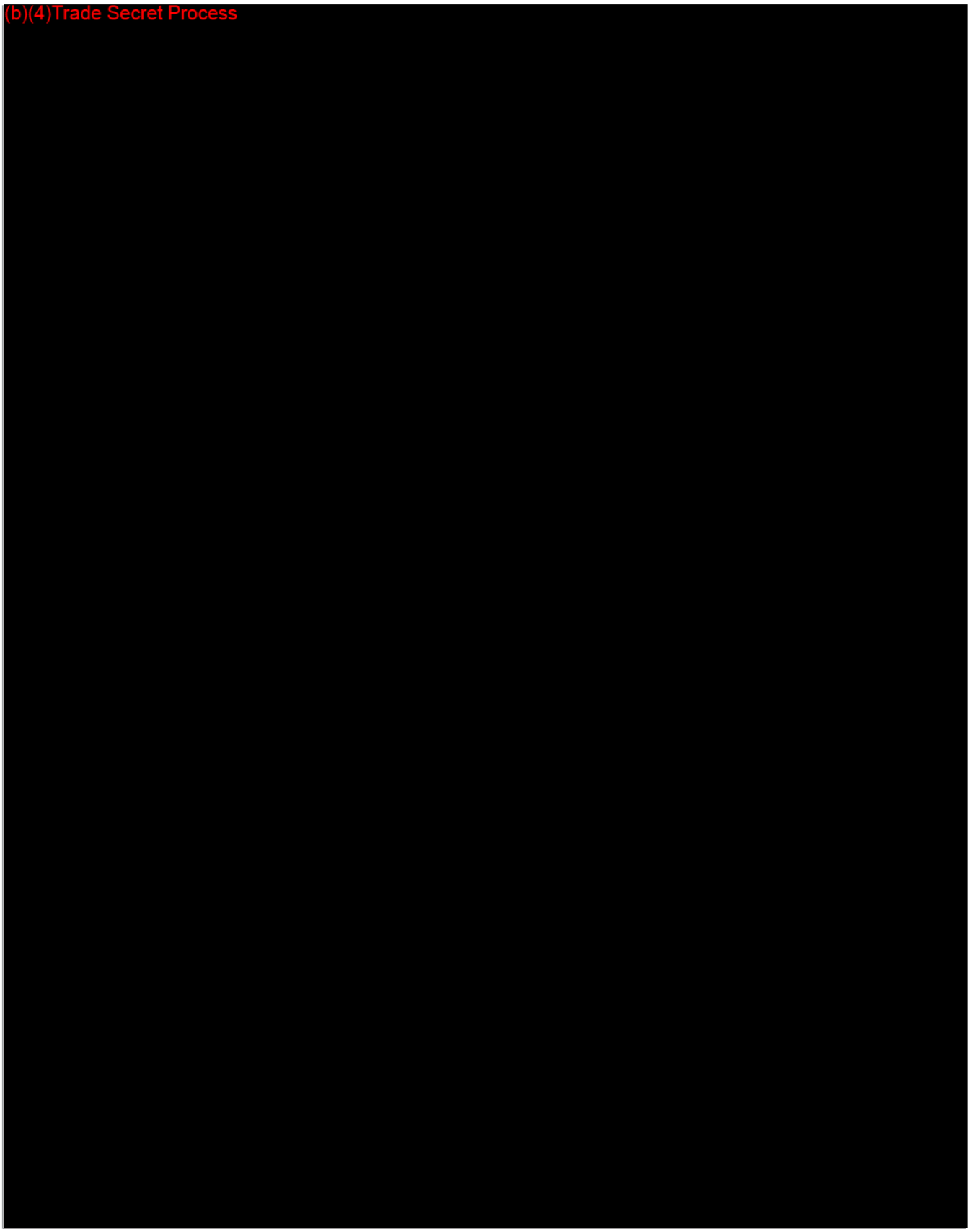

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X. **Sterilization/Reuse** (Section 16)

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XI. **Shelf Life/Stability Testing** (Section 16)

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XII. **Manufacturing** (Section 13)

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Dressing Materials

Material	Item	Specification
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Pump Casing Materials

Material	Function	Specification Reference
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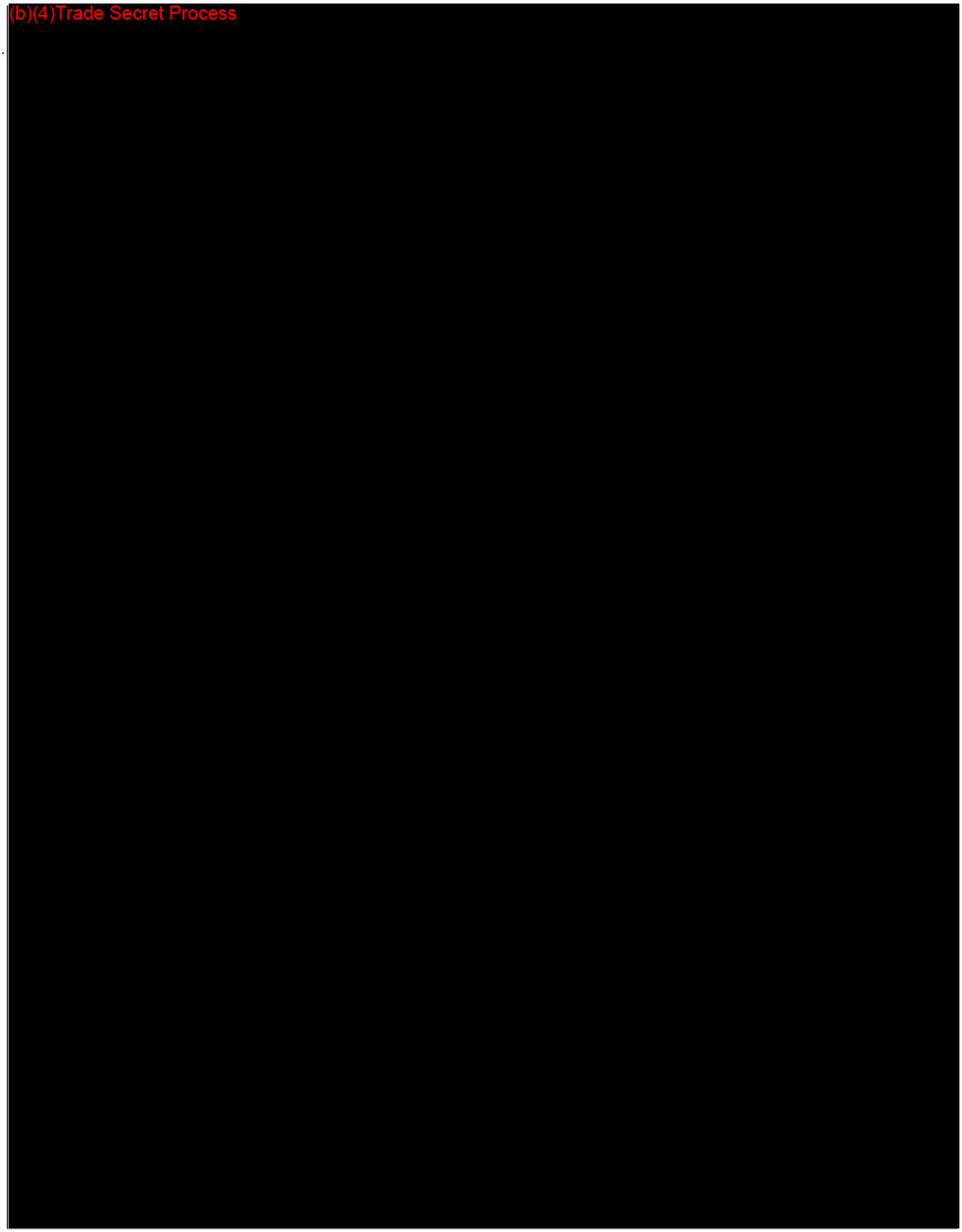

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XIII. Biocompatibility (Section 17)

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XIV. Software (Section 18)

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XV. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety (Section 19)

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XVI. Performance Testing – Bench (Section 20)

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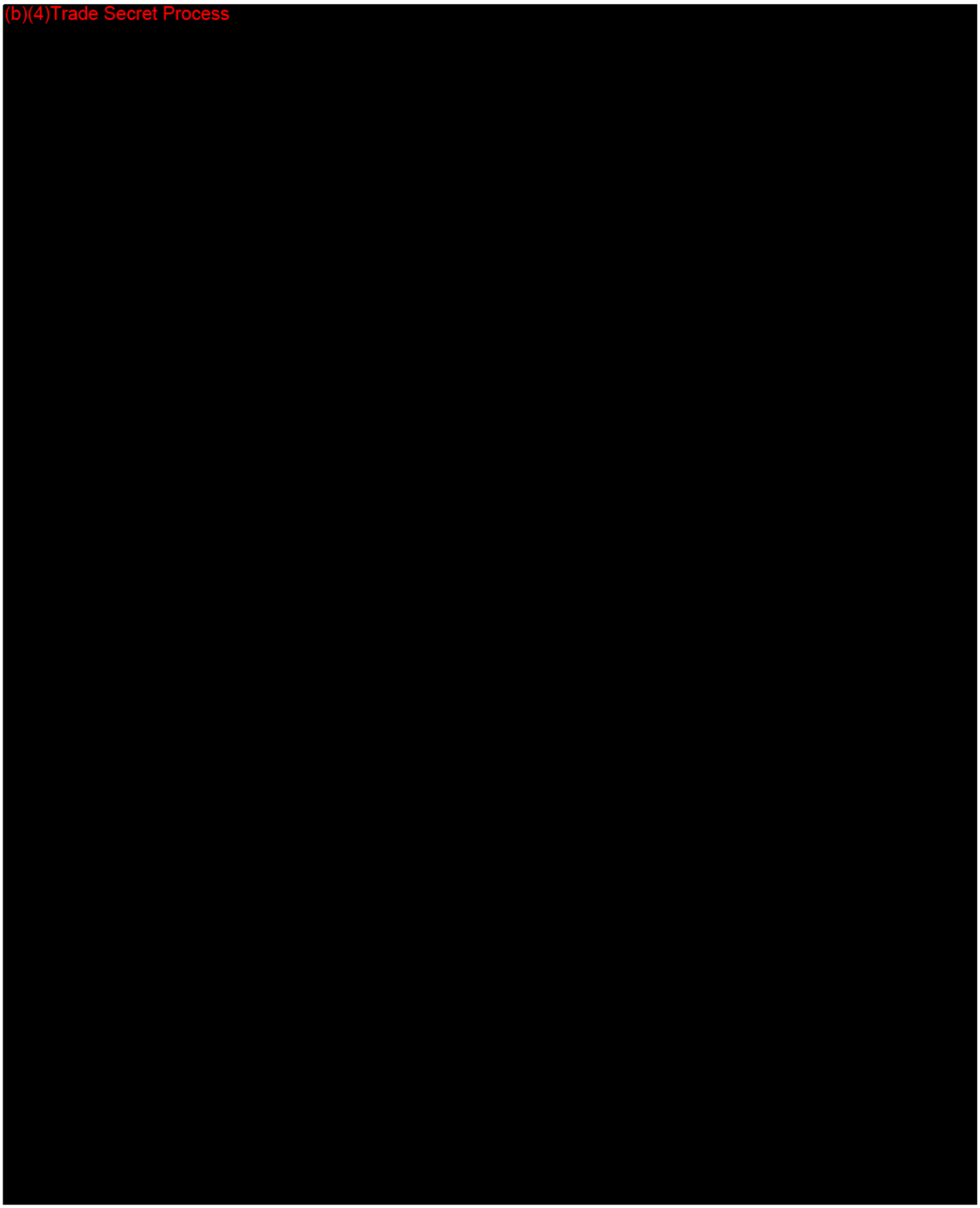
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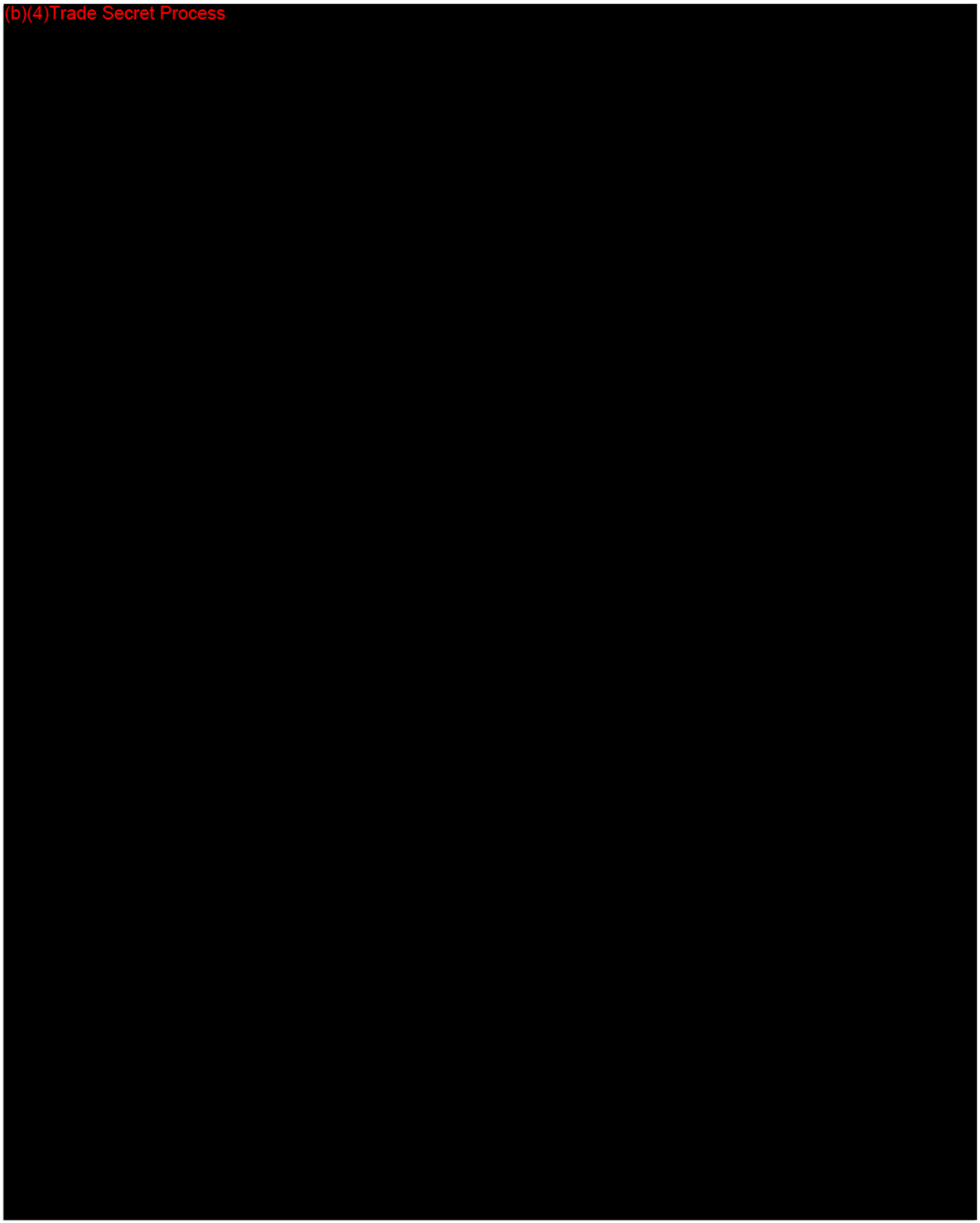

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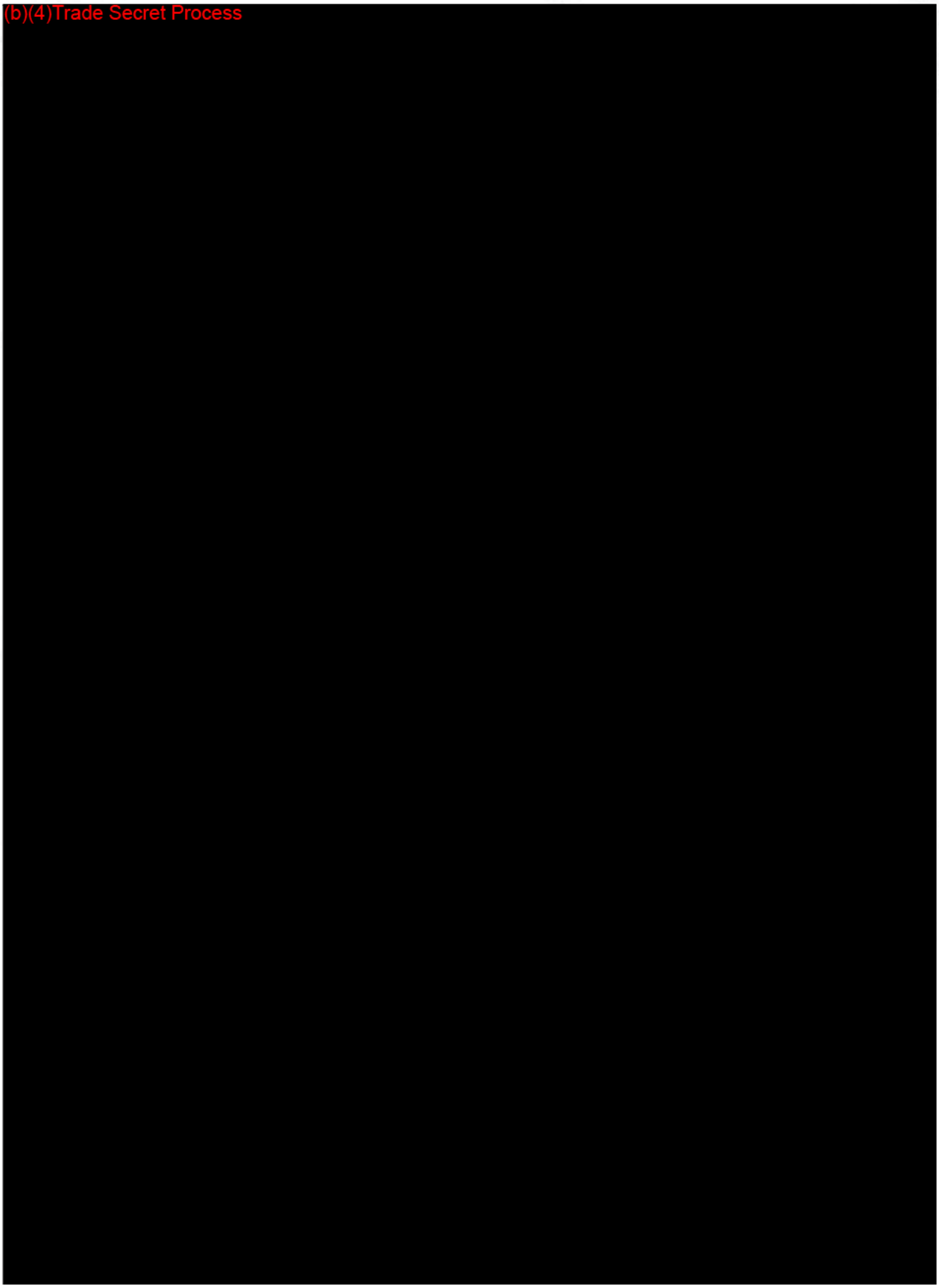

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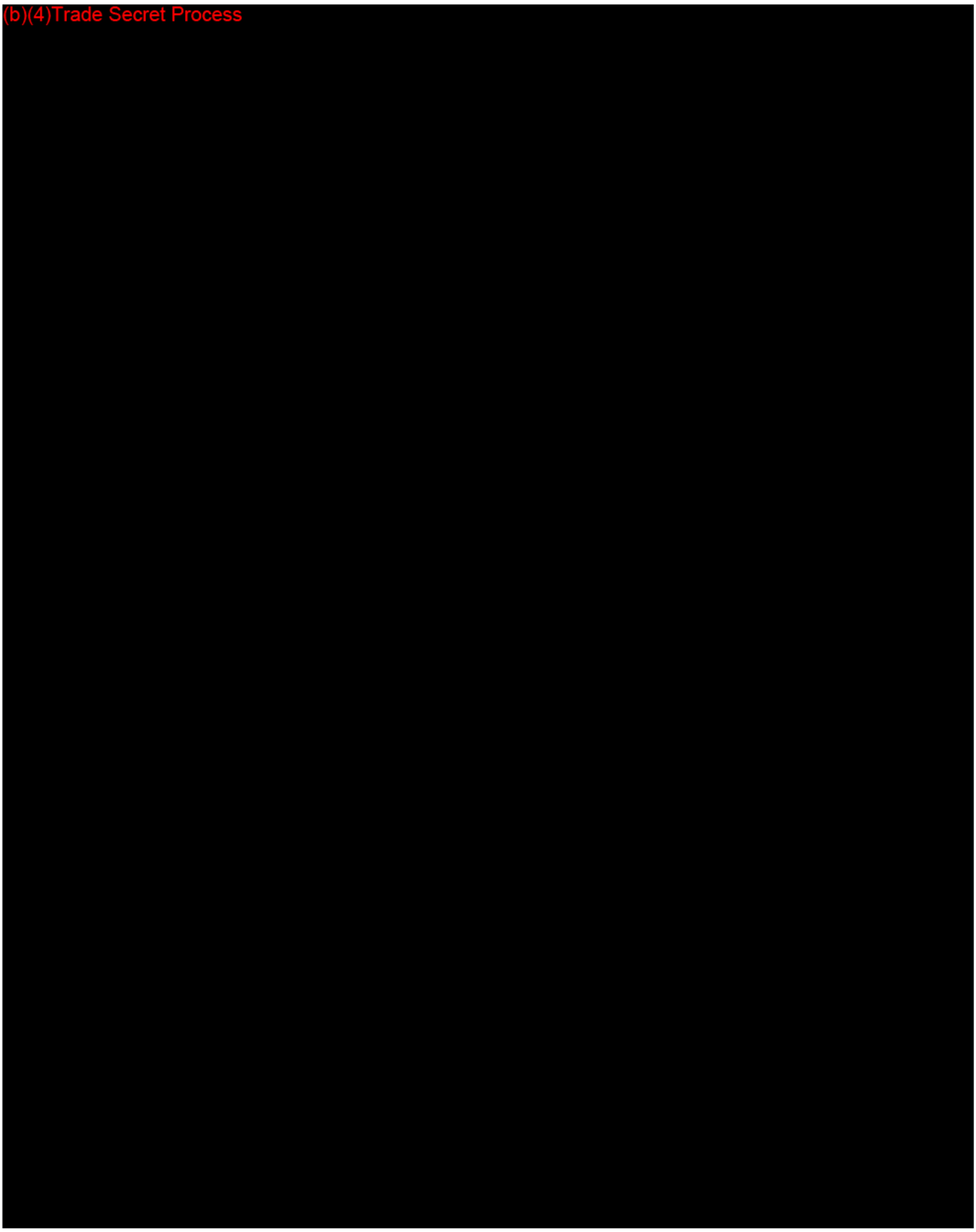

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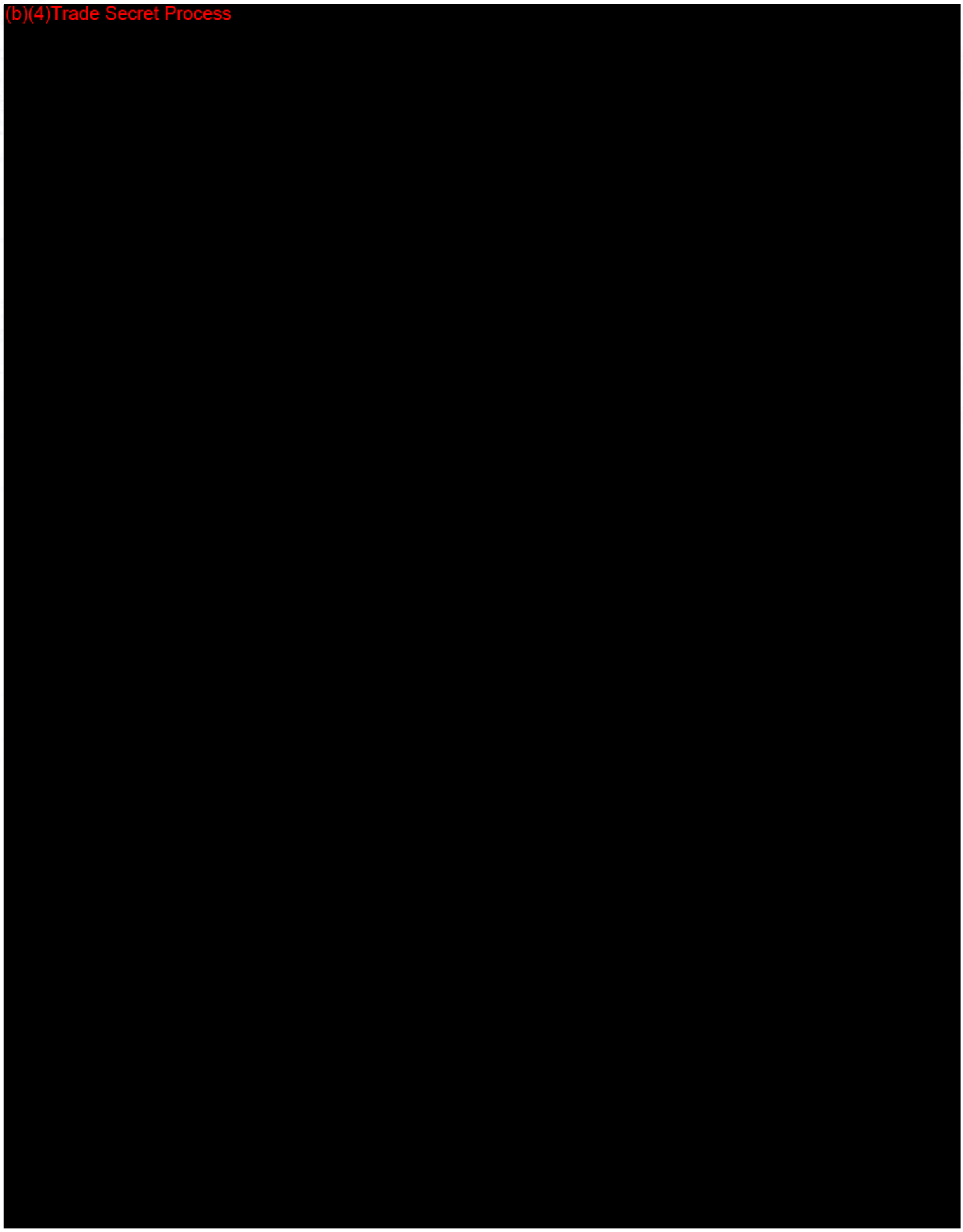

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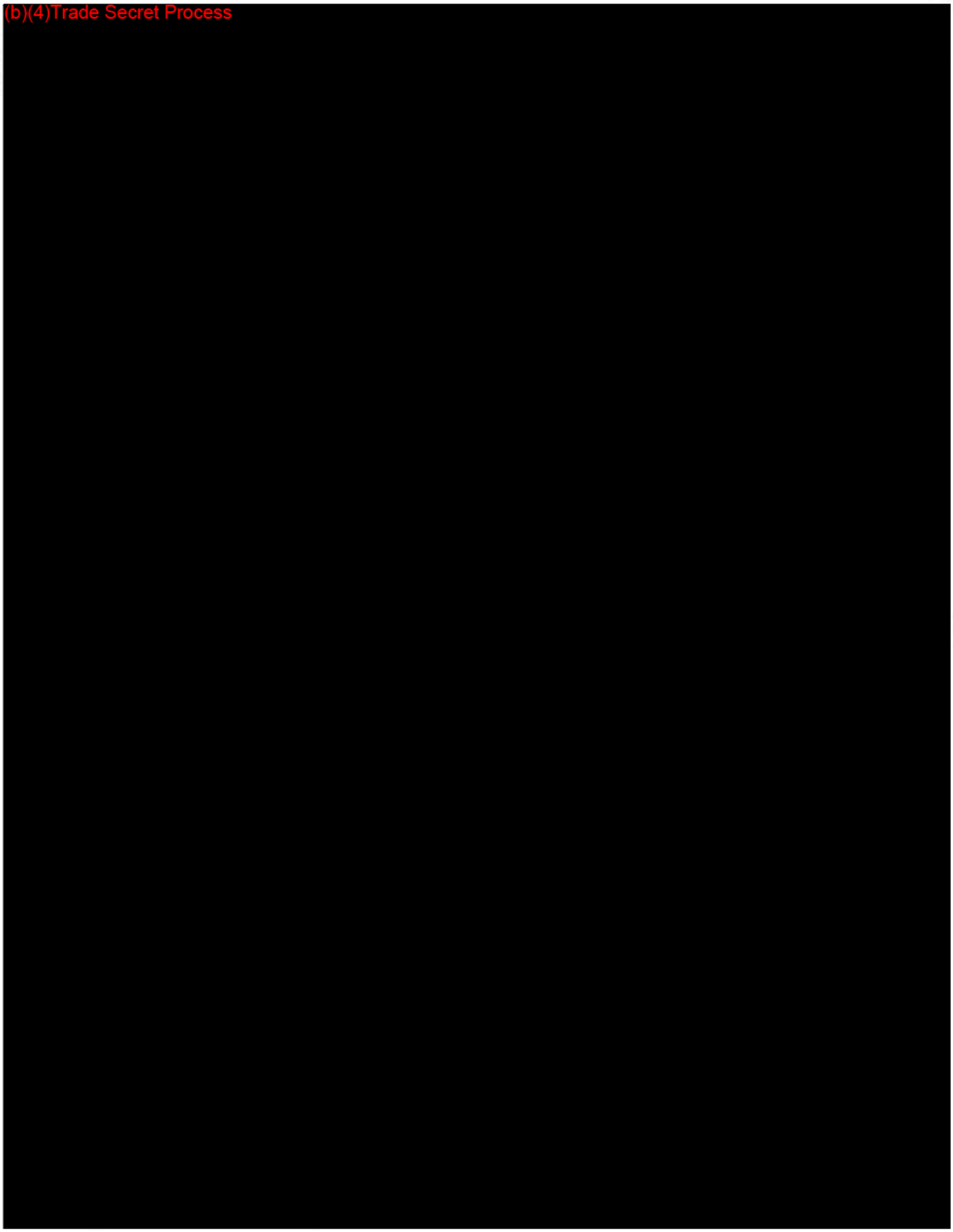

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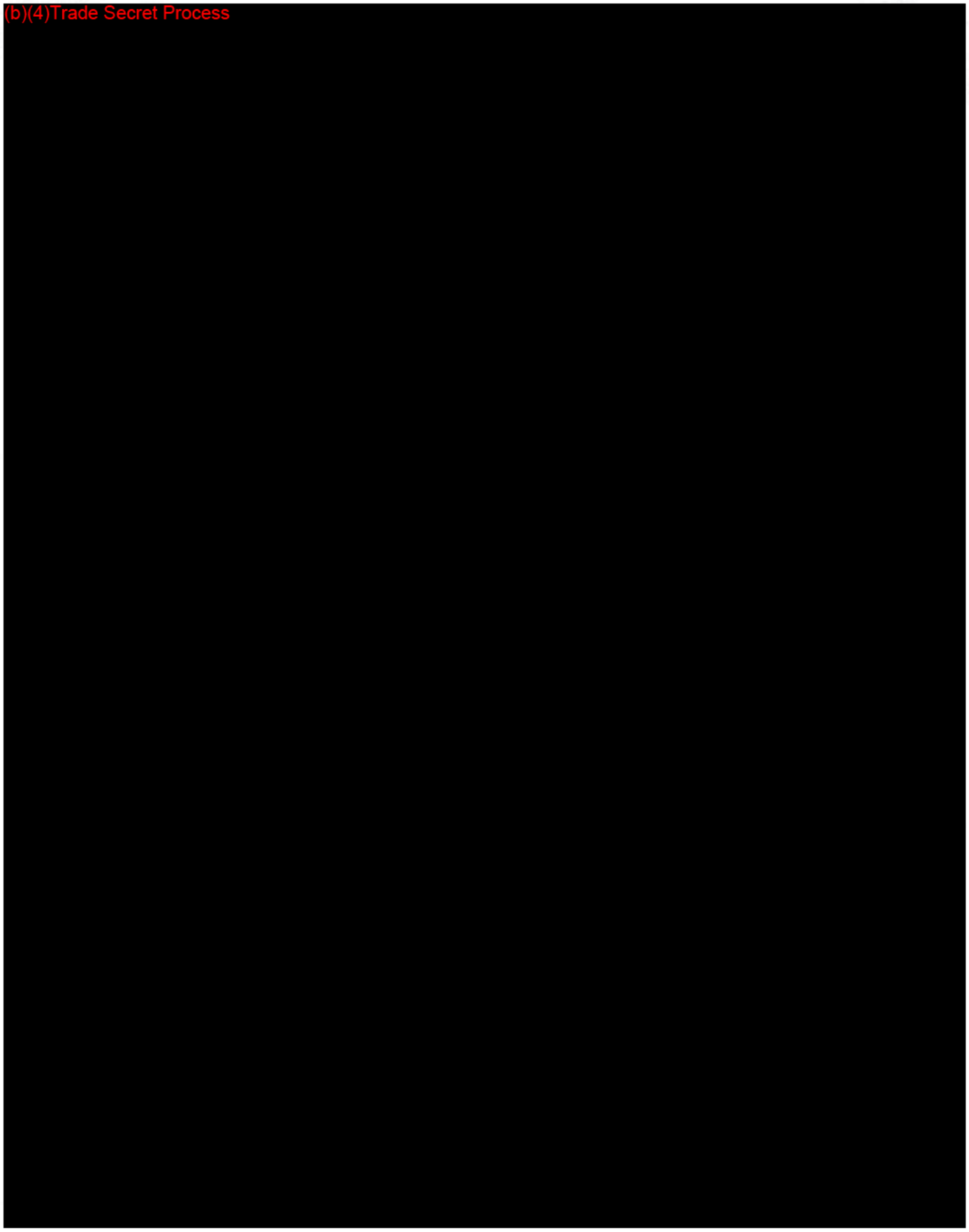

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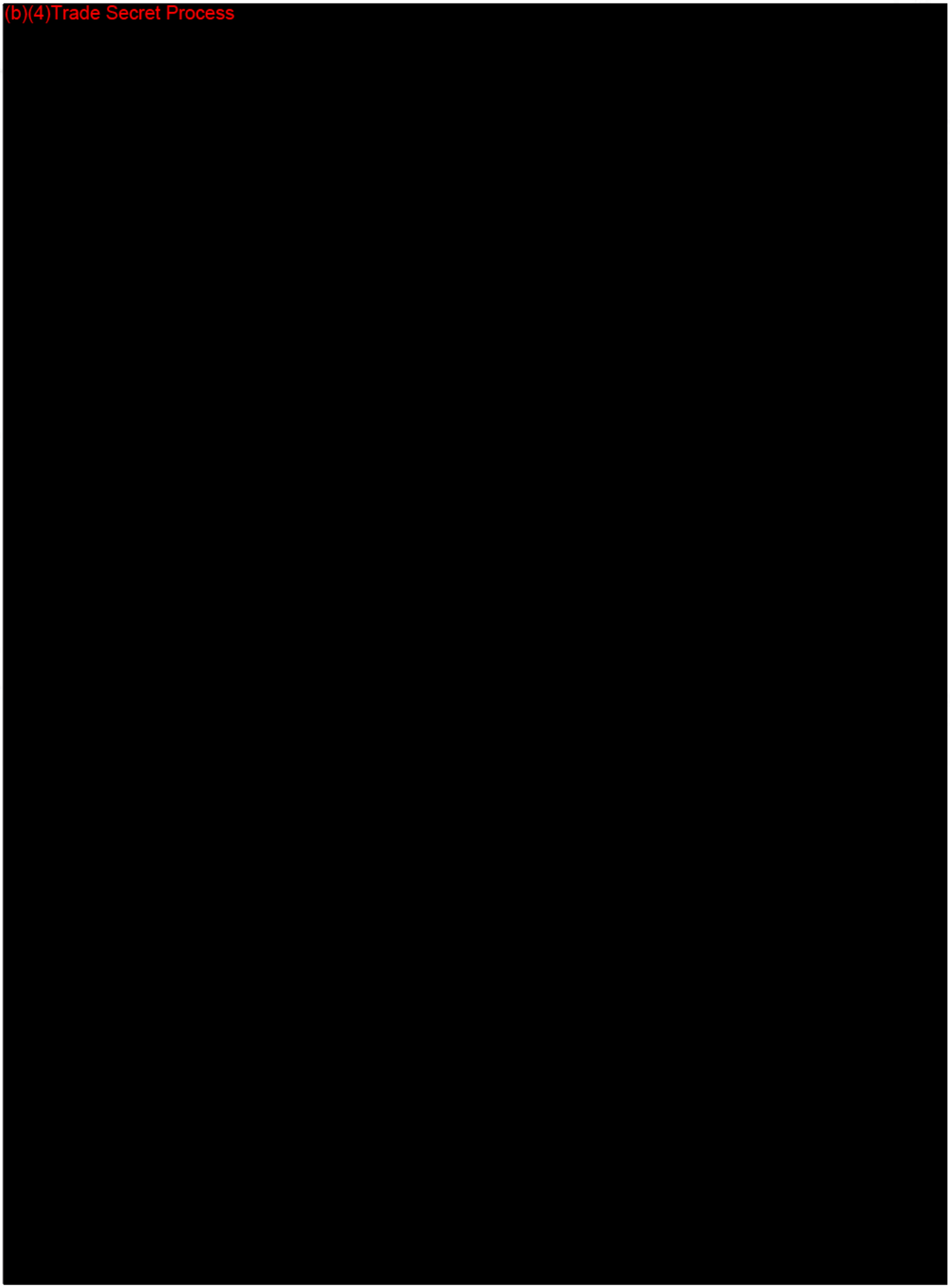

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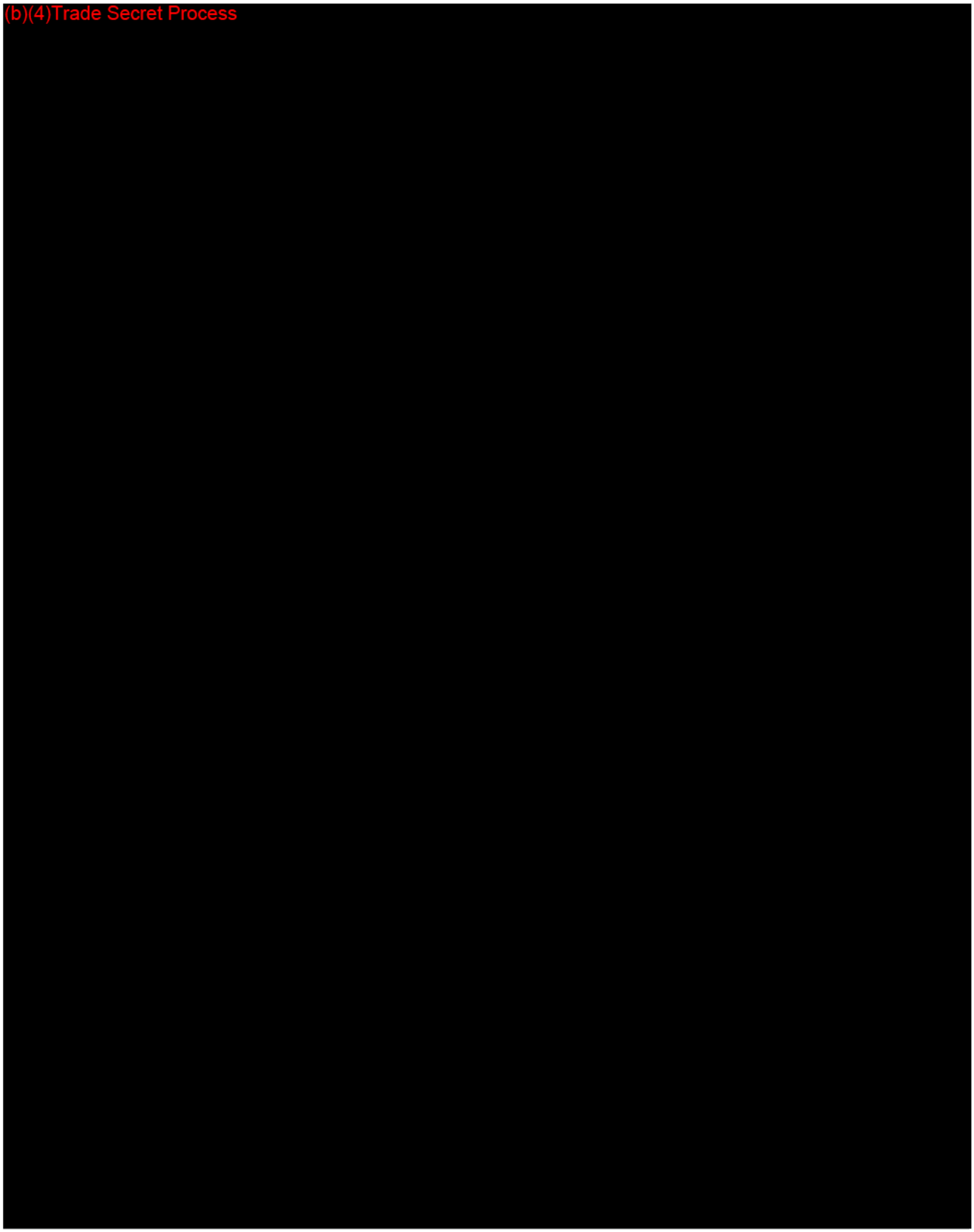

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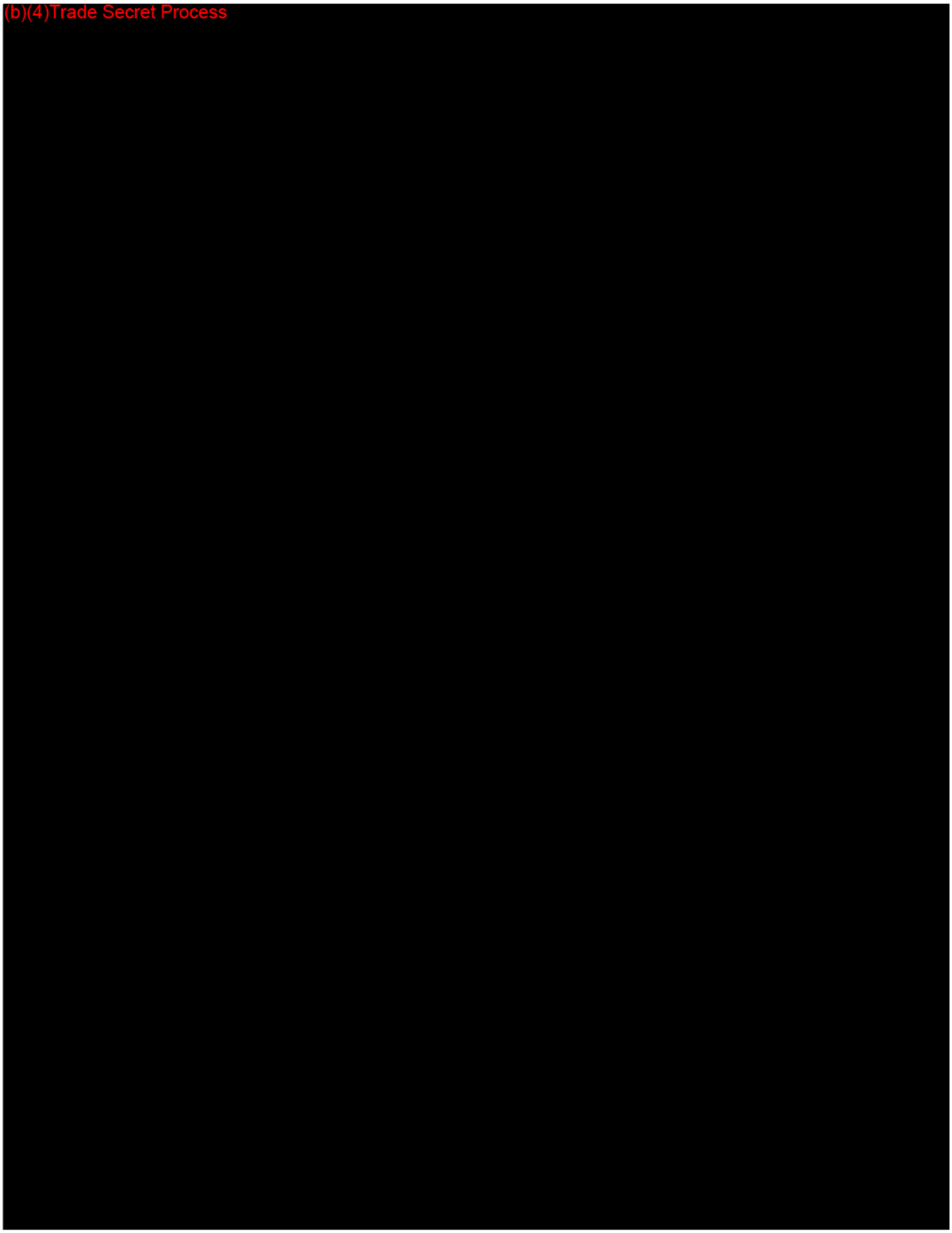

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XVIII. **Performance Testing – Clinical** (Section 20)

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XIX. **Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	X		If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:

(b)(4)Trade Secret Process

[redacted]

2. Explain why there is or is not a new effect or safety or effectiveness issue:

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[redacted]

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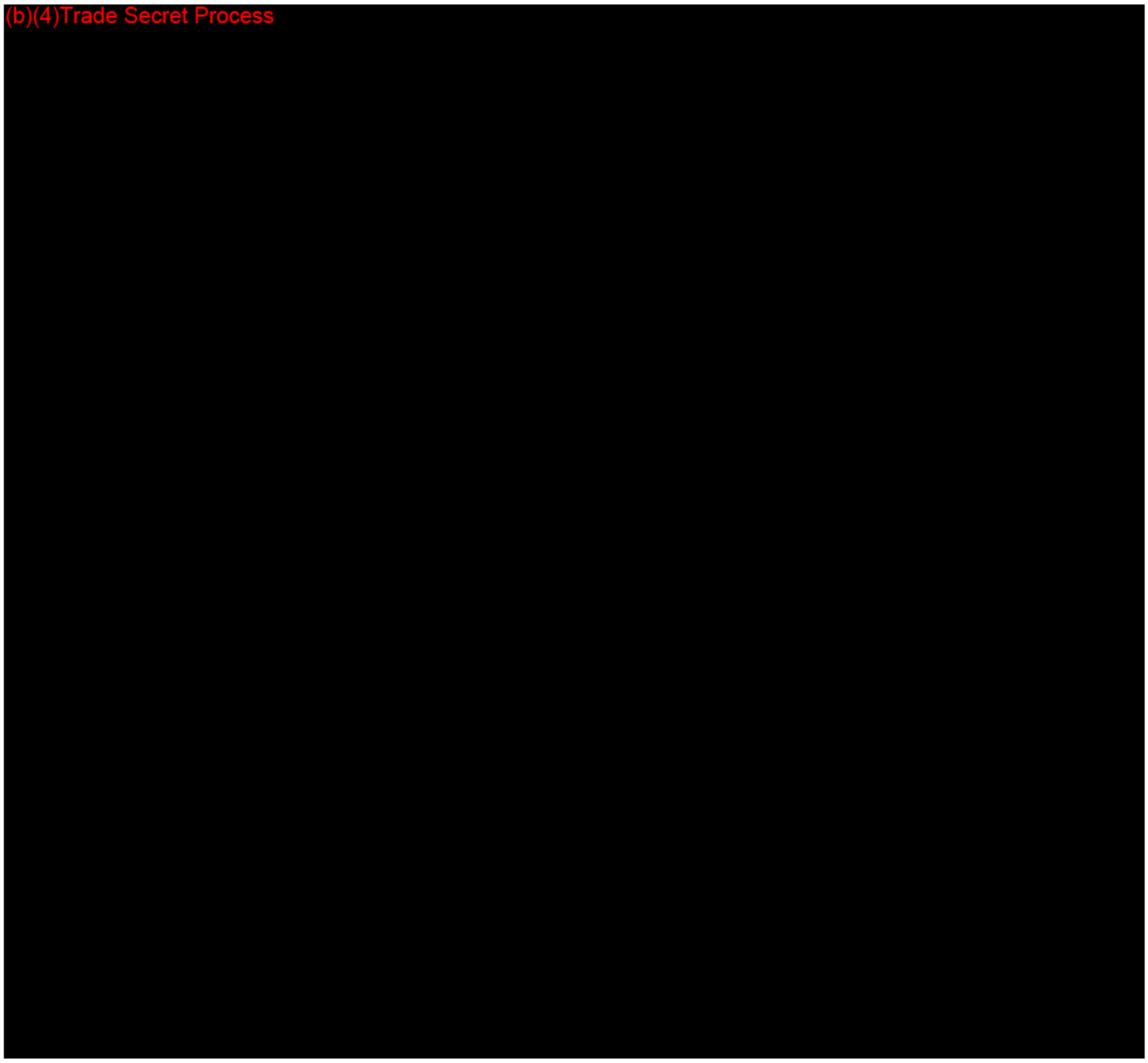

XXI. Contact History

No contact with sponsor.

Kelley Burridge

Kelley Burridge, Ph.D.
Scientific Reviewer, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

7/25/11
Date

I concur

David Krause

David Krause, Ph.D.
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

July 25, 2011
Date

Reference List

1. Lebleu, N., C. Roques, P. Aimar, and C. Causserand. 2009. Role of the cell-wall structure in the retention of bacteria by microfiltration membranes. Journal of Membrane Science 326: 178-185 ISI:000261906700023.
2. Moues, C. M., F. Heule, and S. E. R. Hovius. 2011. A review of topical negative pressure therapy in wound healing: sufficient evidence? American Journal of Surgery 201: 544-556 ISI:000289311700022.

Office of Device Evaluation
Division of Surgical, Orthopedic and Restorative Devices
Plastic and Reconstructive Surgery Branch

K111170
Clinical Consulting Review Memorandum

Date: July 21st, 2011

To: Kelley Burridge, PhD
Scientific Reviewer
CDRH/ODE/DSORD/PRSB

Concur
David Krause
7/25/2011

CC: David Krause, PhD - Branch Chief Plastic and Reconstructive Surgery
"The Record"

From: Suzanne Schwartz, MD
Clinical Reviewer
CDRH/ODE/DSORD/PRSB

Device Name: Pico Single Use NPWT System

Sponsor: Smith and Nephew

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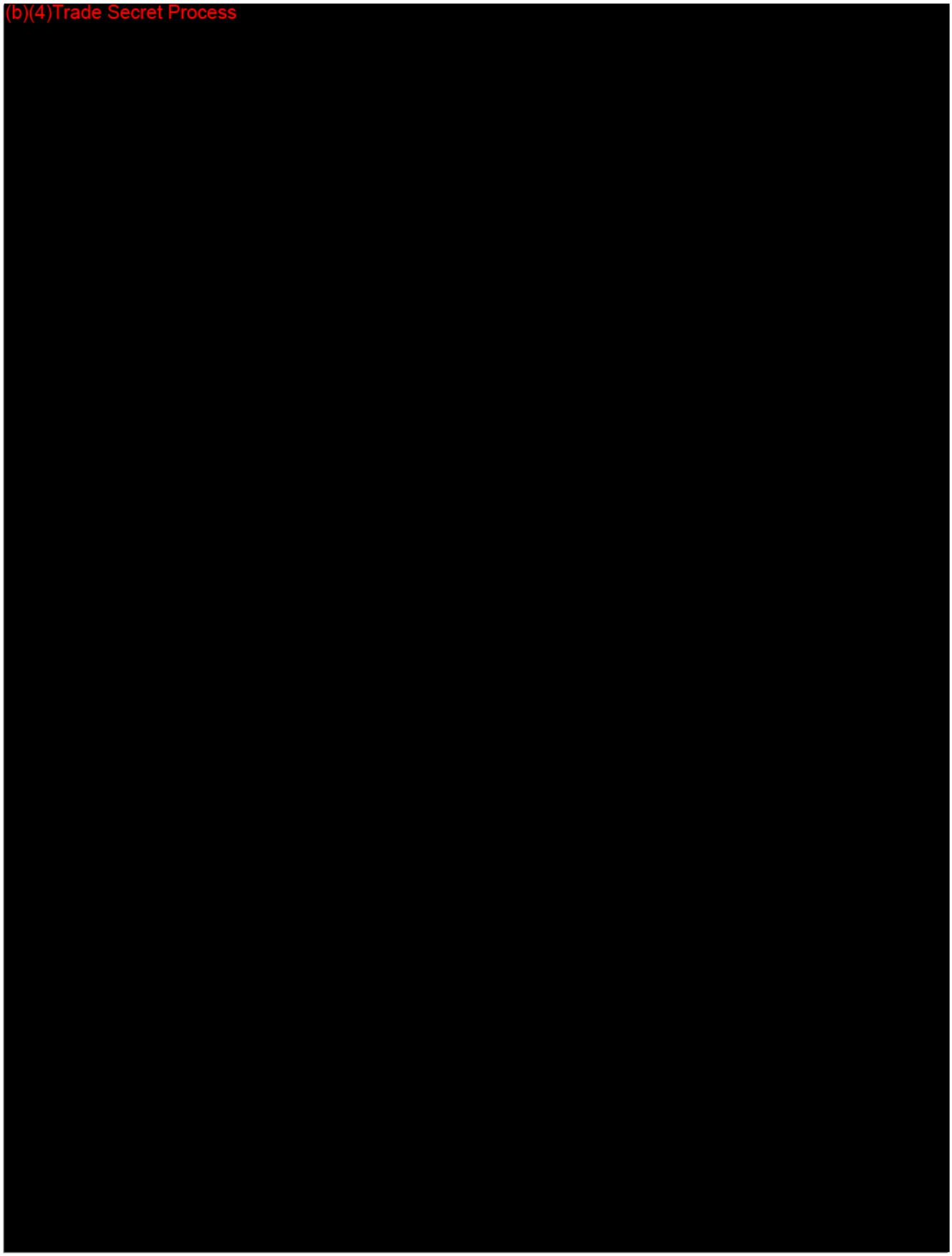

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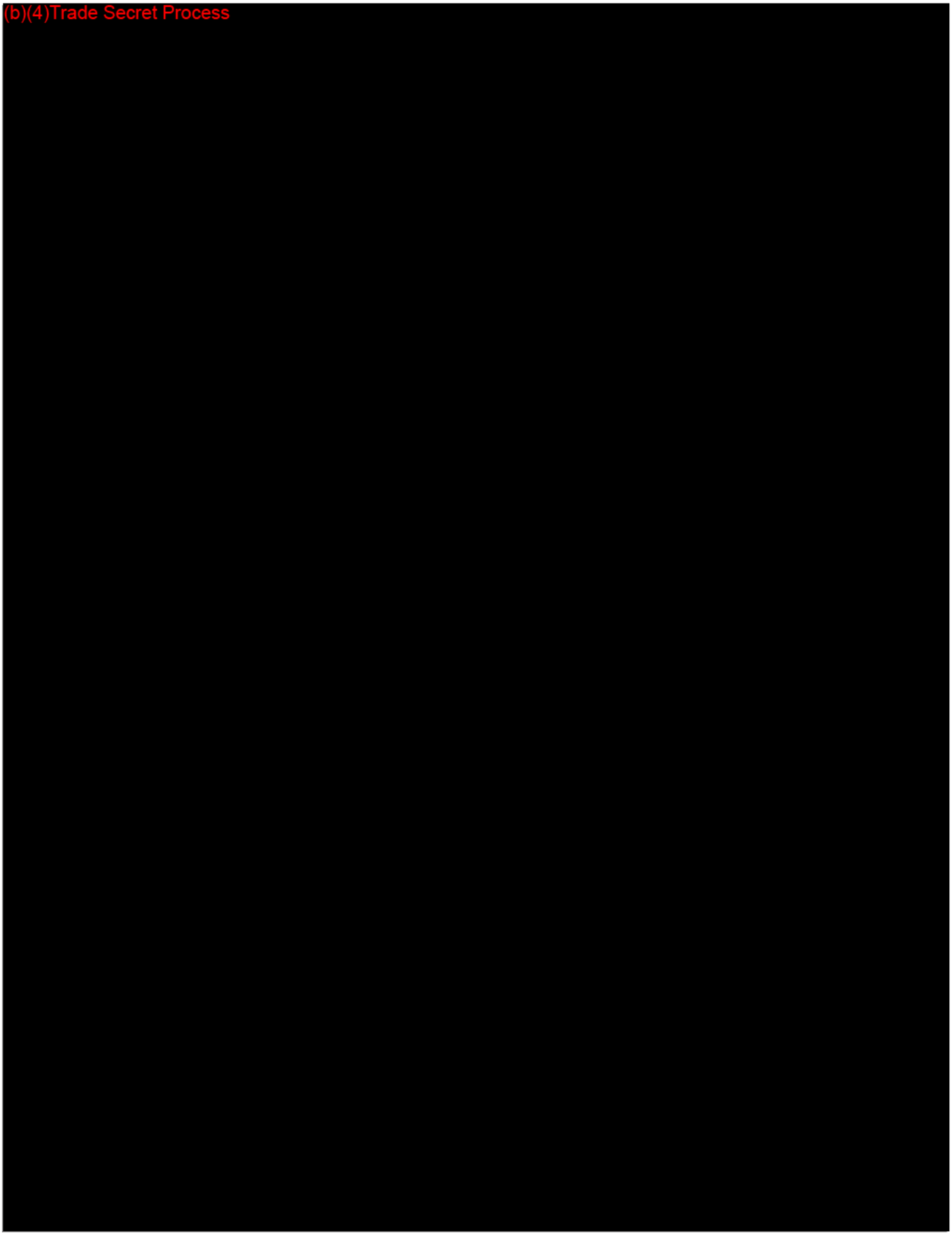

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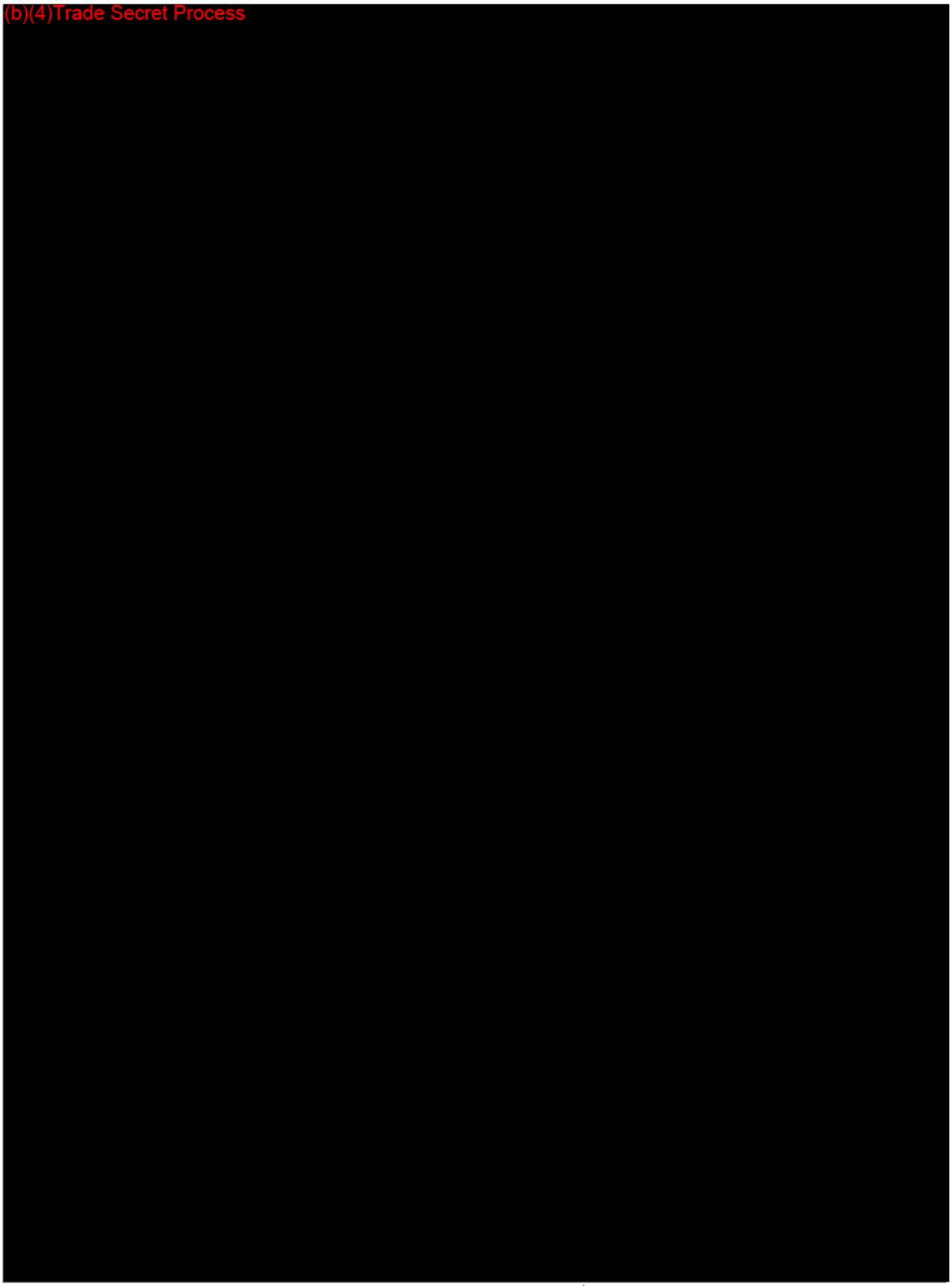

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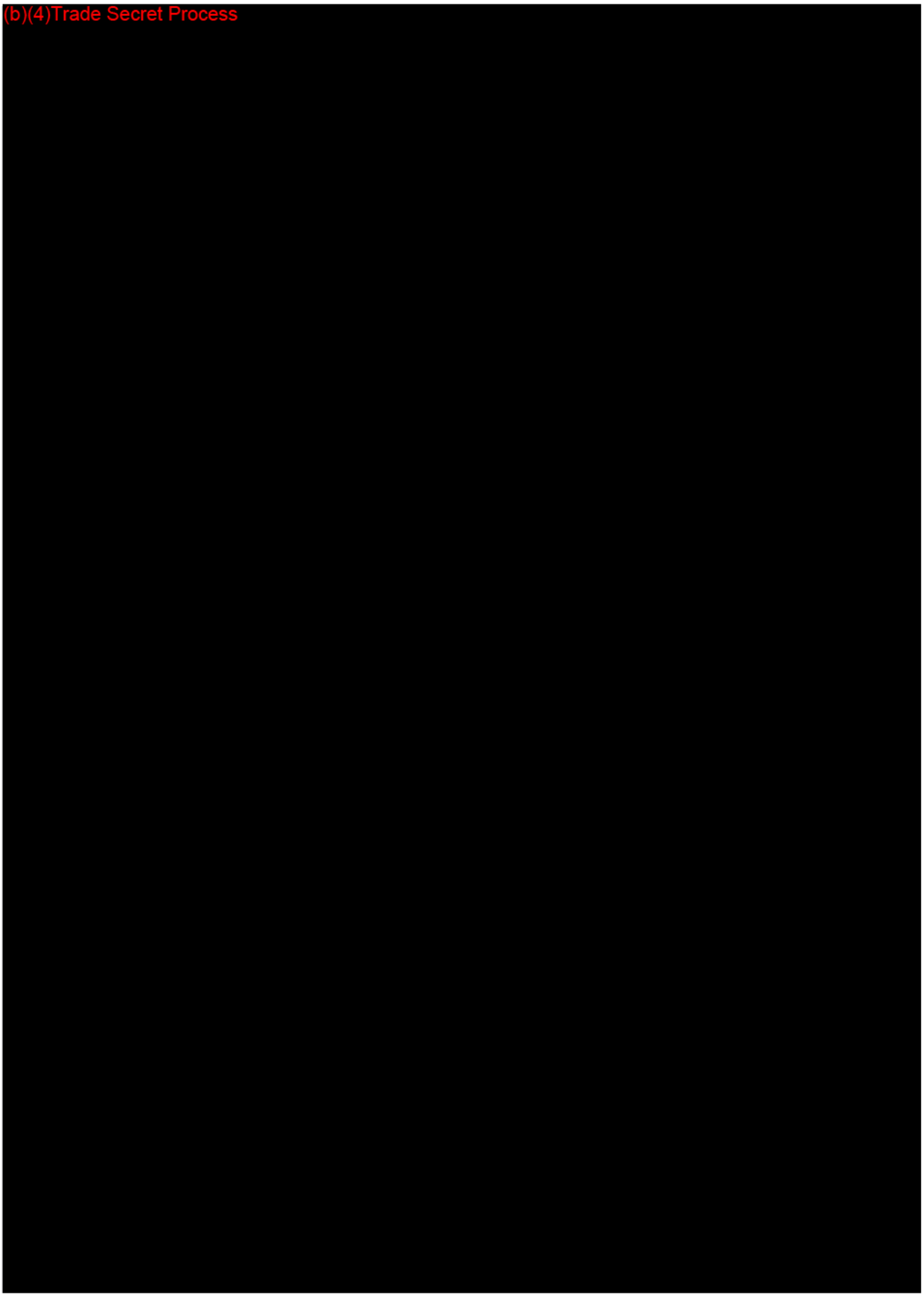

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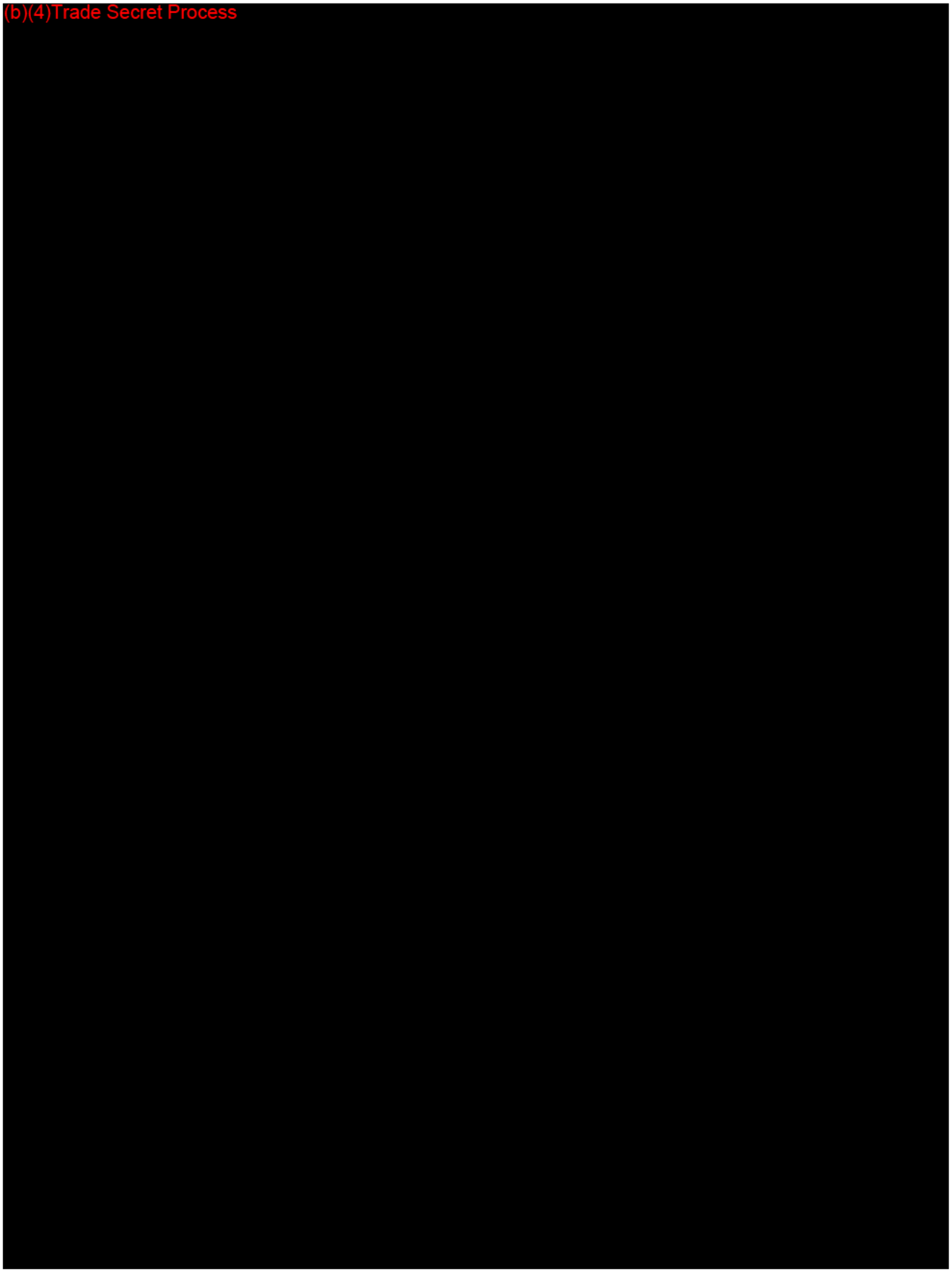

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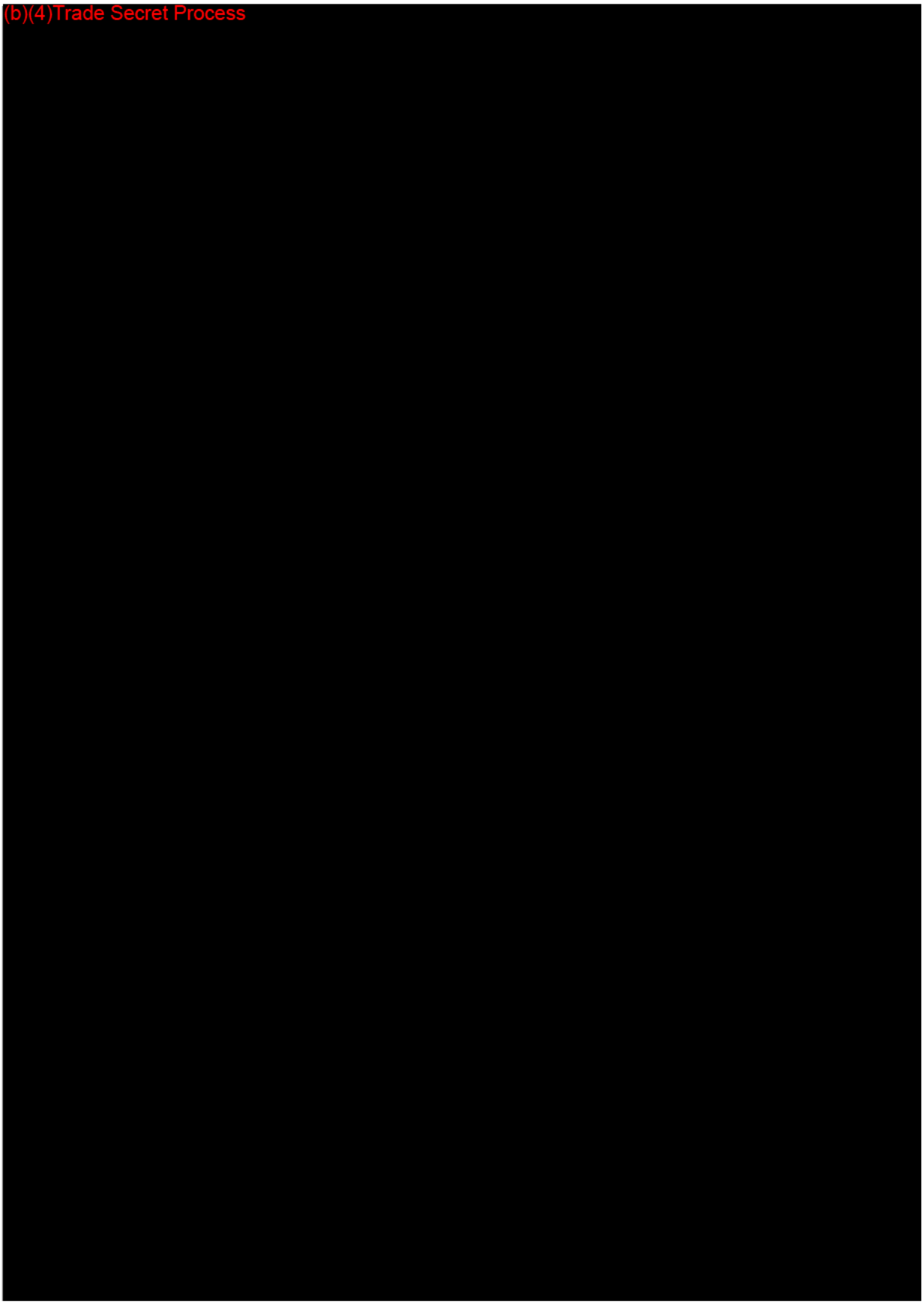

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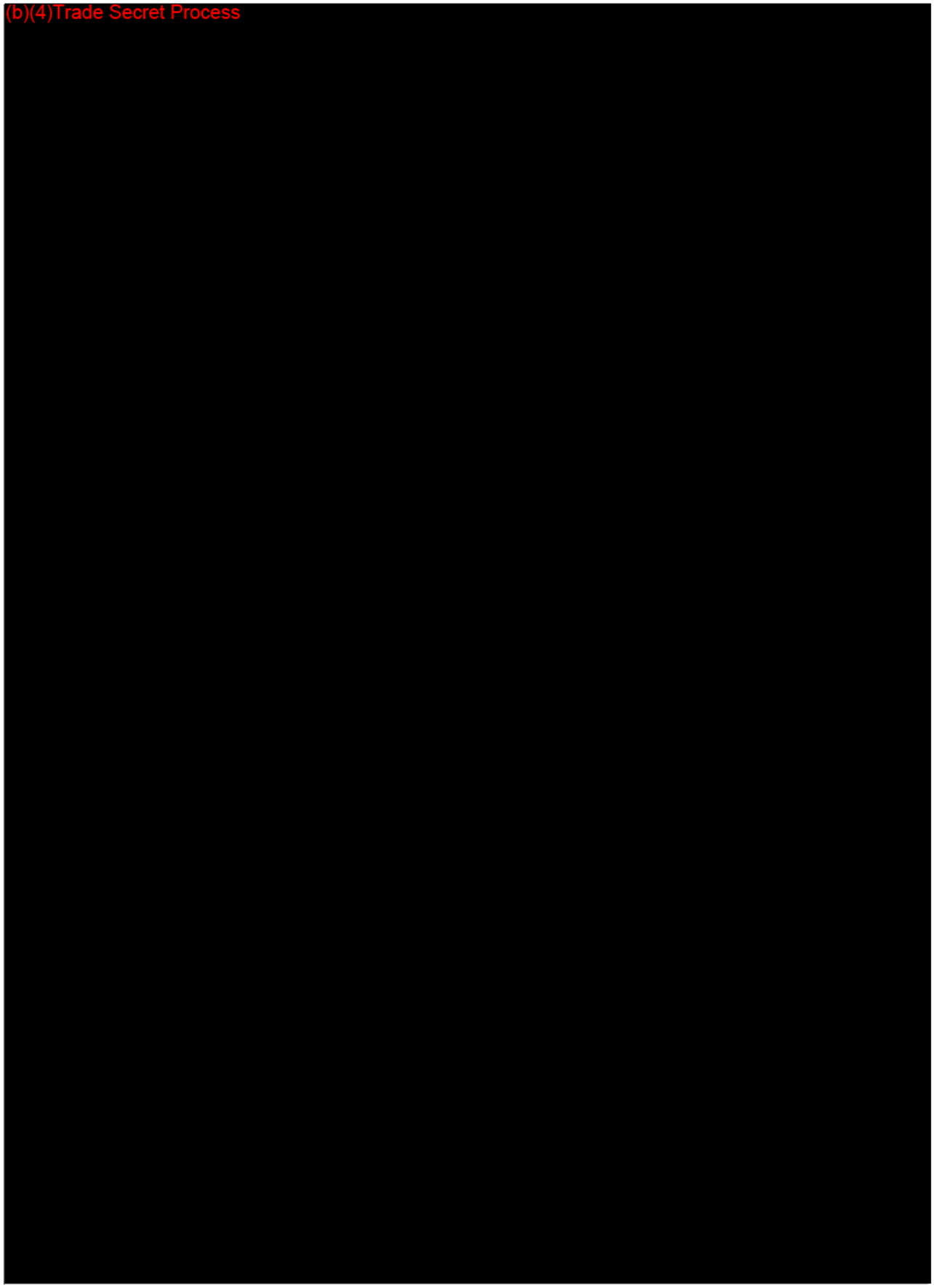

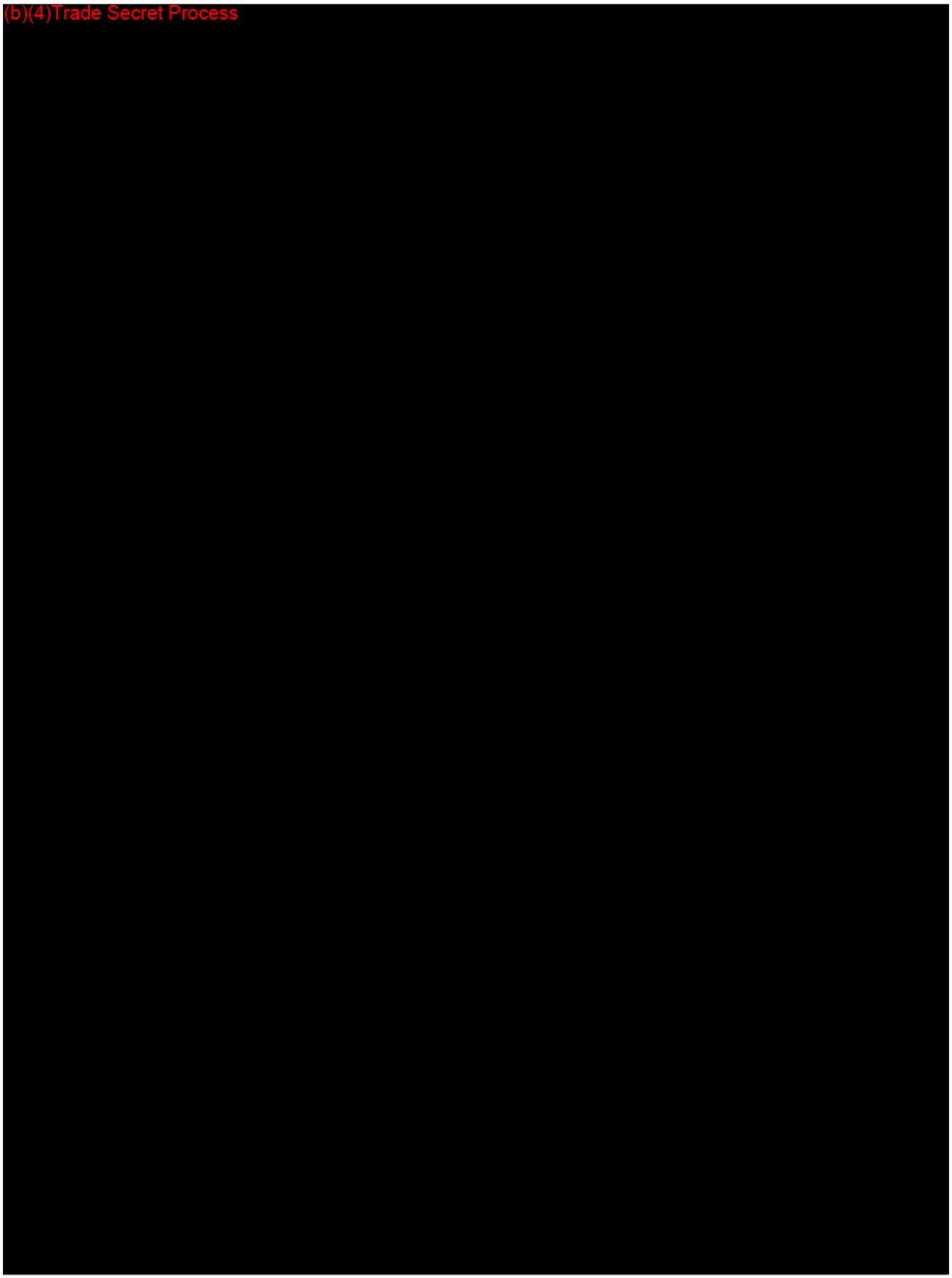
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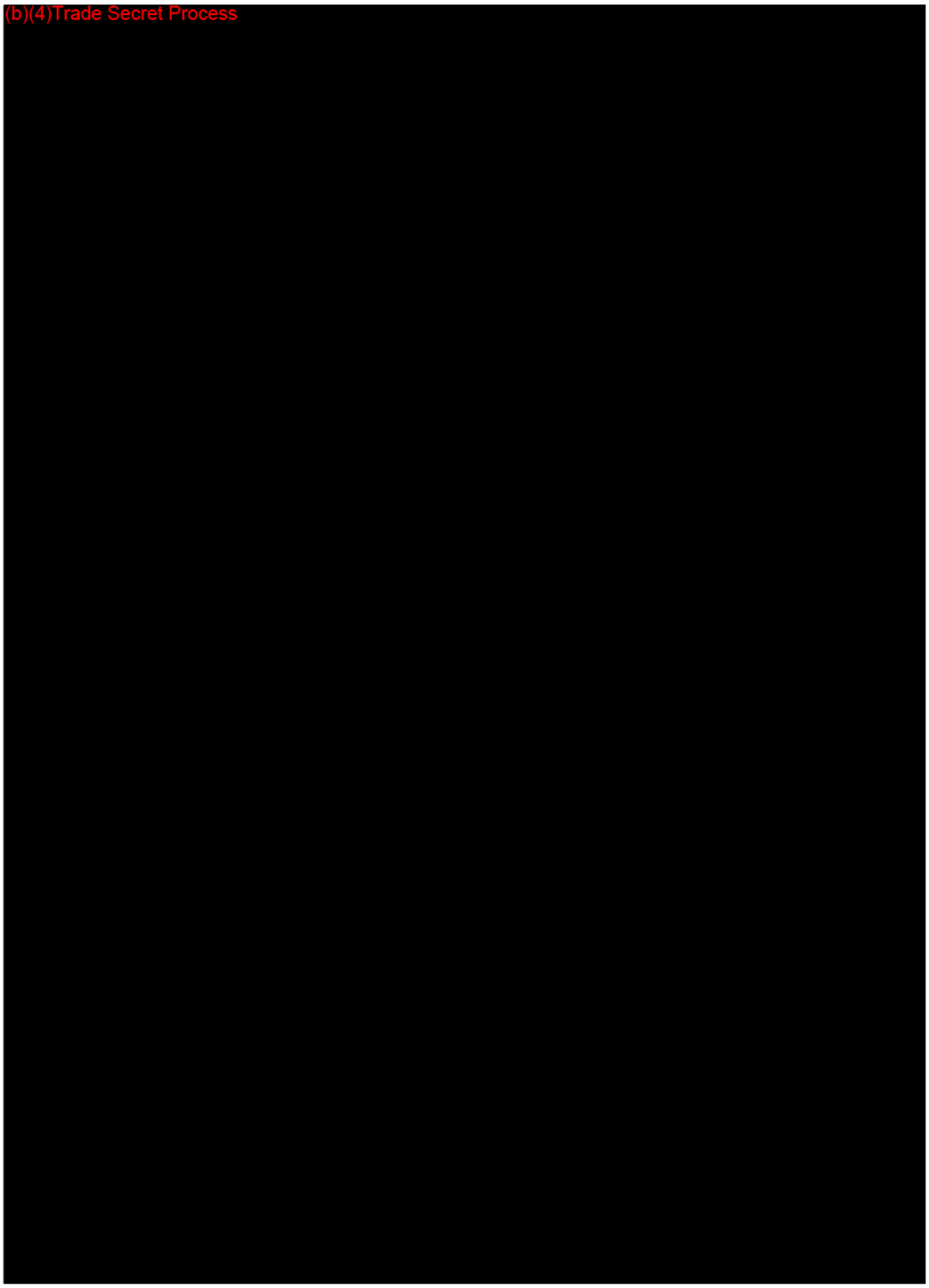

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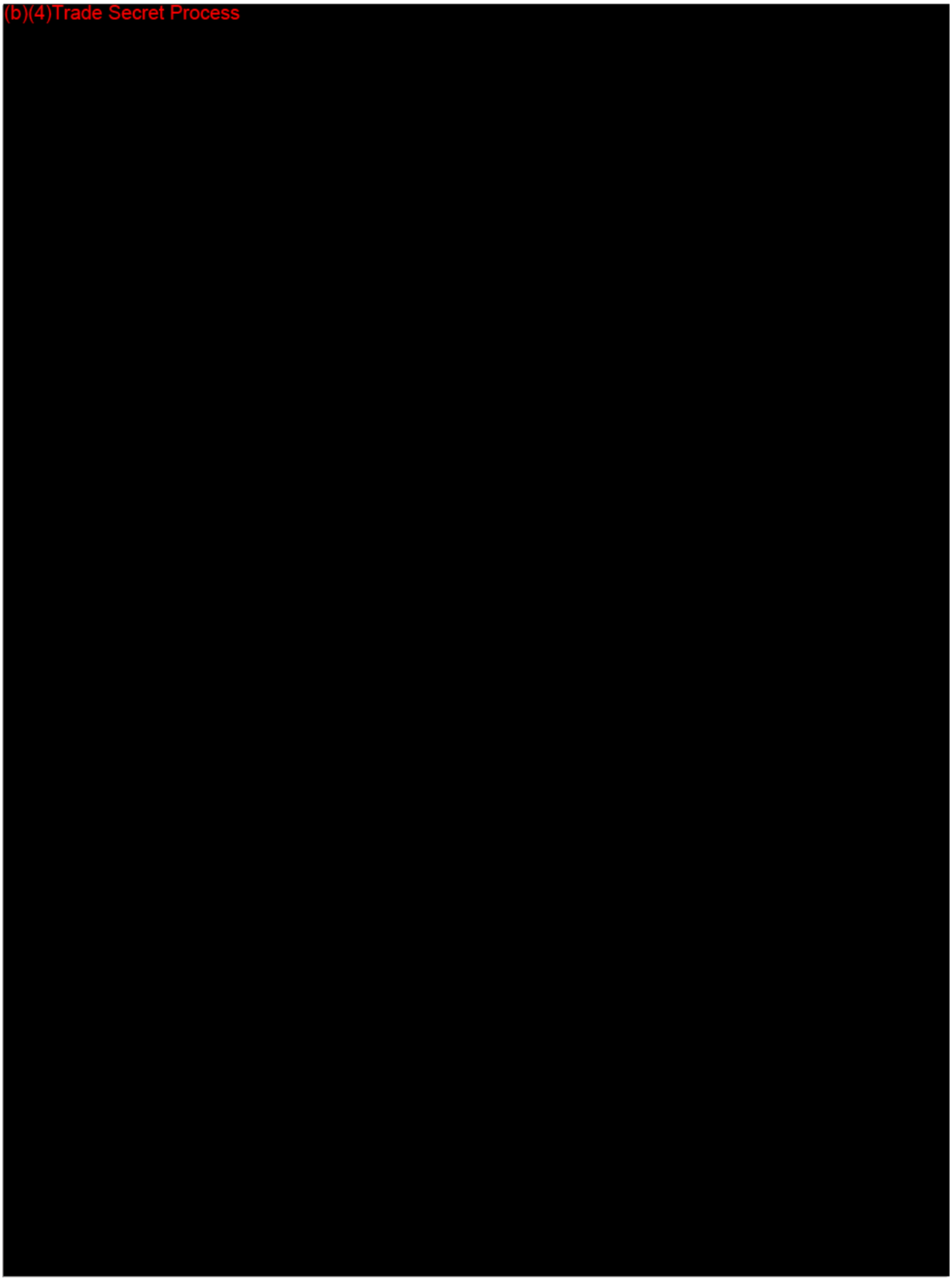

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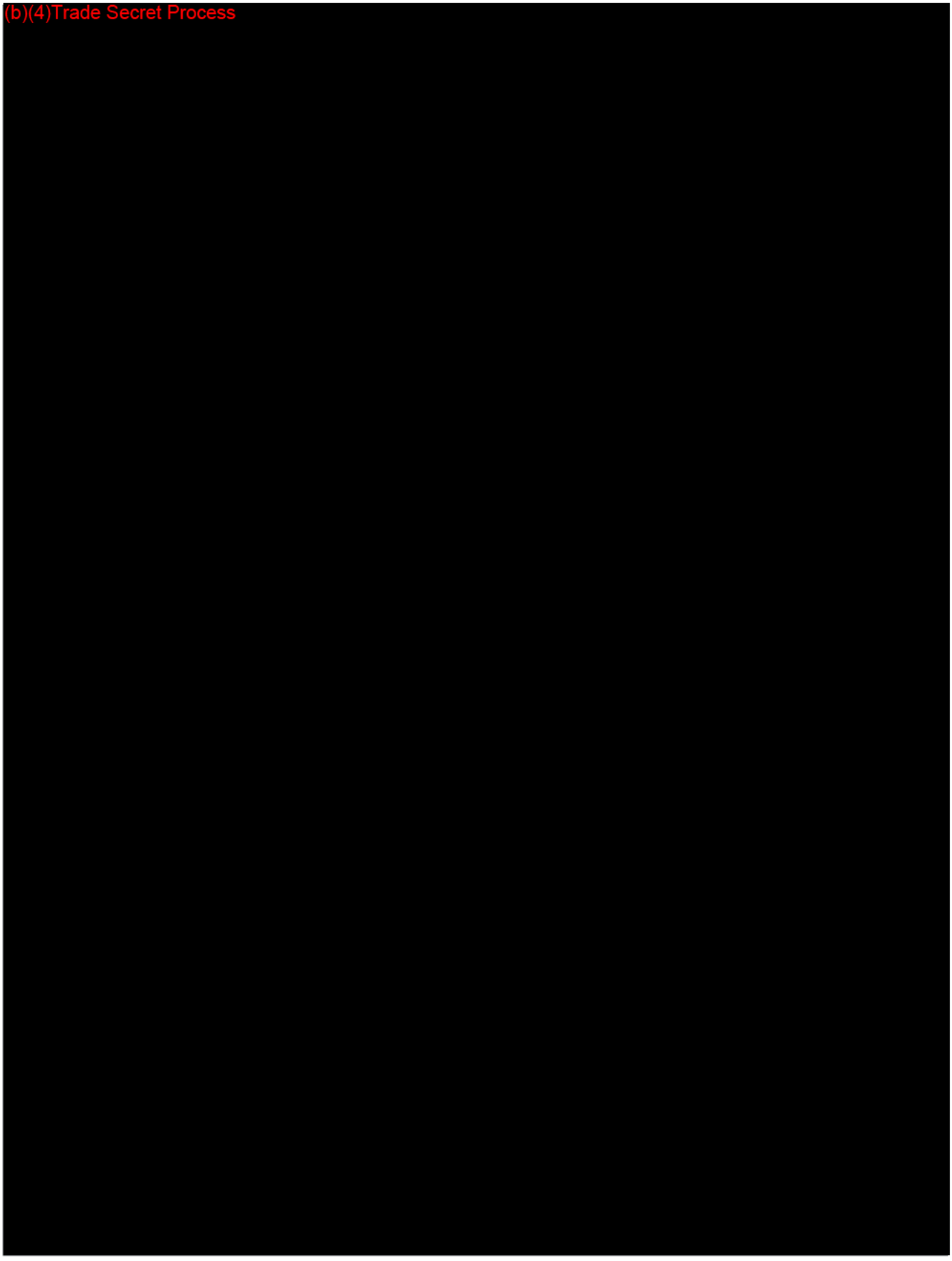

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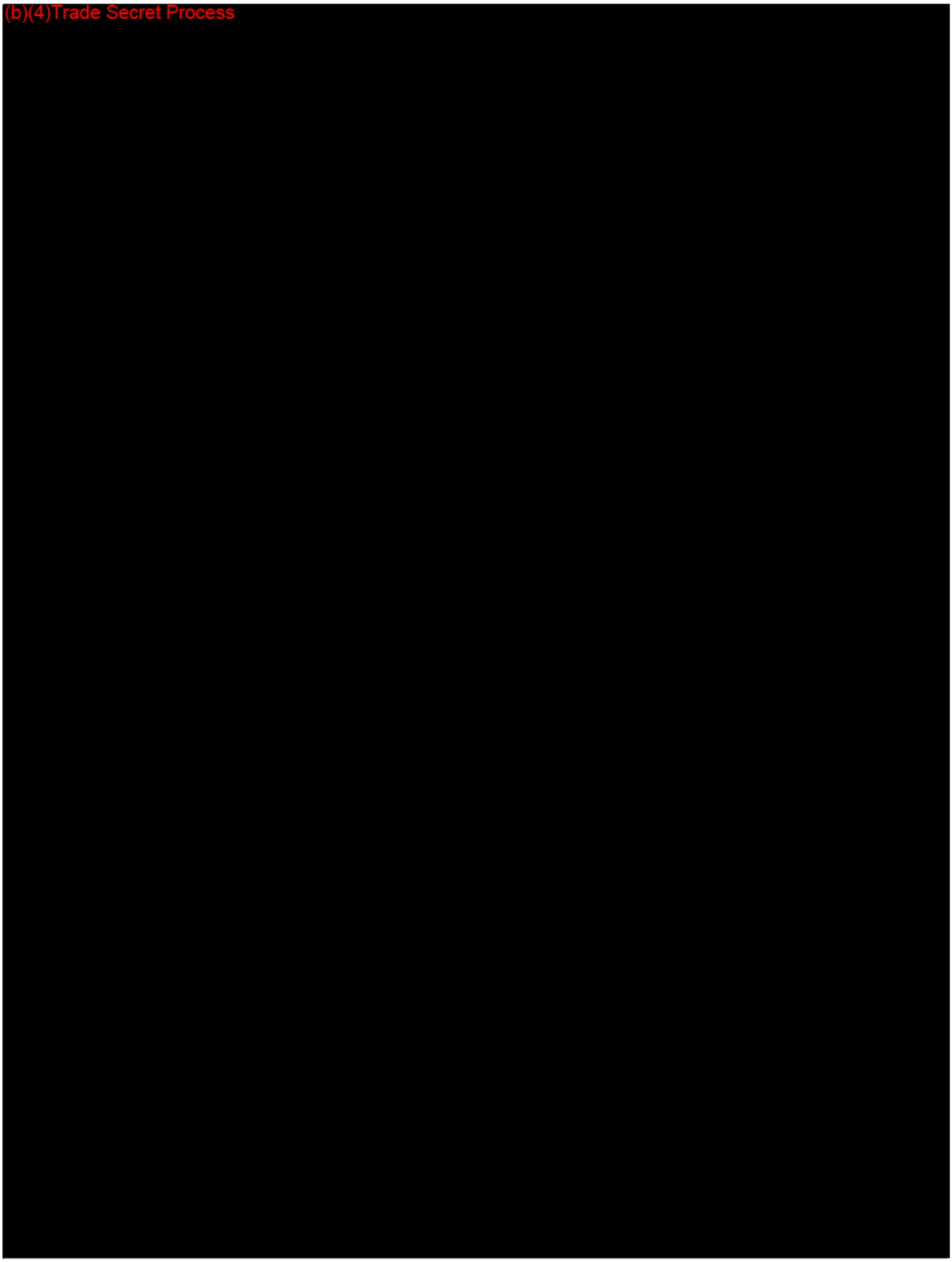

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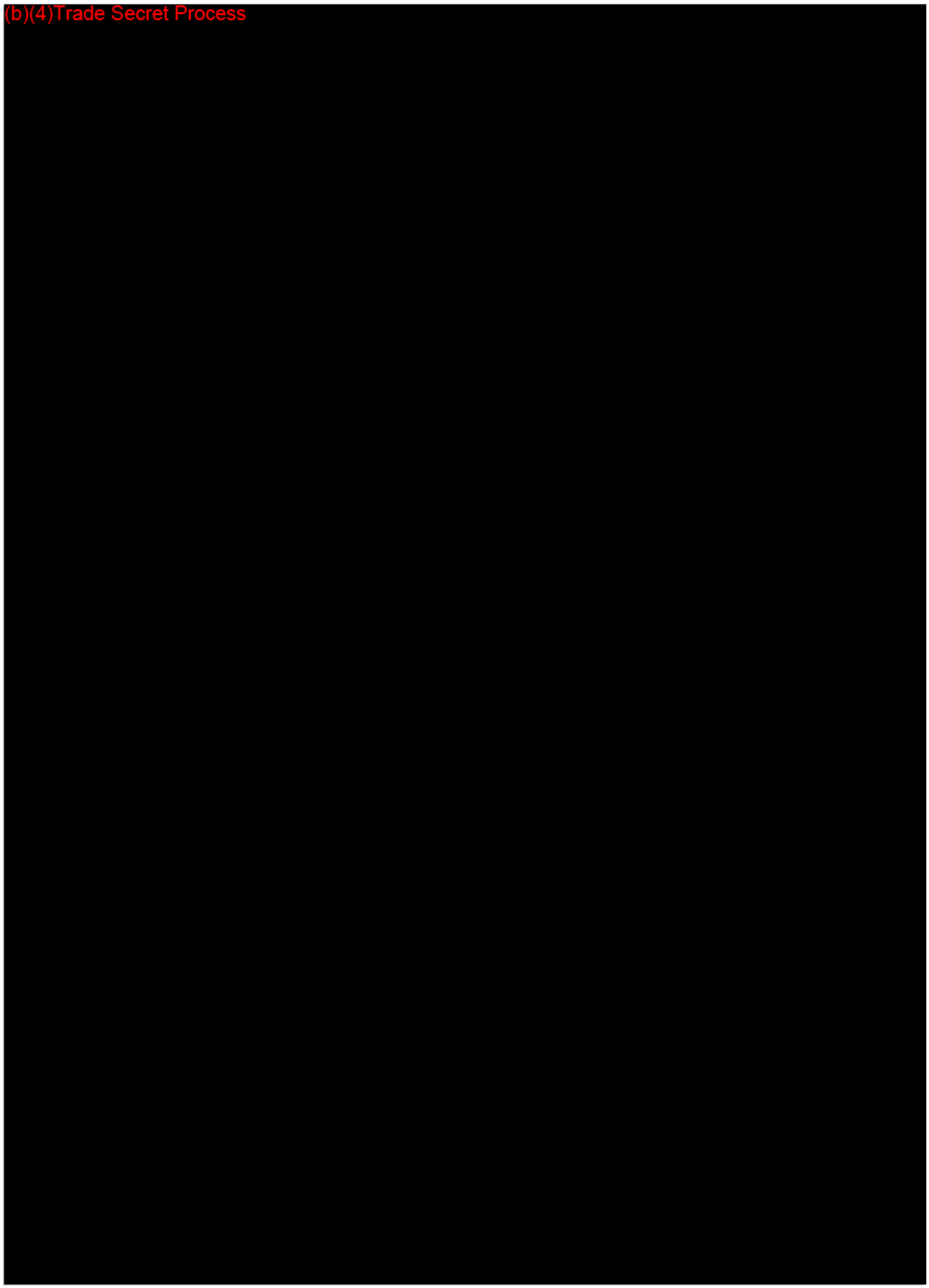

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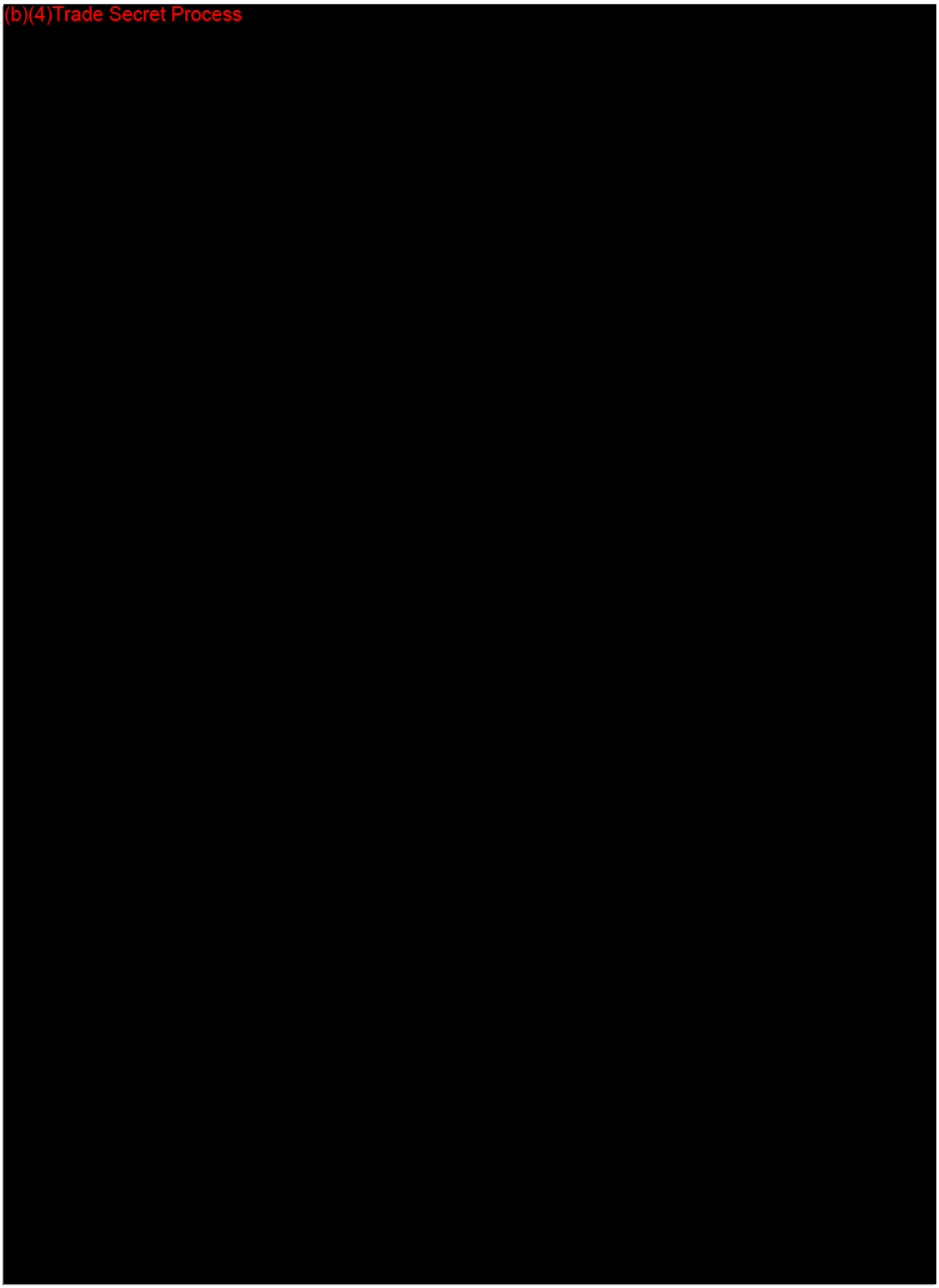

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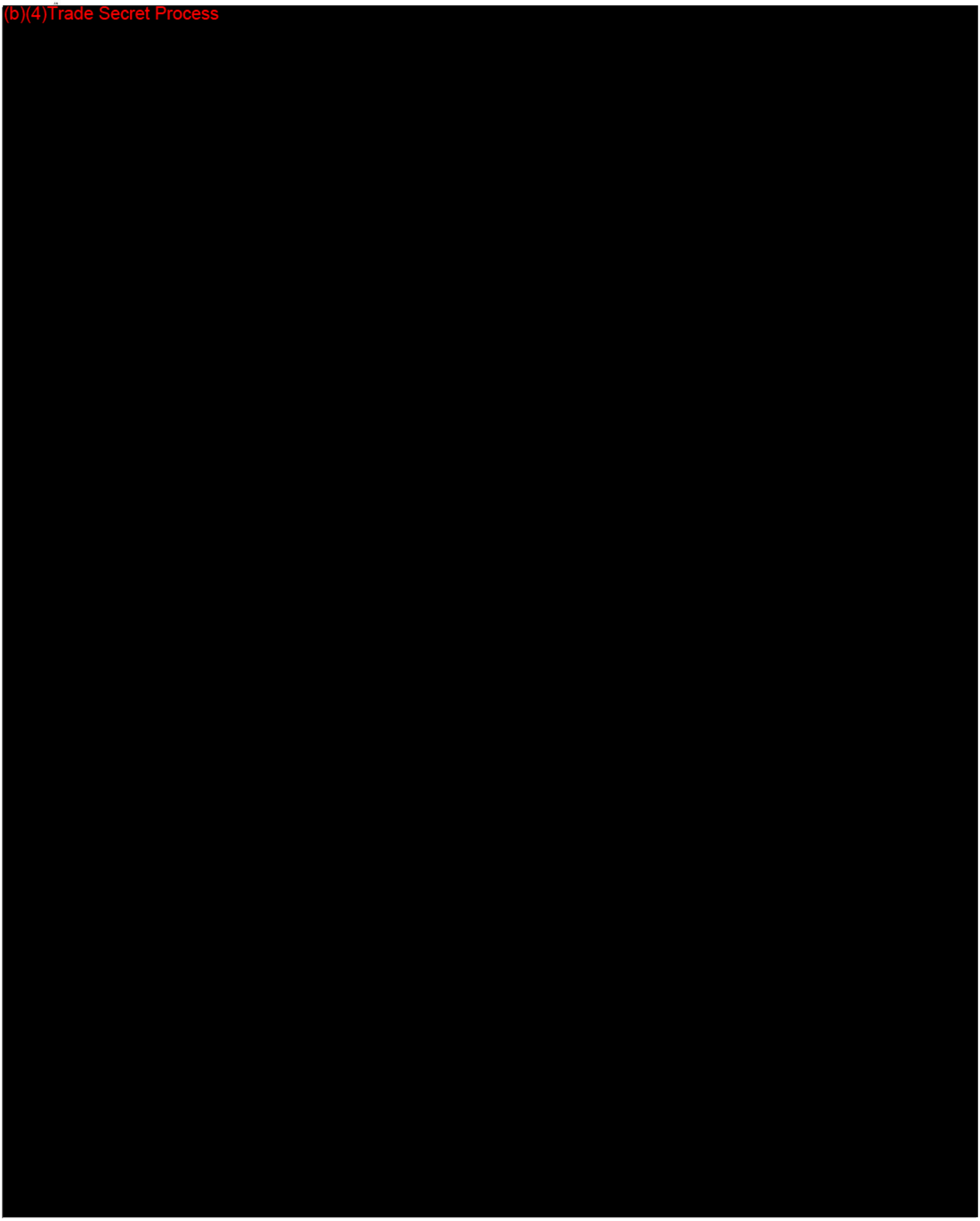

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date July 21, 2011

From Senior Electronics Engineer (Jeffrey L. Silberberg), CDRH/OSEL/DESE

Subject Electrical safety and EMC consult for K111170 – Smith & Nephew Pico negative pressure wound therapy system

To Kelley Burridge, CDRH\ODE\DSORD\PRSB

CC Director, Division of Electrical and Software Engineering (Alford R. Taylor, Jr.,), CDRH/OSEL

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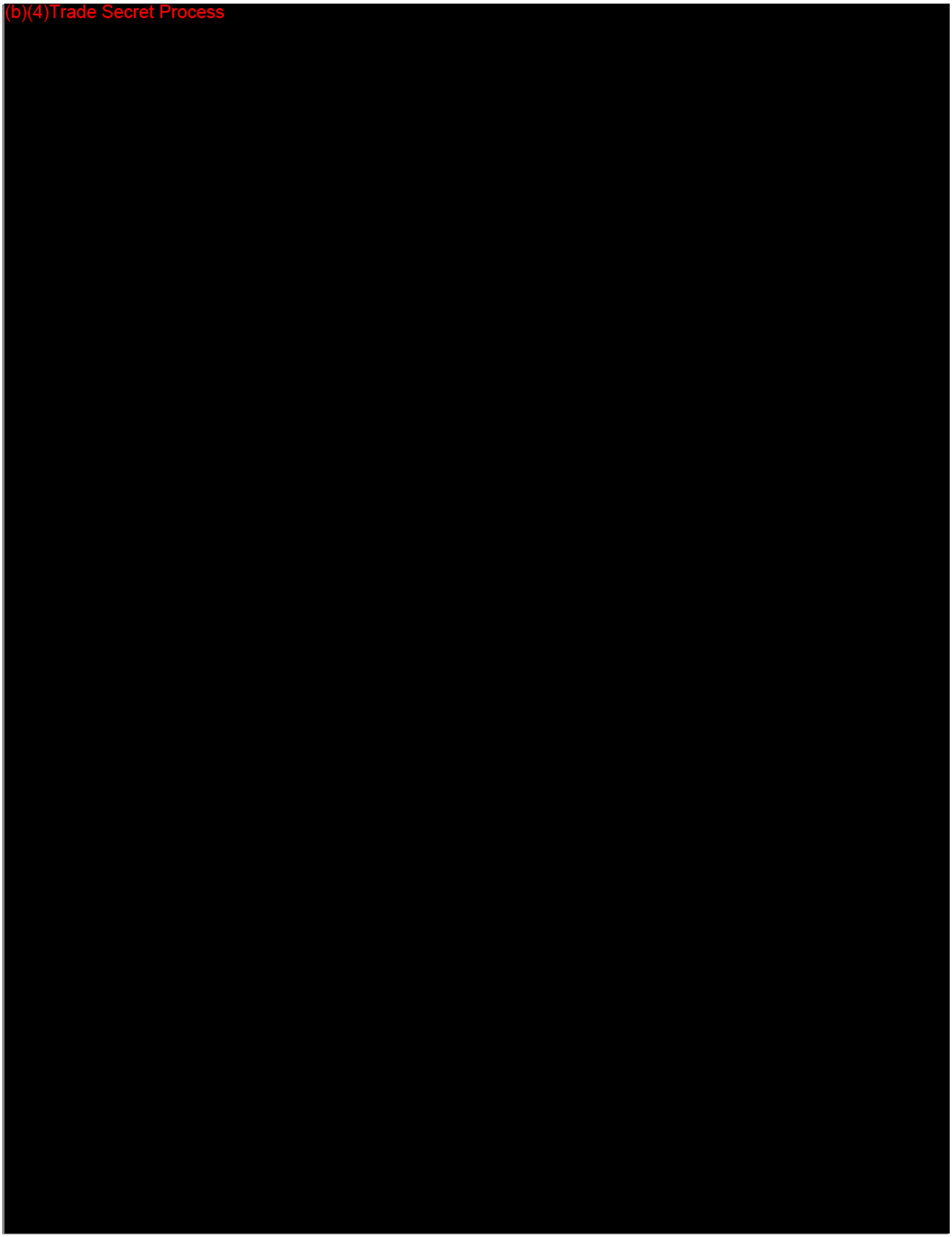

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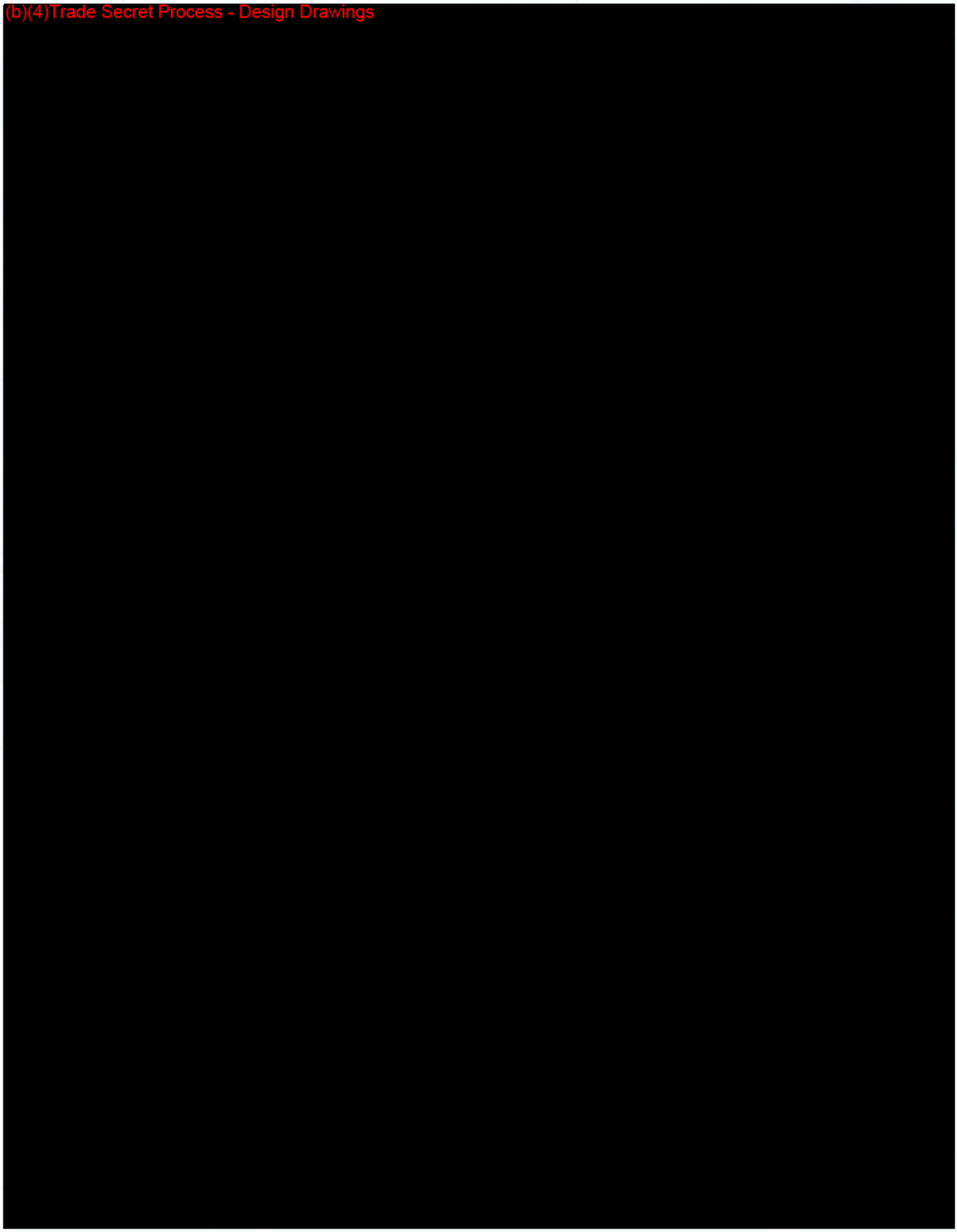

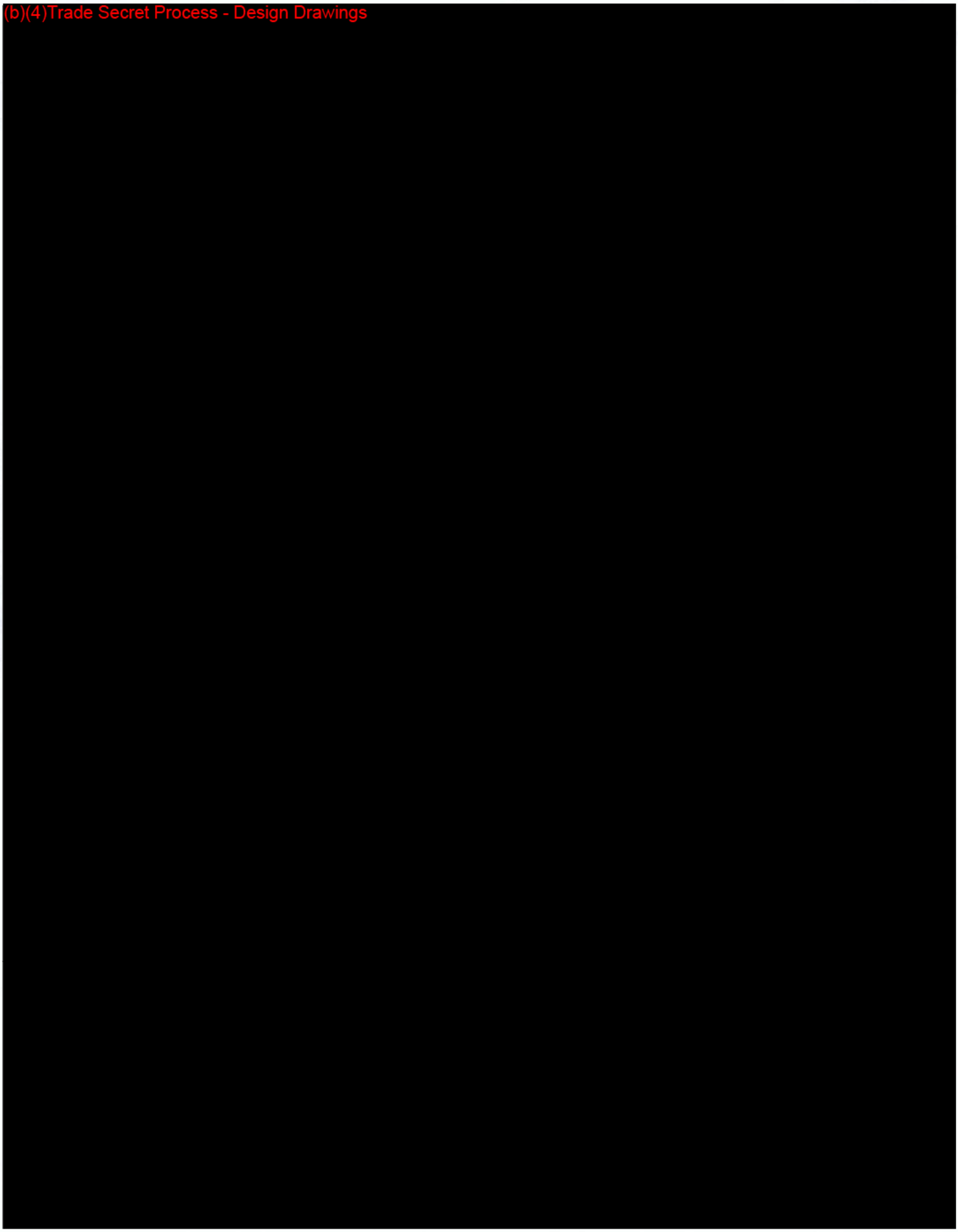
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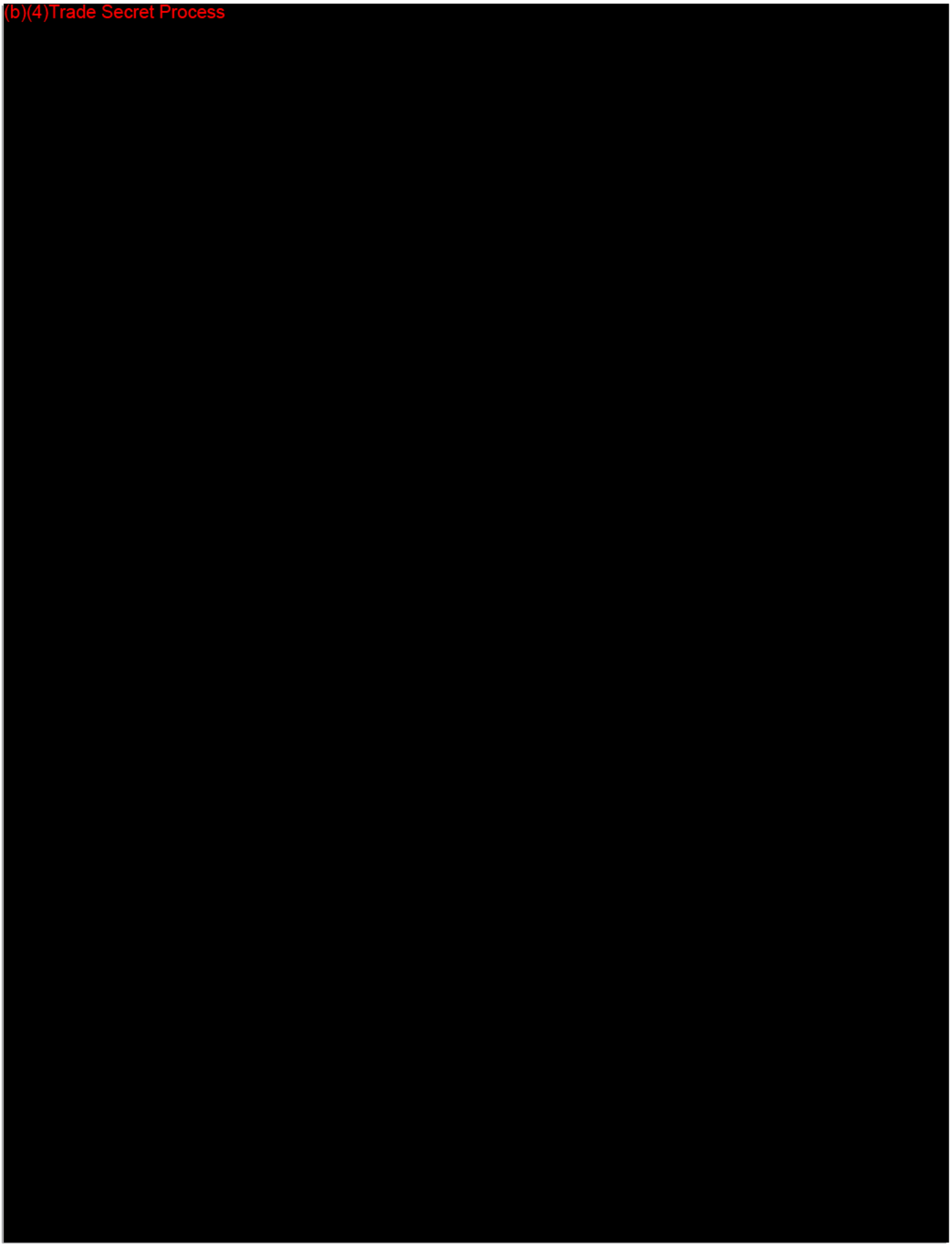

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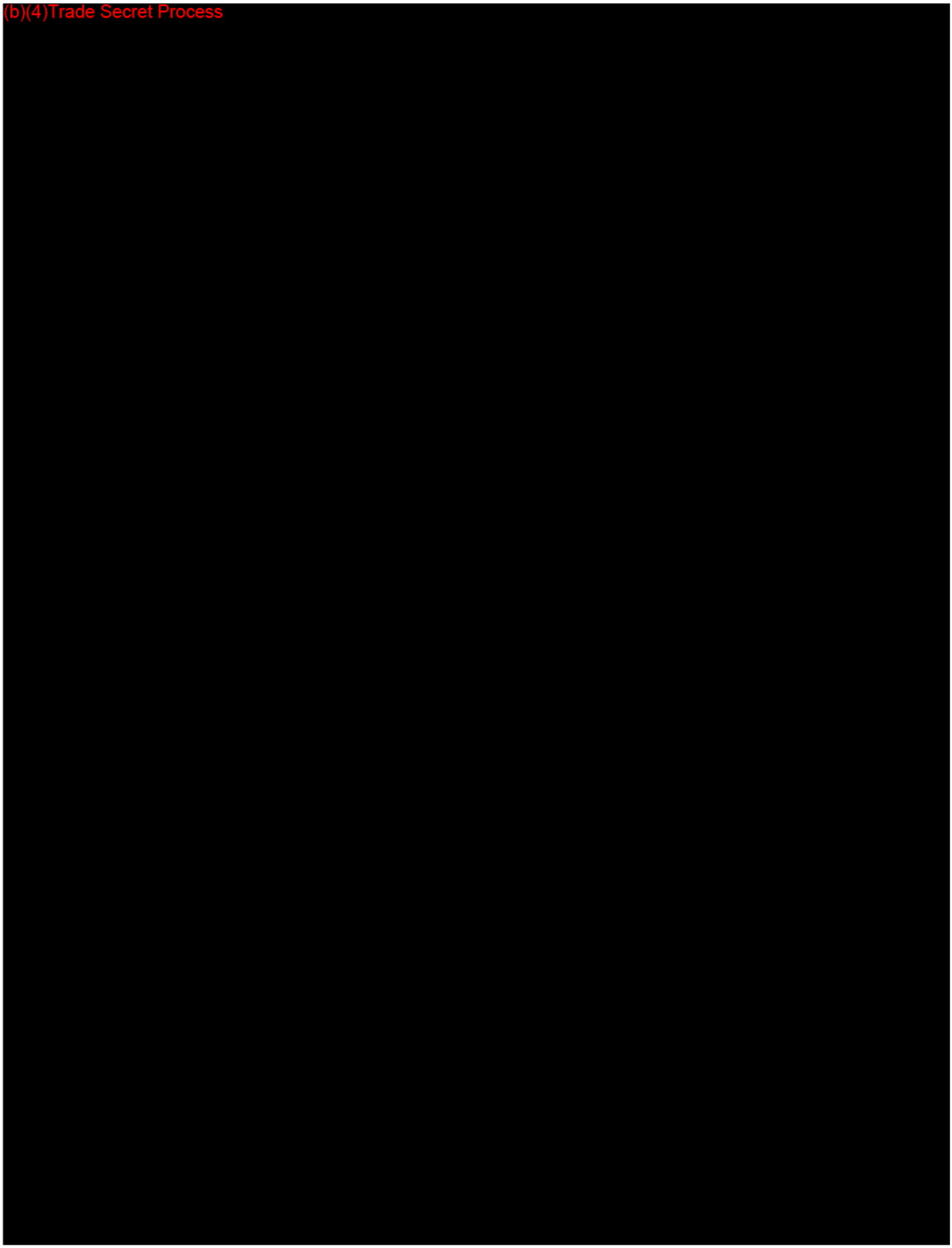

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Jeffrey L. Silberberg 7/21/2011
Jeffrey L. Silberberg
Senior Electronics Engineer
DESE/OSEL/CDRH
Date

A R Taylor 7-21-11
Alford R. Taylor, Jr.
Director, Division of
Electrical and Software
Engineering, OSEL/DESE
Date

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(b)(4)Trade Secret Process - Software Specs

(b)(4)Trade Secret Process - Software Specs

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(b)(4)Trade Secret Process - Product Legal Docs

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(b)(4)Trade Secret Process - Product Legal Docs

CITIZEN PETITION

OF

KALYPTO MEDICAL, INC. ("PETITIONER")

Re: Smith & Nephew PLC's Section 510(k) premarket notification of intent to market the "PICO" single use negative wound therapy device

DATE: June 10, 2011

TABLE OF CONTENTS

INTRODUCTION/EXECUTIVE SUMMARY 3

BACKGROUND ON NPWT AND SYSTEM CONFIGURATIONS 5

A. ACTION REQUESTED 10

B. STATEMENT OF GROUNDS 11

1. The PICO Patient Home Care Information guide and product description released with the European version of the device raise significant issues which may bar FDA clearance unless addressed.

2. Technological considerations to be examined before clearance of the PICO system.

CONCLUSION 18

C. ENVIRONMENTAL IMPACT 18

D. ECONOMIC IMPACT 18

E. CERTIFICATION 18

F. EXHIBITS 20

DUVAL & ASSOCIATES, P.A.

DuVal & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

612-338-7170 *Main*
612-455-0665 *Fax*
www.duvalfdalaw.com

June 10, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

Re: Citizen Petition under 21 C.F.R. § 10.30 (accompanied by a concurrently filed Petition for Stay of Action under 21 C.F.R. § 10.35).

To Whom It May Concern:

INTRODUCTION AND EXECUTIVE SUMMARY

On behalf of Kalypto Medical ("Petitioner"), the undersigned respectfully submits this Citizen Petition and accompanying Petition for Stay of Action under 21 C.F.R. § 10.30 and 21 C.F.R. § 10.35. Specifically, we request that the Commissioner refrain from and stay the FDA from granting Smith & Nephew, Inc. ("Smith & Nephew) marketing clearance for its recent 510(k) submission of the PICO single use negative pressure wound therapy (NPWT) device (the device hereinafter referred to as "PICO"). Petitioner obviously does not have knowledge of the precise device intended use statement and technological features submitted to FDA in its 510(k) submission or even that the trade name of the device will be "PICO" in the United States. The PICO device appears to be a second in class (the Petitioner's NPD 1000 being the first) electrically powered NPWT system that utilizes the wound dressing (or wound kit) to provide the wound exudates collection function. There are apparent technological similarities (and differences) between the PICO device and the already-cleared Petitioner NPWT system which can be gleaned from the PICO European Smith & Nephew website.[1]

Petitioner also recognizes that it does not know the predicates chosen by Smith & Nephew to support its 510(k) submission, nor does it know the scope of system testing

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[1] *See*, Smith & Nephew's PICO product information at http://wound.smith-nephew.com/uk/Standard.asp?NodeId=3865#WhatisPico (last visited June 2, 2011).

conducted by Smith & Nephew, so this Citizen Petition cannot comment with specificity on the substantial equivalence of the PICO device to Petitioner's NPD 1000 negative pressure wound therapy system (NPWT) or to any other device. This Citizen Petition, however, can and does comment generally on these issues. Petitioner points out to the Agency that there are two distinct pathways for analysis of the submission to determine substantial equivalence (and ensure patient safety):

1) **Using the NPD 1000 as a predicate**--What the Citizen Petition and Petition for Stay of Action do comment upon, are the issues Petitioner addressed in obtaining 510(k) clearance for its NPD 1000 system and a) issues that arise considering the similarities between the NDP 1000 and the PICO, and b) the potential issues raised by the unique features of Smith & Nephew's PICO system that differ from the NPD 1000. Petitioner wants to ensure that any NPWT device employing the wound interface (dressing) for exudate storage should be required to provide at least as much performance data as was needed to clear the NPD 1000. If the predicate is not the Petitioner's NPD 1000 NPWT system, it should be, and the Agency should require Smith & Nephew to demonstrate substantial equivalence (SE) to the NPD 1000, which would also include a comparison to it. In addition, Smith & Nephew must conduct performance testing demonstrating substantial equivalence especially focusing on differences in intended use and/or technological characteristics. ***In this situation, Petitioner suggests that its own deliberations with the Agency should serve as a guide for the examination of the submission.***

2) **Using the Legacy NPWT device(s) as a predicate(s)**--If the predicate(s) chosen by Smith & Nephew is not the NPD 1000 NPWT System, but relies on the legacy devices from Kinetic Concepts, Inc. ("KCI") and Smith & Nephew, then under the Agency's own 510(k) flow chart, the PICO's unique features represent technological characteristics that are different from those legacy devices for which there are unanswered questions of safety and effectiveness. This was the same analysis the NPD 1000 device went through to establish SE to the legacy devices. The first, most obvious, difference is that the PICO device, like the NPD 1000, employs a dressing for exudate storage instead of a canister. Smith and Nephew should be held to analysis and testing of the PICO device that would assure that safety and effectiveness questions have not been created by the obvious technological differences between a canister-based NPWT system and a NPWT system with a wound exudates stored in the wound interface (dressing). Again, these comparisons should be clear from an examination of the Agency/manufacturer deliberations associated with the clearance of Petitioner's NPD 1000.

For either chosen pathway, Petitioner respectfully requests that the Agency consider the dialogue its own reviewers had with Petitioner during the clearance process for the NPD 1000 NPWT System. A thorough analysis of previously discussed relevant technology will prevent subtle safety and effectiveness issues from being missed during the review. In particular, within this petition, Petitioner has identified several key technological discussion points that it feels are very relevant to the clearance process as the Agency works toward a precise determination that the PICO device is at least as safe and effective as its predicate(s).

Petitioner requests that the review process, standards and final performance data required of Smith & Nephew include the following, such that it:

a) compares their device to Petitioner's as the proper predicate;

b) truly meets the substantial equivalence standard by establishing same intended use and same technological characteristics and, if there are differences in technological characteristics, that unanswered questions of safety and effectiveness be addressed with appropriate data;

c) require performance data that are no less than what Petitioner submitted in its 510(k) submission and clearance;

d) take into consideration the additional and unique claims and technological features depicted by Smith & Nephew in its submission and ensure that any unanswered questions of safety and effectiveness raised by the new technological characteristics be answered by Smith & Nephew;

e) should be informed by the intended use claims made by Smith & Nephew for the PICO device depicted and represented on Smith & Nephew's website; and

f) be reviewed by knowledgeable technical personnel with a great deal of experience in the wound management field, powered suction pumps devices and superabsorbing dressing technology who can appreciate the issues discussed in this Citizen Petition;

g) require that Smith & Nephew follow the FDA's guidance document entitled "Guidance Document for Powered Suction Pump 510(k)s" dated September 30, 1998.

BACKGROUND ON NPWT AND SYSTEM CONFIGURATIONS

Negative Pressure Wound Therapy (NPWT) is the application of a controlled level of subatmospheric (negative) pressure, at 40 to 125 mm Hg below ambient pressure to the entire bed of a wound. A NPWT system is generally understood to consist of 1) a source of vacuum (most commonly an electrically powered mechanical vacuum pump), 2) a pneumatic connection mechanism (tubing), 3) a structure for storage of wound exudates, and 4) a wound interface (or dressing). Negative pressure is applied to the wound bed, from the vacuum source, through the pneumatic connection and the wound dressing. Subsequently, wound exudates are drawn from the wound and deposited in the storage structure (either a canister or in the dressing itself). The V.A.C. from Kinetic Concepts, Inc. was the first commercially available NPWT system in the United States, 510(k) #K945062. Since that time, NPWT has been revealed to be one of the most effective therapies in the treatment of chronic non-healing wounds.

In 2008, the Petitioner submitted for marketing clearance a NPWT system that changed the exudates collection paradigm from a canister to the wound dressing/interface itself. Since the issuance of the 510(k) clearance for the NPD 1000 NPWT system, this system has been used on

over 8000 patients in the US, and has become a valuable clinical tool for the wound care clinician. The work done by the Petitioner to attain 510(k) clearance was extensive and has been proven to have been thorough as evidenced by not a single adverse event being reported by clinicians/patients/vendors using this device on a daily basis for 2 ½ years. The lack of reported problems with the Kalypto system should not be construed as a proxy for the innocuous nature of the therapy. In fact, in November 2009, the Agency released a notification to public and health care professionals on observed complications associated with the use of negative pressure wound therapy in certain situations.[2] This warning was updated in February 24, 2011. Thus, with safety issues in mind, the Petitioner has, with the public information available, prepared a Table comparing the NPD 1000, KCI's V.A.C. and Smith & Nephew's PICO so the FDA understands the similarities and differences between them and the issues of safety and effectiveness they may present. The pictures remind the Agency that the NPD 1000 and PICO NPWT systems utilize a small portable pump and a wound interface/dressing that also plays the role of a canister.

With respect to the PICO system, it almost appears that in an attempt to capitalize on their existing technological platform. Smith & Nephew has force fit portions of their current passive wound dressing into an active NPWT system. This "one-size-fits-all" mentality, which in our opinion stretches the capabilities of their existing passive wound dressing, may not fit with the rigors of a wound interface (dressing) design needed when the system meets the realities of a patient engaged in activities of daily living. As evidence of this fact, please the following discussion thread on LinkedIn between Mr. Filippo Secchi, Global Director of Marketing NPWT at Smith & Nephew and United States wound care professionals:

> The top film of the PICO dressing has a high MVTR (moist vapour transmission rate), allowing evaporation, but is 100% impermeable to microrganisms, using an established S&N technology (it's the same top film used in other S&N products like Allevyn or IV3000).
>
> Posted by: Mr. Filippo Secchi, Global Director of Marketing NPWT at Smith & Nephew.

The advantage that Smith & Nephew could/should have taken advantage of is that it can compare itself to its true regulatory and market predicate –the NPD 1000 NPWT system. The 510(k) program requires that an applicant demonstrate that its device is at least as safe and effective as the chosen predicate. Whether or not Smith & Nephew has chosen the NPD 1000 as its predicate, FDA is informed by the features and benefits of this cleared device and surely can and will employ its pre-existing knowledge during its review of the PICO NPWT system. As such, to the extent Smith & Nephew has used labeling and technological variations from the NPD 1000 system, it should come under the microscope of FDA's review. We believe the PICO system differs markedly in many respects from the NPD 1000 and may not be "as least as safe and effective as" the NPD 1000. The remainder of this Citizen Petition raises the considerations that Petitioner believes FDA needs to examine very closely.

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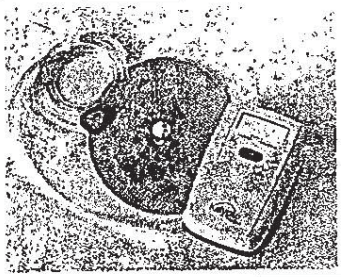
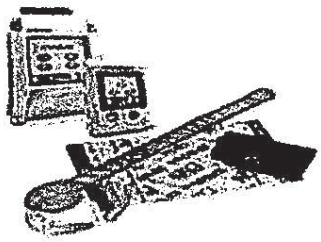
[2] *See*, FDA's website, FDA Preliminary Public Health Notification: Serious Complications Associated with Negative Pressure Wound Therapy Systems *at* http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm (last visited June 10, 2011.

Table 1: Comparison to Predicate Devices

	Petitioner Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	PICO (information below based on publically available information)
System Images			
510(k) Number Decision Date	K080275	K063692 06/07/2007	N/A
Manufacturer	Petitioner Medical, Inc.	KCI USA, Inc	Smith & Nephew, PLC
Classification	Class II	Class II	Class II
Product Code	OMP	OMP	OMP
Regulation	878.4780	878.4780	878.4780
Intended Use/Indication Statement	The NPD 1000 Negative Pressure Wound Therapy (NPWT) System is a portable, low powered, battery operated, suction pump intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudate and infectious material, which may promote wound healing.	The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	Unknown at this time. Description for CE Marked product made on Smith & Nephew website.[3]
Device Design	The NPWT system consists of a pump/control unit, tubing and a dressing with	The device consists of a pump/control unit with attached exudate collection	The NPWT system consists of a pump/control unit,

[3] *See e.g.*, Smith & Nephew's PICO Patient Home Care Information guide at http://wound.smith-nephew.com/FileManager/Public/RetrieveFile.aspx?DocumentGUID={EB580AD6-EEC9-4553-B2CC-0817703897AA}&b=2-PICO-patient-info-leaflet.pdf (last visited June 2, 2011).

Table 1: Comparison to Predicate Devices

	Petitioner Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	PICO (information below based on publically available information)
	an integrated exudate canister function and minimally adherent wound interface.	canister, tubing and a foam wound dressing that is not a minimally adherent wound interface.	tubing and a dressing with an integrated exudate canister function and minimally adherent wound interface.
Dimensions	3.2" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	–Exact dimensions unknown. Appears to be similar in size to Petitioner device. Smith & Nephew states, "PICO" is small enough to fit into a pocket or handbag. It's very discrete."[4]
Pump Pressure	40-125 mm Hg	25-200 mm Hg	80 mm Hg
Pressure Modes	Intermittent and continuous	Intermittent and continuous	Continuous only.
Weight	8 oz	2.4 lbs	Exact weight unknown. Appears to be similar in weight to Petitioner device.
Power; Battery Life	Alkaline battery; 3 weeks or more battery life	Lithium ion rechargeable battery; 14 hour average battery life	Lithium ion AA battery; up to 7 days life
Operating Temp. Operating Humidity	5°C to 40°C 0-95% non-condensing	5°C to 40°C 0-95% non-condensing	??? Exudate management is stated to rely on evaporation of exudate stored in dressing.
Operating Alt. Range	-1000 to 10,000 feet	0 to 8000 feet	???
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error	Visual alarms for low battery and low vacuum[5]

[4] *See*, Smith & Nephew's PICO product information at http://wound.smith-nephew.com/uk/Standard.asp?NodeId=3865#WhatisPico (last visited June 2, 2011).

[5] *See*, Smith & Nephew's PICO Patient Home Care Information guide at http://wound.smith-nephew.com/FileManager/Public/RetrieveFile.aspx?DocumentGUID={EB580AD6-EEC9-4553-B2CC-0817703897AA}&b=2-PICO-patient-info-leaflet.pdf (last visited June 2, 2011).

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Table 1: Comparison to Predicate Devices

	Petitioner Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	**V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)**	**PICO (information below based on publically available information)**
Collection Device	Intensively engineered NPWT dressings, featuring superabsorbing non-woven technology to maintain negative pressure at therapeutic levels with exudate capacities from 25 cc to 140 cc	300 cc collection canister attached to pump	Website states NPWT dressings with a gelling super-absorbing layer with exudate capacities greater than 300 cc[6]; no statements made about maintaining therapeutic levels of negative pressure during collection of wound exudate
Bandage	Multilayer assembly (from wound up): • minimally adherent wound contact layer • non-woven superabsorber pad for exudate collection • hydrogel gasket at perimeter of non-woven pad to maintain negative pressure, prevent air leaks common to NPWT dressings • hydrophobic filter to prevent exudate from leaving dressing • semi-occlusive laminate adhesive cover for maintenance of pressure and attachment of dressing to patient • negative pressure port with patient tubing with fail safe exudate stop in the patient tubing to prevent exudates	Multilayer assembly (from wound up): • hydrophobic reticulated polyurethane foam wound interface for passage of fluid from wound to canister • adhesive polyurethane film cover for maintenance of negative pressure and attachment of dressing to patient • T.R.A.C.® Pad and tubing to serve as negative pressure port and exudate delivery to canister	Multilayer assembly (from wound up): • minimally adherent wound contact layer • pressure distribution layer • gelling superabsorber layer for exudate collection • hydrophobic filter to prevent exudate from leaving dressing • semi-occlusive adhesive cover for maintenance of pressure and attachment of dressing to patient • negative pressure port with patient tubing

[6] *See*, Smith & Nephew's PICO product webpage indicating 300+cc capacity with 25cm x 25cm wound dressing, at http://wound.smith-nephew.com/uk/popup.asp?NodeId=3881&Hide=True&Tab= (last visited June 1, 2011).

Table 1: Comparison to Predicate Devices

	Petitioner Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	PICO (information below based on publically available information)
	from reaching the pump and subsequent aerosolization		
Sterility	Only bandage provided sterile	Only bandage provided sterile	Assumed dressing provided sterile
Sterilization Method	Radiation	Radiation	???

A. ACTION REQUESTED

By this Citizen Petition, the undersigned hereby requests that FDA refuse to grant 510(k) clearance for Smith & Nephew's PICO device until Smith & Nephew has addressed, to the satisfaction of the Agency, the ability of the PICO pump and dressing technology to mitigate the potential patient safety issues discussed in this Petition. These safety issues are raised by the potential differences in intended use and the known technological characteristics of this device (system) relative to previously cleared devices, as ascertained from publically available information. The issues discussed in this Citizen Petition (with impact on patient safety and therapeutic performance) which Petitioner believes the Agency must apply are, in short, as follows:

- **Does the dressing exudate capacity for the PICO dressing configuration meet FDA's definition of "small amount?"**—The PICO system offers a wound dressing with a wound exudate capacity of >300cc, comparable to the exudate capacity found in canister-based NWPT systems, such as KCI's V.A.C. The Agency has unequivocally stated in the past that a volume this large would not be considered small and may compromise the ability of a portable NPWT system to function in a safe and effective manner. Petitioner's system is labeled for a "small amount" which is defined in its quality system as 150cc or less, per Petitioner's deliberations with the Agency;

- **Compatibility with wound fillers?**—The Smith & Nephew PICO website makes claims regarding the compatibility of the system with wound fillers. Has verification testing data been submitted with the PICO 510(k) to substantiate this claim? In particular, which fillers and foams have been tested for compatibility with the system?;

- **Seal Maintenance**—With a small portable battery-operated pump (with limited pumping capacity), is the PICO dressing technology able to maintain therapeutic levels of negative pressure (i.e. proper seal) given the dressing's size and no discernible "seal" design element on the dressing itself?;

- **Exudates Recirculation**—Has the manufacturer examined the safety issues surrounding the potential for exudate and infectious material to return to the wound when the dressing reaches its exudates capacity? Additionally, has the manufacturer explained, to potential users both clinicians and patients, in its labeling, how to address such situations?;

- **Is the exudate storage method in the dressing compatible with negative pressure delivery?**—The use of superabsorbing gel in the dressing to store exudate and the ability of the dressing to maintain negative pressure administration at the wound bed would seem to be in conflict given the inability of a truly "gel" layer to breathe and the fact that the gel layer seems to exist between the negative pressure port and the wound bed; and

- **Is evaporation a reliable design aspect?**—The ability of the dressing to utilize evaporation as a method to control exudate levels in the dressing is a questionable engineering strategy. Evaporation is dependent on a positive pressure gradient across the membrane in question. Given that one is trying to move water vapor from a negative pressure environment in the dressing (relative to atmospheric pressure) to a positive pressure environment outside the dressing. This would seem to be violate the laws of diffusion. If one assumes that a positive pressure gradient might somehow exist, then environmental factors such as temperature and relative humidity will play a role. For a patient living in a humid and warm environment, such as the southeastern United States, using a PICO dressing that relies on evaporation for its performance, i.e. effectiveness, will likely fail to meet labeled claims.

By addressing these concerns, which predecessors operating in the NPWT space have done, FDA ensures patient safety, adheres to the substantial equivalence standard and creates a level competitive playing field. We elaborate on the issues identified above, more specifically below.

B. STATEMENT OF GROUNDS

1. Issues of Same Intended Use--The PICO Patient Home Care Information guide and product description released with the European version of the device raise significant issues which may bar FDA clearance unless addressed.

- **300+cc is not a "small amount."**—***The 300+cc dressing capacity of the PICO dressing does not meet the "small amount" standard established for an NPWT device of this type (and incorporated into the indications for use statement) with previous submissions.***

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The larger exudates capacity superabsorbent NPWT wound dressing, marketed on the Smith & Nephew website, for use with the ultraportable PICO pump, creates potential performance issues which may impact patient safety during treatment. The problems associated with such large surface area dressings are potentially many, but first a review of the Agency's thinking on this issue (as discerned by the Agency's discussions with the Petitioner) is in order.

Furthermore, Smith & Nephew has already begun touting the advantages of a 300cc dressing in pre-clearance discussions/promotion with United States health care professionals on LinkedIn as evidenced by the discussion threads set forth below.

> PICO follows a similar concept: does not need a canister, because the dressing uses a proprietary technology to distribute NPWT and managing the exudate at the same time. A 10x20cm PICO dressing will manage up to 300ml of exudate in seven days of therapy, with a combination of absorption and evaporation. The main difference between Kalypto and PICO is that PICO has a fixed -80mmHg NPWT setting, is smaller (2"x2"x0.5"), and is disposable, each kit providing 7 days of therapy, with 1 pump and two dressings. At the moment, PICO is available in Europe, Australia and South Africa. Commercialisation in US will follow FDA approval, expected in the 3rd quarter of the year.
>
> Posted by: Mr. Filippo Secchi, Global Director of Marketing NPWT at Smith & Nephew. Please see discussion thread attached hereto as Exhibit A.

The Agency has indicated in the past that handheld portable negative pressure wound therapy devices (such as both the Petitioner NPD 1000 and the PICO device), utilizing the dressing as a canister, are not as suited to control large amounts of exudate and infectious material as is done with their larger canister-based predecessors, e.g. Kinetic Concepts Inc.'s Vacuum Assisted Closure device. During the clearance process of Petitioner's NPD 1000 Negative Pressure Wound Therapy System, K080275, the FDA recommended Petitioner reform their Indications for Use statement to specifically limit the use of the system to treatment of wounds needing the removal a "small amount" of exudate and infectious material from the wound. This suggestion was made by Dr. David Krause, FDA, Branch Chief, Plastic and Reconstructive Surgery Branch during the review process.

- **Compatibility with wound fillers?**—***The Smith & Nephew PICO website makes claims regarding the compatibility of the system with wound fillers. Has verification testing data been submitted with the PICO 510(k) to substantiate this claim? In particular which fillers and foams have been tested for compatibility with the system?***

This topic was explored during Petitioner's 510(k) review. The Agency specifically requested an explanation for the presence/use of terminology related to this subject in Petitioner's IFU. The exact question is set forth below, taken from the AI letter to Petitioner:

> 1. Please explain this statement found in your labeling: "For cavity wounds a standard wound filler such as gauze or foam must be used." Please submit performance data to demonstrate how your device will function with gauze or foam present in the wound.

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Given this question, Petitioner respectfully requests that the Agency address the same issue with Smith & Nephew, in light of the following language found on Smith & Nephew's website for the PICO system:

> PICO* is compatible with the standard fillers of foam and medicated gauze used with conventional NPWT if this is necessary.

It would seem reasonable and appropriate for FDA to require Smith & Nephew to provide data for each ancillary material that is claimed to be compatible with the function of the PICO NPWT system.

2. Technological considerations to be examined before clearance of the PICO system.

- **Seal Maintenance**—***This issue explores the ability of the PICO dressing to maintain therapeutic levels of negative pressure vacuum (i.e. proper seal) given its size.***

The issue of the dressing "seal" is an important one in the design of an NPWT system. The "seal" allows the air pressure in the interior of the dressing to be maintained at "negative" levels (relative to atmospheric pressure). This negative pressure environment is what causes exudates to flow out of the wound as part of the healing process. Without negative pressures, wounds may "ooze," but the volume of exudates produced will be greatly diminished in general. Thus, the importance of the "seal" becomes self-evident. No negative pressure = No therapy.

Marketing materials and user perception propose that with the canister-based NPWT systems, the "seal" is provided by the adhesives on the polyurethane film that is used to create the barrier in the foam or gauze dressing. In truth, adhesives are generally known to provide a rather poor "seal" and negative pressure is maintained in the dressing by the large flow rate possible with a large electromechanical vacuum pump. That is, the pump is capable of removing much more air per second from the dressing than is seeping in through the rather poor seal created by the adhesives. The Petitioner has demonstrated this on the bench with an "idealized" wound model. The small portable pump of the NPD 1000 NPWT system cannot even pump the air out of a standard canister-based dressing system in this model. Negative pressure is never created. Thus, the Petitioner created its hydrogel gasket system to create a better seal on its own dressings and substantiated its performance with verification testing submitted to the Agency as part of its 510(k) file for the NPD 1000 NPWT System.

The PICO system also has a small pump. Thus, in order to maintain continuous therapeutic negative pressure, consistent with clinical expectations, the system must have design elements that address this dressing "seal" issue. From an inspection of available data on the website regarding product design, and Petitioner knowledge of the internal capabilities and materials available to Smith & Nephew for the design of a "seal" element, it is NOT clear that this important issue has been addressed in a robust way. The Petitioner believes it would be prudent of the Agency to work with Smith & Nephew to assure that this crucial system element for a portable NPWT system is addressed with the concern it deserves.

- **Exudate Recirculation—*This issue explores the potential for exudate and infectious material to return to the wound when the dressing reaches capacity and the management of such a situation, or when there is a power failure with the device.***

Another issue associated with Smith & Nephew's anticipated intended use, as gleaned from the extensive promotional materials on its website, is the potential issue of wound exudate and infectious materials to recirculate into the wound bed due to i) local dressing exudate filling issues, or ii) the loss of dressing exudate storage function due to the application of local mechanical forces. In order for a dressing to function properly without compromising patient outcomes, the dressing needs to be able to "wick away" and "lock" wound exudate and infectious material into the dressing so it is not re-introduced into the wound bed. Recirculation of the wound fluid due to a dressing storage failure can have a couple of major effects on the wound and surrounding tissue, i.e. wound reinfection and tissue maceration from free fluid. Both are long-standing issues in negative pressure dressing technology. In fact, this was another topic on the conference call on April 29, 2008 between the Agency and Petitioner in discussions regarding the safety of the dressing technology. Additionally, this topic was the subject of an Agency request of the Petitioner for Additional Information (AI) with the following question:

> 7. You listed a device component as a "Super absorbent non-woven polymer matrix". Your biocompatibility refers to this product as KM30-V. This does not appear to be a previously cleared 510(k) product for KM30-V. Please characterize this material based on the chemical composition. Please identify how this product has been evaluated for toxic effects and potential leaching effects. Additionally, you have shown that this polymer matrix can be squeezed to release fluid. ***Please demonstrate how this polymer matrix will not release fluid back into the wound.*** Lastly, please demonstrate how will negative pressure be administered to the wound in the presence of this polymer matrix. (Emphasis added).

Smith & Nephew must describe measures to mitigate these risks prior to clearance of the PICO device.

--The problem with "free" wound fluid. "Free" wound fluid is a problem for NPWT performed on chronic wounds. The constituents of wound exudates are bacteria, cytokines, MMPs and other biochemical and biological entities. Chronic wounds often fail to heal due to a dyspopulation, i.e. shortage or excess, of one or more of these elements relative to the biologically needed level. One of the ways NPWT helps correct this dyspopulation is to literally suction away all of the "bad" actors to allow the body to establish a new equilibrium, preparing the wound substrate for healing. Free wound fluid disrupts these effects by allowing already removed elements to return, disrupting the population balance. Once captured the NPWT cannot let the free wound fluid escape or recirculate back into the tissue where it can cause problems.

Additionally, with the large PICO dressing, it is apparent that some of the dressing will be covering healthy tissue, like the Petitioner's wound dressing. If the PICO dressing is indeed covering healthy tissue and there is free fluid, skin maceration will result, potentially destroying the healthy skin and enlarging the wound.

--The issues of local mechanical forces and loss of negative pressure. To prevent recirculation of exudates and the problems listed above, the capabilities of the fluid storage technology must be well-understood and described. With a large 25 cm x 25 cm dressing, the two failure mechanisms are as follows: a) returning of exudates to the wound bed under the application of local mechanical forces, such when a patient with a PICO dressing on his/her leg gets bumped during ambulation--this could cause wound fluid to "squeegee out" of the dressing, like when a sponge is squeezed; and b) local loss of negative pressure due to "gelling of the exudates storage in the area" resulting in a failure to capture exudates as they are produced.

The concept of local loss of negative pressure (i.e. no negative pressure in some discrete physical area within the dressing) is another potential failure mechanism. The absorbent layer is described as a gel. If in a distal portion of the dressing a great deal of wound exudates is produced in the wound bed, the sheer size of the dressing and small pumping capacity of the pump may conspire together to render the system unable to distribute these exudates throughout the dressing. This process may lead to a local gelling of the absorbent layer and a loss of negative pressure under the gel. No negative pressure implies that fluid will no longer be drawn into the dressing and be free to recirculate across the wound bed and surrounding tissues in this area of "no pressure."

For a portable NPWT system, use of the dressing on an ambulatory patient is a foregone conclusion. Unlike large bedside canister systems, which could be plausibly intended for bedridden patients, the PICO system will be and is marketed to wound patients on the go. This being the case, it is very likely that the wound dressing will need to withstand the physical punishment brought on by the activities of daily living (ADLs) of its wearer. In particular, it will need to retain wound exudates in the storage layer even when larger mechanical forces have been applied to the dressing, such as might happen when i) the patient lays on the dressing, ii) has the dressing compressively wrapped (as is common in the treatment of venous ulcers), or iii) the dressing is subjected to accidental mechanical forces, such as banging the dressing against a physical object during ambulation. As a part of the 510(k) submission of the Petitioner's NPD 1000 NPWT system, the company provided testing of its dressing technology that showed the ability of the dressing to retain fluid to its labeled capacity in the presence of large mechanical forces.

--Summary. The issue of "free" wound fluid is a serious one in NPWT, with many ramifications for therapeutic effectiveness of the device and the safety of the patient using the technology. Petitioner requests that the Agency, in conjunction with Smith & Nephew, explore this problem and make sure that it has been i) thoroughly addressed in design and labeling of the PICO product, and ii) appropriate mitigations are in place in the event of product malfunction such that risks to patient safety have been minimized.

- **Is the exudate storage method compatible with negative pressure delivery?—*This issue explores the use of superabsorbing gel in the PICO dressing to store exudate and the ability of the dressing to allow it to maintain negative pressure administration given the inability of gel to breathe.***

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Pressure maintenance under the dressing may be compromised because a "gel" superabsorbent layer is used in the PICO dressing. The main objective of NPWT is to keep the

wound bed subjected to negative pressure to facilitate the flow of harmful wound exudates out of the wound to re-establish biological normalcy to the wound, such that the healing process can begin. Any design aspect of an NPWT system that potentially impedes or suppresses the administration of negative pressure to the wound bed, without notifying the clinician/user, is a patient safety issue. Pressure maintenance under the dressing should be independent of both dressing size and fluid absorbed (up to the dressing fluid capacity, see next item) as it is filled. However, the PICO dressing is described as having a superabsorbing gel layer for the capture of exudates. This gel layer is described as residing as a two-dimensional structure between the pressure port and the wound contact layer. Thus, it would seem that negative pressure must be administered "through" it.

In its commonly understood usage, the term "gel," is an extremely viscous fluid, with no passageways for air, such that the layer would be antithetical to administration of negative pressure to the wound bed. The absorbent layer is described as "gelling" as it absorbs fluid. Assume for a moment that exudates are being produced in one small physical region of the wound, would the gel layer occlude only locally when exposed to the wound fluid right where the fluid enters the layer? Or would it be transported throughout the entirety of the dressing? Petitioner speculates that this would depend on how quickly the "gel" is formed. Once formed however, what is the pressure reading in the vicinity of the occlusion? Is it the therapeutic pressure setting on the pump? Or some lower pressure? The issue of consistency of negative pressure delivery through the absorbent layer was discussed, at great length by Petitioner with the Agency on June 27, 2008 (Dr. Krause and Susan Malli in attendance for the agency among others). Petitioner's design, testing and labeling passed muster with the reviewers. We encourage FDA to explore this issue further with Smith & Nephew.

- **Is evaporation a reliable design aspect?—*This issue explores the ability of PICO to allow for the dressing to utilize evaporation (the term "transpiration" is used somewhat inappropriately by Smith & Nephew) as a method to control exudate levels is questionable given the large rate at which exudate is produced by most wounds, (300+cc) and is especially questionable when the system is used in of the dressing and the humid and warm environments of the wound bed.***

  (**Note**: If Smith and Nephew truly does mean "transpiration," which is defined as the transport of waste products (not fluid) through the pores of the skin of plant tissue, the implication is that bacteria and other noxious biochemical entities leach out of the dressing. This would seem to be a huge patient safety issue since most wound dressings are designed to contain these wound byproducts. Smith & Nephew has assigned marketing cachet and import to the word "transpiration" since it has been using this term in public forums. The Agency needs to ensure it both understands the context of this term and that it is substantiated before Smith & Nephew uses this term promotionally.)

In order for the PICO dressing to work, it is dependent on evaporating large amounts of fluid. Relying on evaporation as a design characteristic is a shaky design strategy. Assuming it is possible, this fluid control mechanism presents issues in certain climates where conditions are not ideal. The design of the PICO dressing is dependent on evaporation for management of exudates. As to why evaporation is needed with a superabsorbing gel layer in the dressing is a mystery to the Petitioner and poses a safety issue upon closer inspection. Petitioner's dressing

wicks and locks a known volume of fluid into its absorbent pad and it stays there until the dressing is changed. This technology was discussed a great length with the Agency and Petitioner submitted data showing the fluid capacity of the dressing in bench top testing. The storage volume is marked on the labeling of every dressing package for easy clinical decision-making based on the estimate of the daily volume of wound fluid produced by the treated wound while receiving NPWT. (Note: The volume of fluid produced by a wound greatly increases under the influence of applied negative pressure, making dressing fluid capacity a vitally important input to the clinical decision.) With the PICO product, it does not seem that this clinical decision will be that easy to make.

The transport rate of vapor across a membrane (evaporation), in this case the transparent cover of the PICO dressing, depends upon many factors. In the field of medical films, such as a product like Tegaderm™ from 3M, this evaporation rate is known as MVTR (Moisture Vapor Transmission Rate also known as Water Vapor Transmission Rate (WVTR)).[7] A simple derivation from Fick's first law of diffusion quantitatively models MVTR and allows us to predict evaporation. MVTR is directly proportional to the difference in partial pressure across the membrane through which the vapor is to be transported (or its proxy, relative humidity). It is a potential physics conundrum that if the interior of the dressing is at a "negative" pressure, relative to atmospheric pressure outside the dressing, how is it possible to transport any water vapor across the membrane? In fairness, the interior of the dressing is at 100% relative humidity and the exterior will be somewhat lower depending on local conditions, so some evaporation "may" occur. However, in a humid environment like Savannah, Georgia in the summer, it is a dubious fluid management strategy at best. Additionally, the science of evaporation is dependent on temperature in a complicated exponential fashion.

Since PICO's product performance may be dependent on suspect physics and is clearly dependent upon uncontrollable external environmental conditions. The device, at the very least, cannot be cleared the way it is currently marketed on its European website. This fluid management issue is complex enough that it may not be SE at all the way the product is currently designed. Perhaps the dressing could be labeled to indicate a range of exudate capacities that are achievable depending on the relative humidity and temperatures. This would obviously require testing and investigation to assemble a table, for the IFU, covering the possible temperature and humidity extremes seen in the US. However, we think this would just create confusion in the physician and patient community by asking them read such a table and to factor such esoteric and uncontrollable atmospheric conditions into the treatment decision. This confusing information is most likely to be ignored, resulting in potential patient harm when the PICO system does not behave according to expectations and therefore delivers a substandard therapeutic result.

Petitioner is not the only one raising this issue. In the same LinkedIn discussion attached hereto as Exhibit A, one participant raises this same issue. Please see the comment below.

[7] The concept of WVTR is discussed more fully in the following peer-reviewed article: Lahtinen, K. &Kuusipalo, J. 2007. Prediction of WVTR with general regression models. 11th TAPPI European PLACE Conference, 14-16 May 2007, Athens, Greece pp. 1-17. Available at: http://www.tappi.org/content/events/07europlace/papers/07europl36.pdf (last visited June 10, 2011).

> The Kalypto device uses a high pressure, which enables it to handle a wound with a higher effluent rate. True, it is not disposable, but that may be reflected in a lower cost/patient. This remains to be seen when the PICO is introduced in the USA. ***Furthermore, I am curious about the evaporation of exudate. Does this mean that there is exposure of the dressing to air? How would this work??? Would this allow discharge of wound bacteria into the environment?*** (Emphasis added.)
>
> Posted by: David Wishnew, M.D. Chief, Wound Care Division, Austin Surgical Hospital at Austin Wound Care and Hyperbaric Center . Dr. Wishnew has no affiliation with Kalypto Medical, Inc. (**Note:** the last sentence quoted above underscores concern with the use of the term "transpiration" that was discussed earlier in this Citizen Petition.)

When independent third parties of this stature and experience raise the same issue, it should be considered. We encourage FDA to explore this issue further.

CONCLUSION

There are many serious issues for FDA to explore with Smith & Nephew on its PICO system. We encourage FDA to not only revisit with Smith & Nephew the types of questions it has raised with Petitioner, but to also consider the differences in the intended use/indications for use and the technological characteristics raised by the unique features of the PICO system. FDA should also consider issues that may be raised by a review of statements made by Smith & Nephew on its website regarding the capabilities of the PICO system. We respectfully request that the Agency not clear the Smith & Nephew PICO NPWT system unless and until these unanswered questions of safety and effectiveness are answered to the Agency's satisfaction.

C. ENVIRONMENTAL IMPACT

According to 21 C.F.R. § 25.30(h), this Citizen Petition qualifies for a categorical exclusion from the requirement for the submission of an environmental assessment.

D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this Citizen Petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Citizen Petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Citizen Petition.

279

Respectfully submitted,

Mark E. DuVal, Esq.
Mark E. Gardner, Esq.
On behalf of Petitioner Kalypto Medical, Inc.

DuVal & Associates, P.A.
Medical Arts Building, Suite 1820
825 Nicollet Mall
Minneapolis, MN 55402
Phone: (612) 338-7170

EXHIBIT A

Follow Karl

PR Newswire

Smith & Nephew introduces the first, pocket-sized, canister-free, portable Negative Pressure Wound Therapy system in the EU | SYS-CON MEDIA *sys-con.com*

SYS-CON Media, NJ, The world's leading i-technology media company on breaking technology news.

16 days ago

Pam Chelesvig, **Harald Kuhlmann**

13 comments

Follow Pam

Pam Chelesvig • I think that the "first, pocket-sized, canister free, portable" description is not accurate. I believe that "first" belongs to Kalypto Medical.

14 days ago

• Flag as inappropriate

Follow Linda

Linda Hertz • I can't even read the article..it makes you download or buy some free program?

9 days ago

Follow Lisa

Lisa Hezel, RN WCC CHT • I agree with Pam. I'm surprised at S&N

9 days ago

Follow Paul

Paul Saunders • Is Kalypto's device disposable? I think that's where S&N are heading, the combination of all the features.
8 days ago

Follow David

David Wishnew • The key in this announcement is that the device from Smith & Nephew is being introduced in the EU (Europe). I have spoken with the Kalypto rep, and he tells me that Kalypto is not in Europe. So S&N announcement is technically correct
7 days ago

Follow Filippo

Filippo Secchi • Yes, actually PICO has been introduced in Europe, where Kalypto is not present, but I would also kindly invite you to try to carry Kalypto in your trousers pocket and then try PICO... All the devices currently in the market, except PICO, require to use some sort of bag, which can be carried attached to your belt or with a strap:
6 days ago

Follow David

David Wishnew • Actually, the Kalypto pump is quite small and easily fits in a pocket or clipped to a waistband. Furthermore, it does NOT require a canister or bag to collect wound effluent.
6 days ago

Follow Filippo

Filippo Secchi • PICO follows a similar concept: does not need a canister, because the dressing uses a proprietary technology to distribute NPWT and managing the exudate at the same time. A 10x20cm PICO dressing will manage up to 300ml of exudate in seven days of therapy, with a combination of absorption and evaporation. The main difference between Kalypto and PICO is that PICO has a fixed -80mmHg NPWT setting, is smaller (2"x2"x0.5"), and is disposable, each kit providing 7 days of therapy, with 1 pump and two dressings. At the moment, PICO is available in Europe, Australia and South Africa. Commercialisation in US will follow FDA approval, expected in the 3rd quarter of the year.
5 days ago

Follow Mindy

Mindy Schuller BSN, RN, CWOCN, CFCN • I agree with these points. The key point S/N is making is first in Europe of its kind. As WOCN nursing, I have used the Kalypto on occasion and this product is likely the same. It seems misleading however, that the advertising states "first" even though it is first in Europe. Perhaps there could have been a stronger selling point to differentiate so the first thoughts on the product do not seem misleading and unclear to anyone who has used Kalypto or aware of it. Just my thoughts.
5 days ago

Follow David

David Wishnew • The Kalypto device uses a high pressure, which enables it to handle a wound with a higher effluent rate. True, it is not disposable, but that may be reflected in a lower cost/patient. This remains to be seen when the PICO is introduced in the USA. Furthermore, I am curious about the evaporation of exudate. Does this mean that there is exposure of the dressing to air? How would this work??? Would this allow discharge of wound bacteria into the environment?
4 days ago

Follow Filippo

Filippo Secchi • The top film of the PICO dressing has a high MVTR (moist vapour transmission rate), allowing evaporation, but is 100% impermeable to microrganisms, using an established S&N technology (it's the same top film used in other S&N products like Allevyn or IV3000).
3 days ago

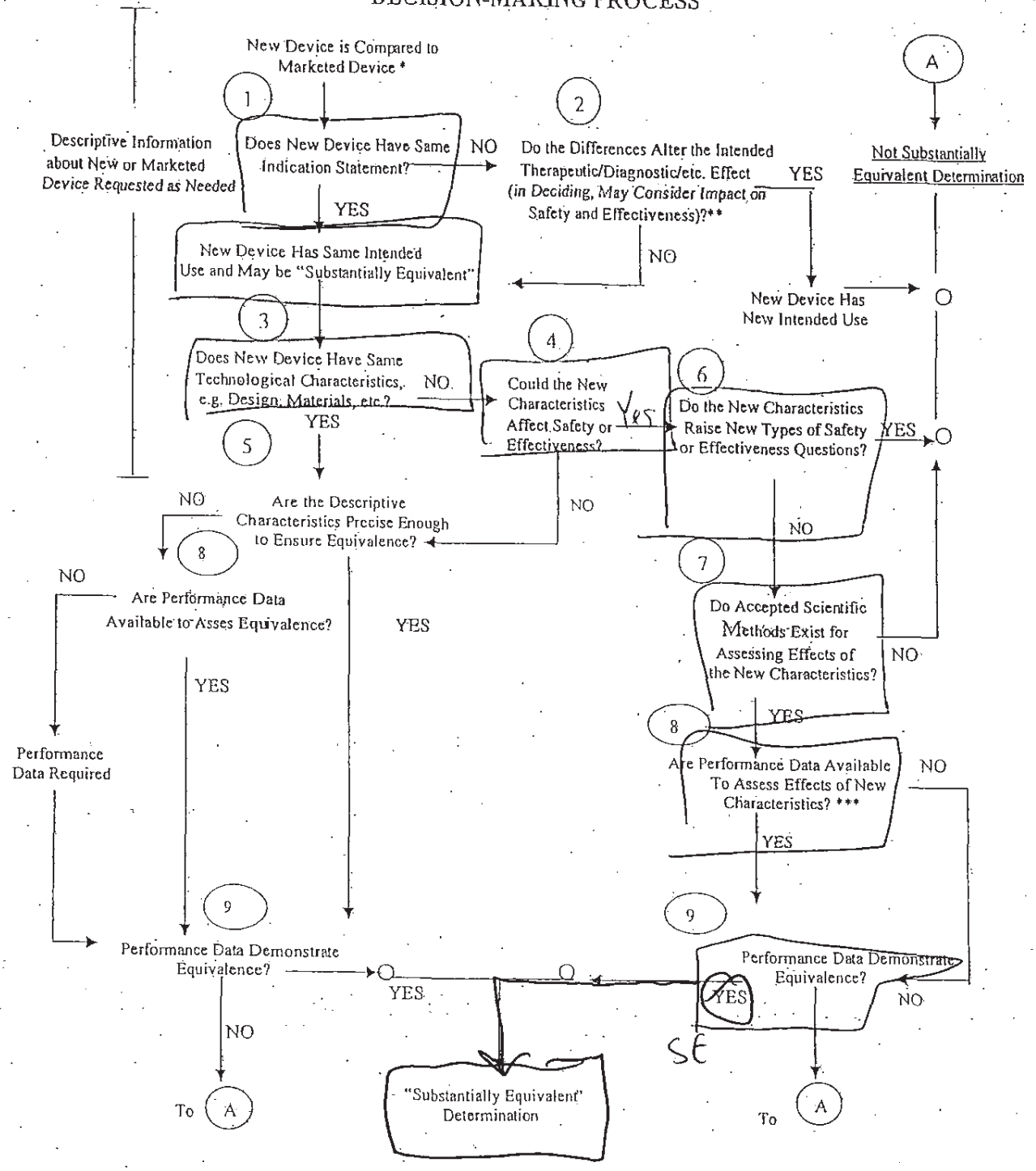
Follow Caryl

Caryl Perdaems • I am not convinced with either of the products. Research, and customer support is essentially in any and all NPWT devices. Just because it pulls drainage doesn't mean it delivers full VAC therapy. I may be convinced otherwise, someday.
23 hours ago

Follow David

David Wishnew • I feel that we were discussing the claim by S&N that PICO was the first non-cannister device in Europe. And although it may well be, it is not the first device of its type. I have used the Kalypto on shallow, low effluent wounds with good success. It is NOT a VAC and I do not think that the Kalypto competes with the KCI device. They compliment each other and each ought to be used in particular circumstances.
23 hours ago

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

SU / DSORD

K111870/S1

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F 727 392-6984 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com

September 20, 2011

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Center for Devices and Radiological Health
Document Mail Center – WO66-G609
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Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 21 2011
Received
K59

RE: (b)(4)Trade Secret Process - Product Specs

Dear Sir or Madame:

(b)(4)Trade Secret Process - Product Specs

Sincerely,

Terry C. McMahon
Director, Regulatory Affairs and Quality – N.A.
Smith & Nephew, Inc.
Advanced Wound Management

K111170/S2
SUDSORO

We are smith&nephew

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December 12, 2011

FDA CDRH DMC
DEC 13 2011
Received
K23

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Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: (b)(4)Trade Secret Process - Product Specs [redacted]

Dear Sir or Madame:

(b)(4)Trade Secret Process - Product Specs [redacted]

Sincerely,

Terry C. McMahon
Director, Regulatory Affairs and Quality – N.A.
Smith & Nephew, Inc.
Advanced Wound Management

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We are smith&nephew

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Sincerely,

Terry C. McMahon
Director, Regulatory Affairs and Quality – N.A.
Smith & Nephew, Inc.
Advanced Wound Management

INFORMATION FOR THE 510(k) #K111170 PICO SINGLE USE NEGATIVE PRESSURE WOUND THERAPY SYSTEM INFORMATION TO RESPOND TO FDA REQUEST FOR ADDITIONAL INFORMATION DATED 18TH NOVEMBER 2011

December 2011

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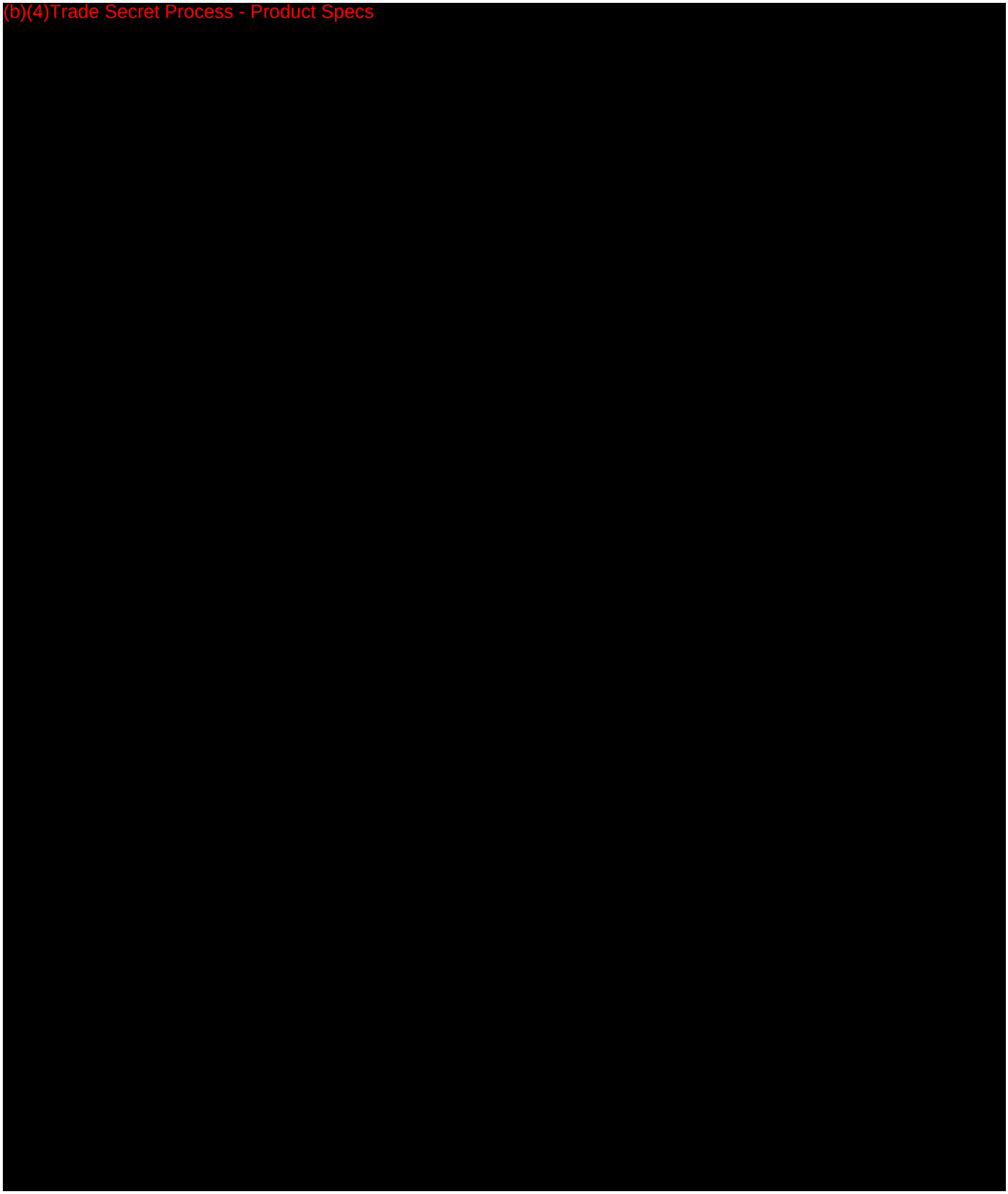

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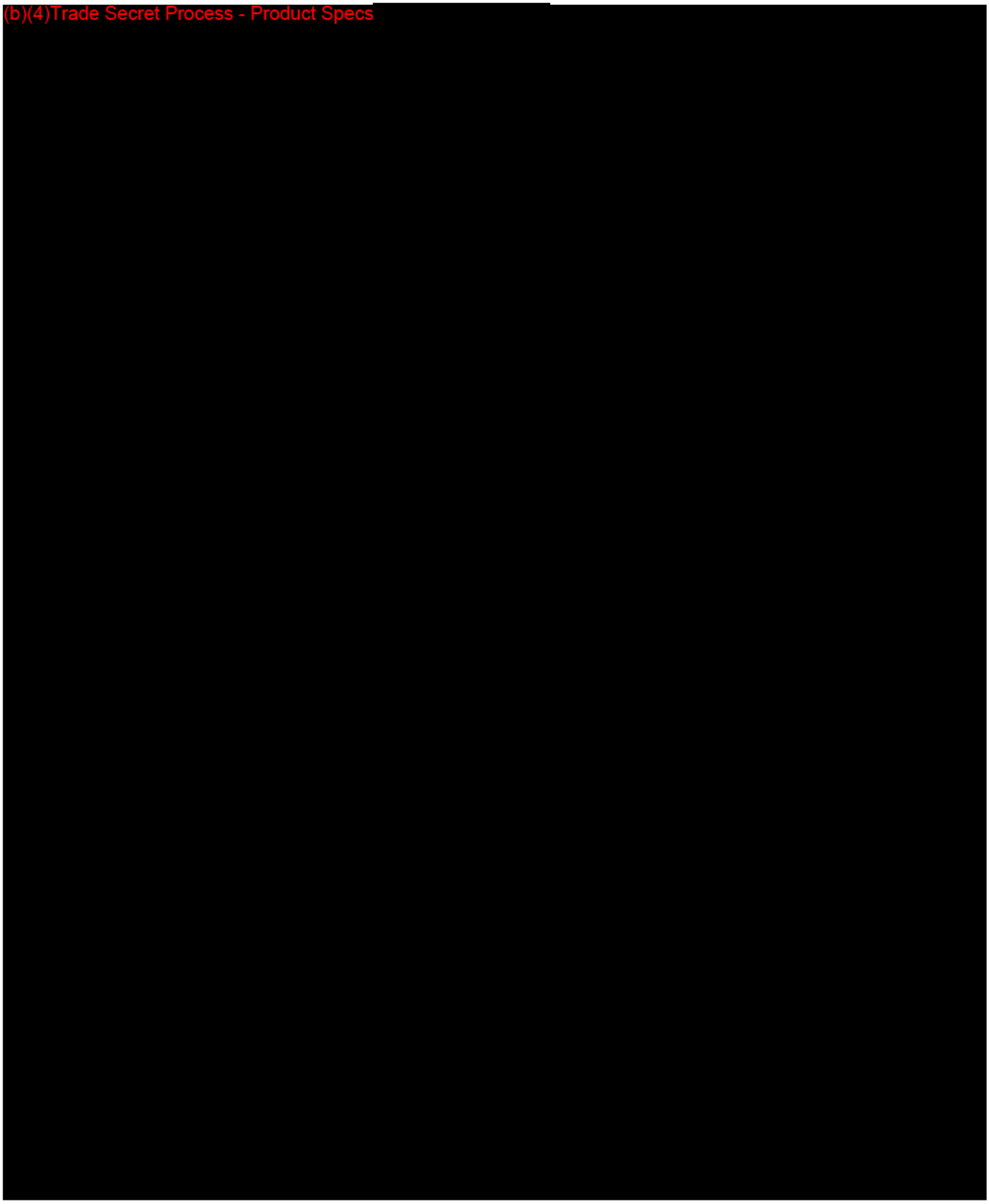

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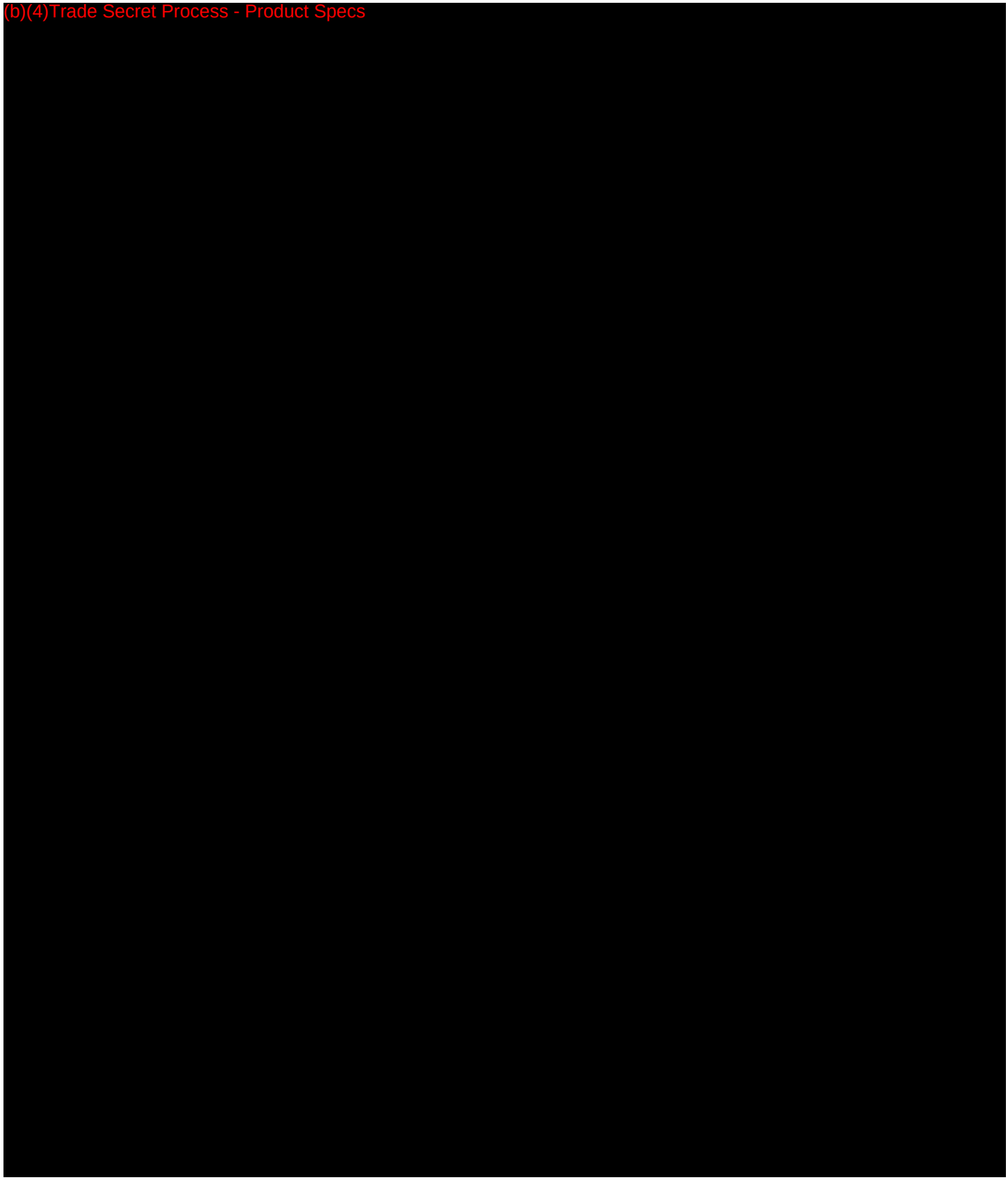
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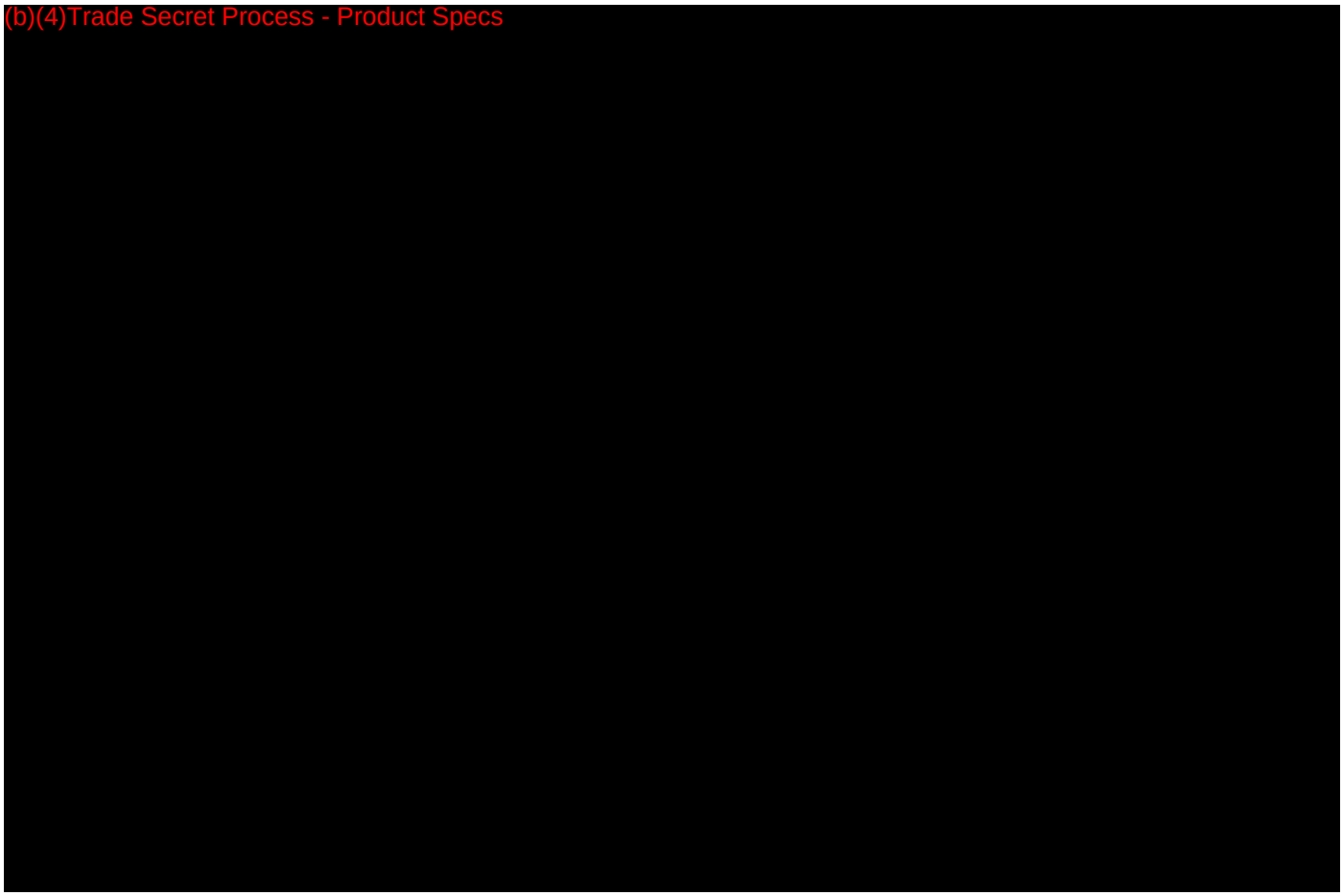

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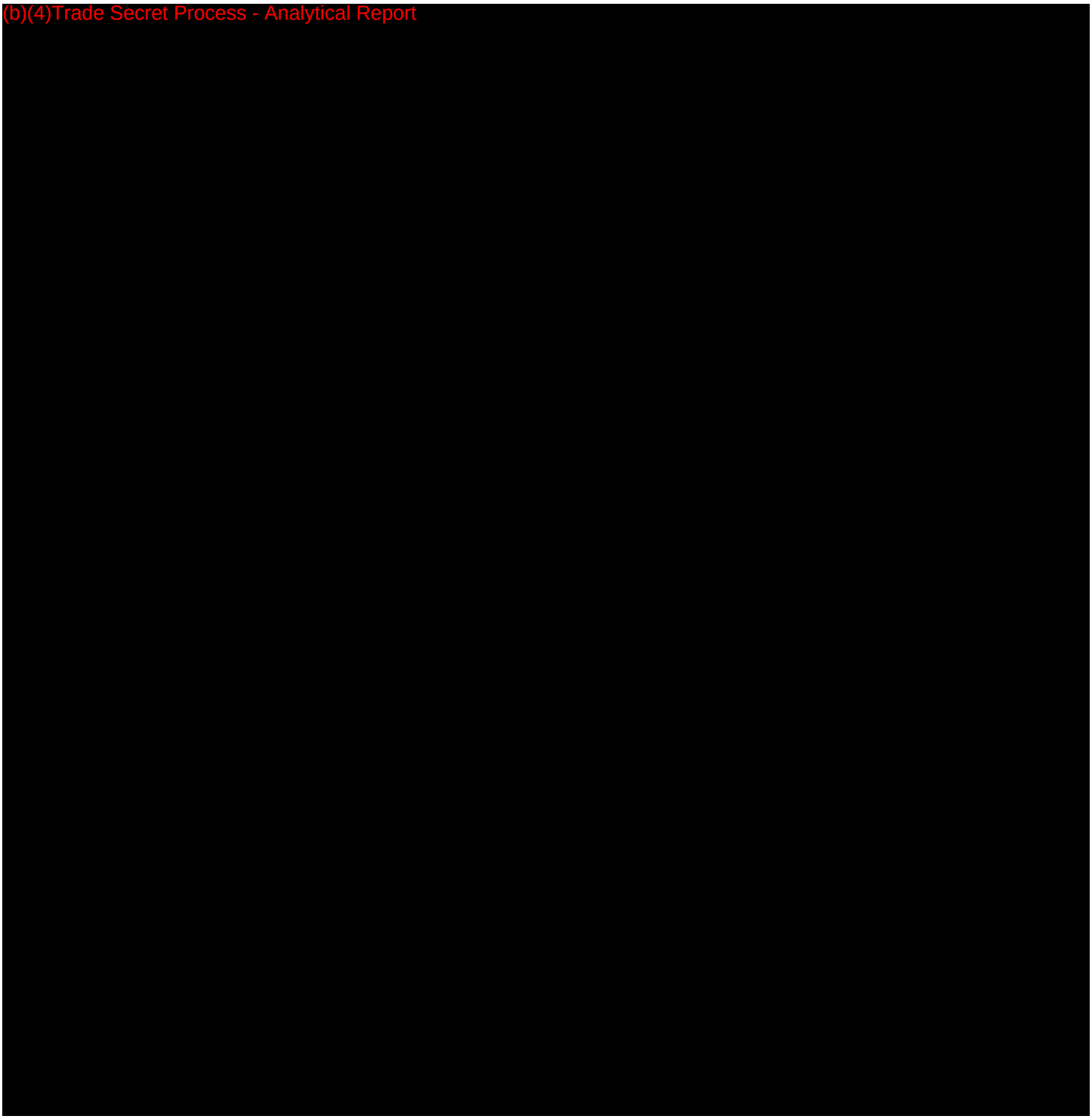

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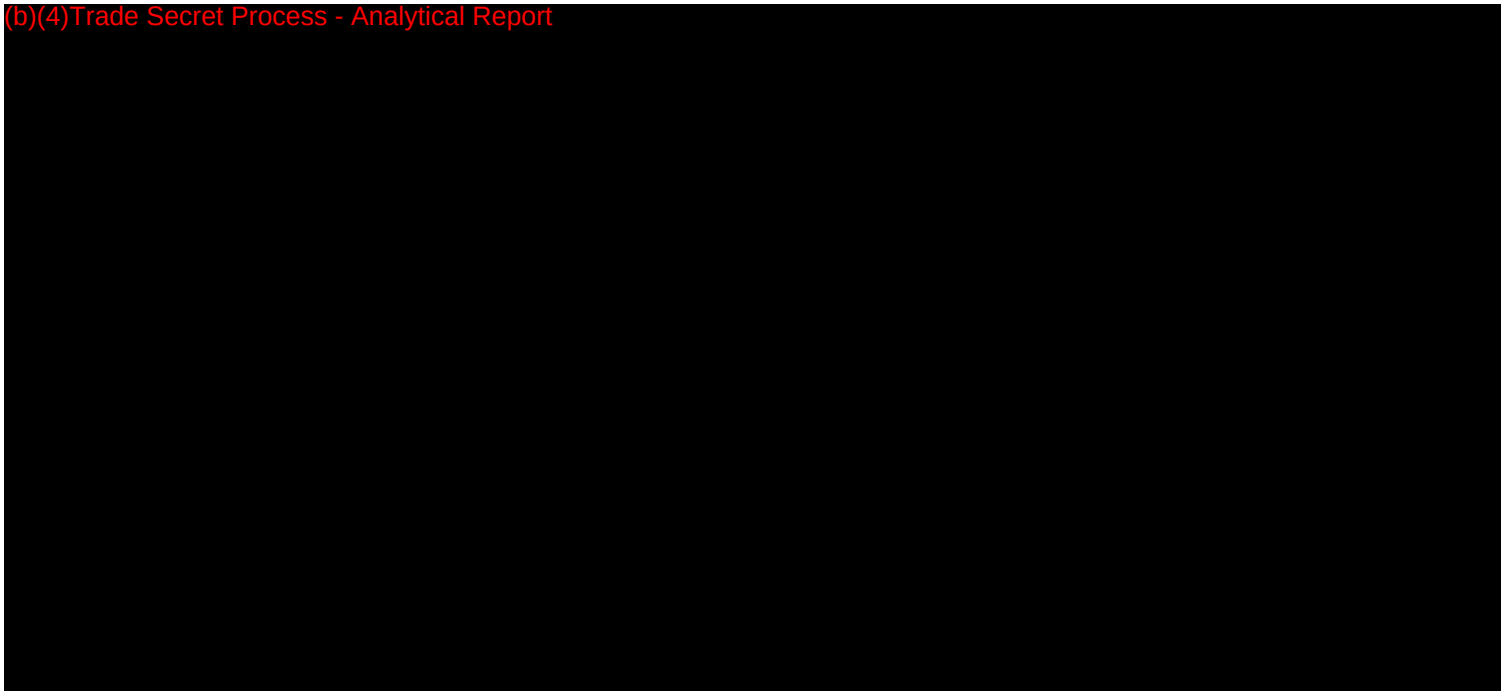

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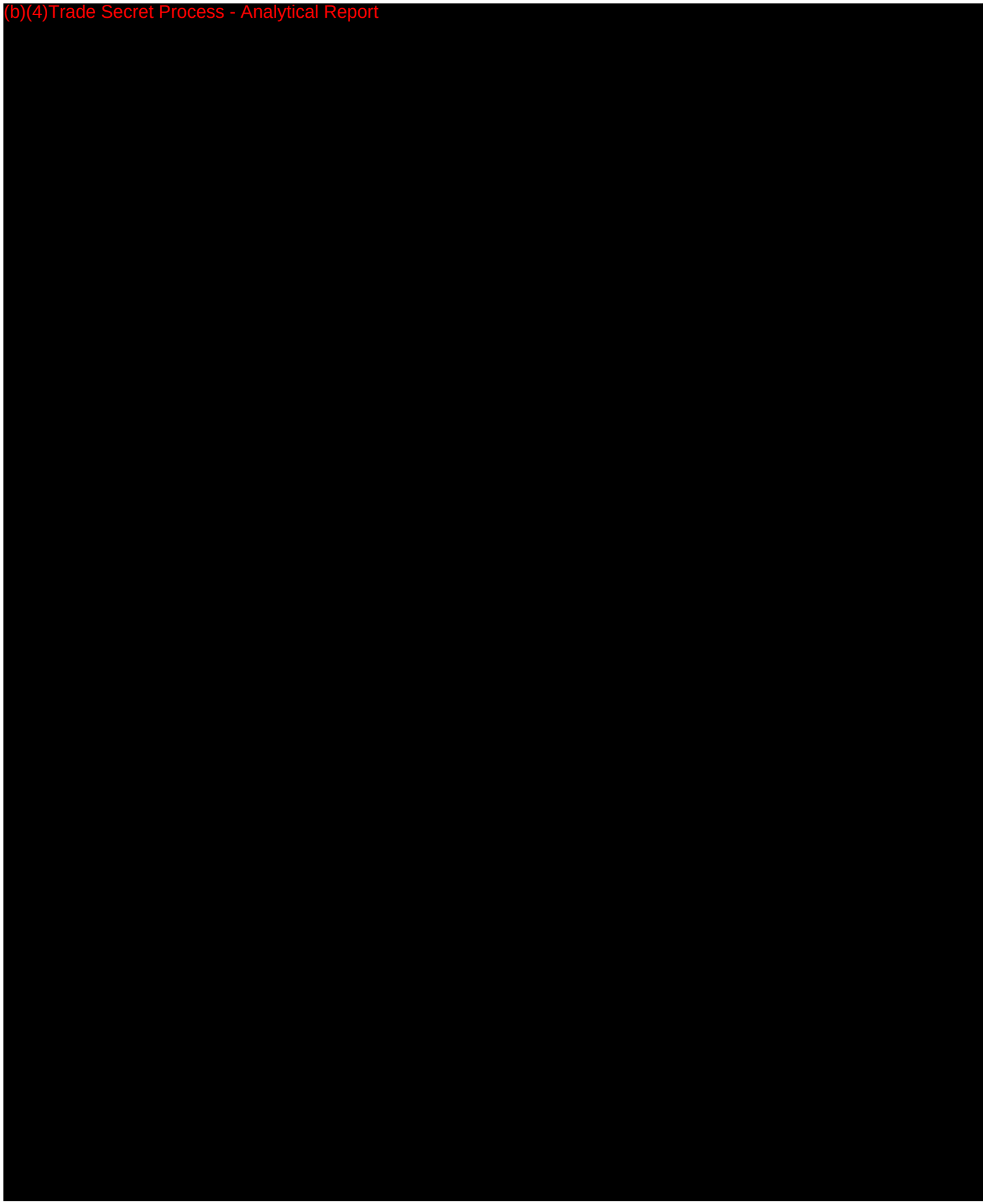

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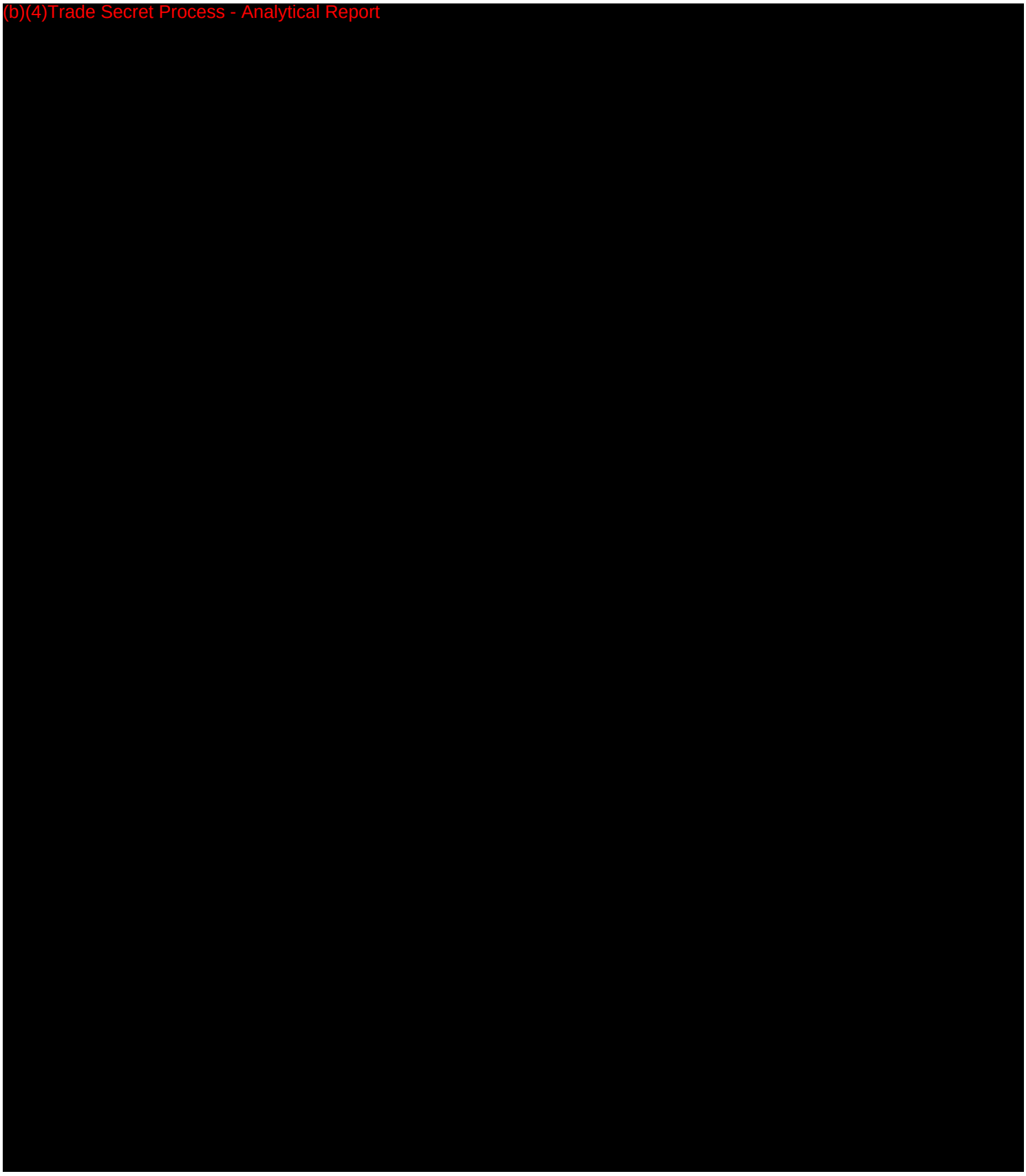

DEVICE DESCRIPTION

PICO Single Use Negative Pressure Wound Therapy System is a single use Negative Pressure Wound Therapy System (NPWT) consisting of a small portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. PICO is capable of delivering 80mmHg (nominal) negative pressure to the wound surface and managing low to moderate levels of exudate generated by the wound. The super absorbent dressing absorbs exudate generated by the wound. The system comprises of 2 tray sets to provide therapy for up to 7 days.

Indications for use:

PICO Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Device Description

Conventional Negative Pressure Wound Therapy is intended for use across a range of wound types but is not the sole means by which clinicians treat such wounds. In addition to NPWT, clinicians use a range of advanced wound management dressings designed to maintain a moist wound environment at the dressing/wound interface and manage wound exudate.

However, there are challenges with the use of conventional NPWT systems such as difficulties in dressing application and achieving an air tight seal, the use of cumbersome pumps to provide suction and the inconvenience of canisters.

The rationale for developing PICO was to address the challenges of conventional NPWT by designing a simple NPWT system that was single use and disposable (pump included), canister-less and easy to use. By doing so it was Smith & Nephew's intent to develop a negative pressure wound therapy device providing the benefits associated with the delivery of NPWT to the wound and to combine this with the simplicity and ease of use of an advanced wound dressing.

PICO was designed to bring to market a product that would allow clinicians to use NPWT on low to moderately exuding wounds and not those wounds that are highly exuding. The judgement of the clinician will determine the suitability for use of PICO on a wound by reference to the intended uses and indications.

The PICO dressing component uses a polyurethane film outer layer to provide a **"closed system"** environment for the pump to deliver negative pressure to the wound. This is consistent with the predicate NPWT systems.

NPWT is delivered by PICO using a software controlled pump just as NPWT is delivered with conventional systems. The pump is smaller than earlier negative pressure pumps but has the capacity to deliver appropriate NPWT across the dressing for the duration of the therapy. The PICO system design means that the pump is only required to pull air and not exudate as opposed to NPWT systems with a canister.

In order to design a canister-less NPWT system, Smith & Nephew has used its knowledge and expertise in advanced dressing technology to develop the PICO Negative Pressure Wound Therapy System dressing component. The dressing has been designed to manage the exudate levels associated with low to moderately exuding wounds that would benefit from Negative Pressure Wound Therapy. Unique to the PICO dressing is an airflow (spacer) layer which provides physical separation between the wound contact layer and the absorbent layer of the dressing. The structure of the dressing component is illustrated below in Figure 1.

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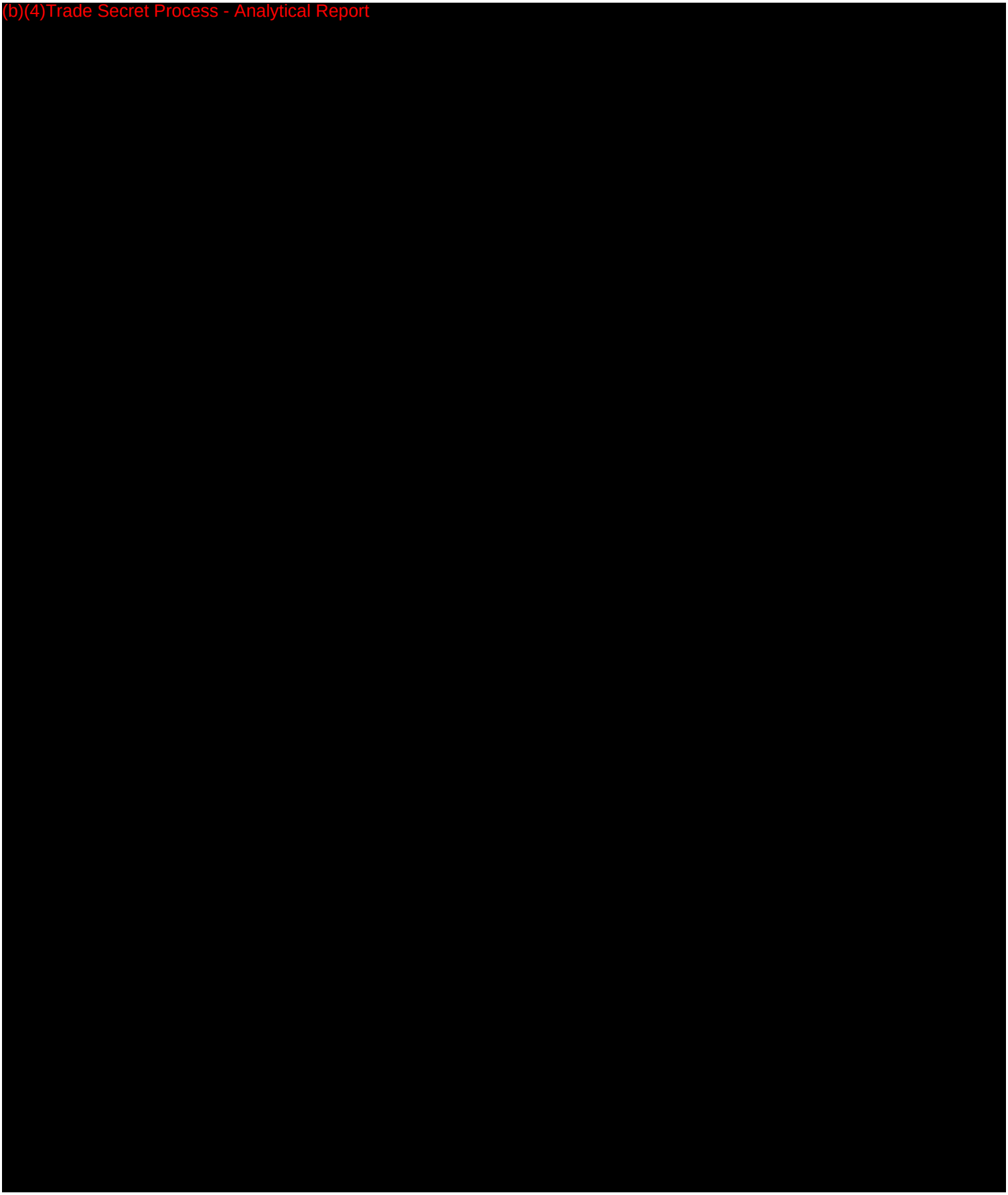

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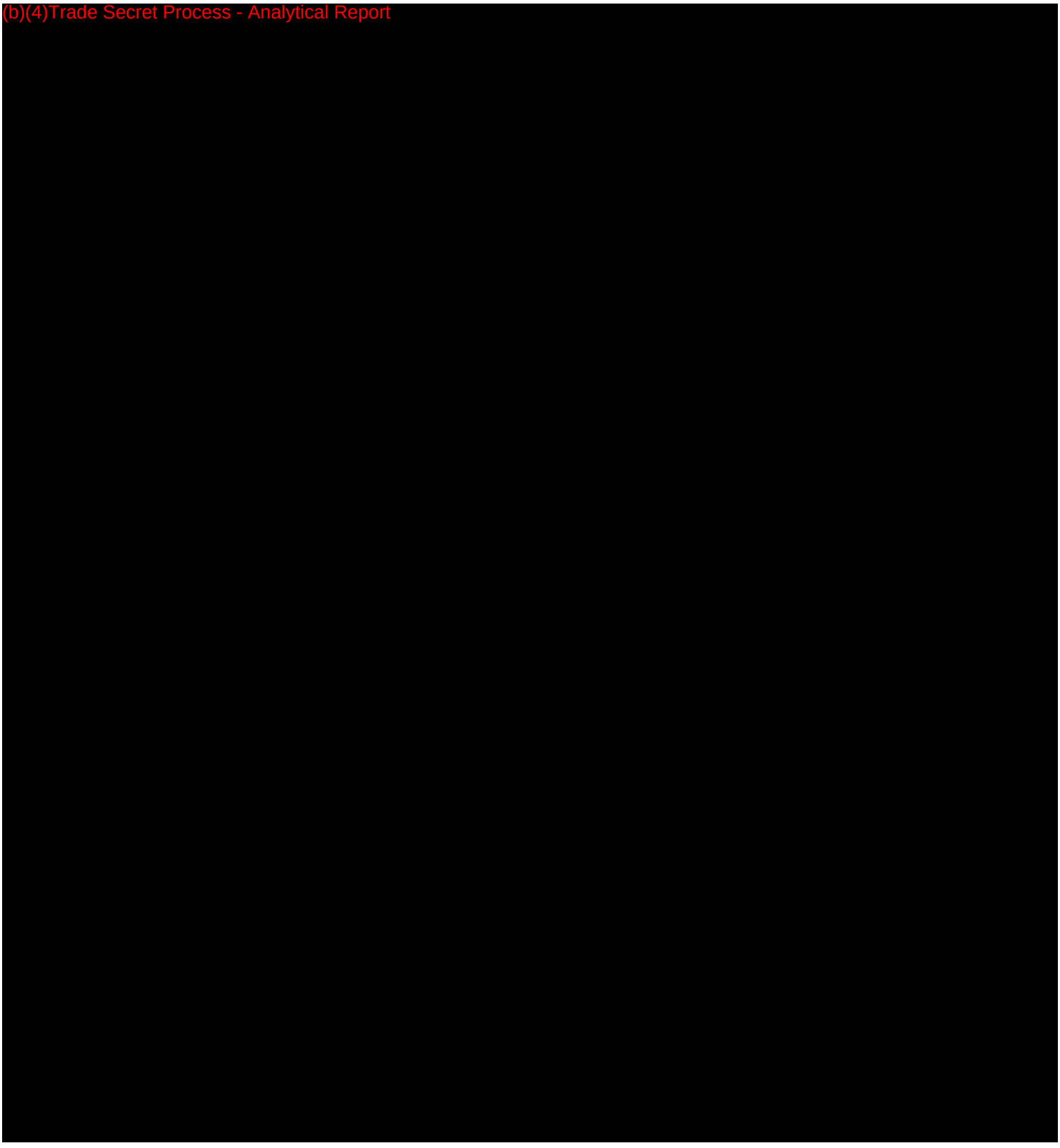

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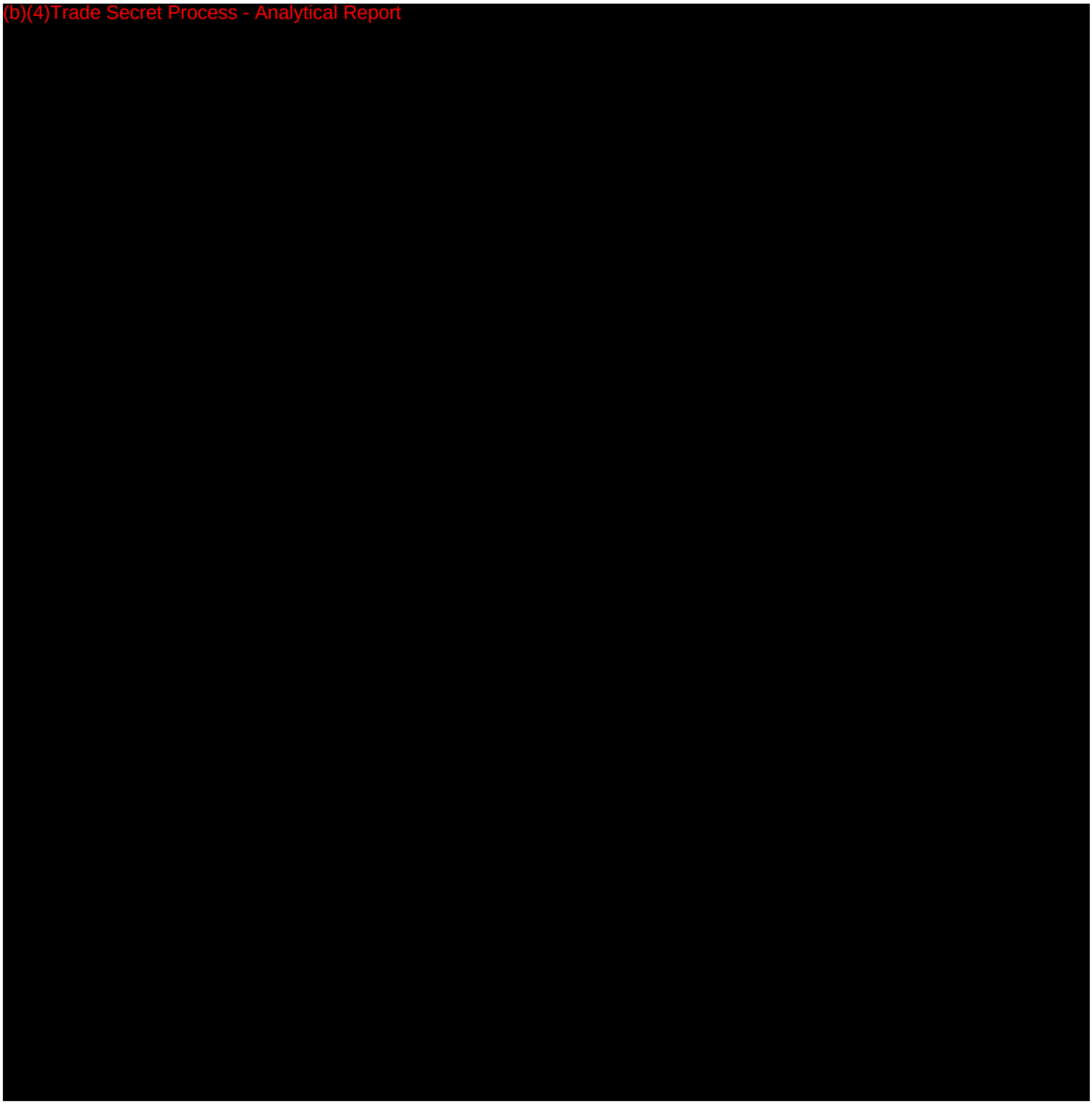

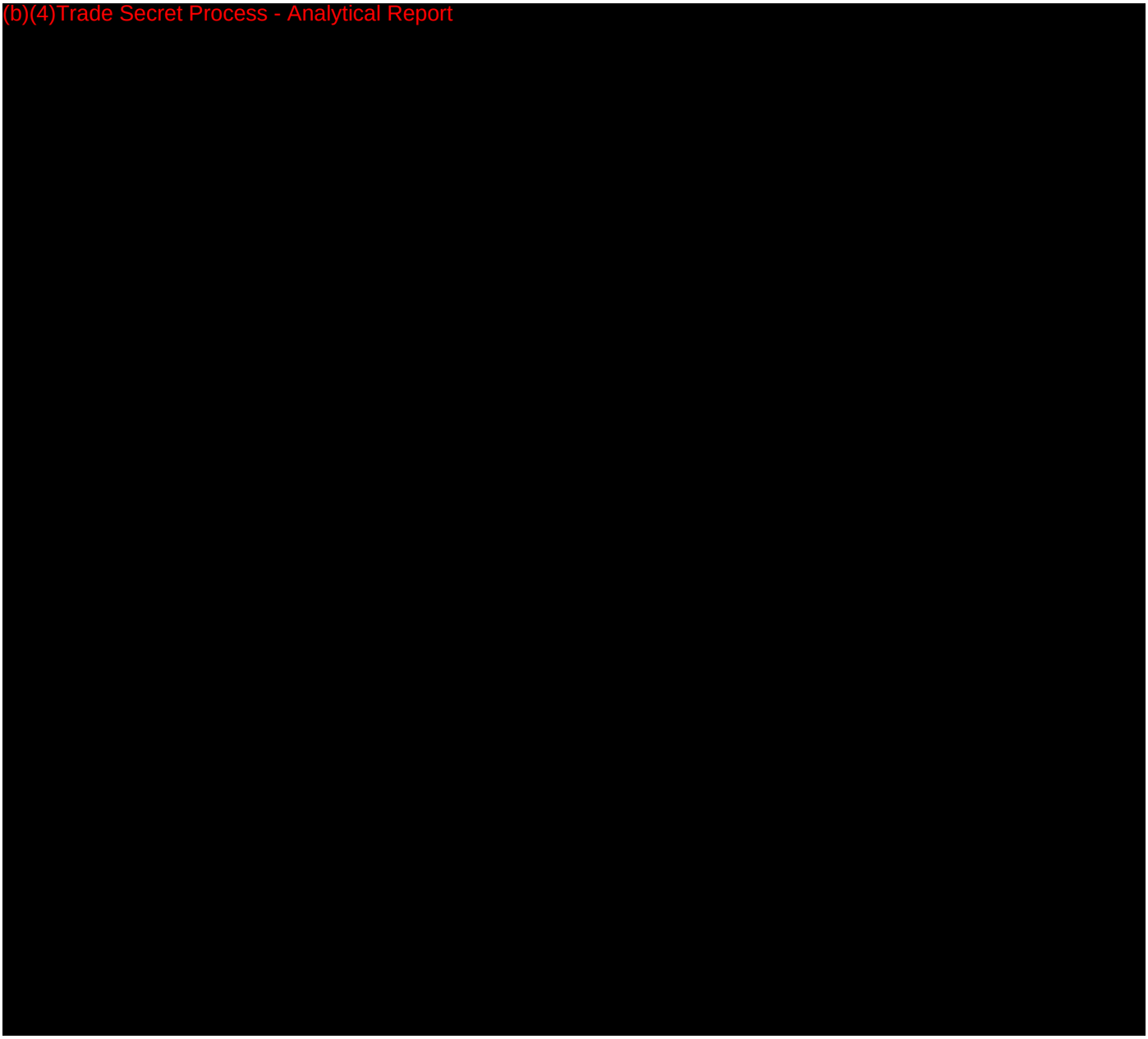
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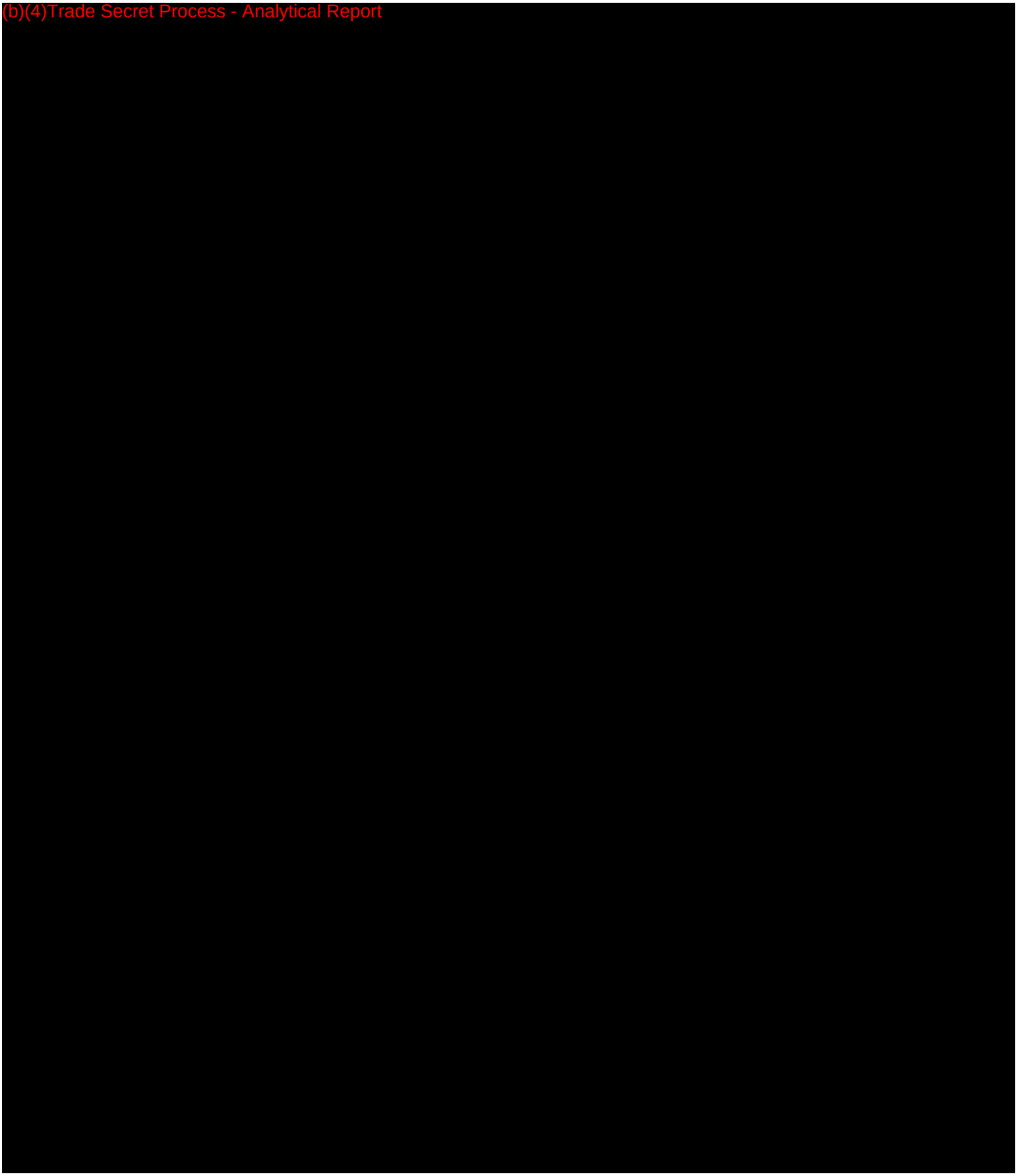

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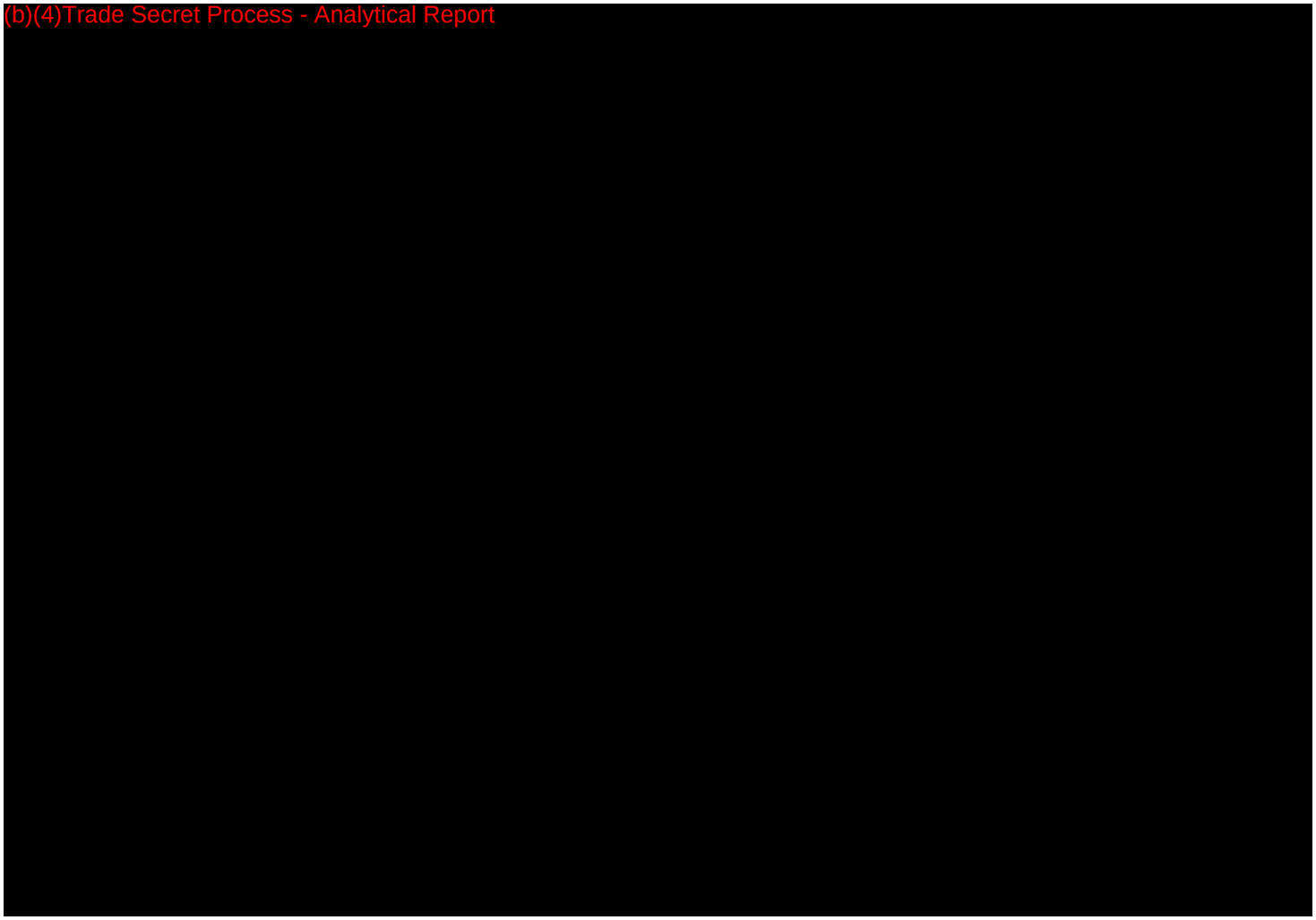

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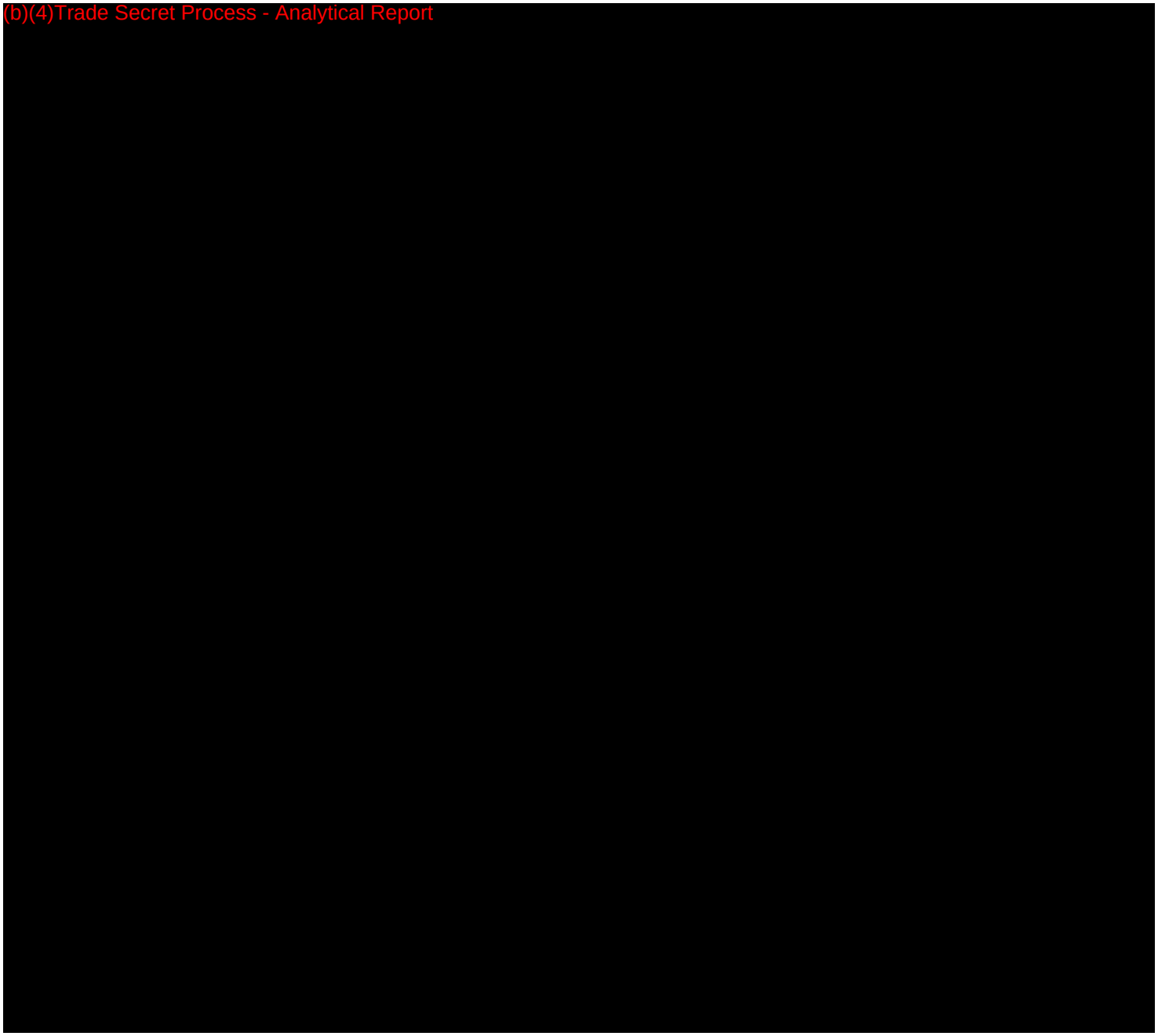

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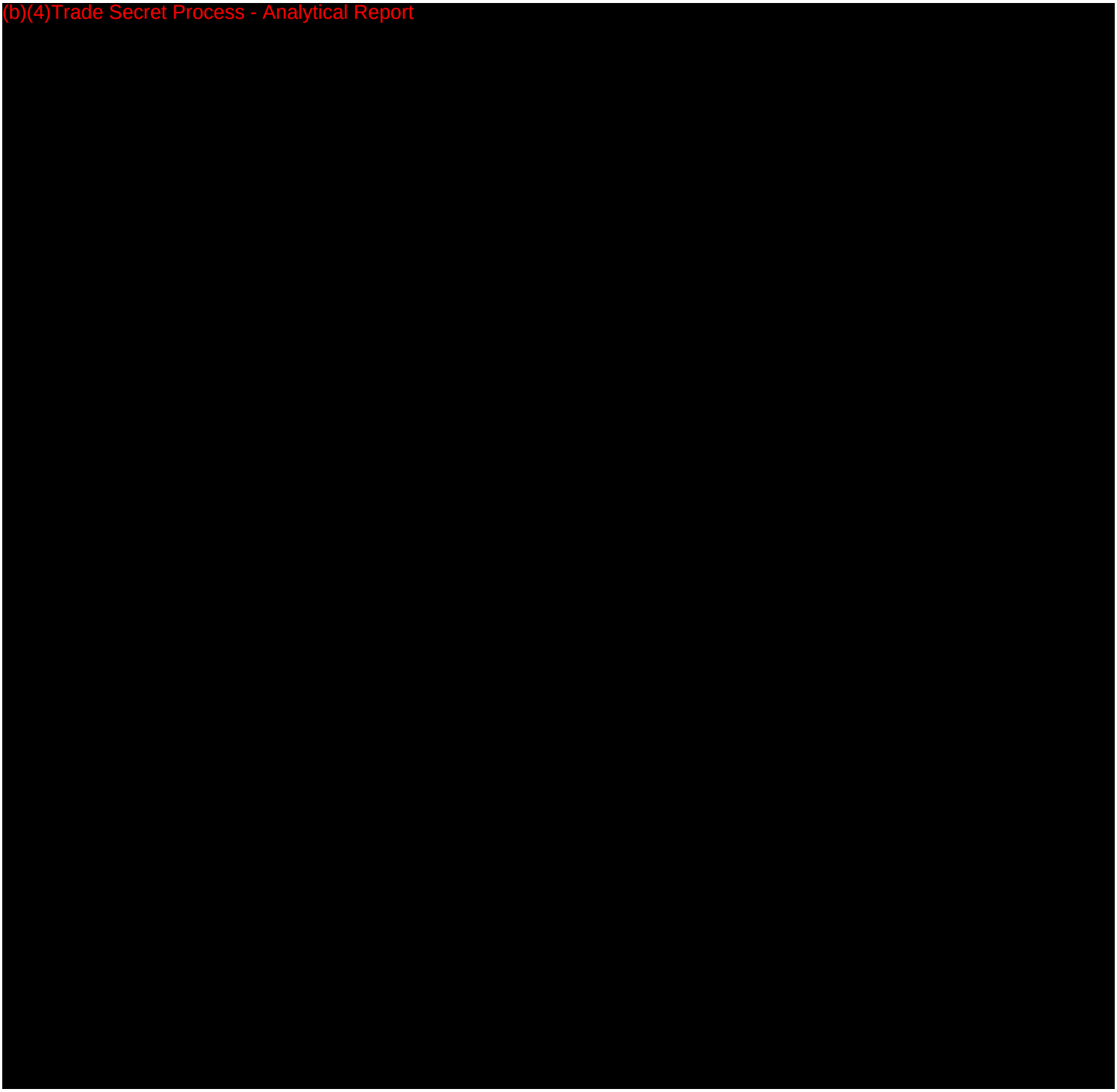

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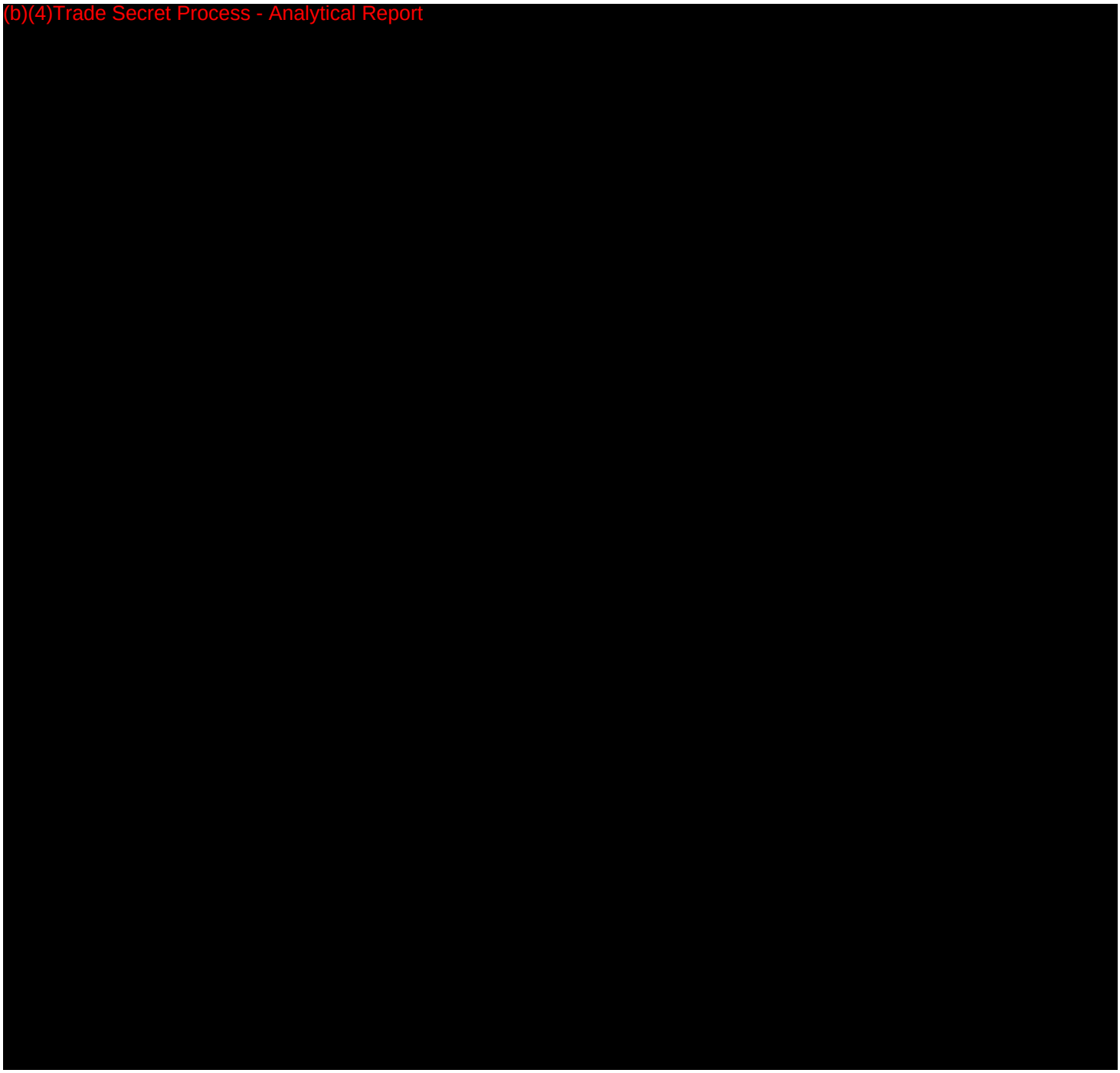

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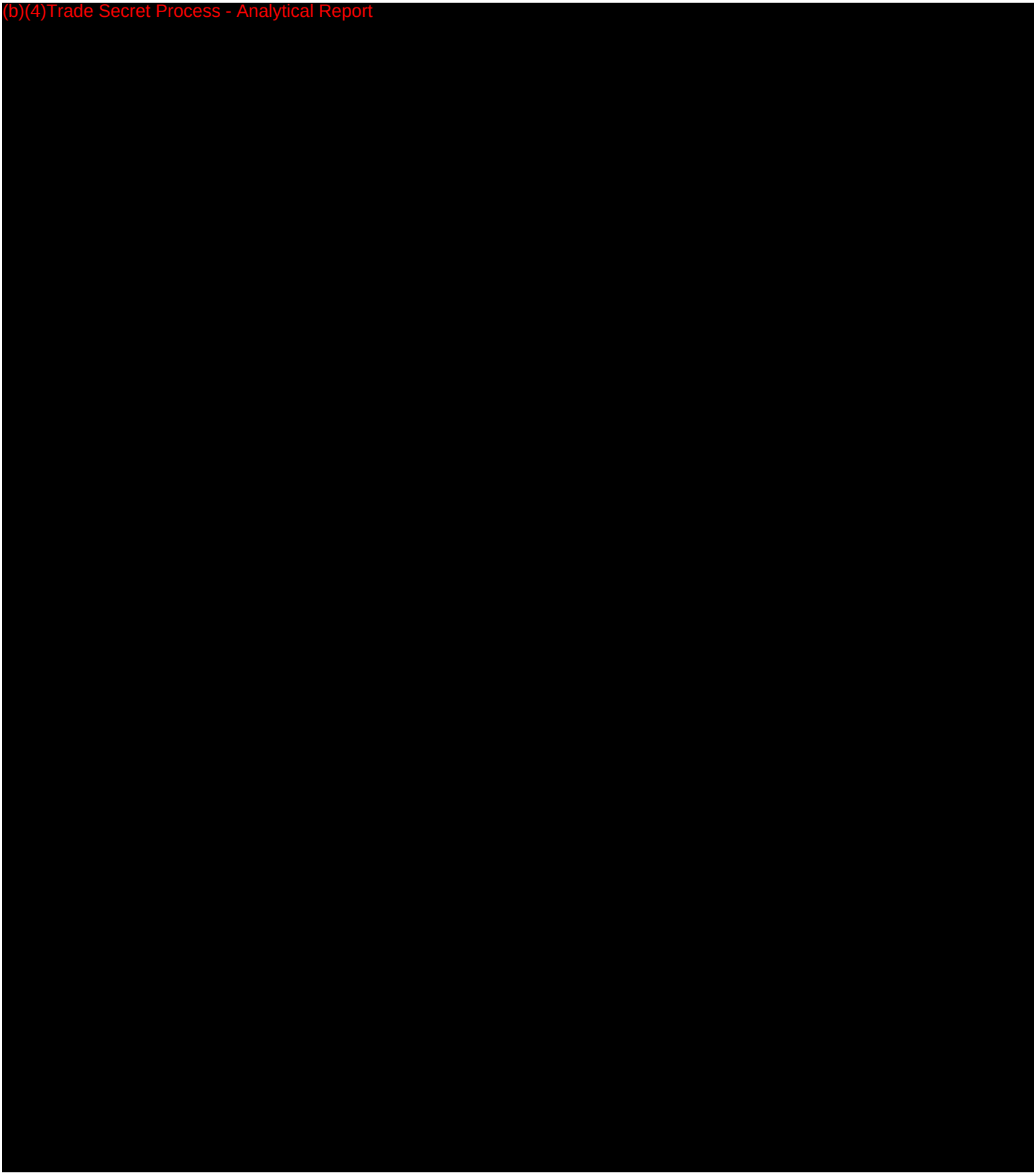

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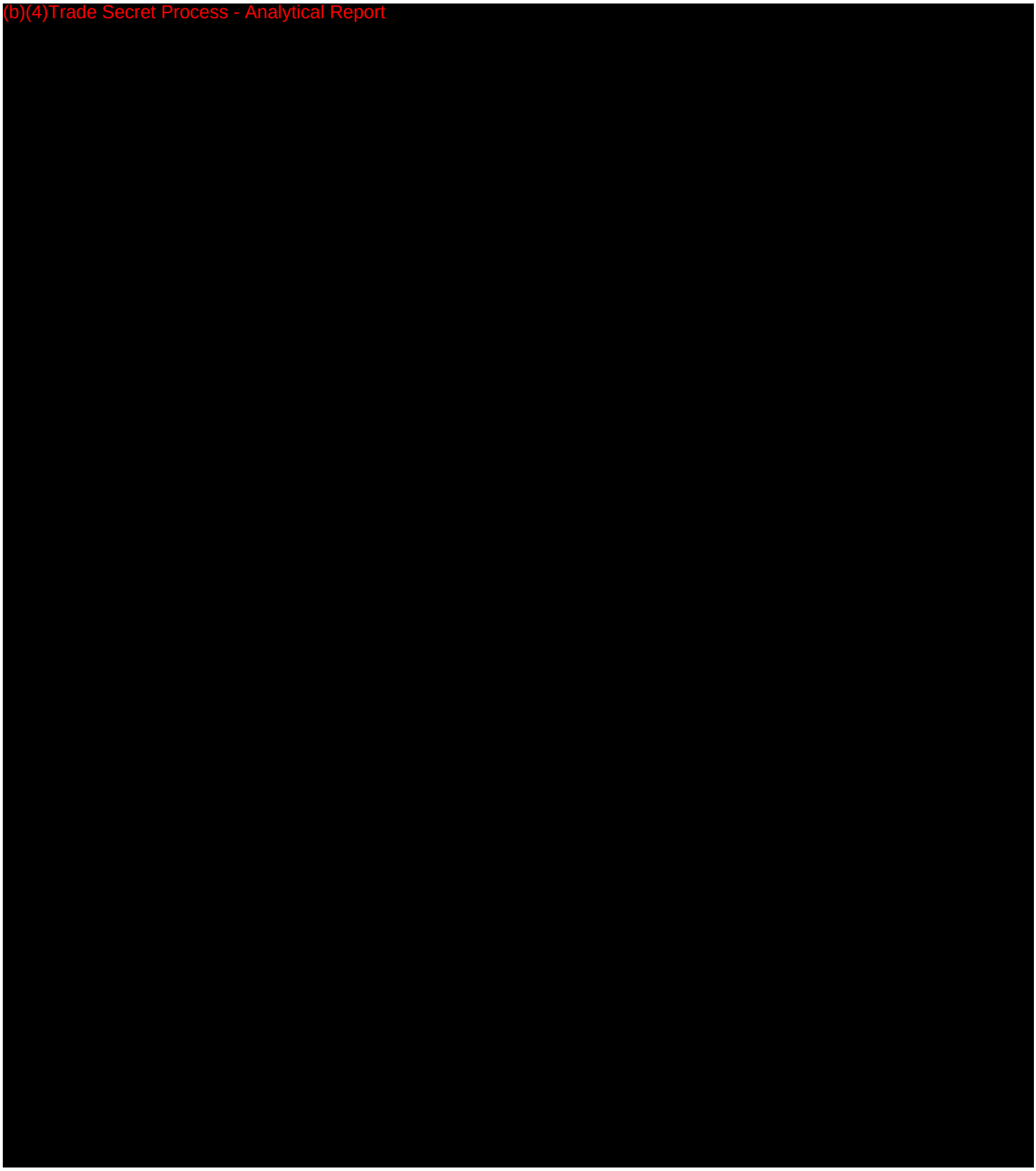

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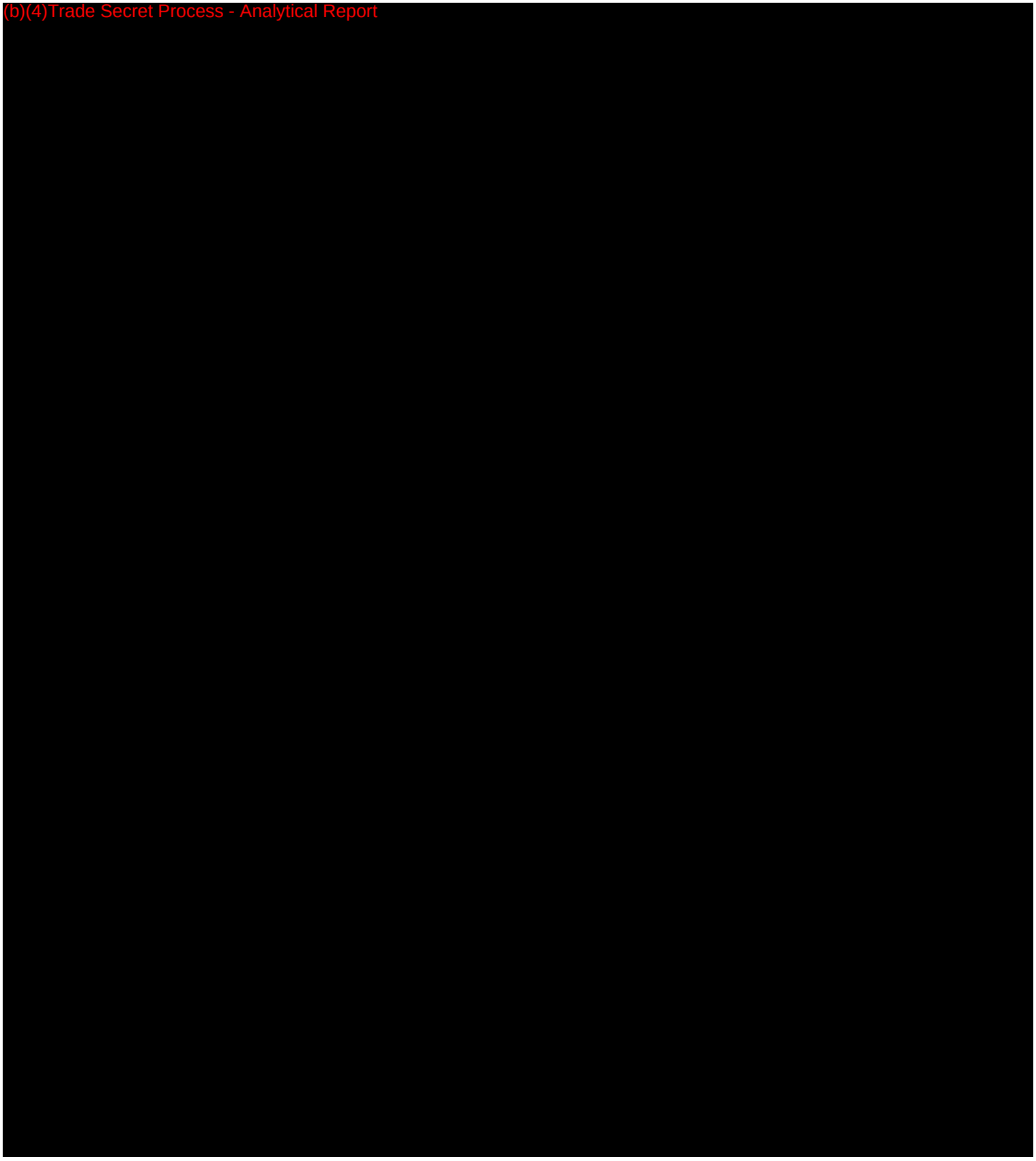

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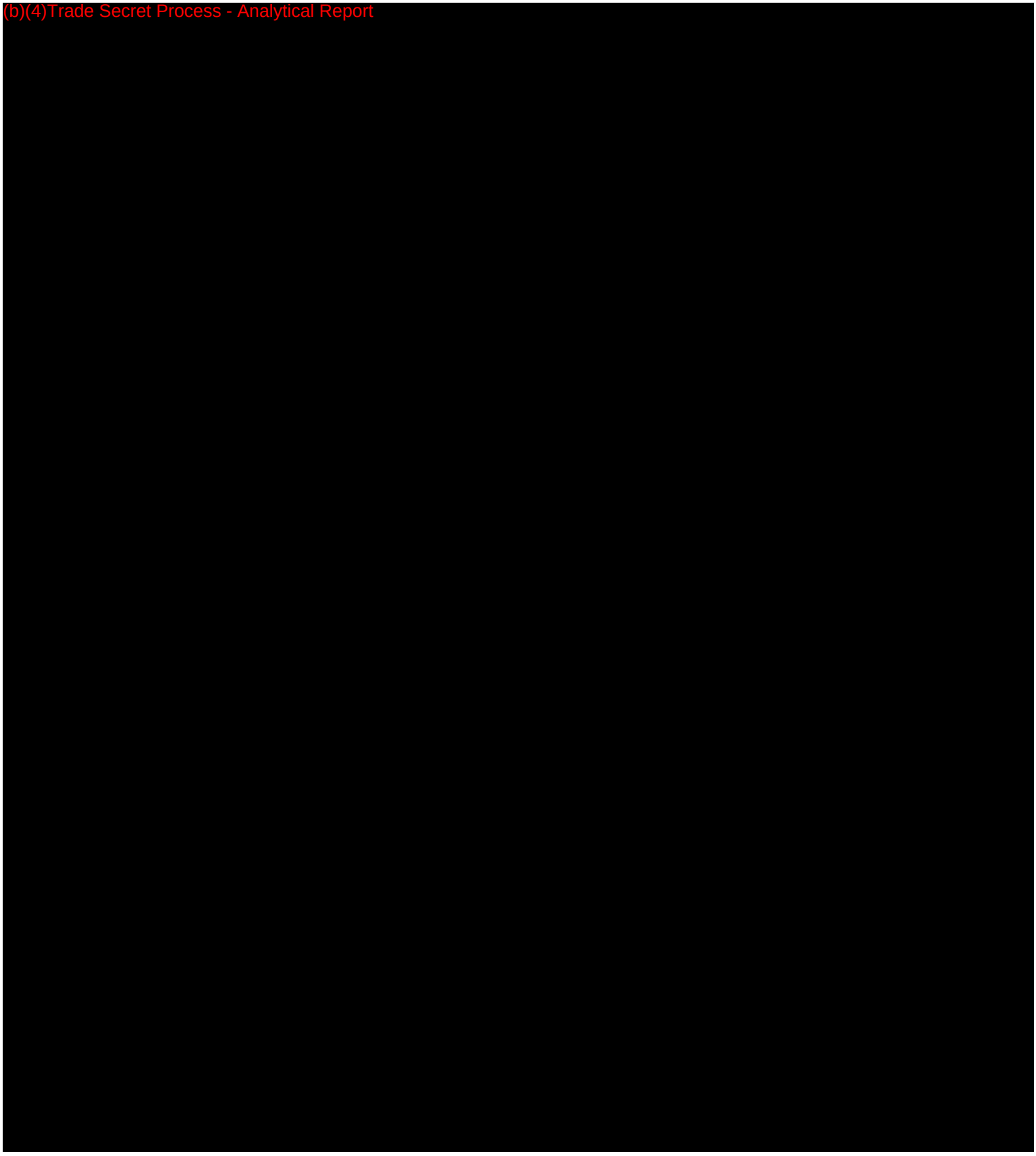

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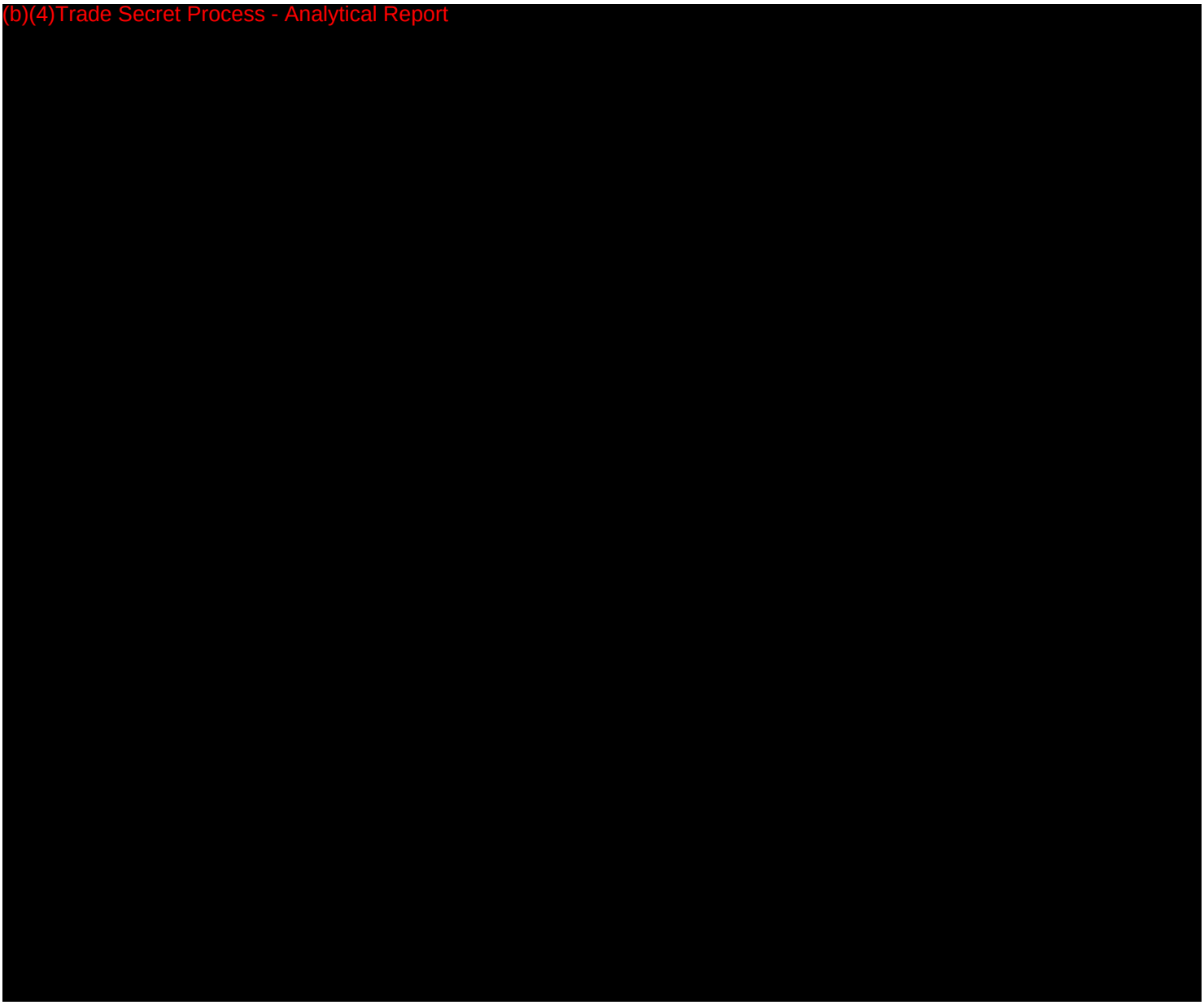

EXECUTIVE SUMMARY

Indications for use:

PICO Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Device Description

Conventional Negative Pressure Wound Therapy is intended for use across a range of wound types but is not the sole means by which clinicians treat such wounds. In addition to NPWT, clinicians use a range of advanced wound management dressings designed to maintain a moist wound environment at the dressing/wound interface and manage wound exudate.

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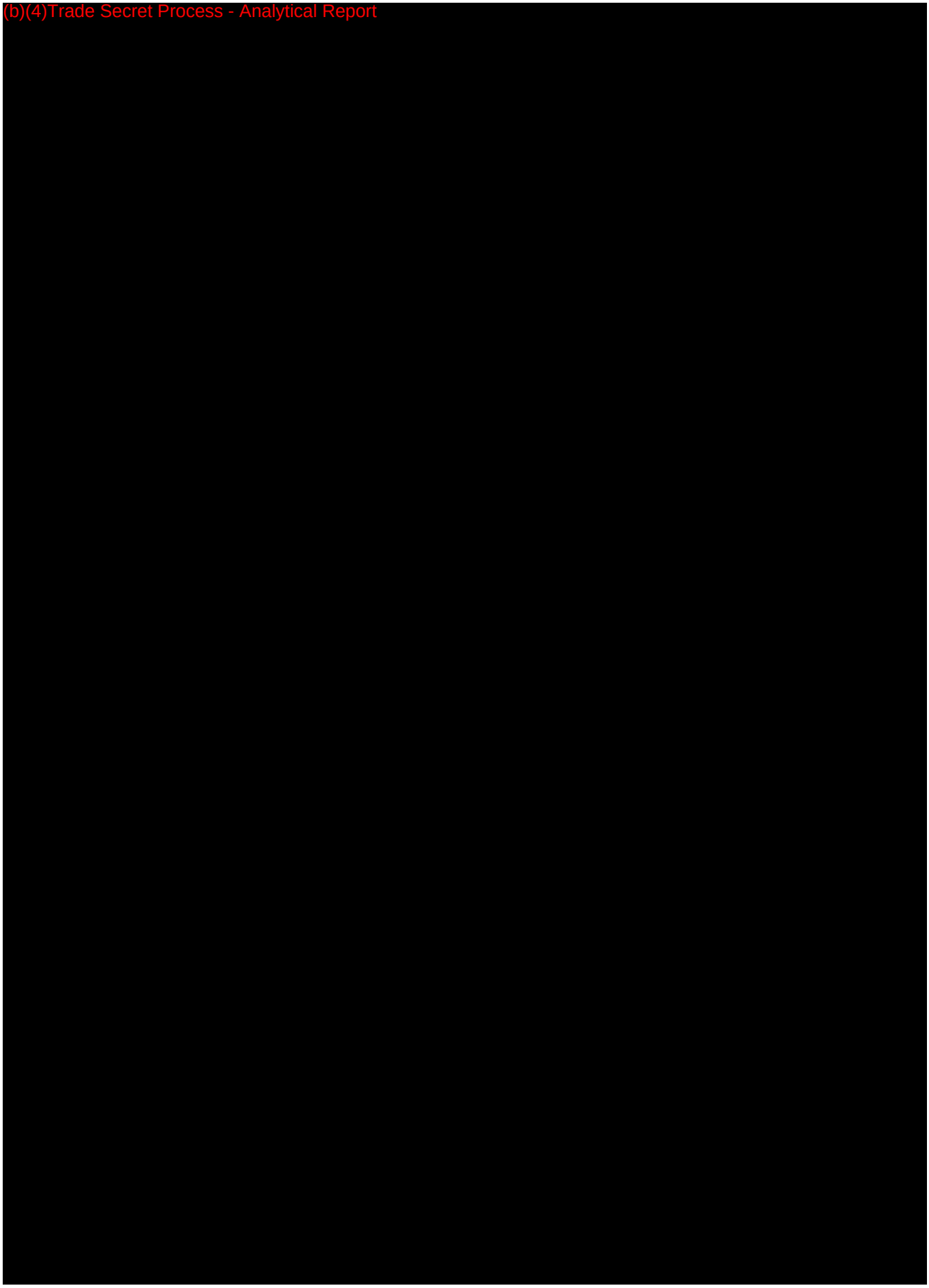

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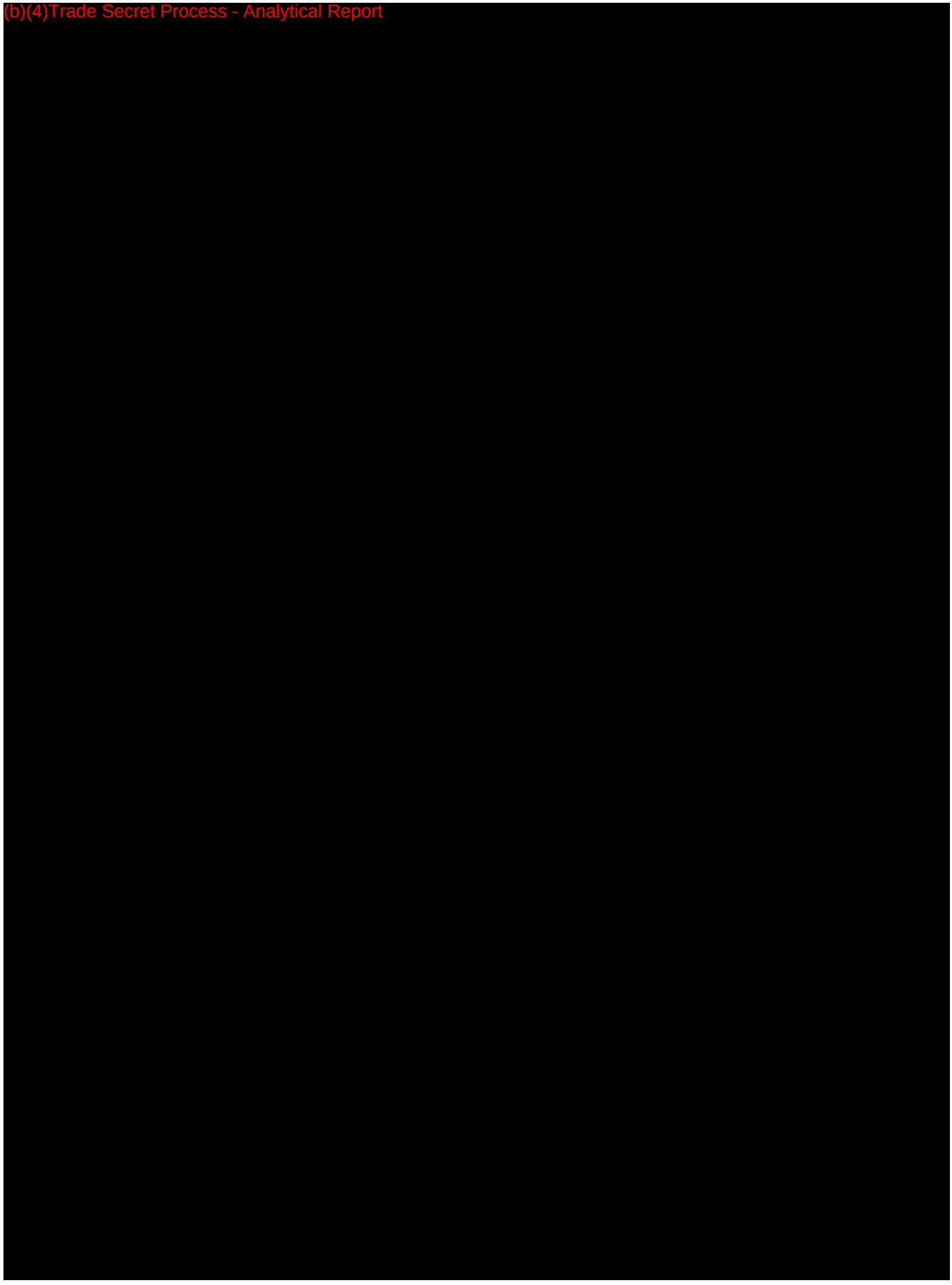

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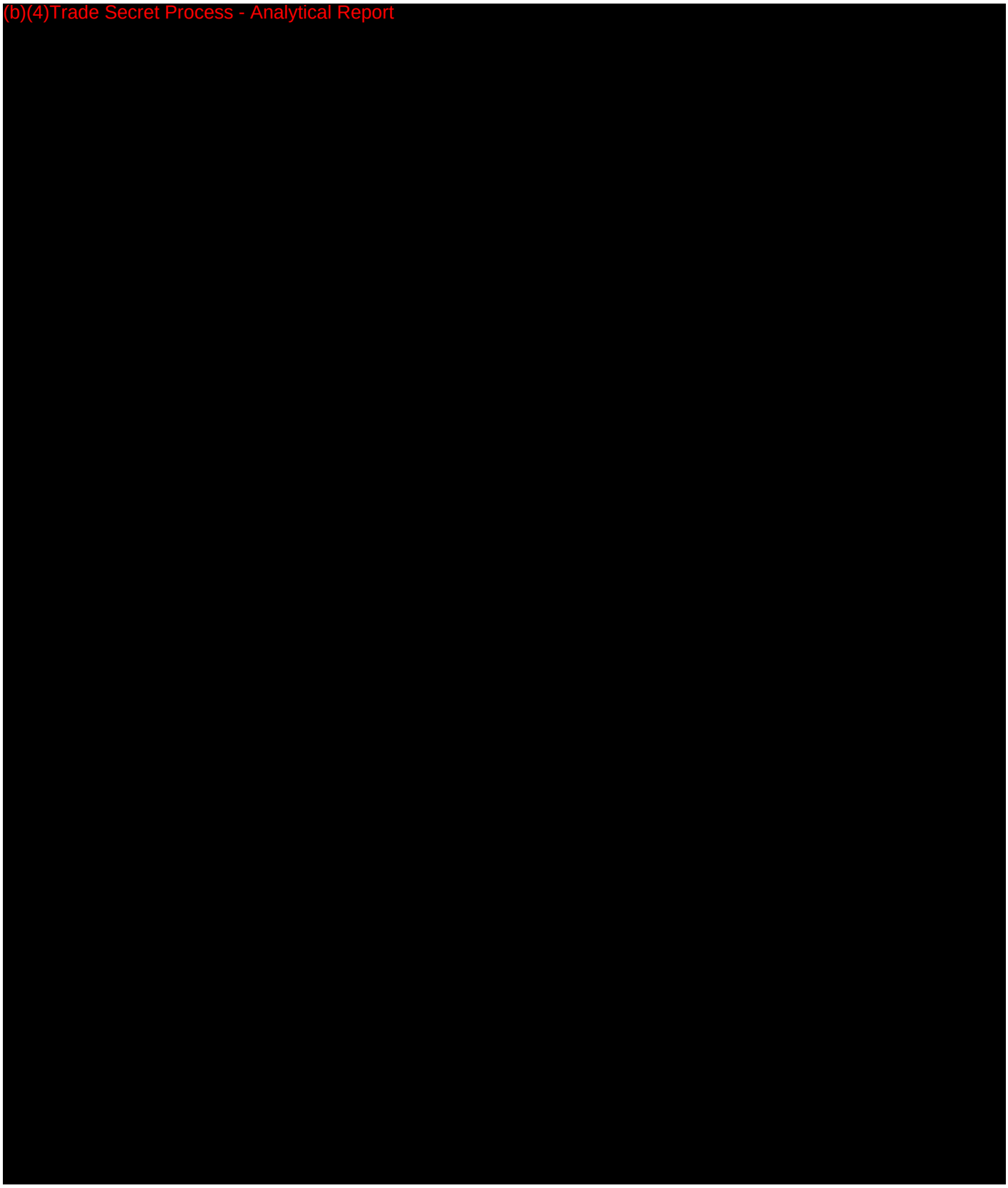

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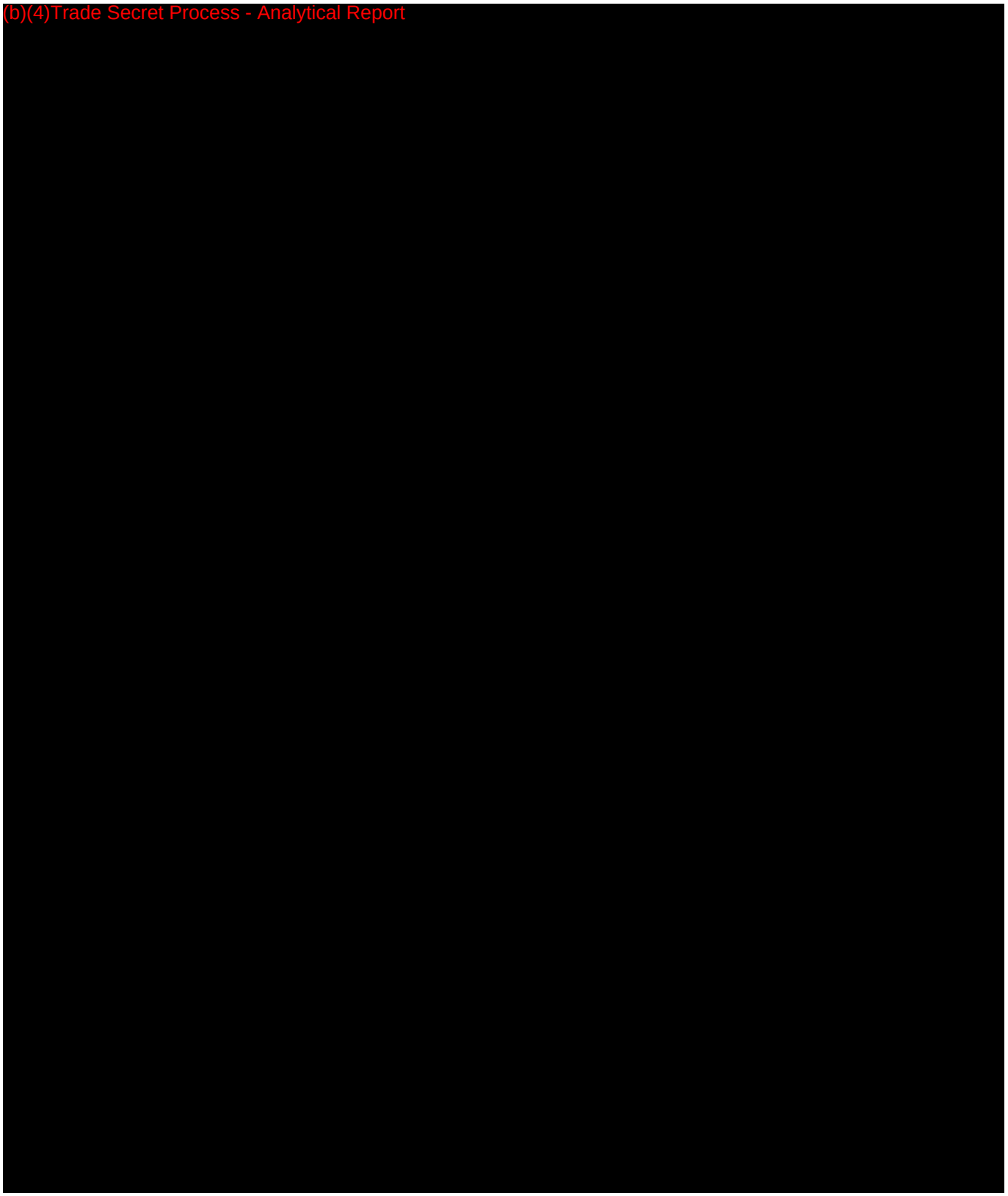

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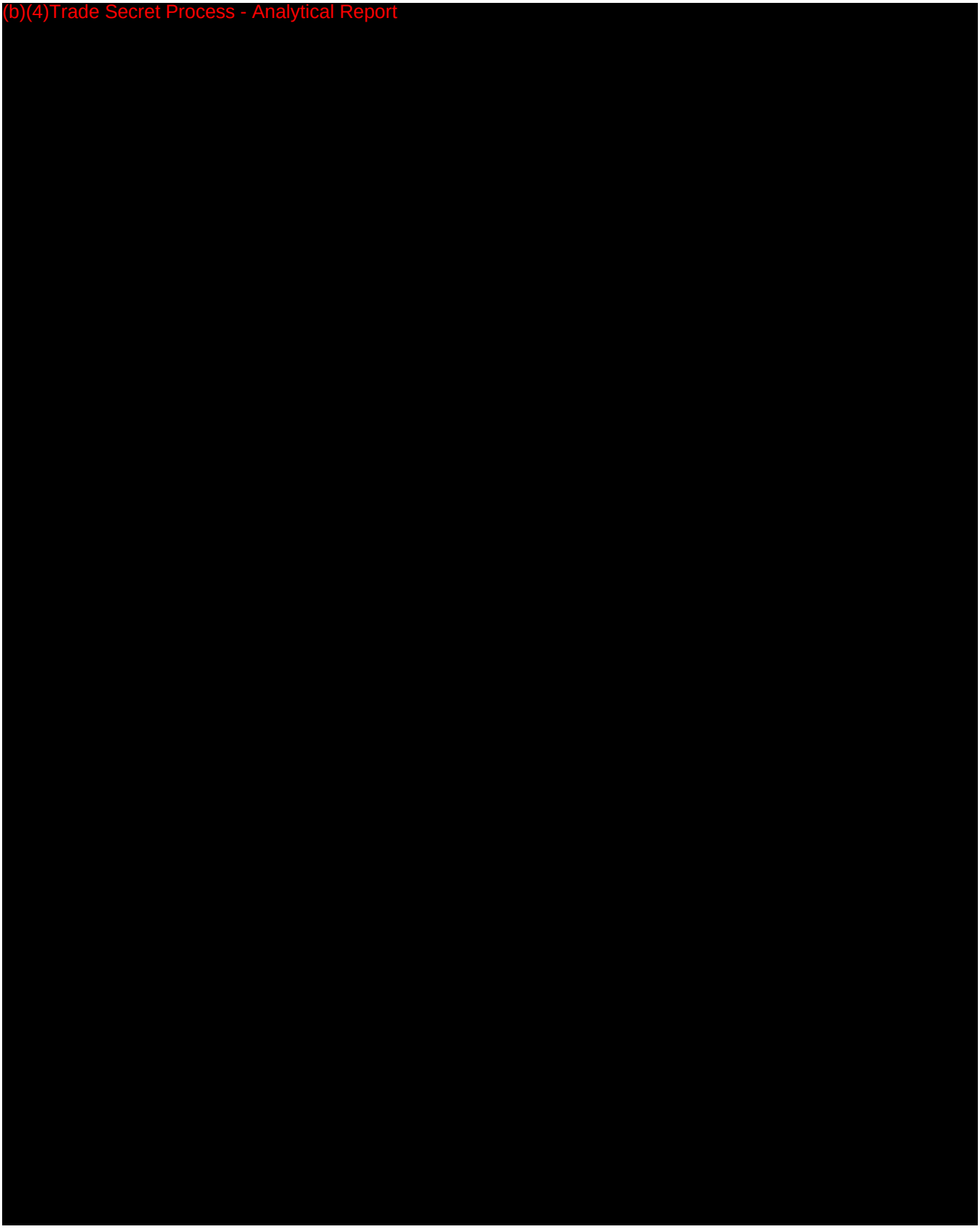

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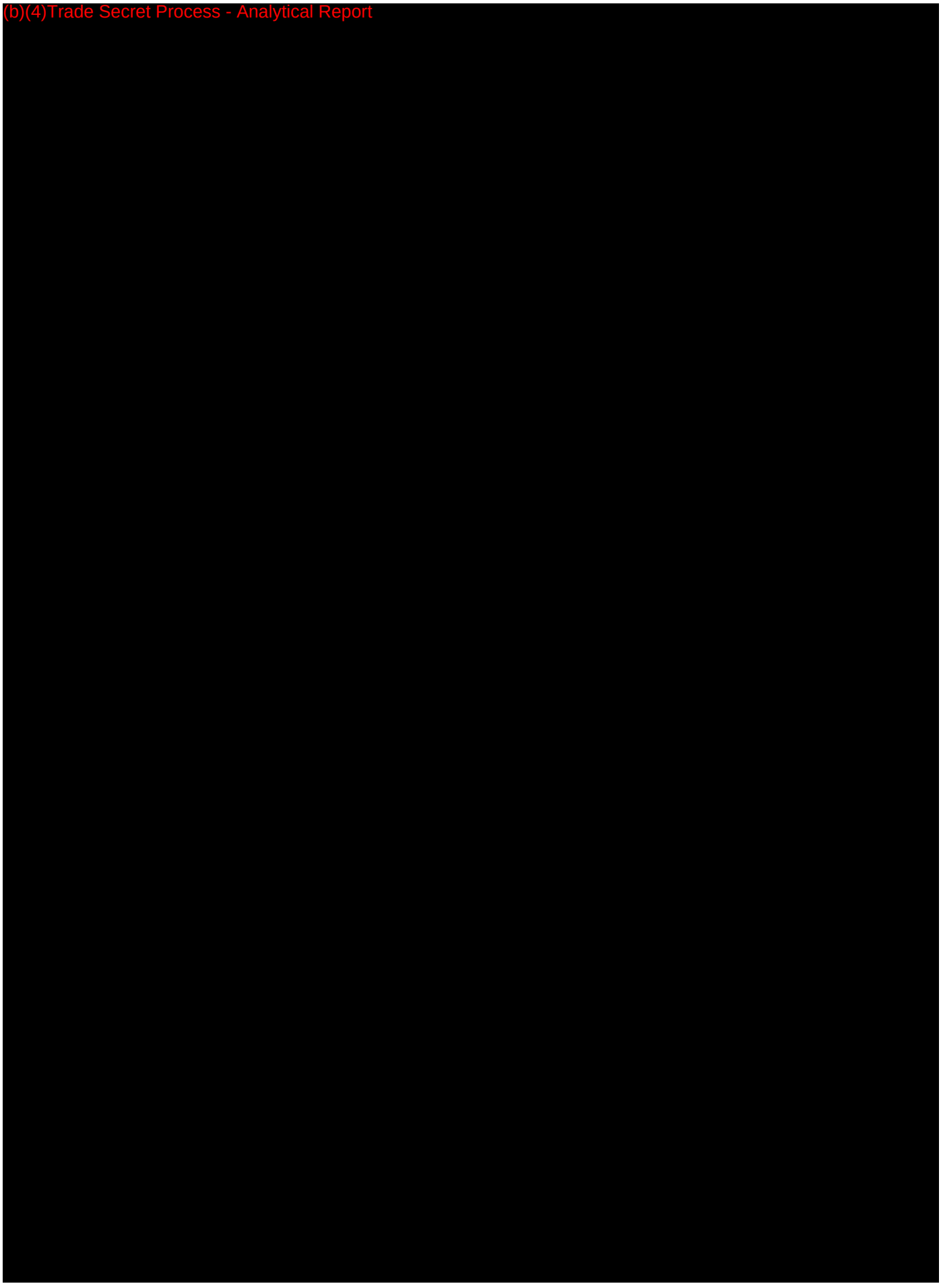

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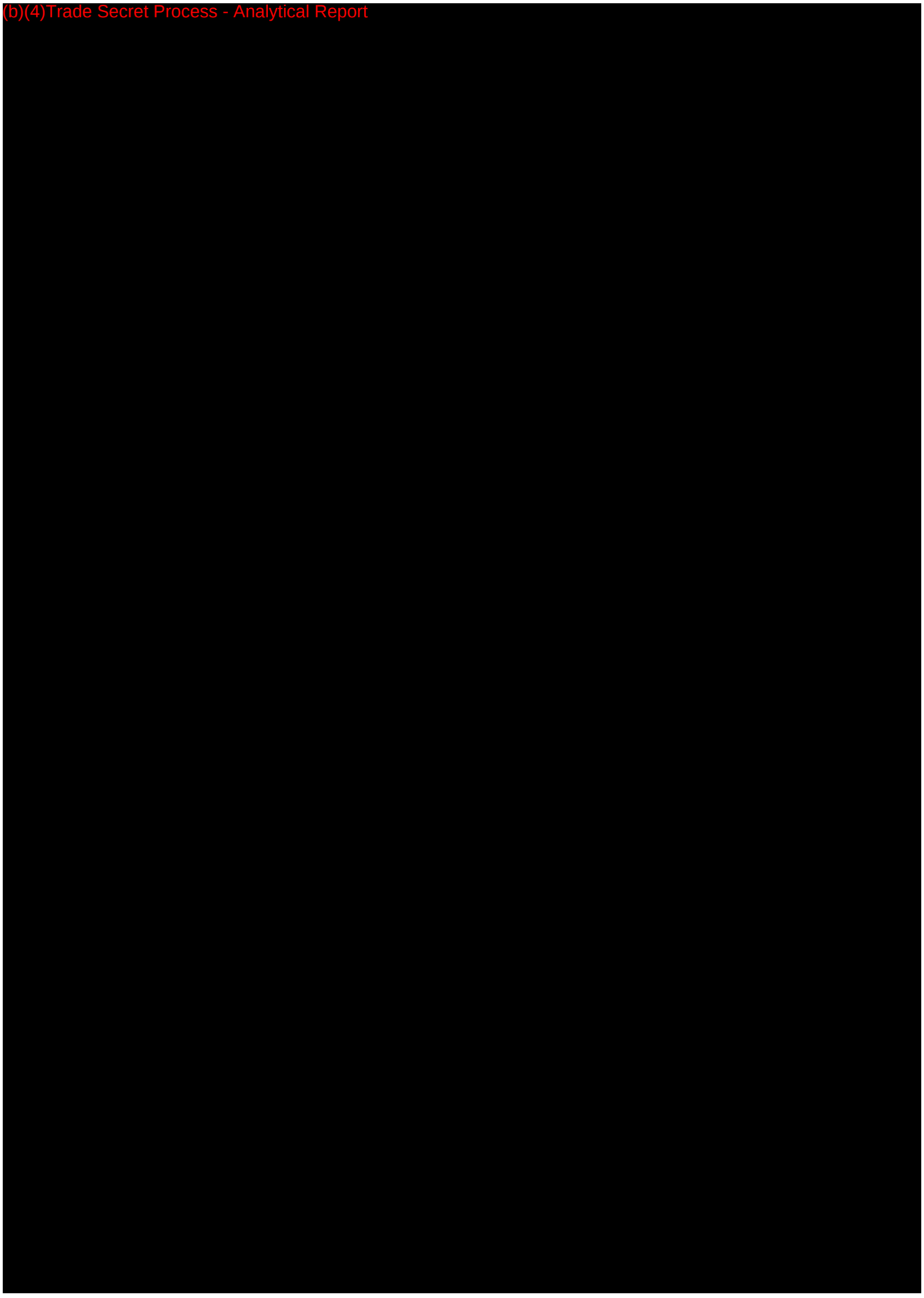

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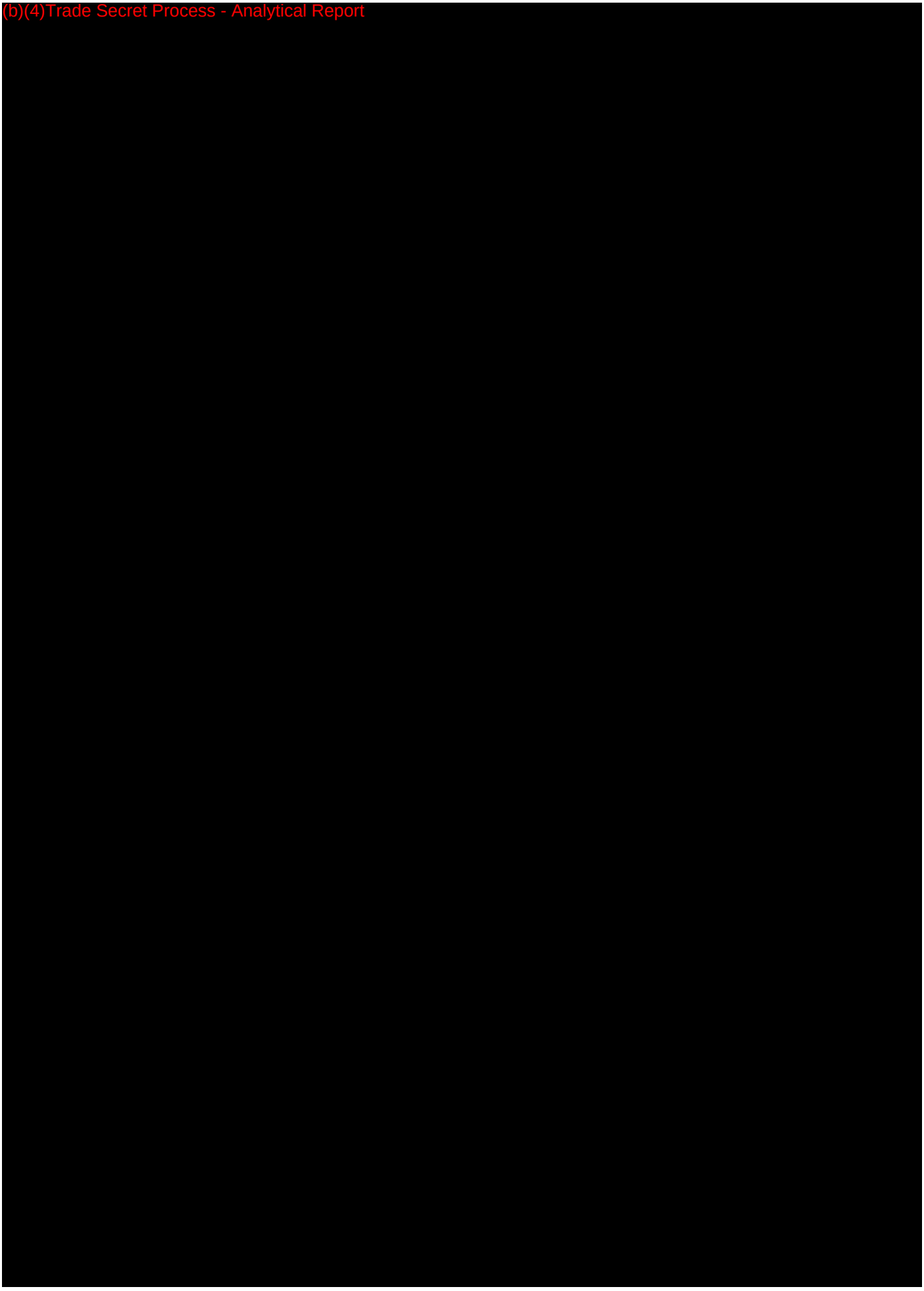

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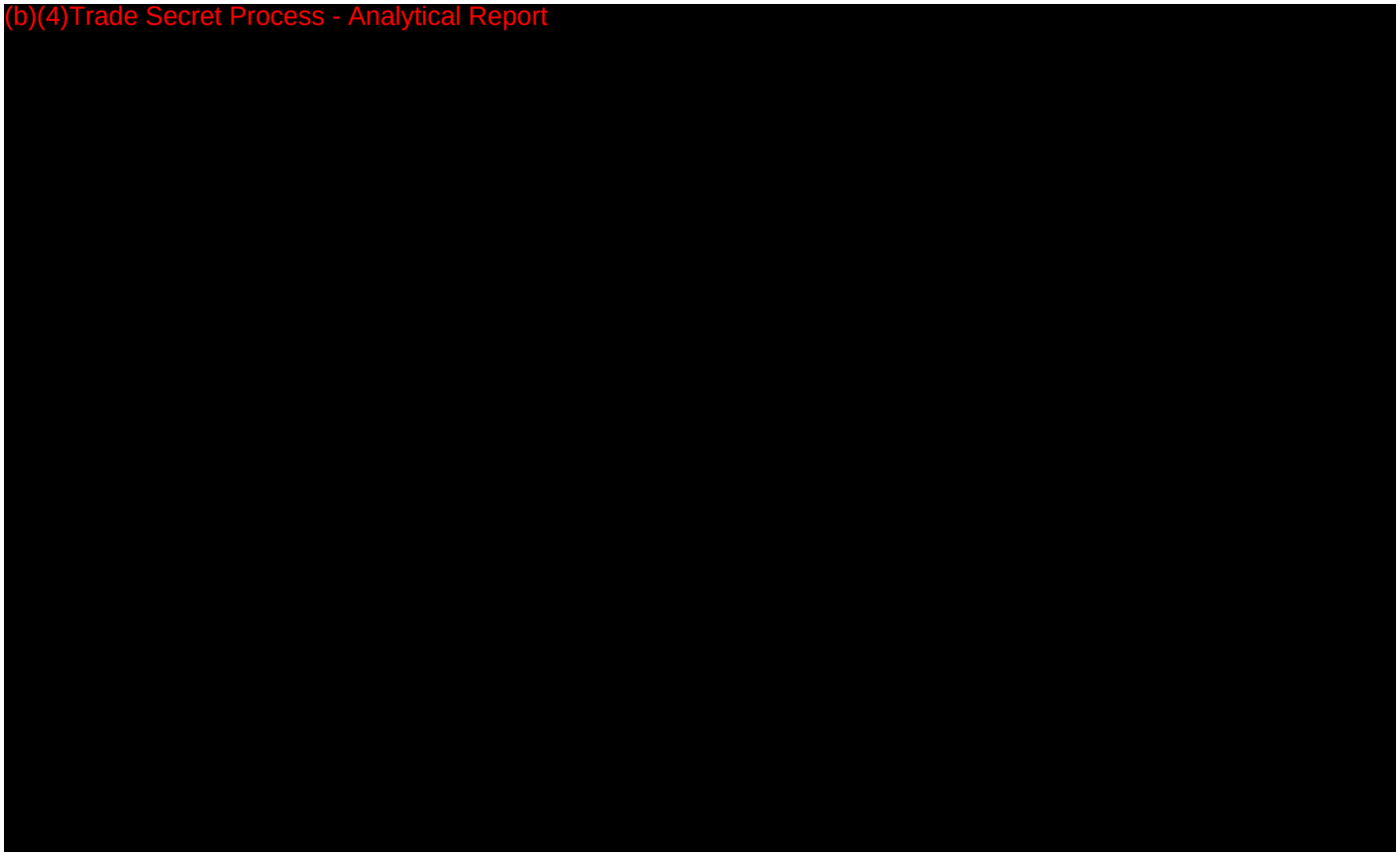

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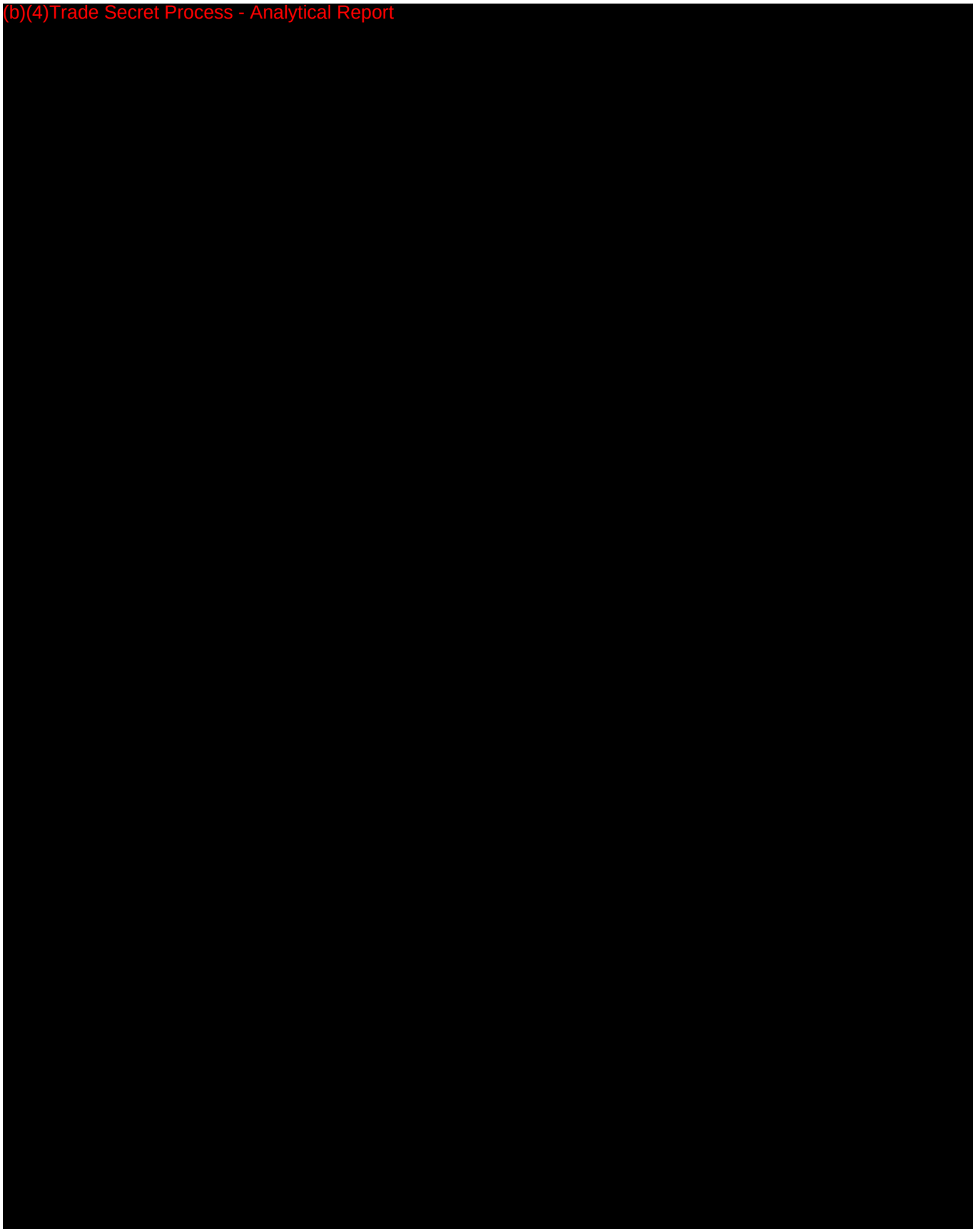

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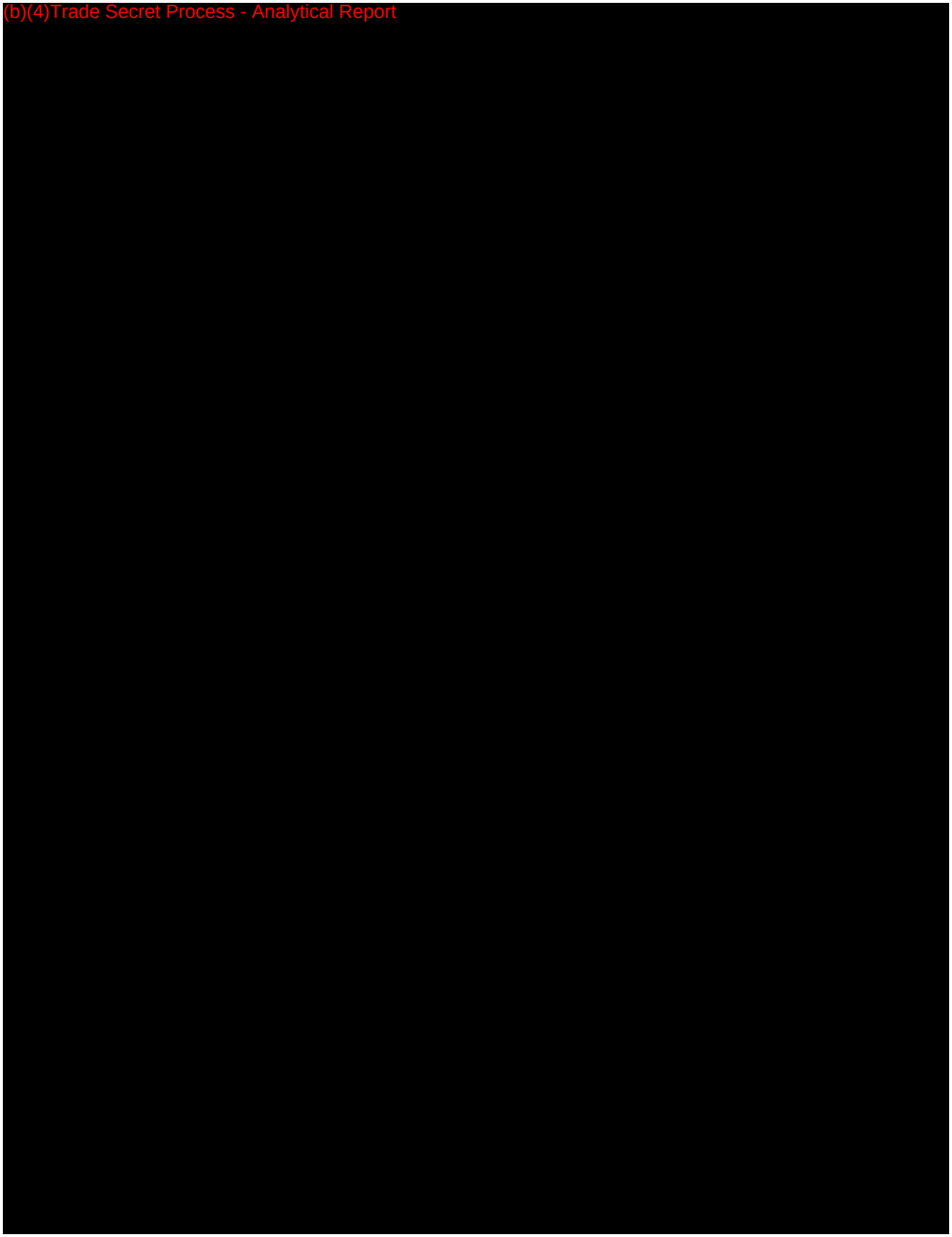

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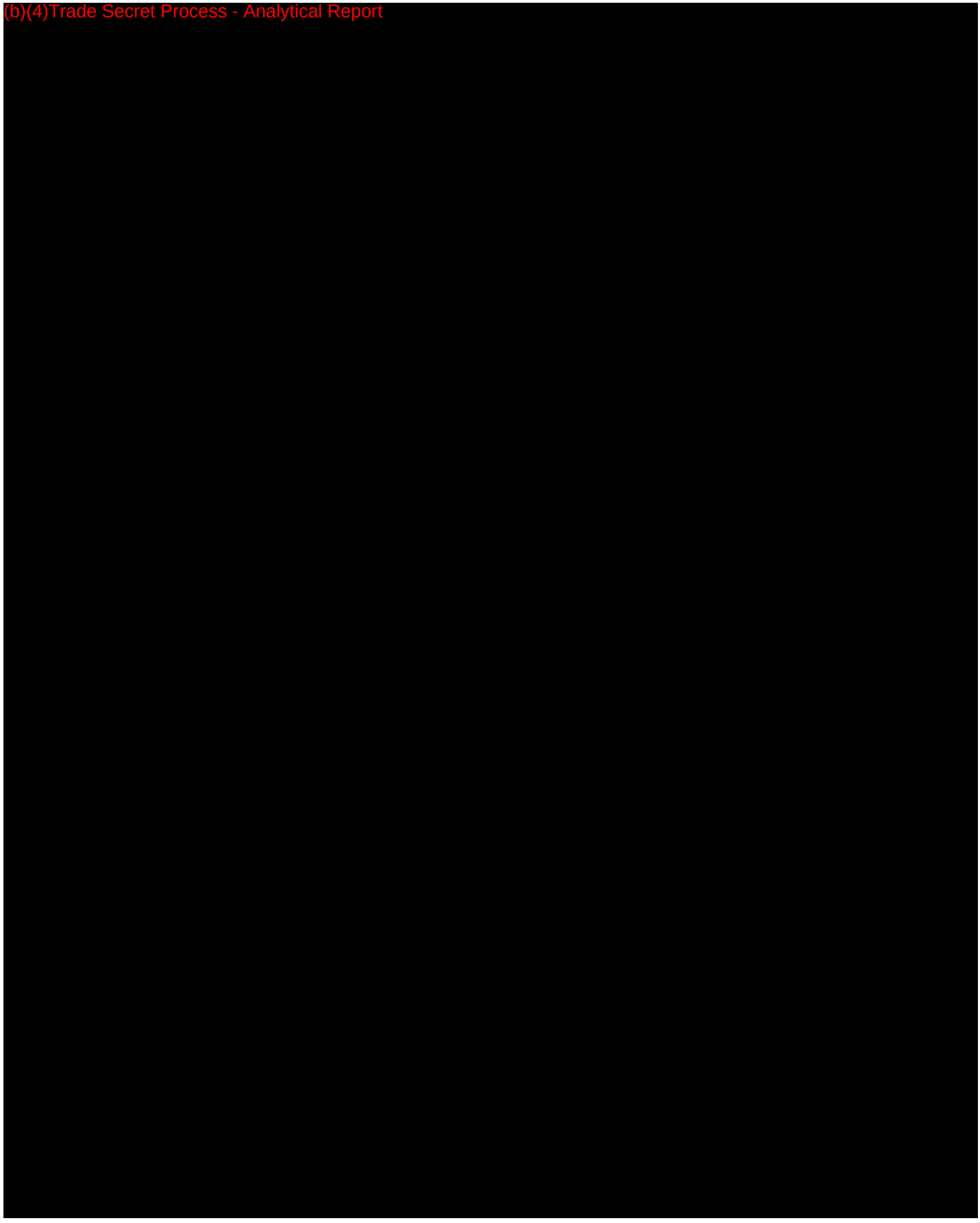

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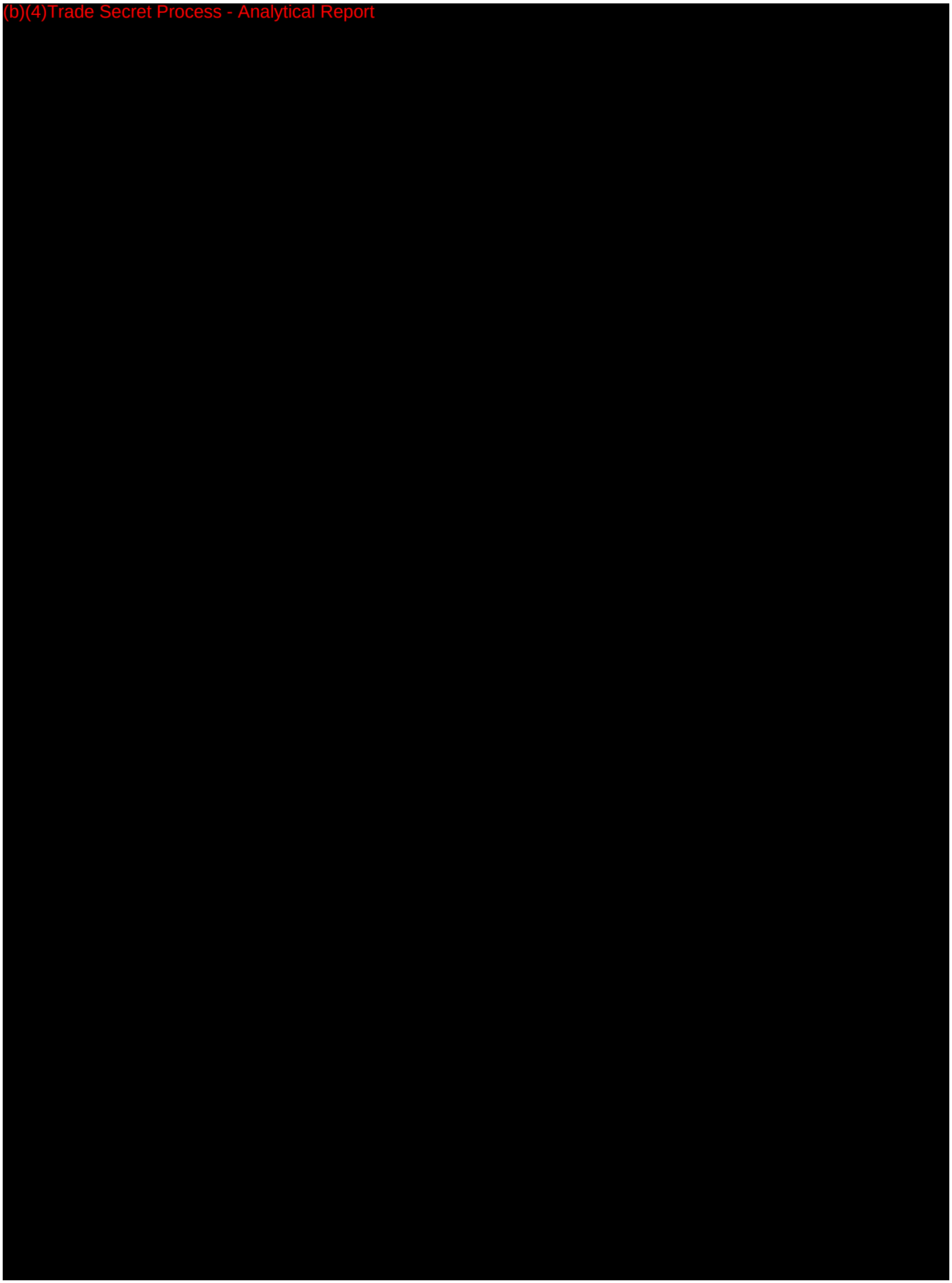

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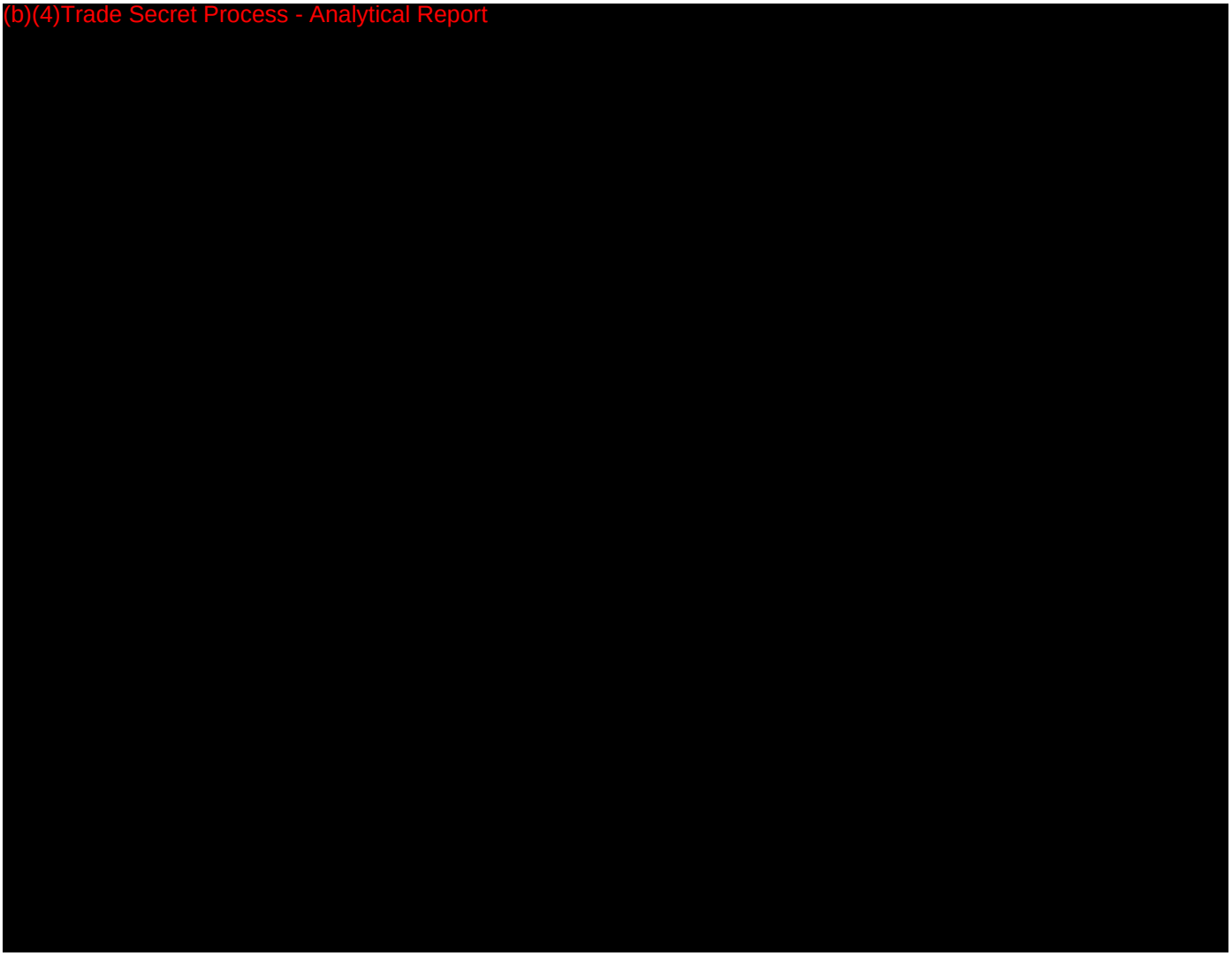

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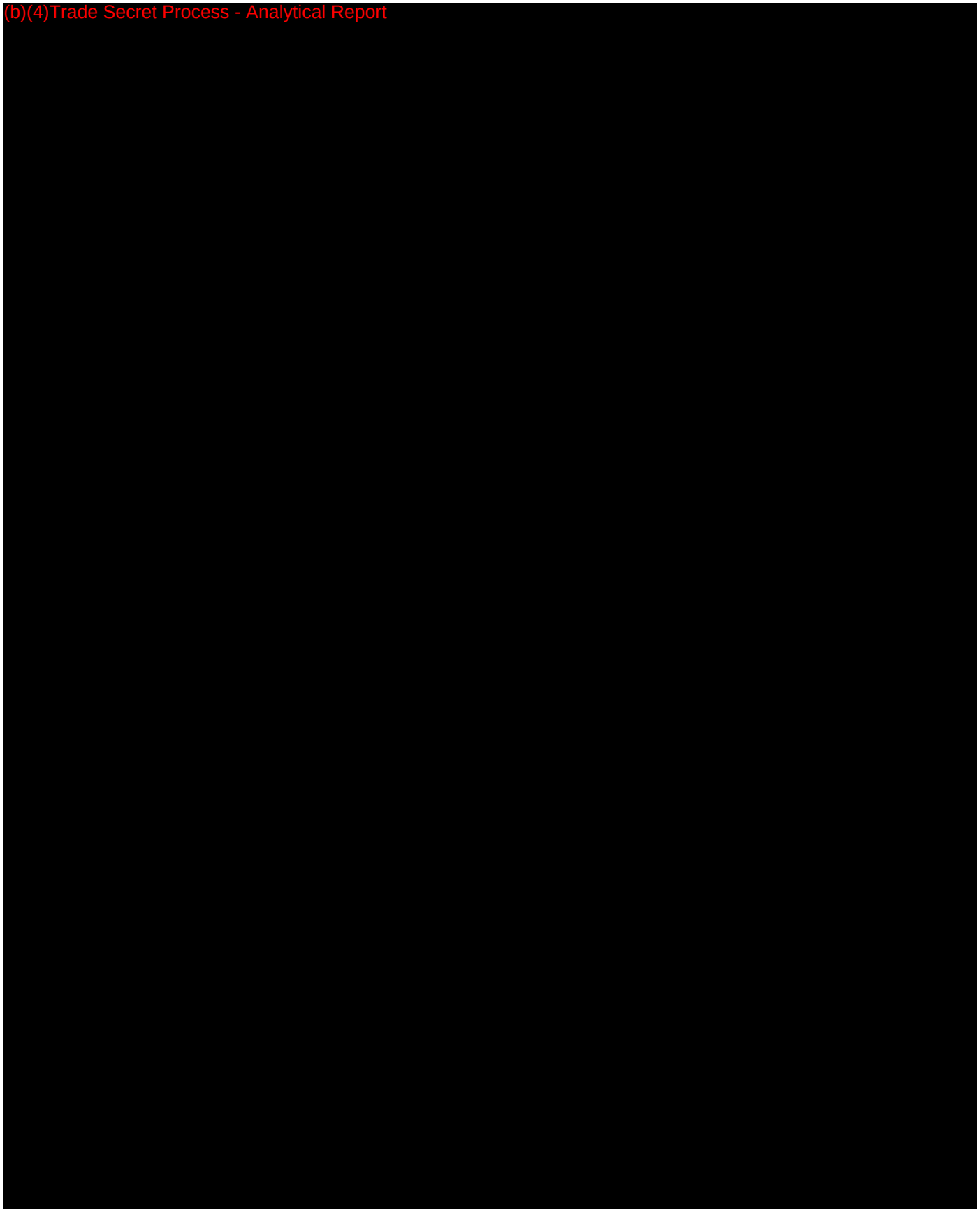

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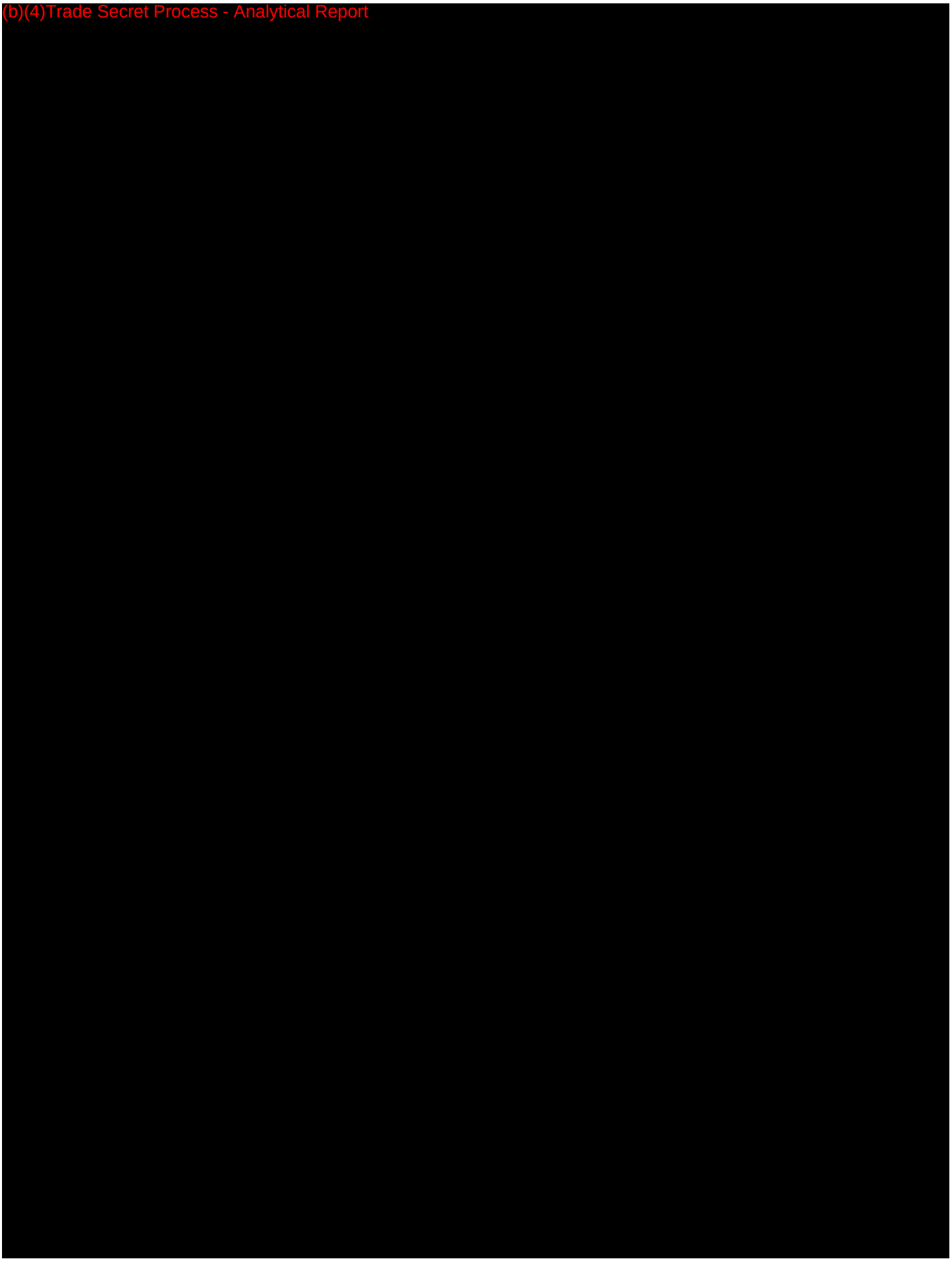

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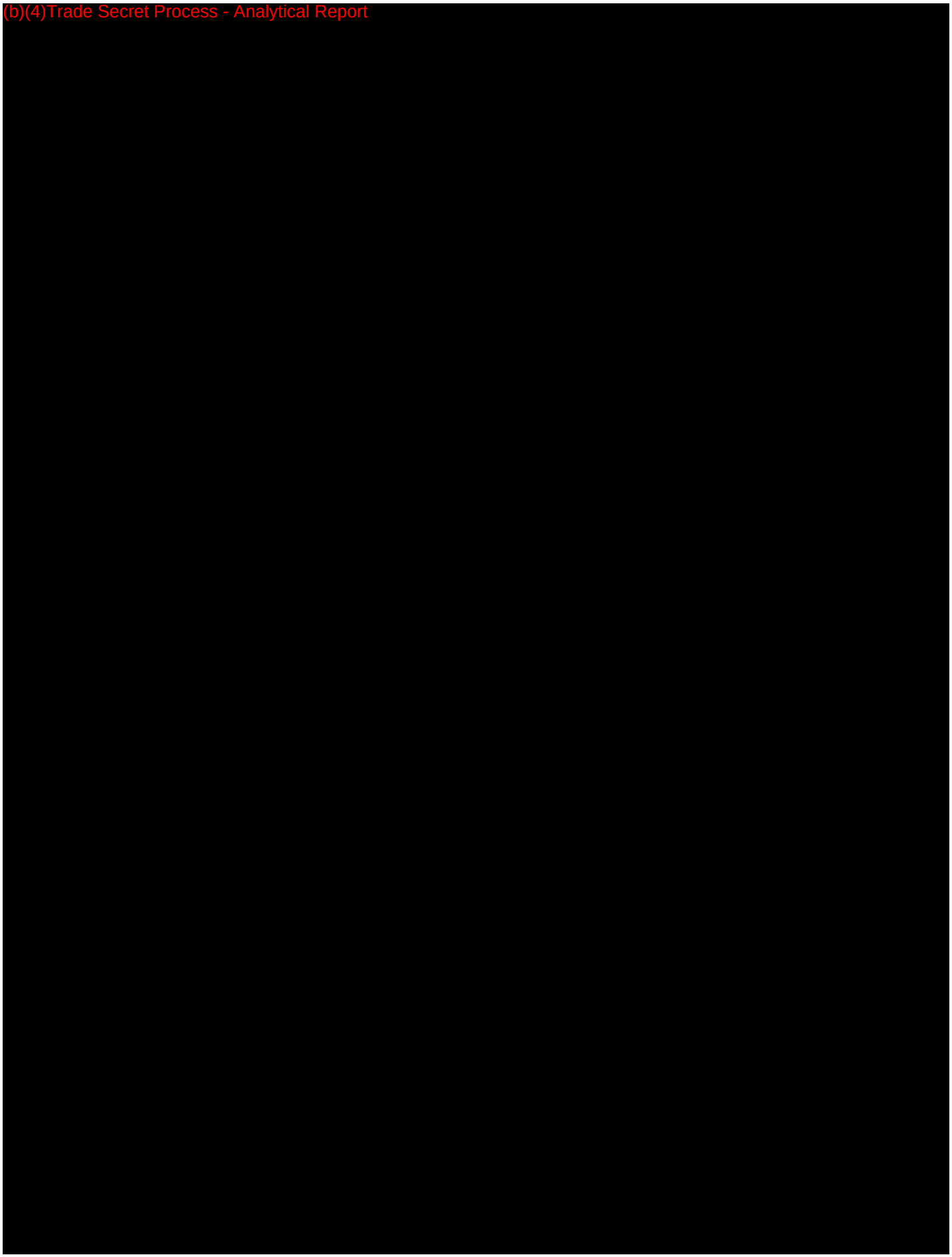

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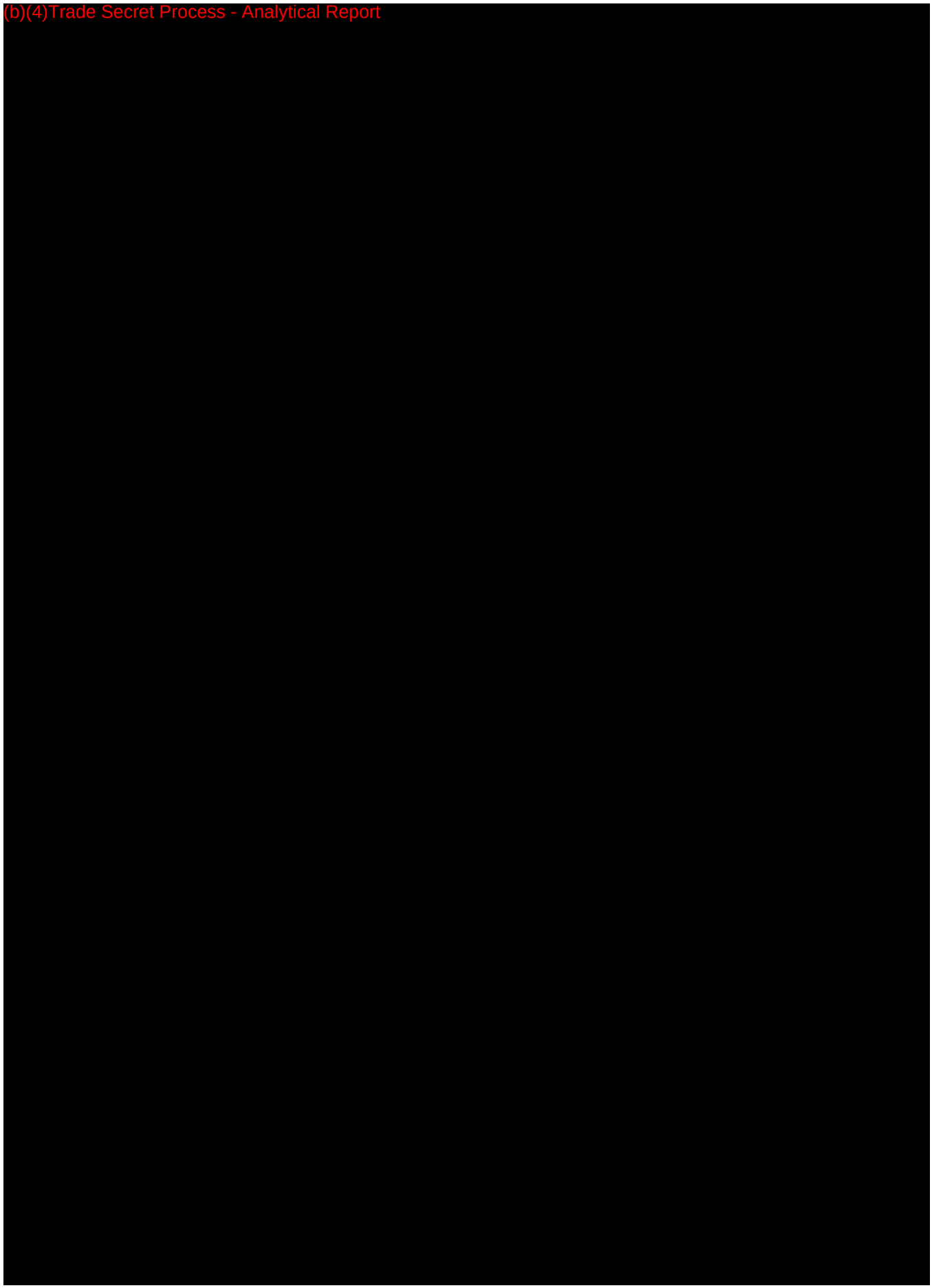

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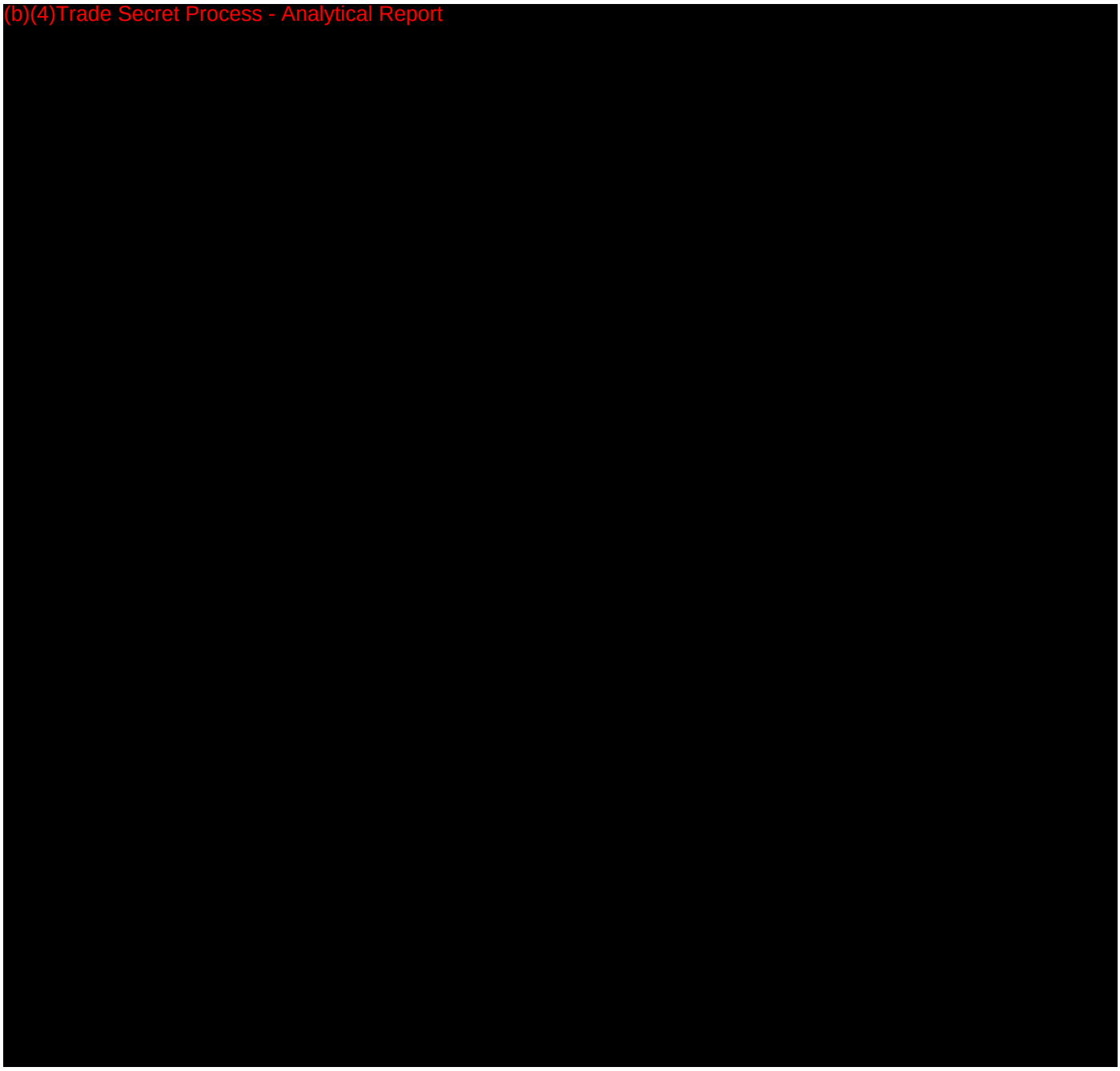

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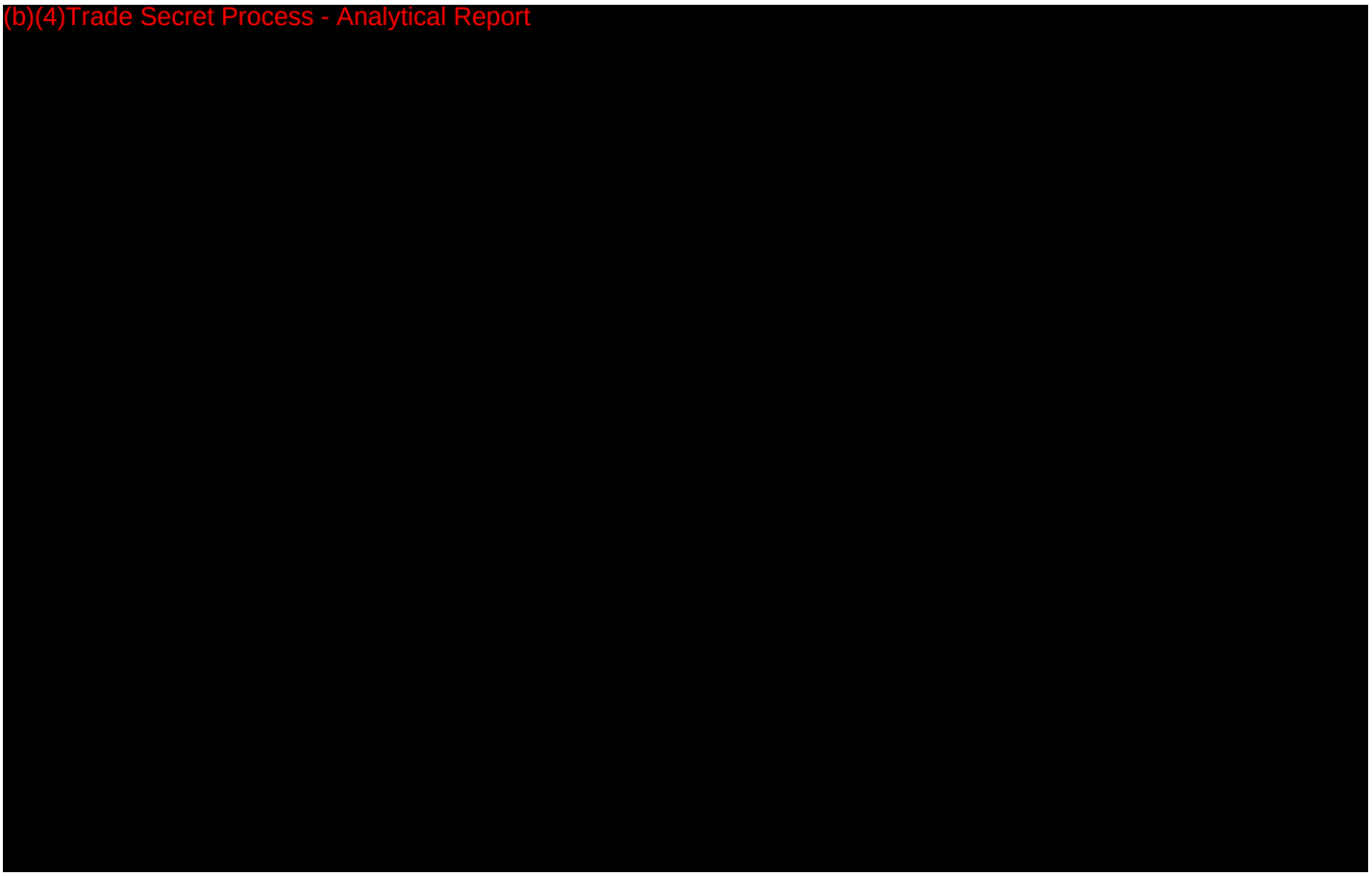

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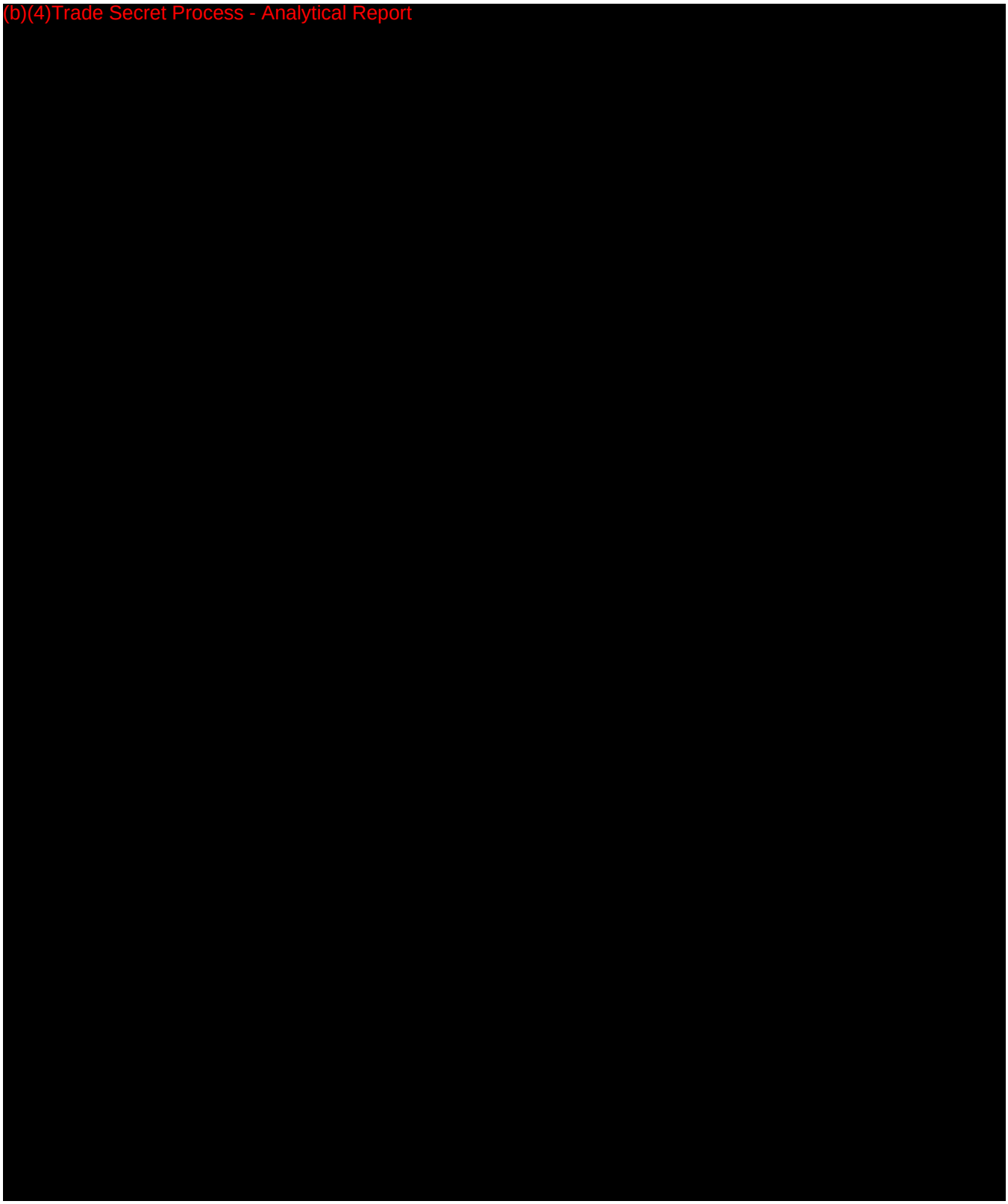

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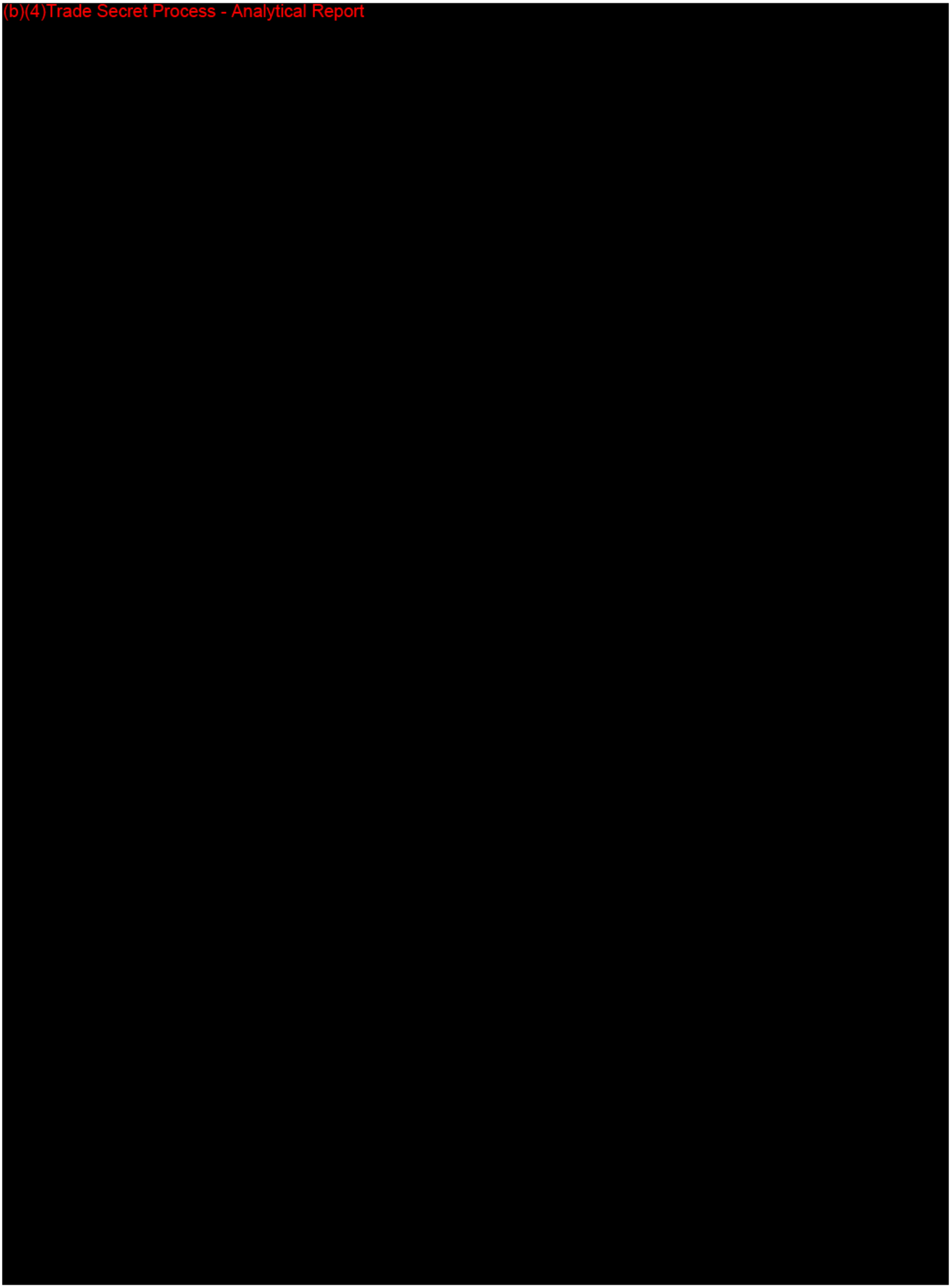

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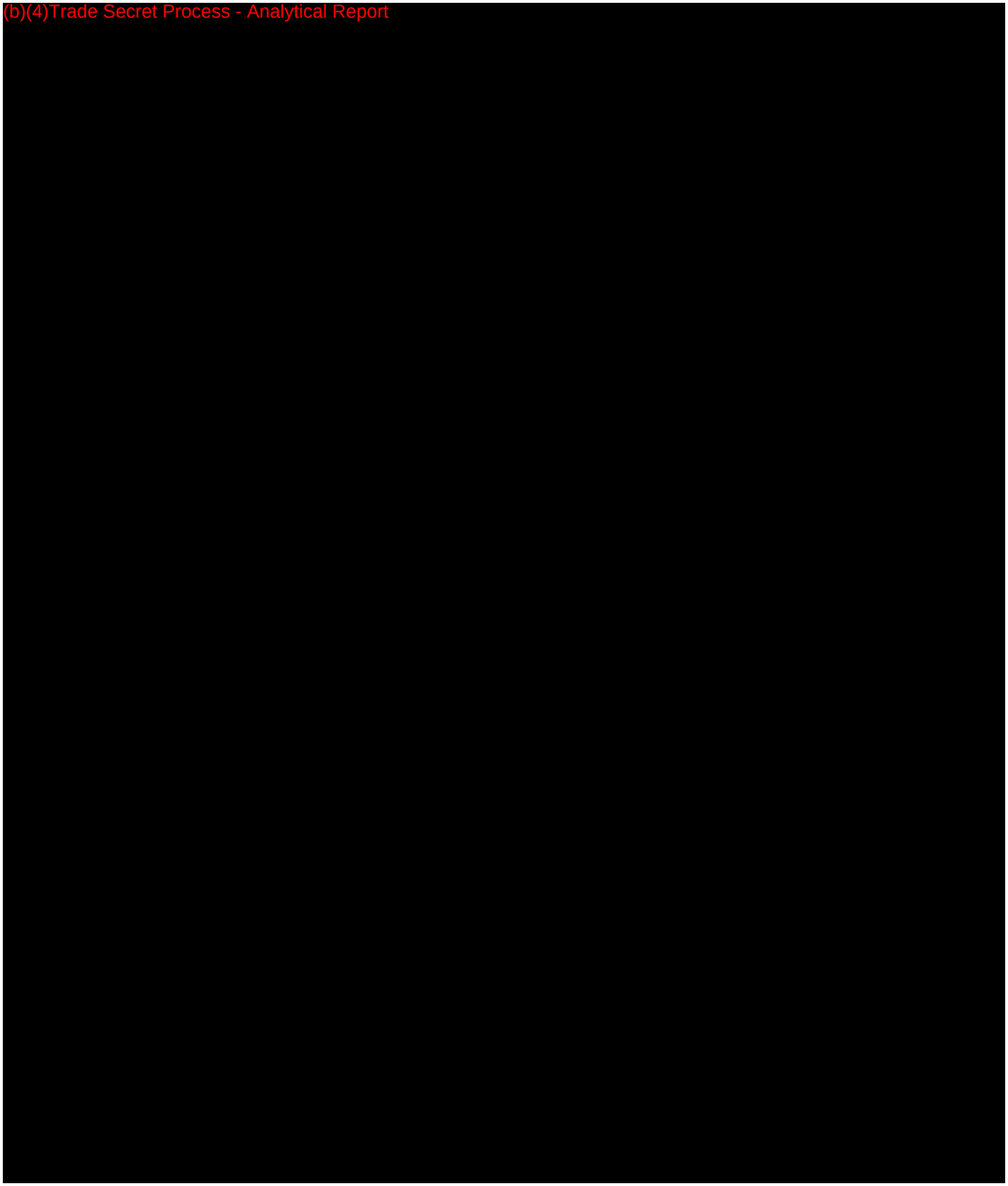

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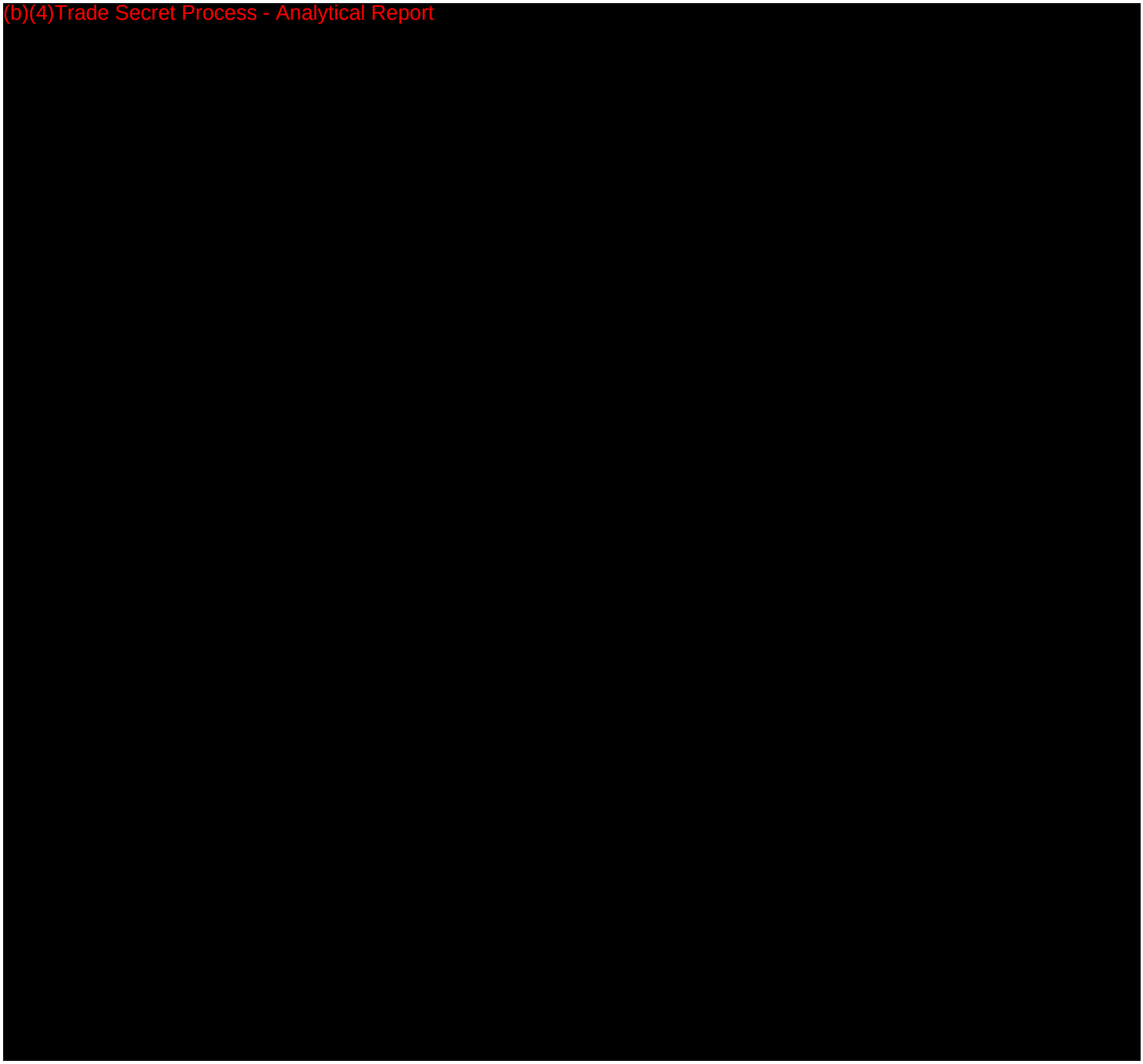

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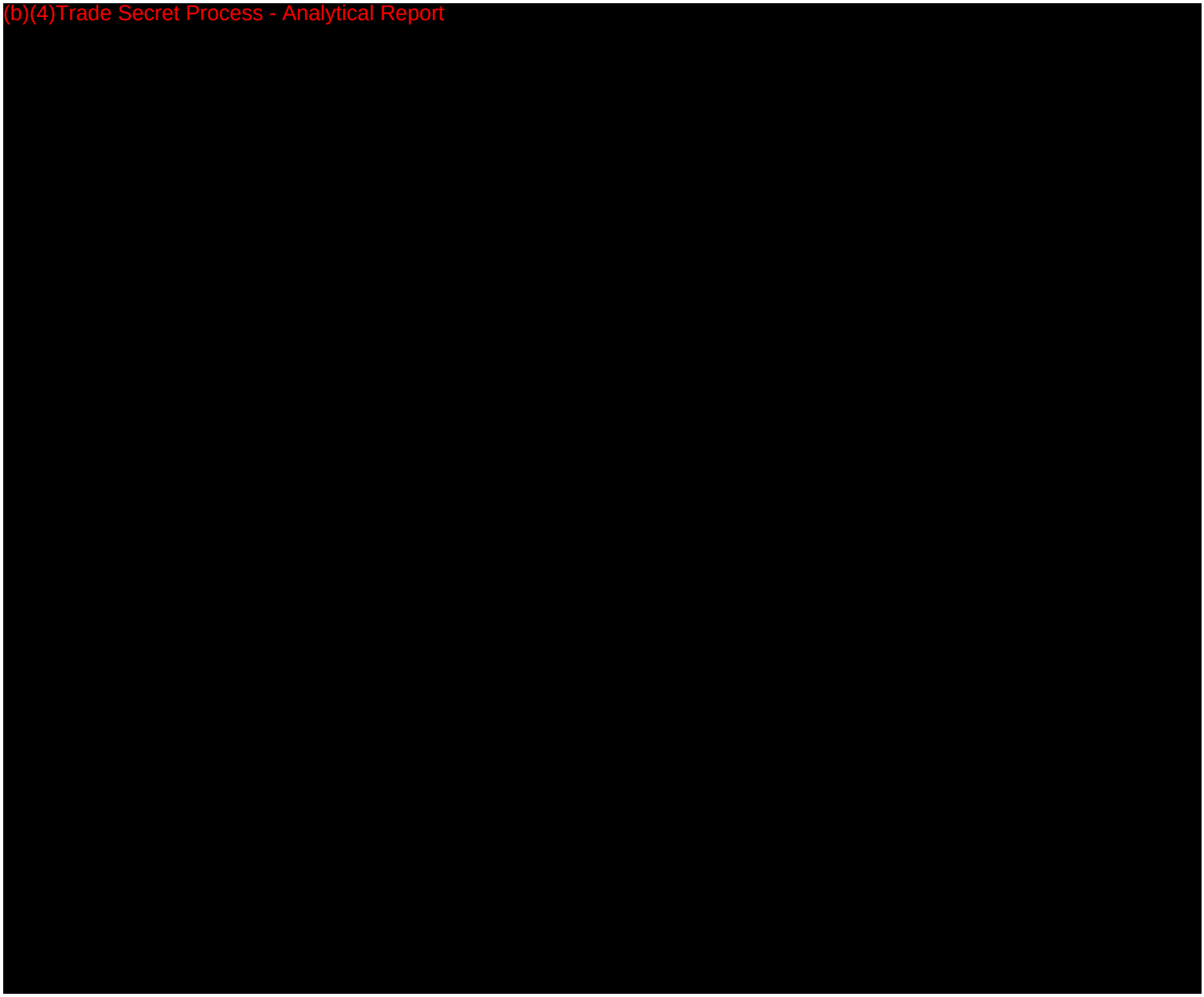

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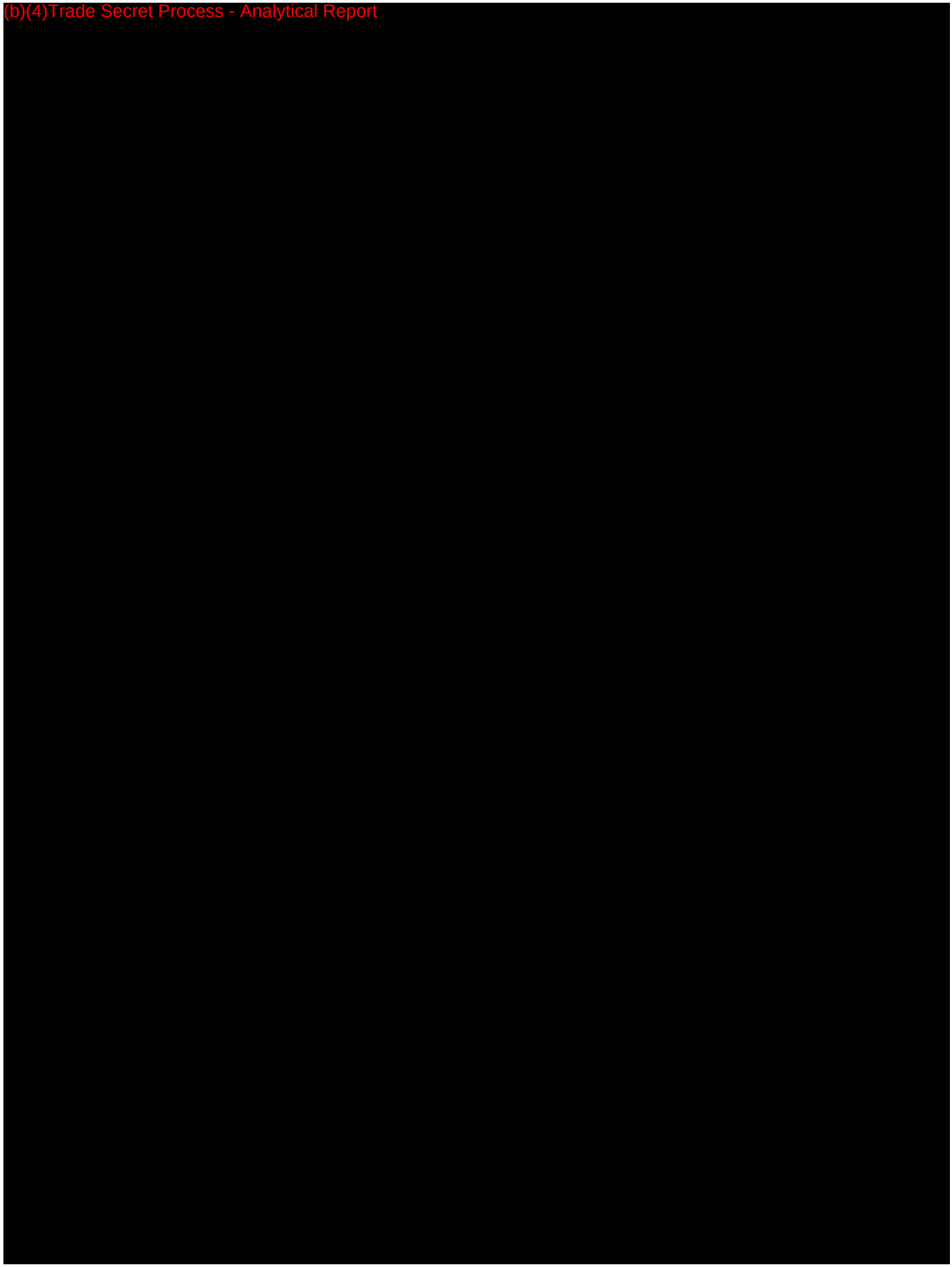

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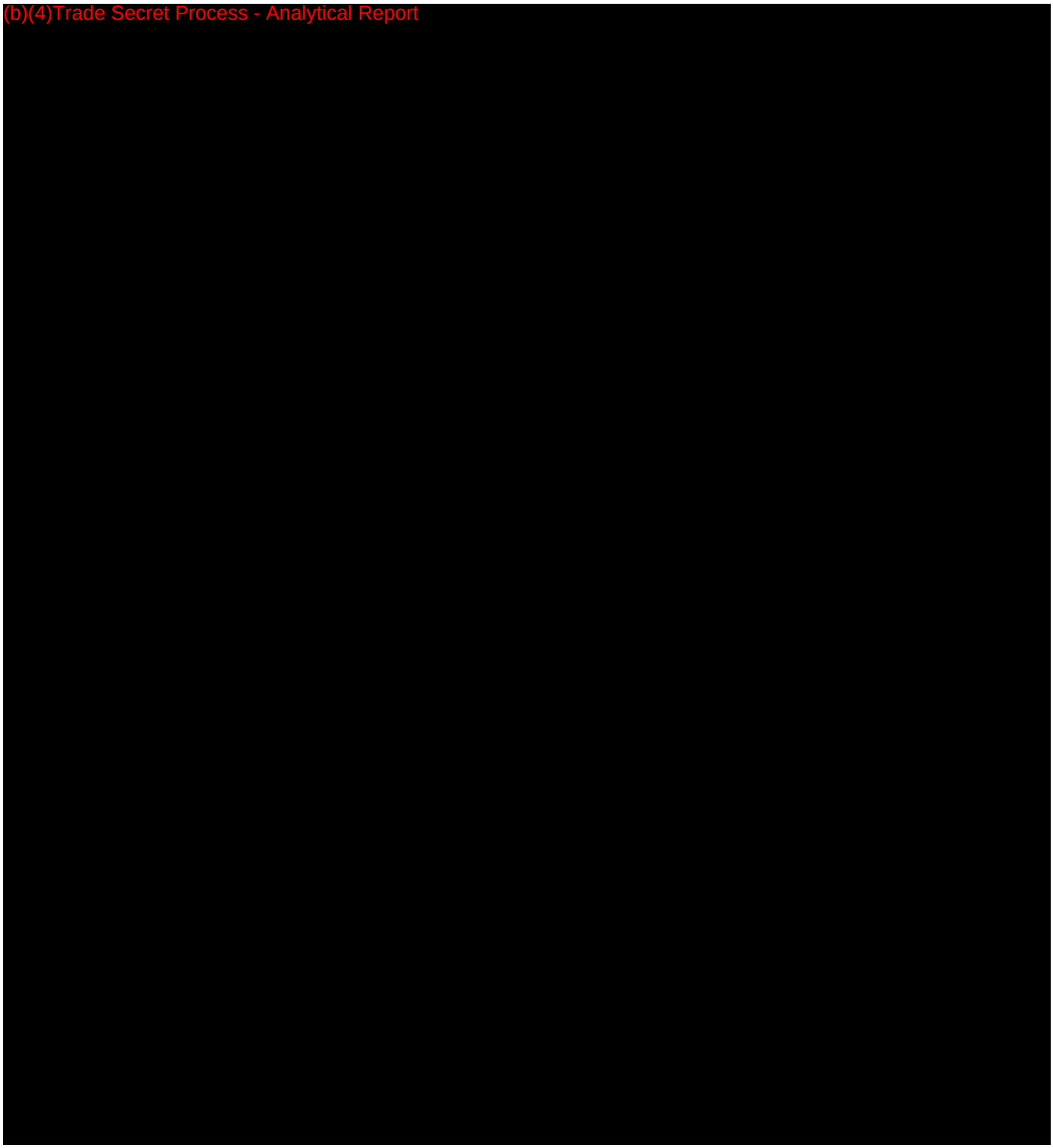

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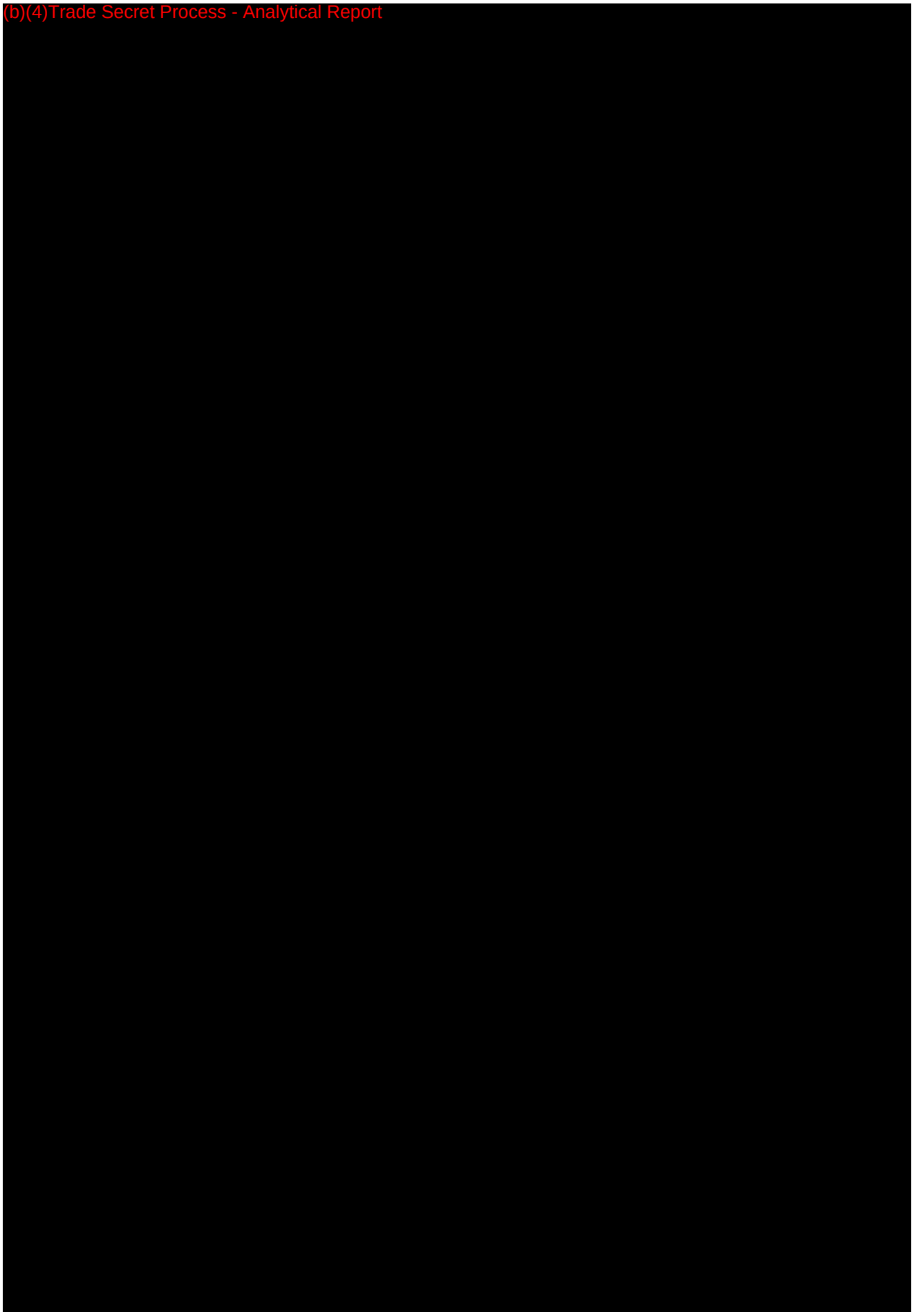

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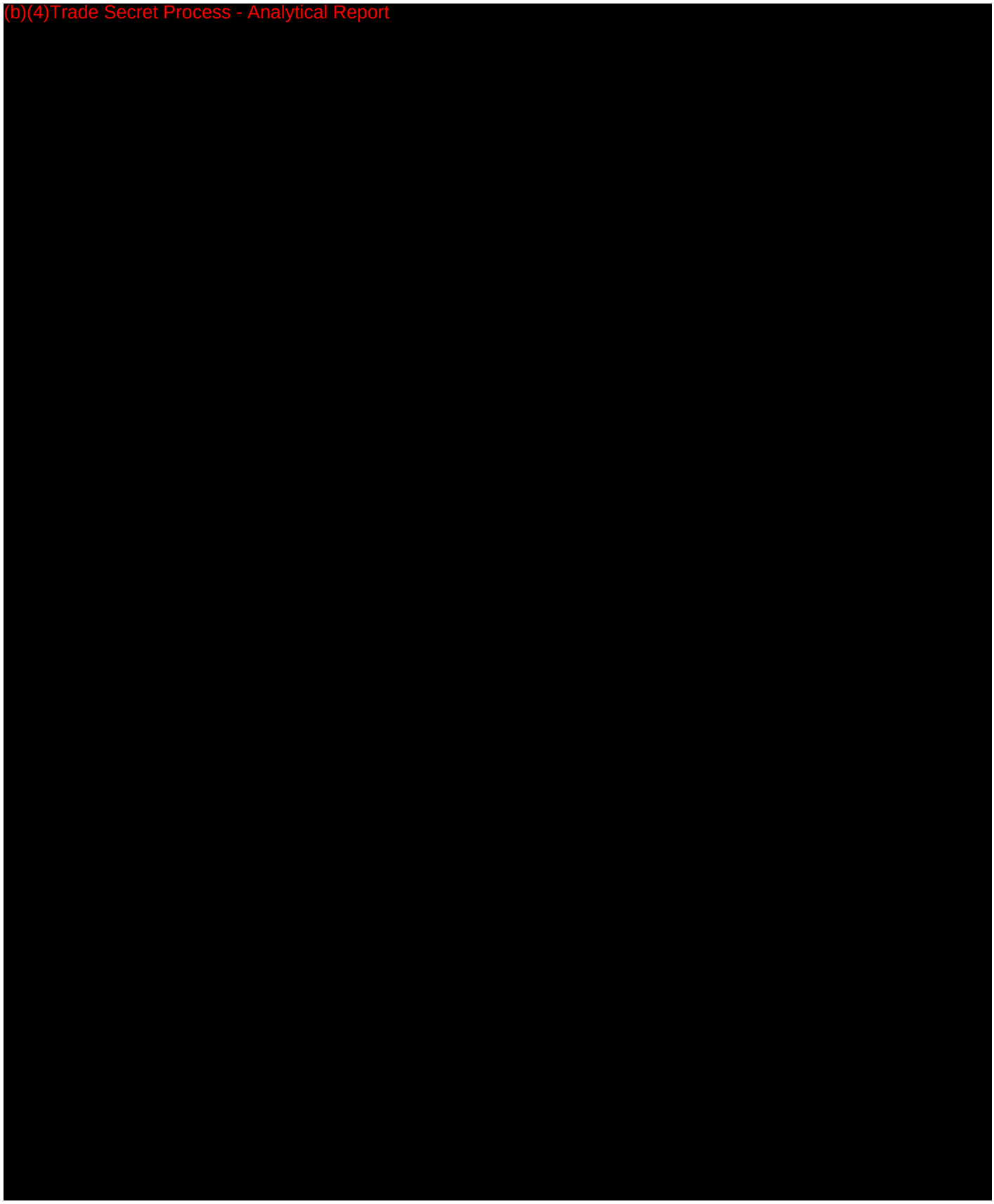

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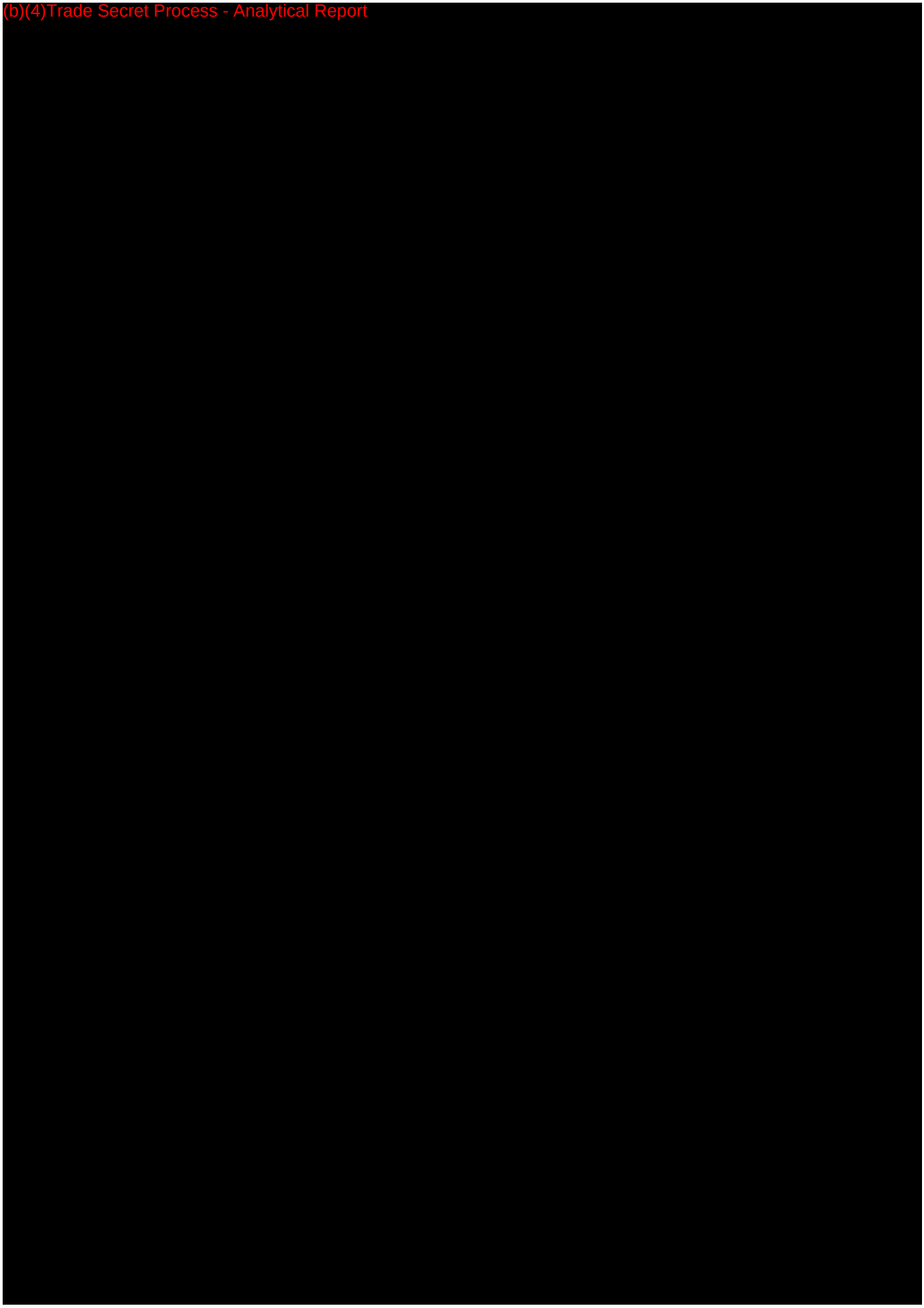

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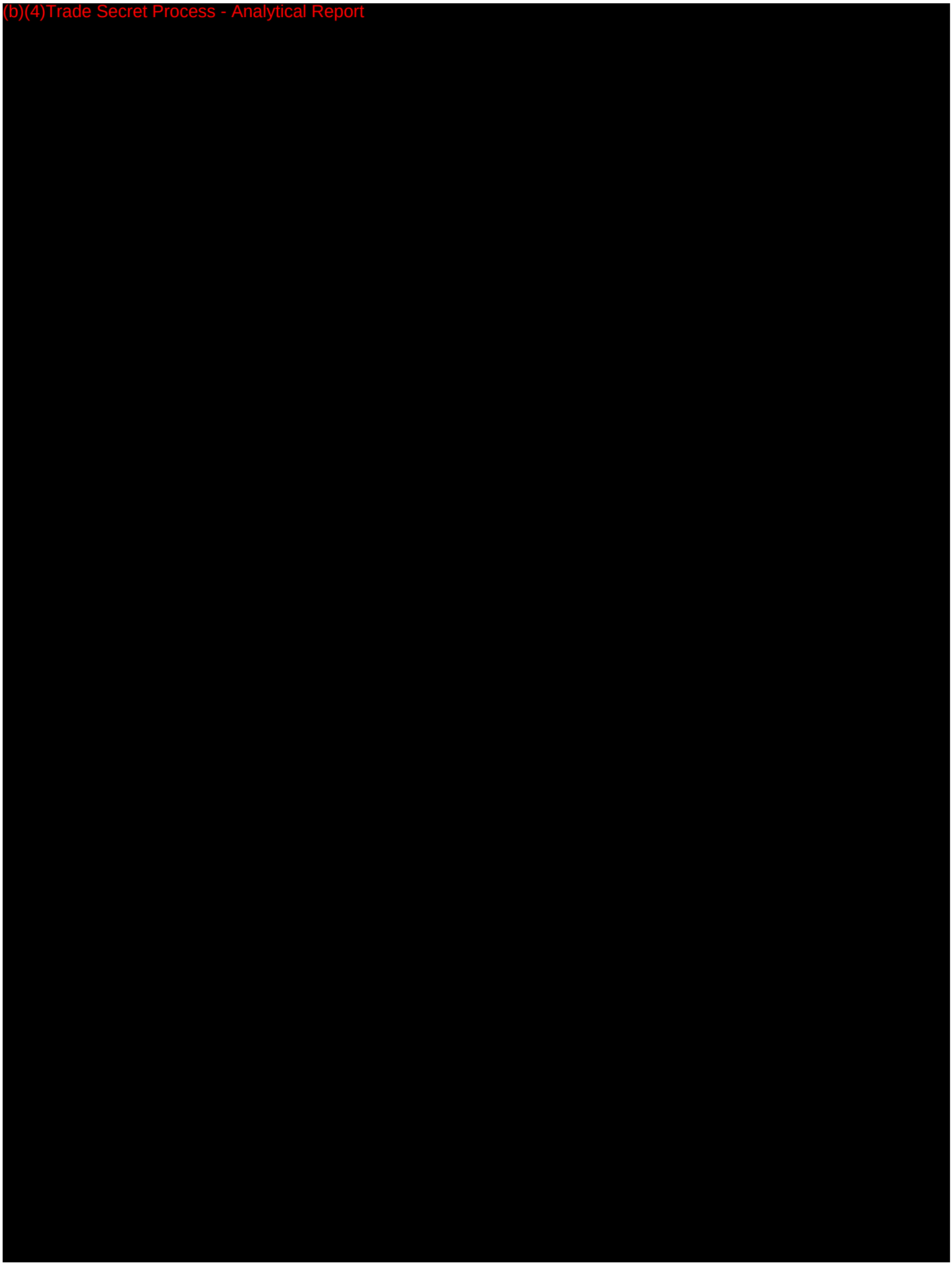

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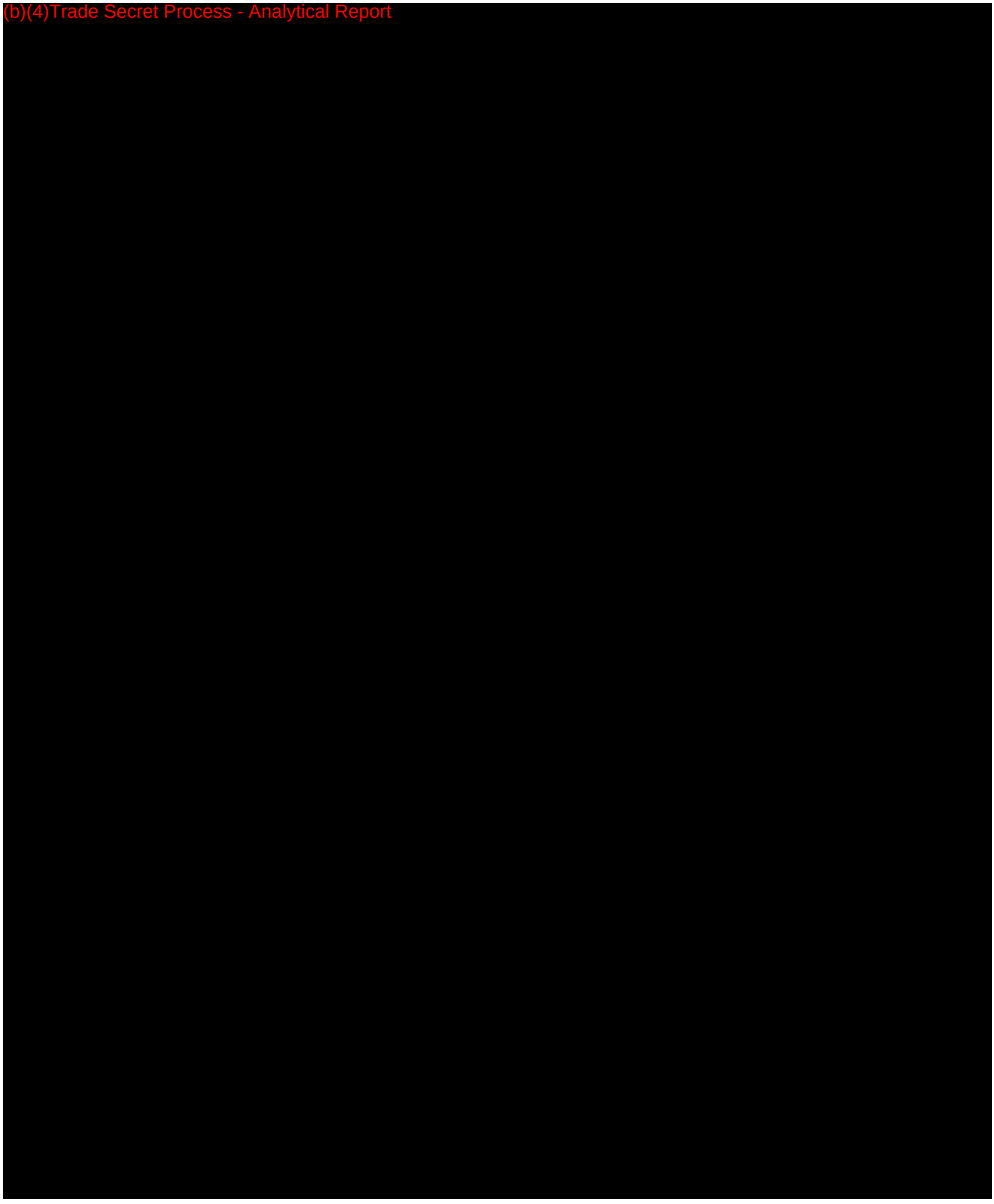

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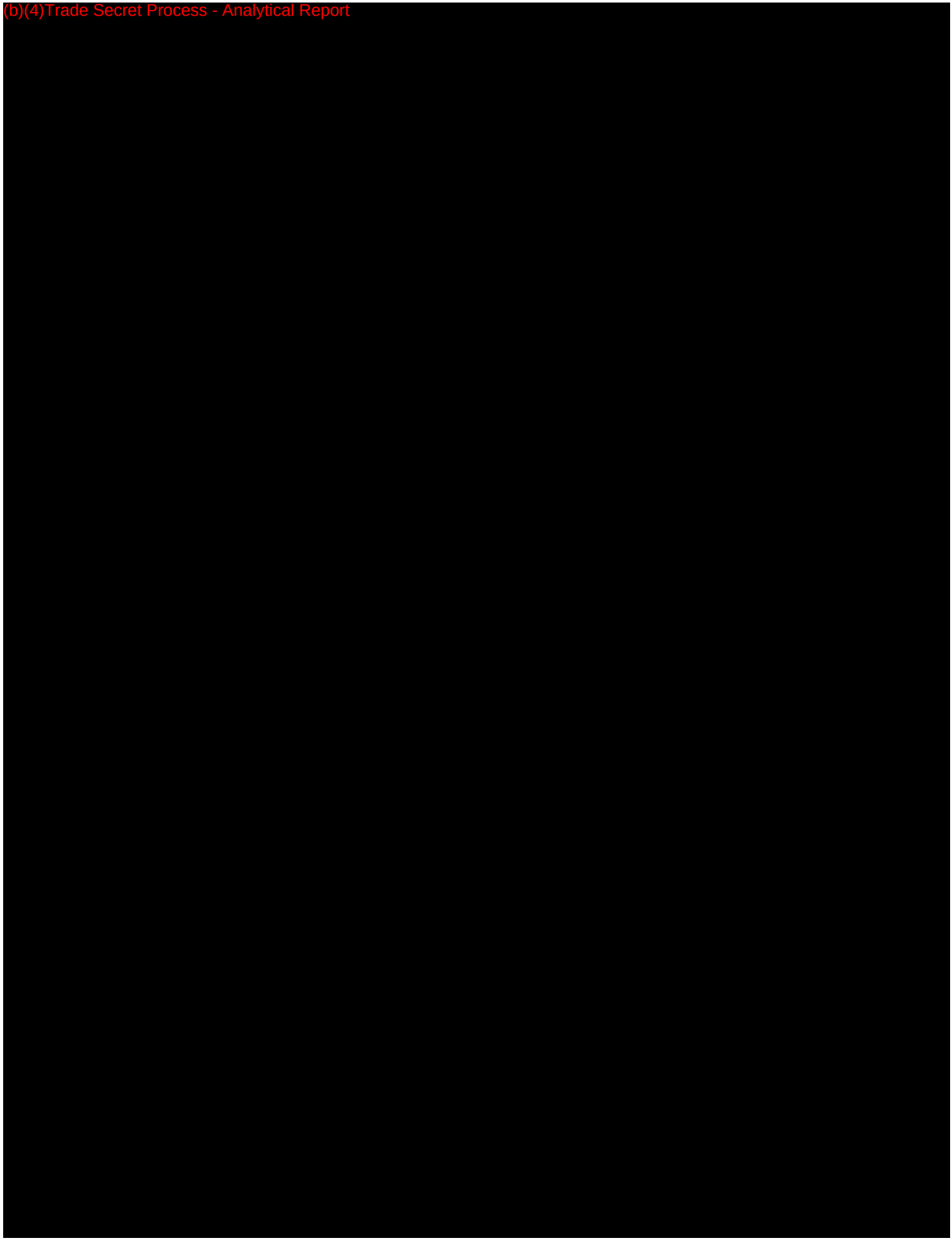

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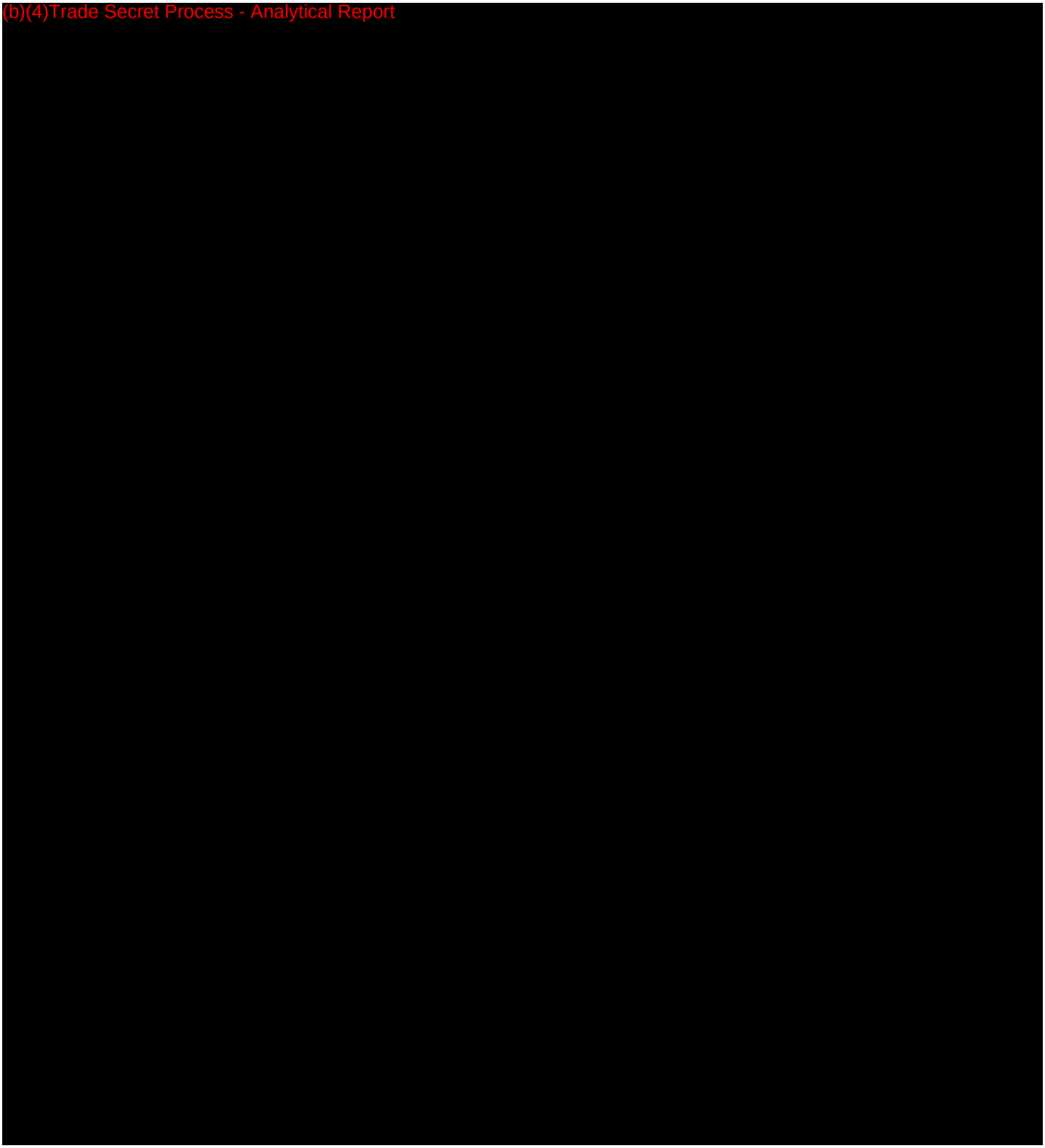

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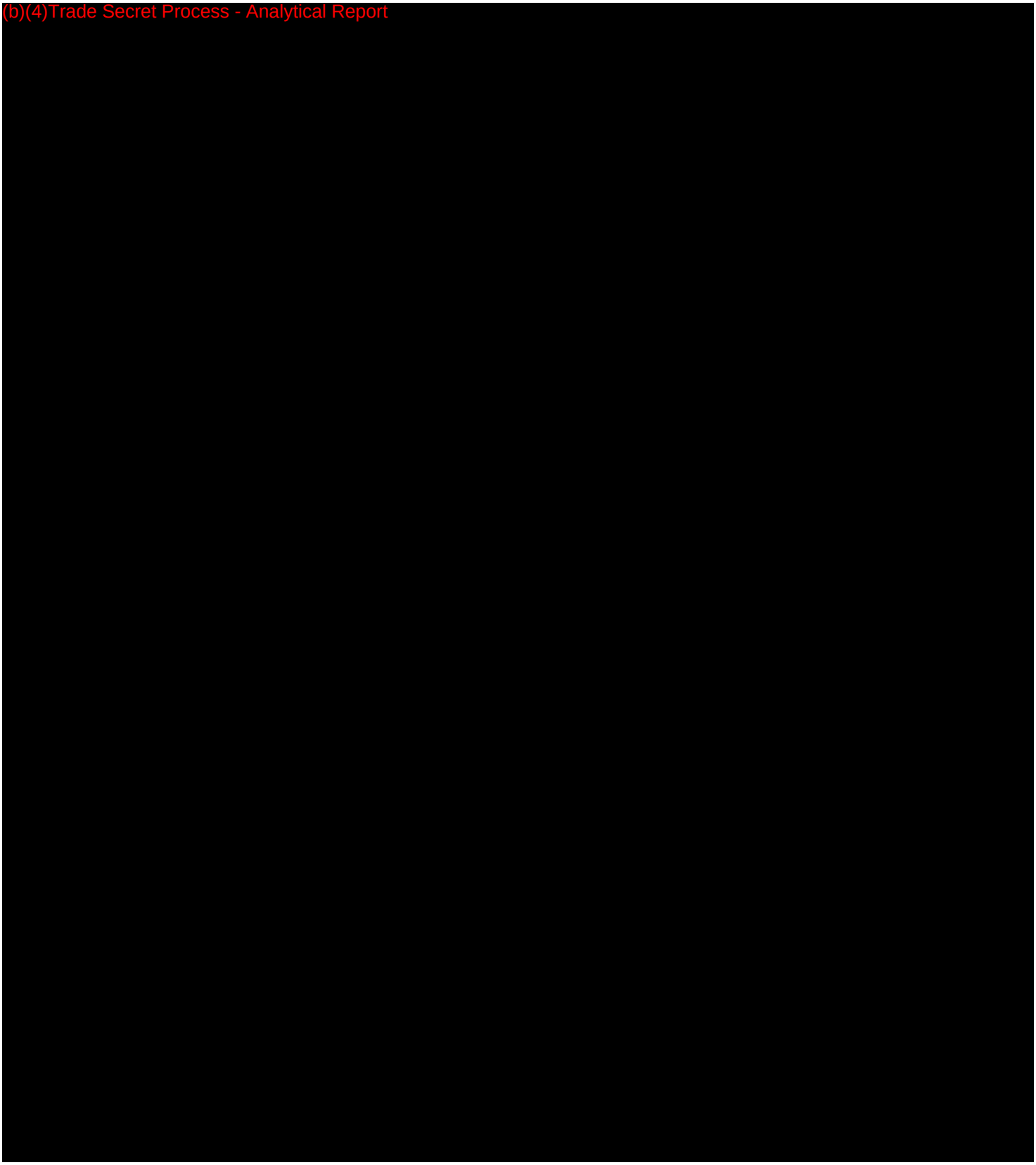

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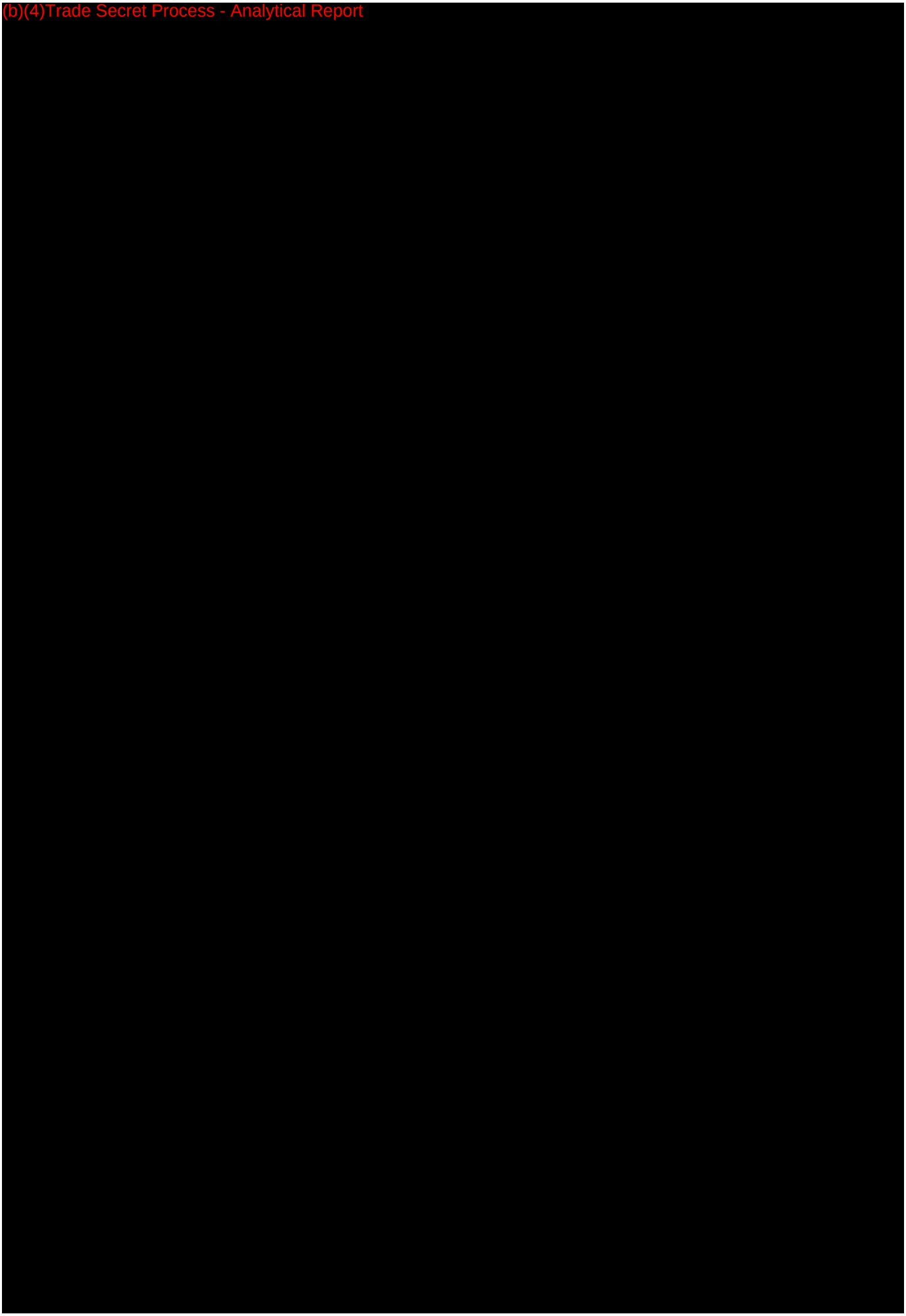

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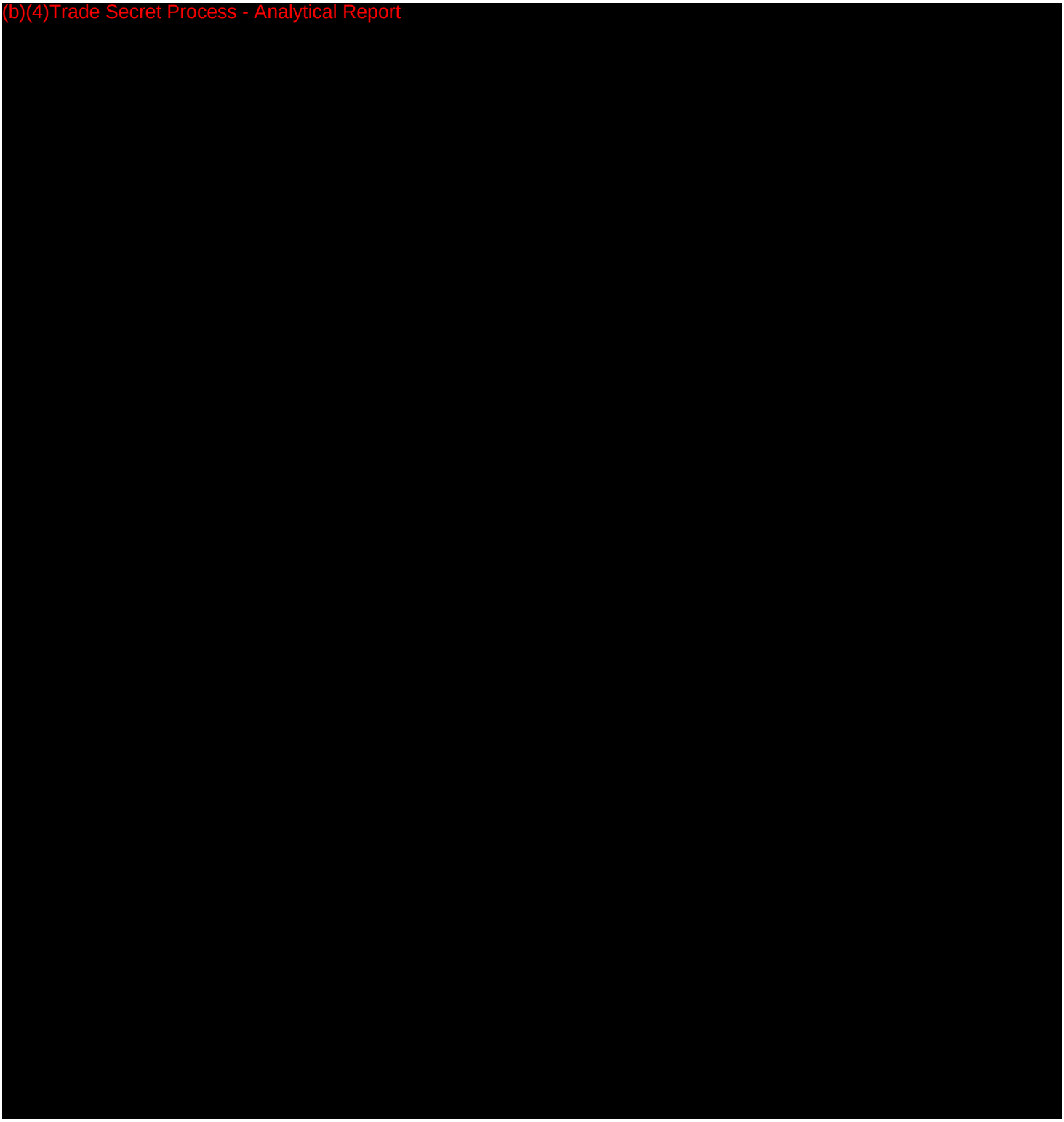

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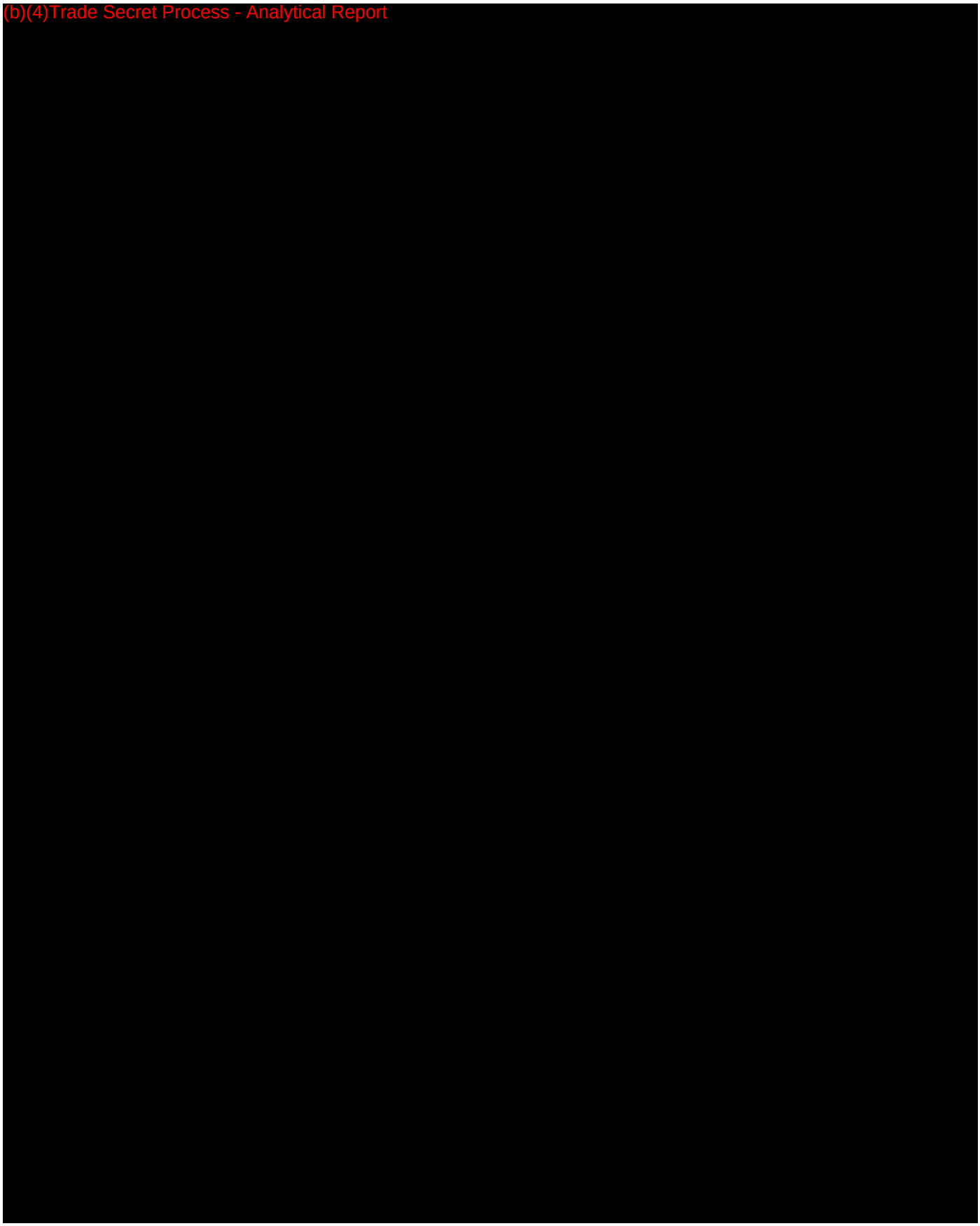

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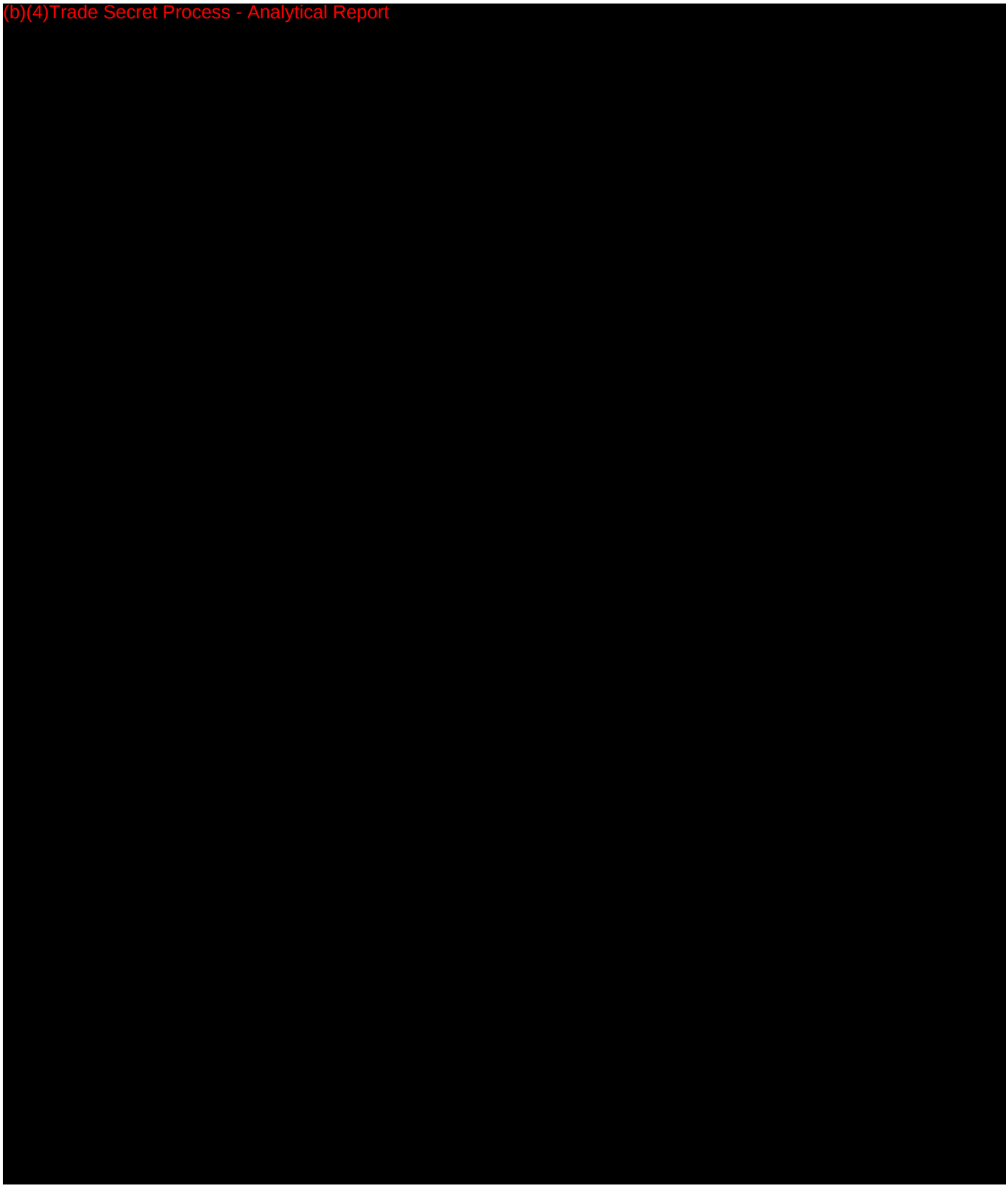

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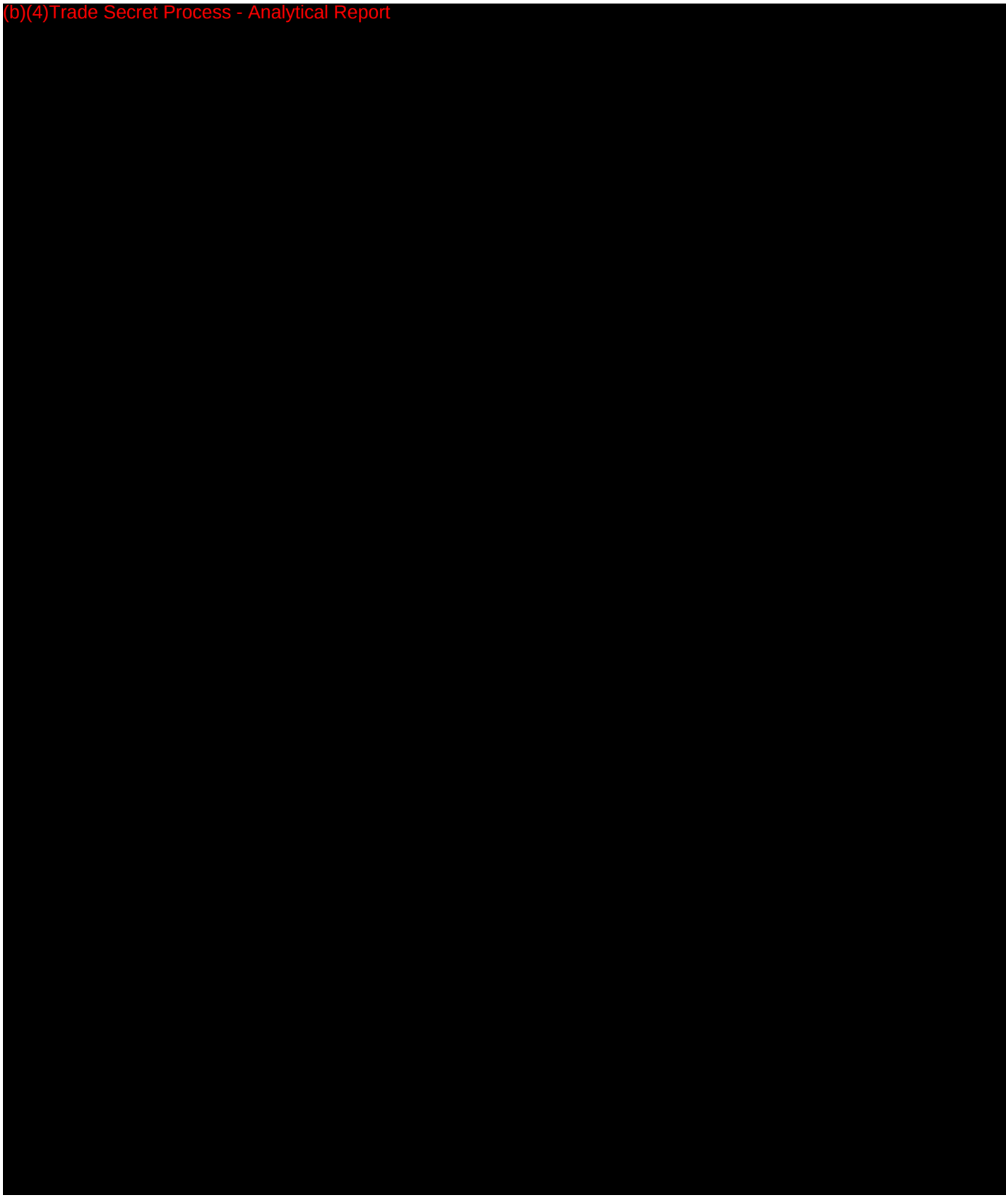

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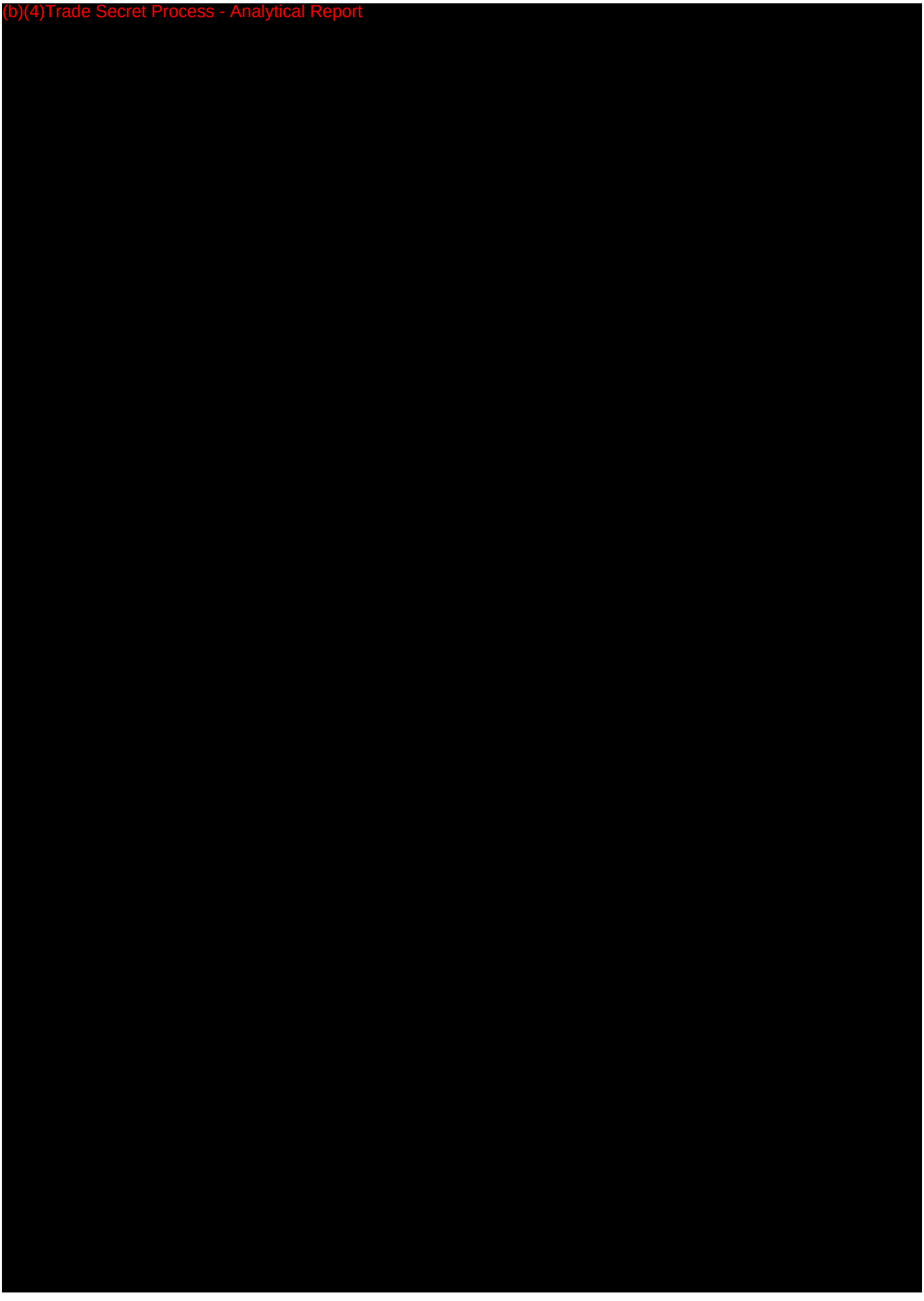

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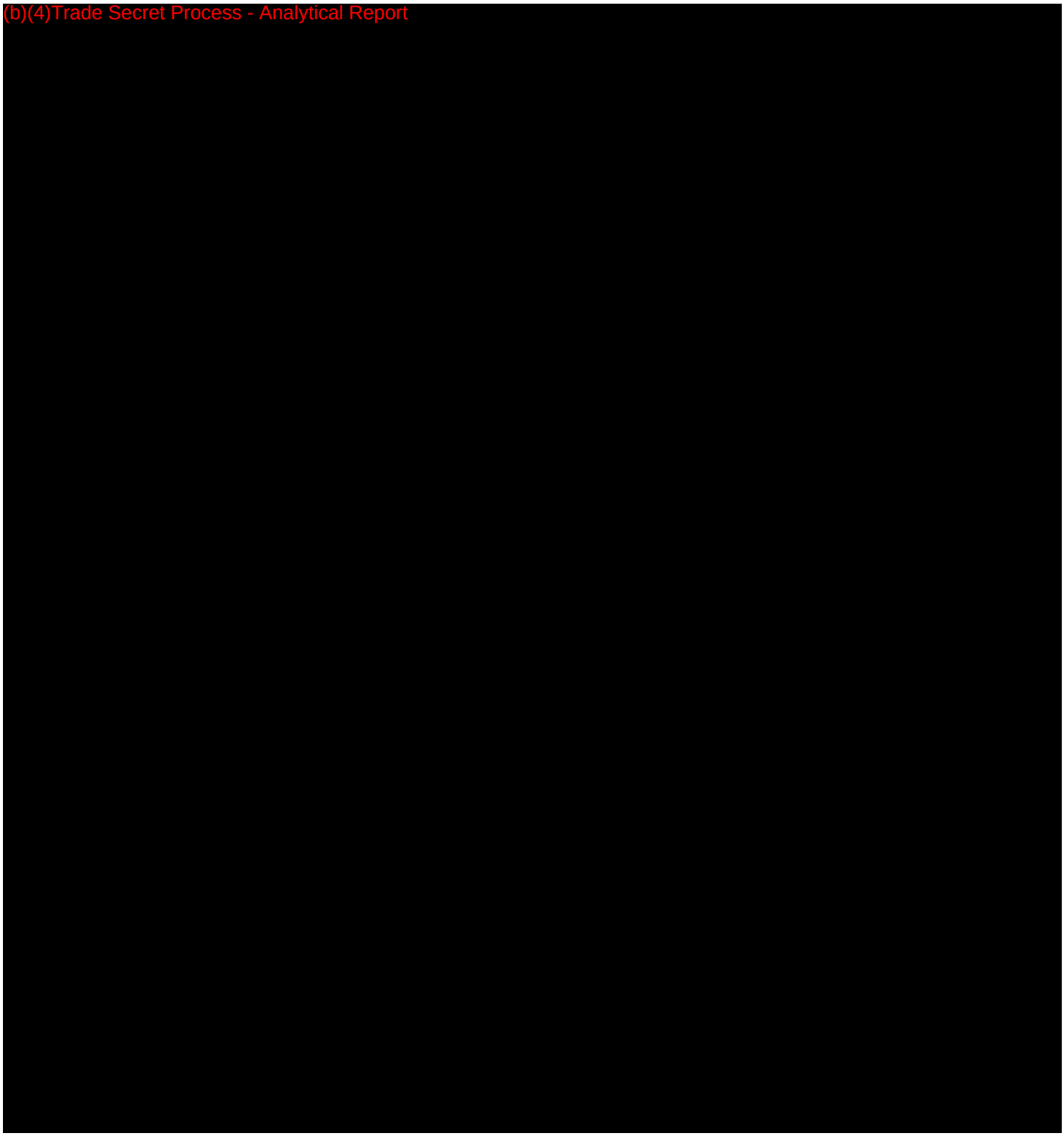

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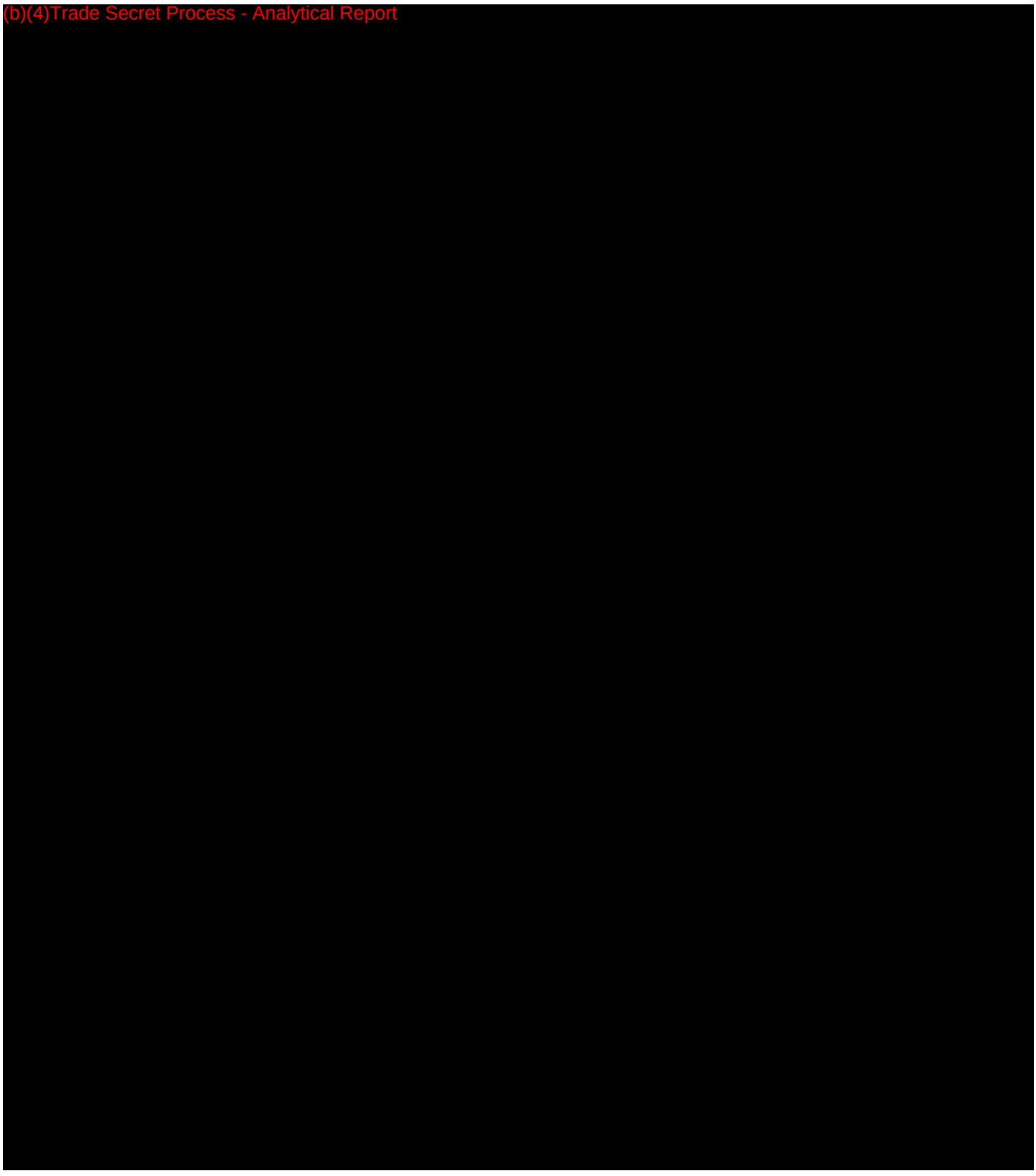

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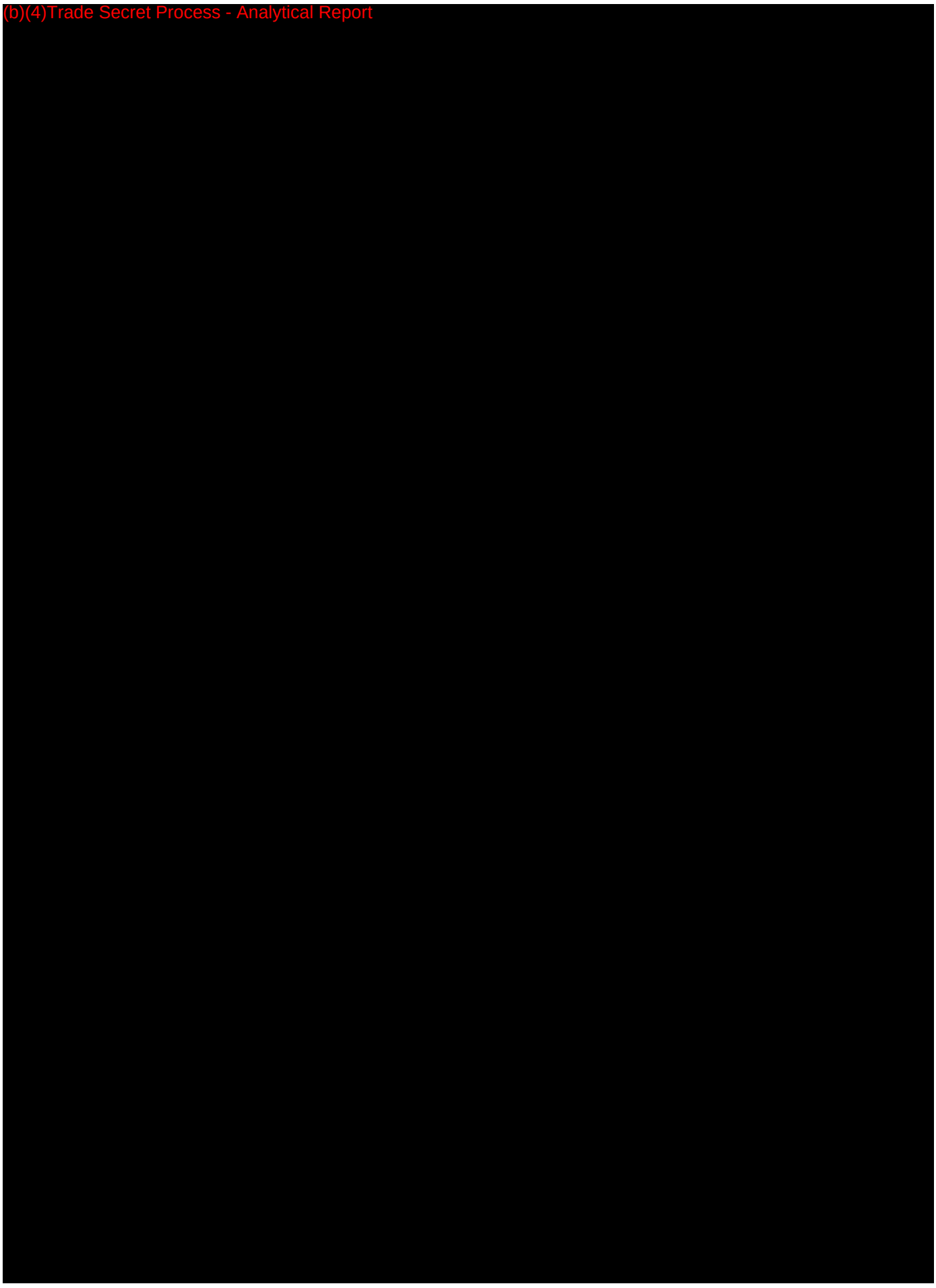

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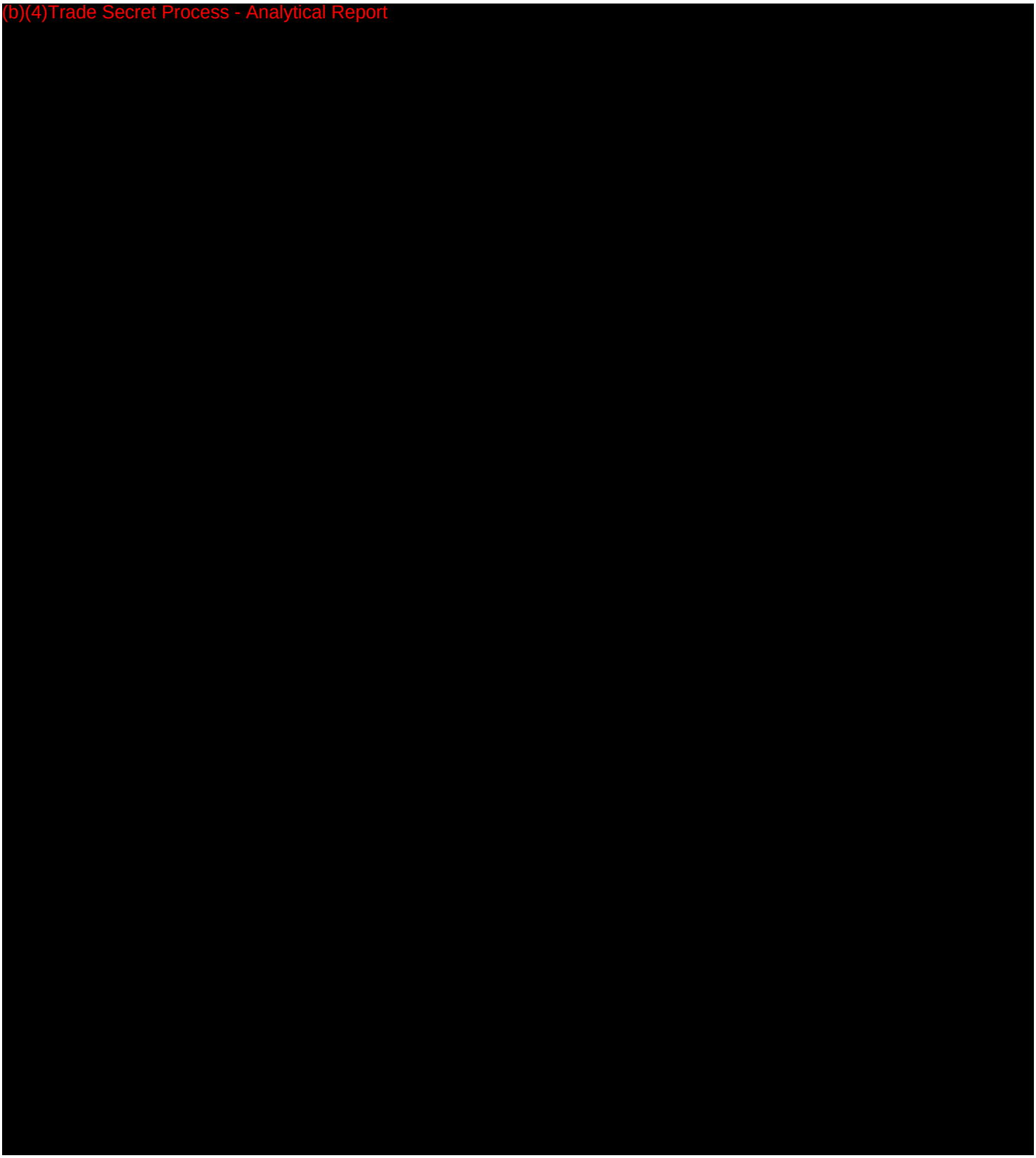

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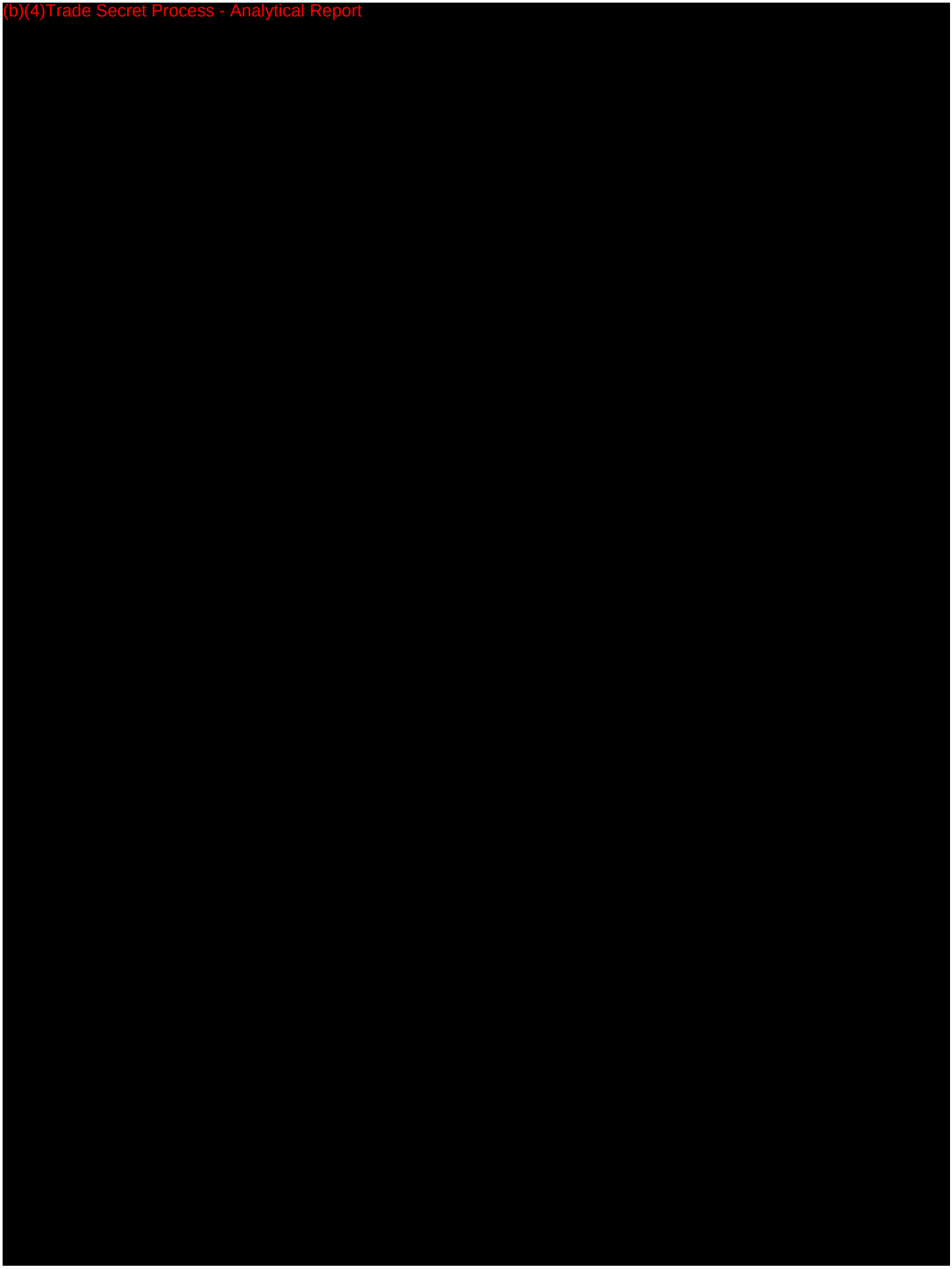

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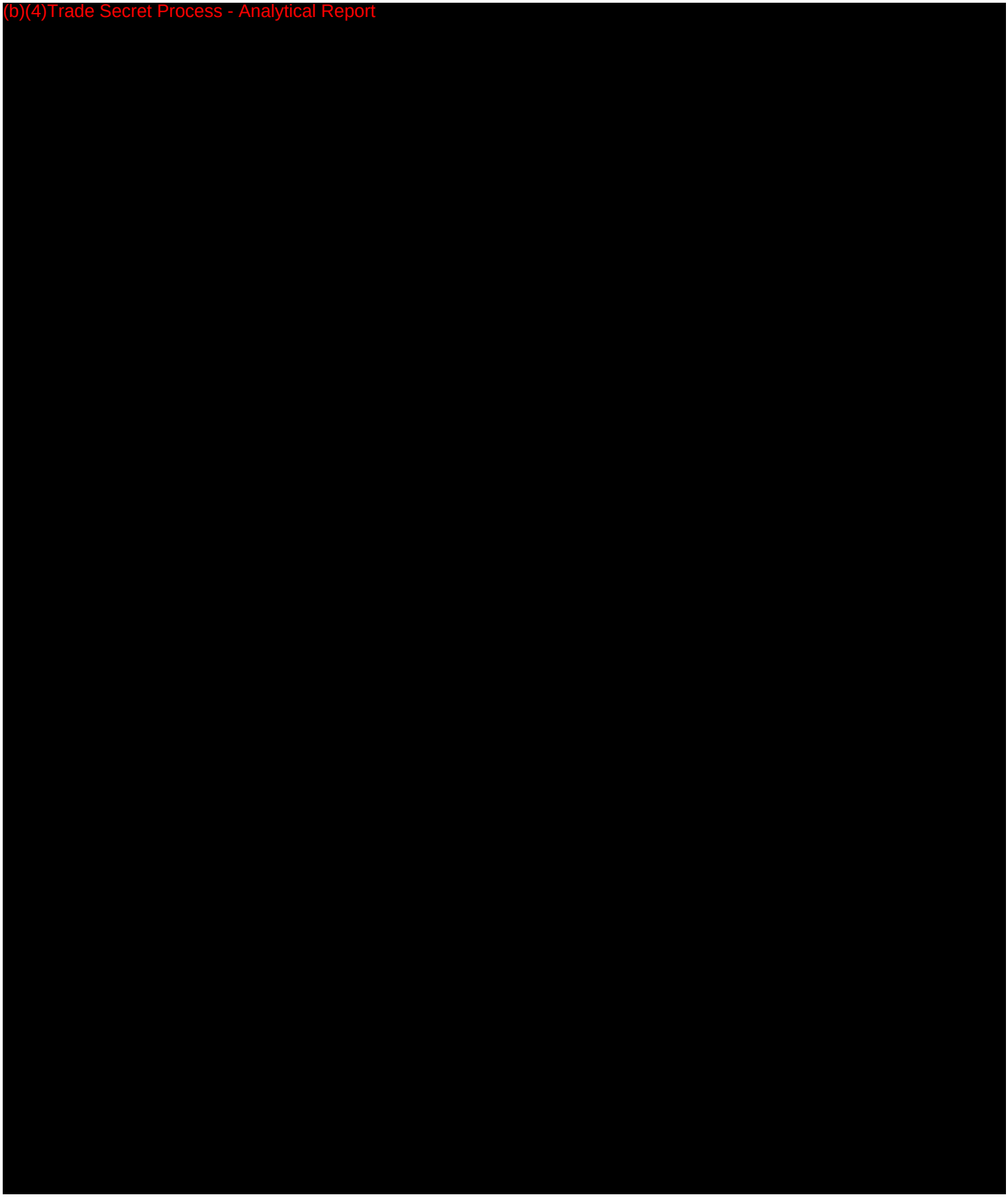

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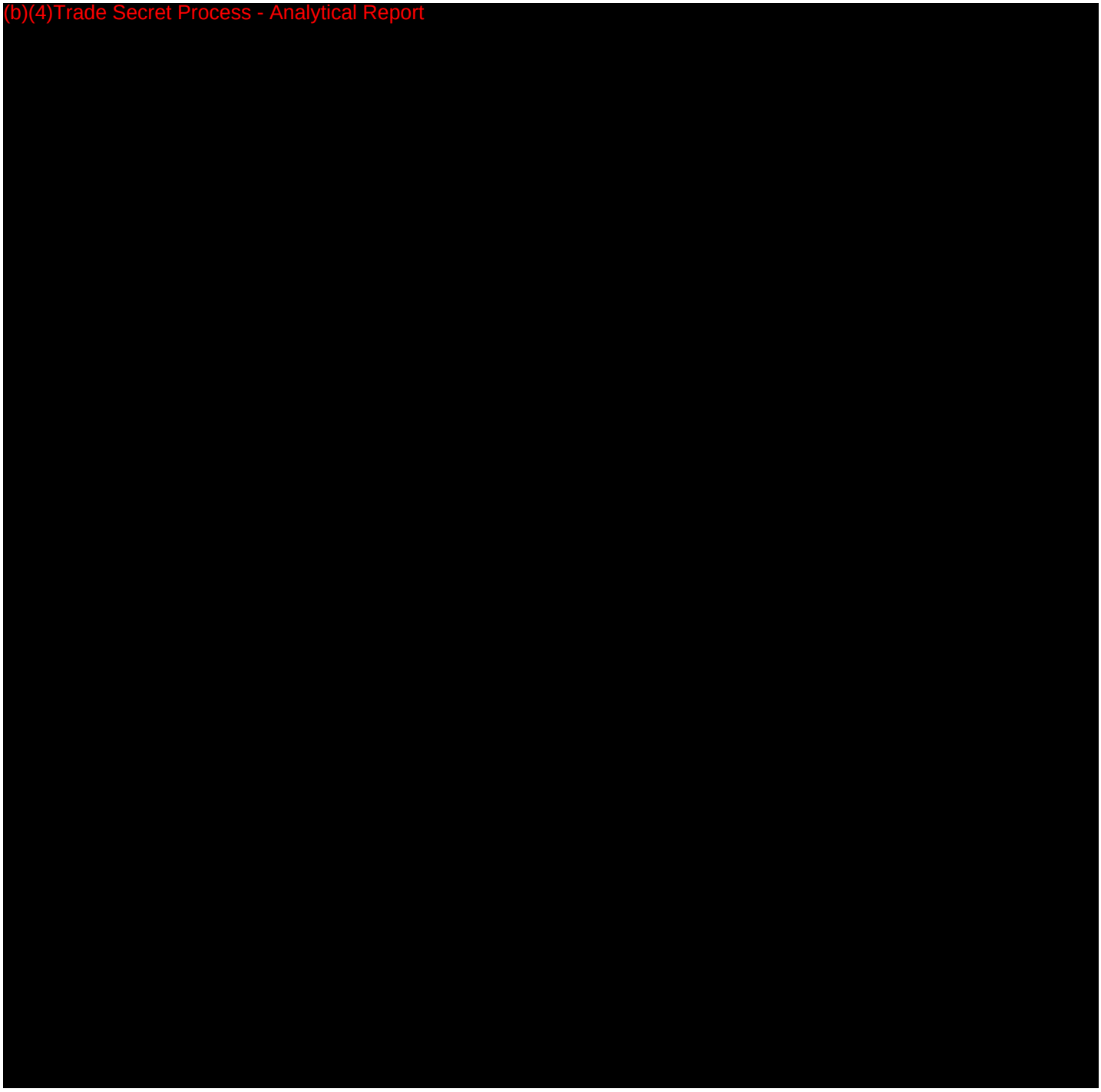

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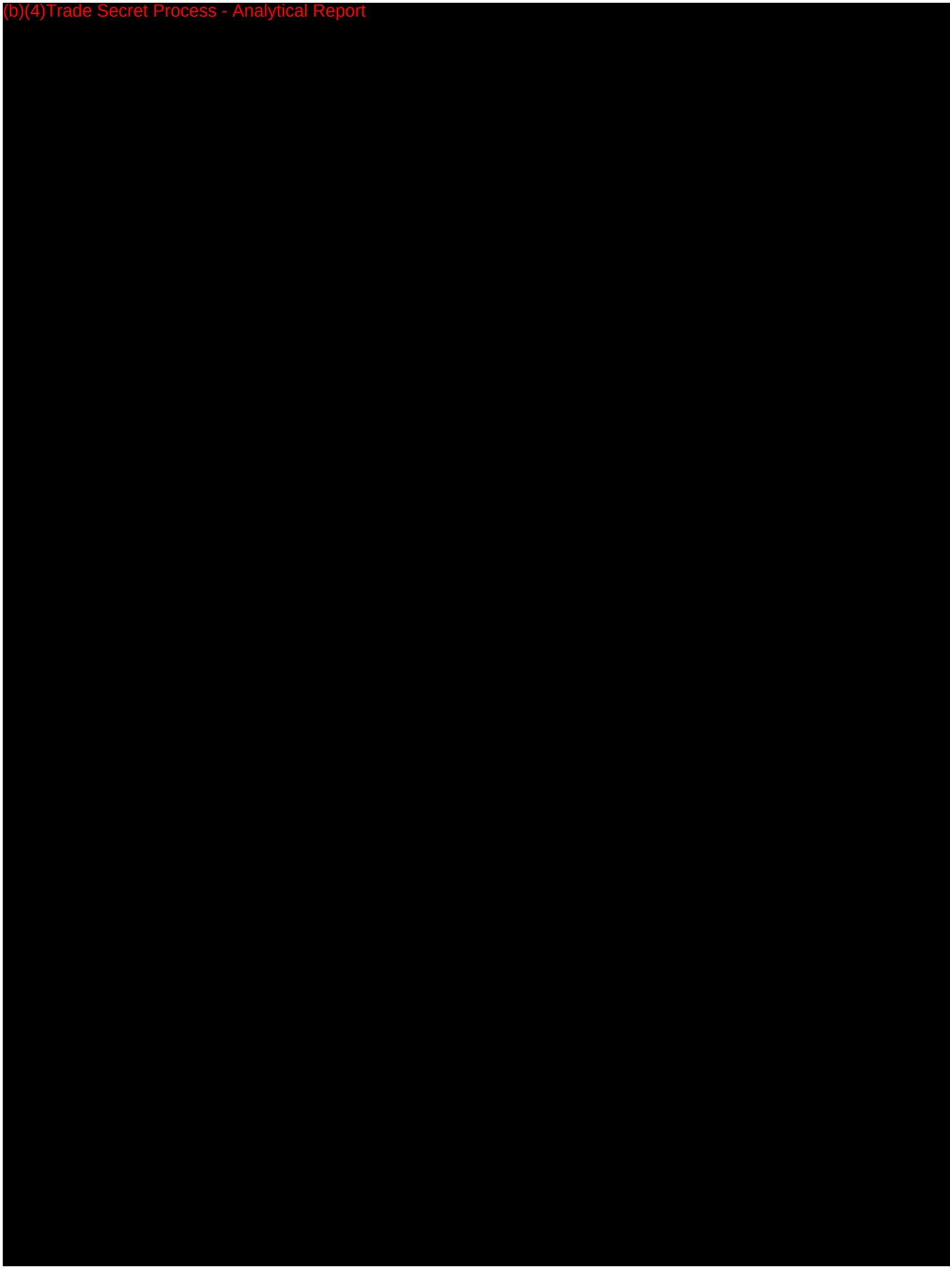

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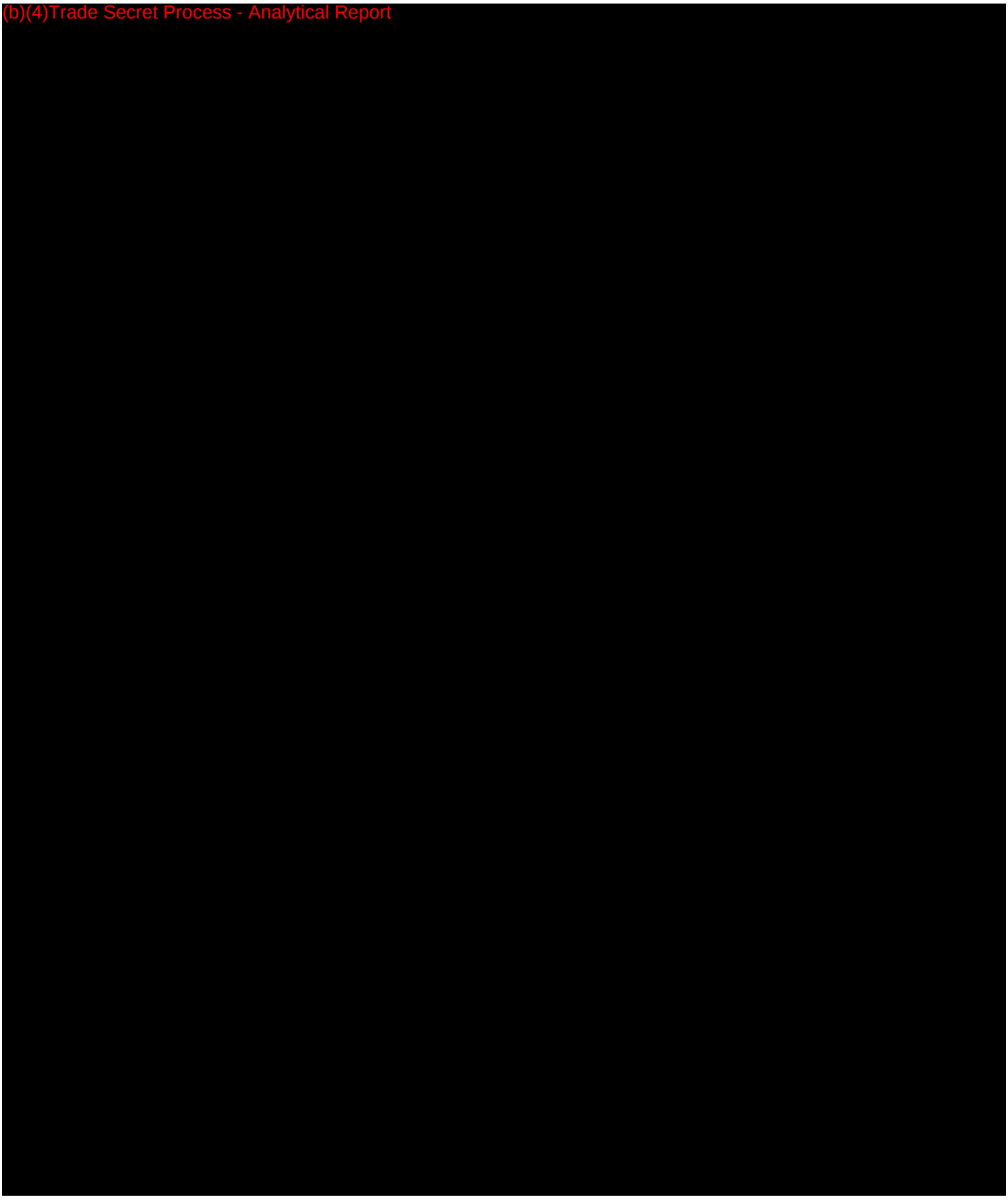

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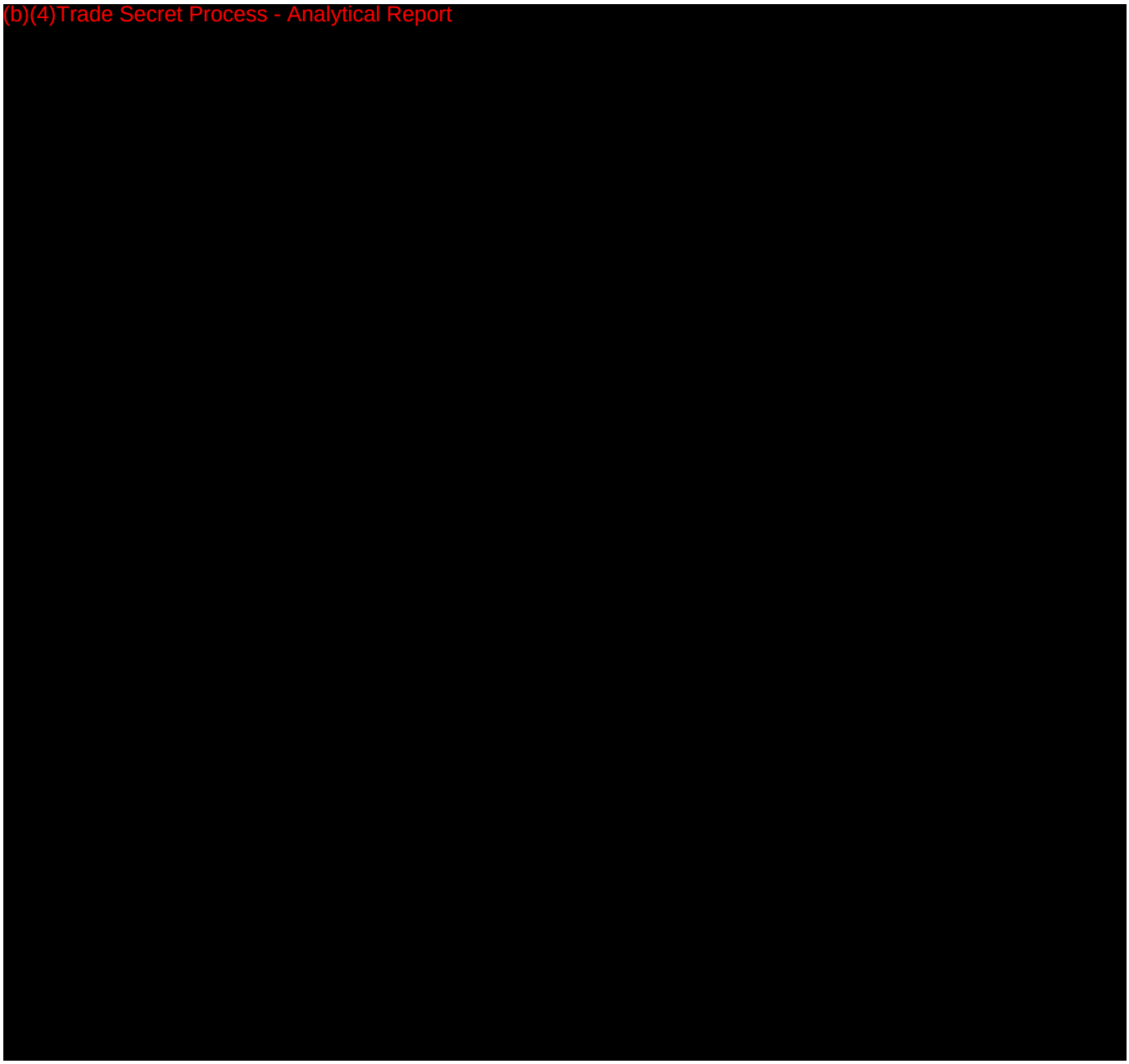

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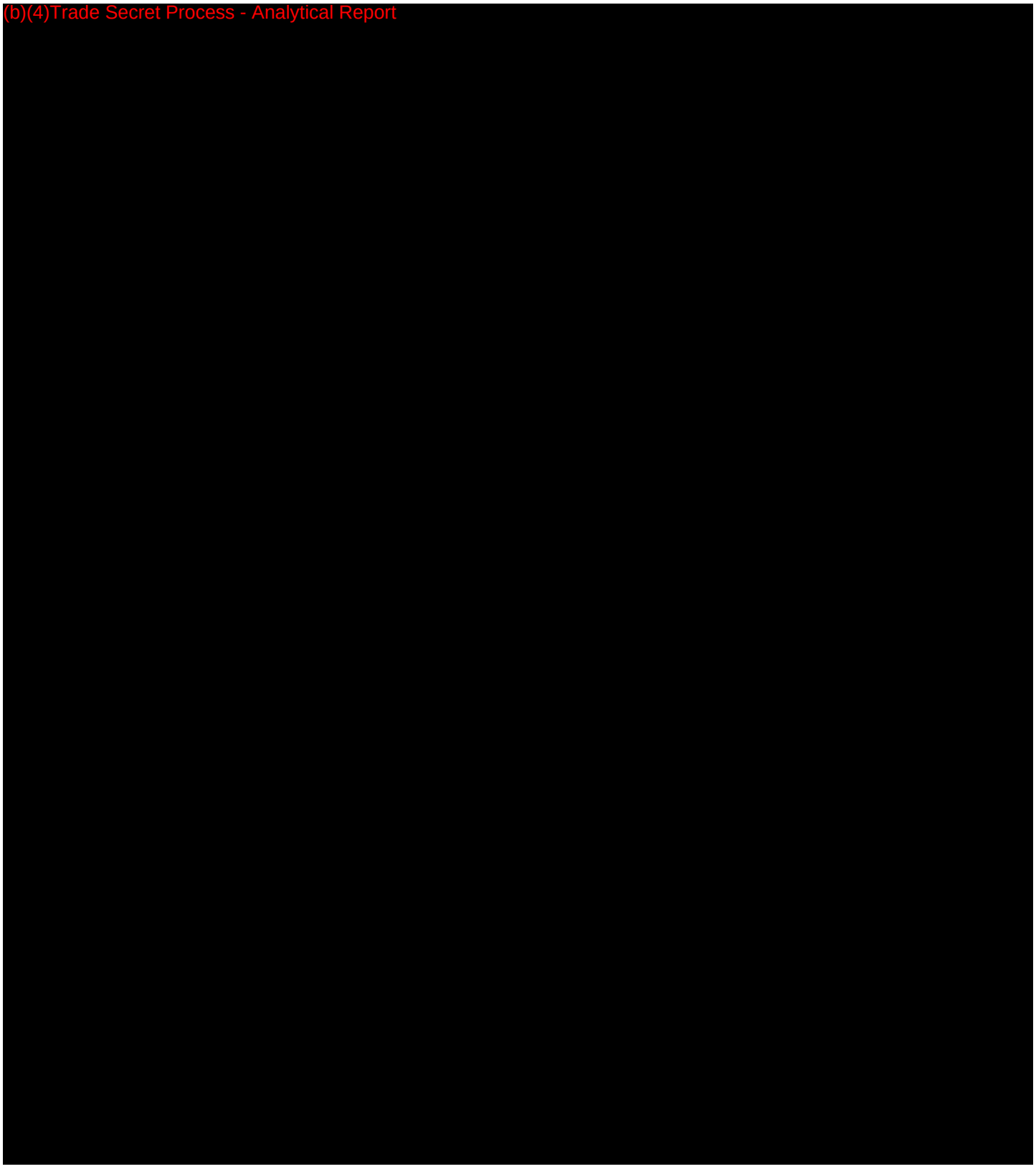

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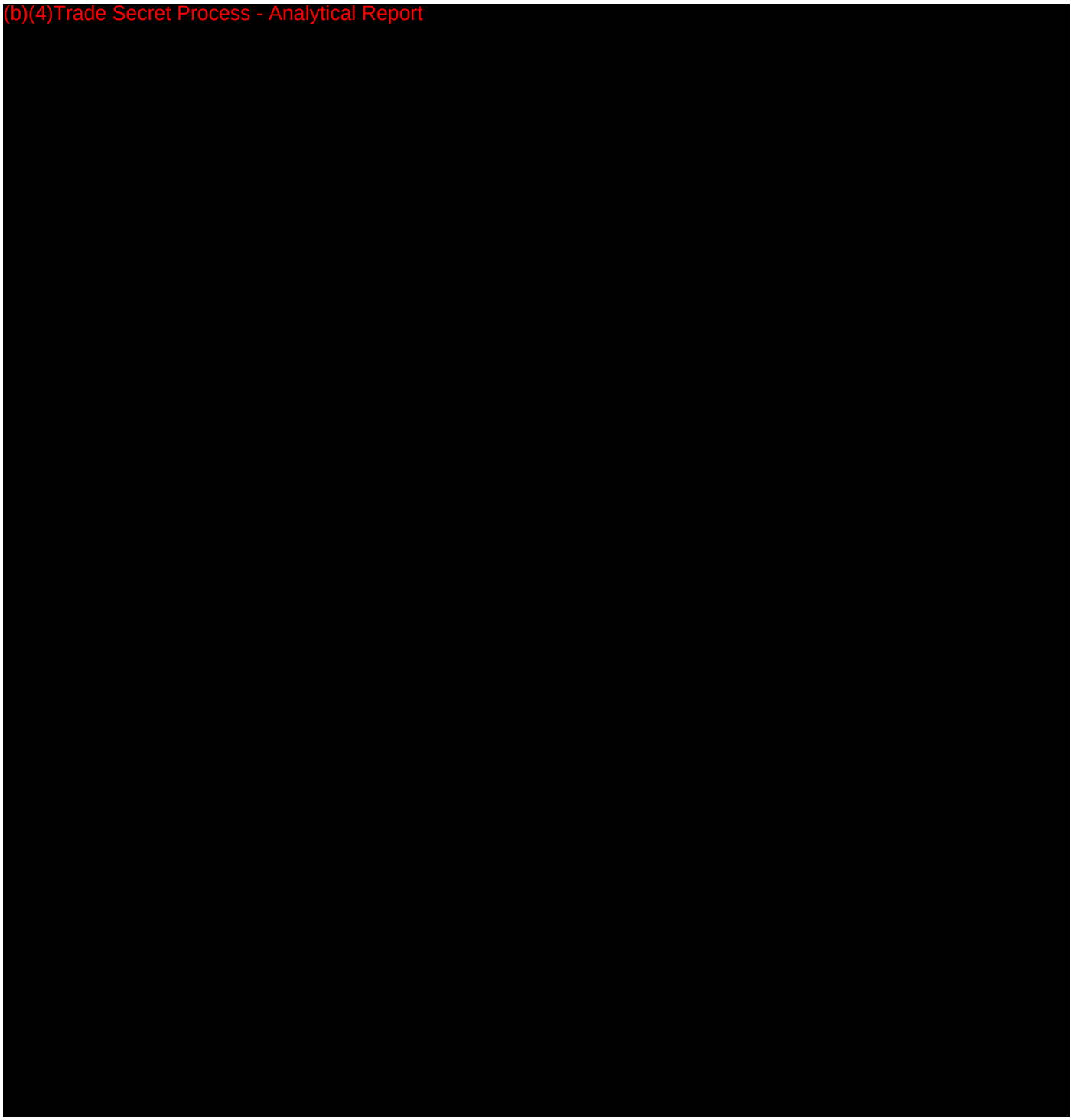

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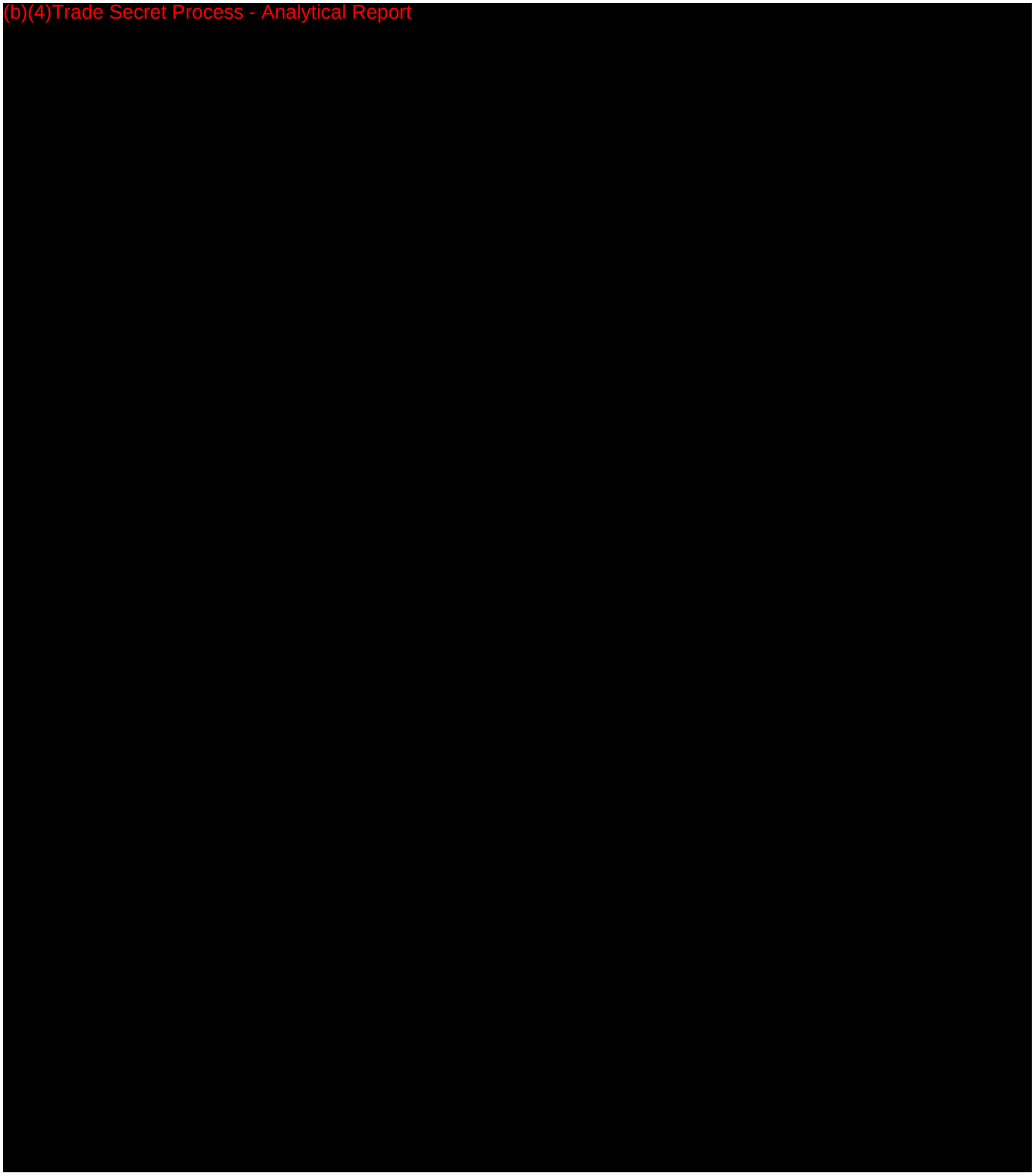

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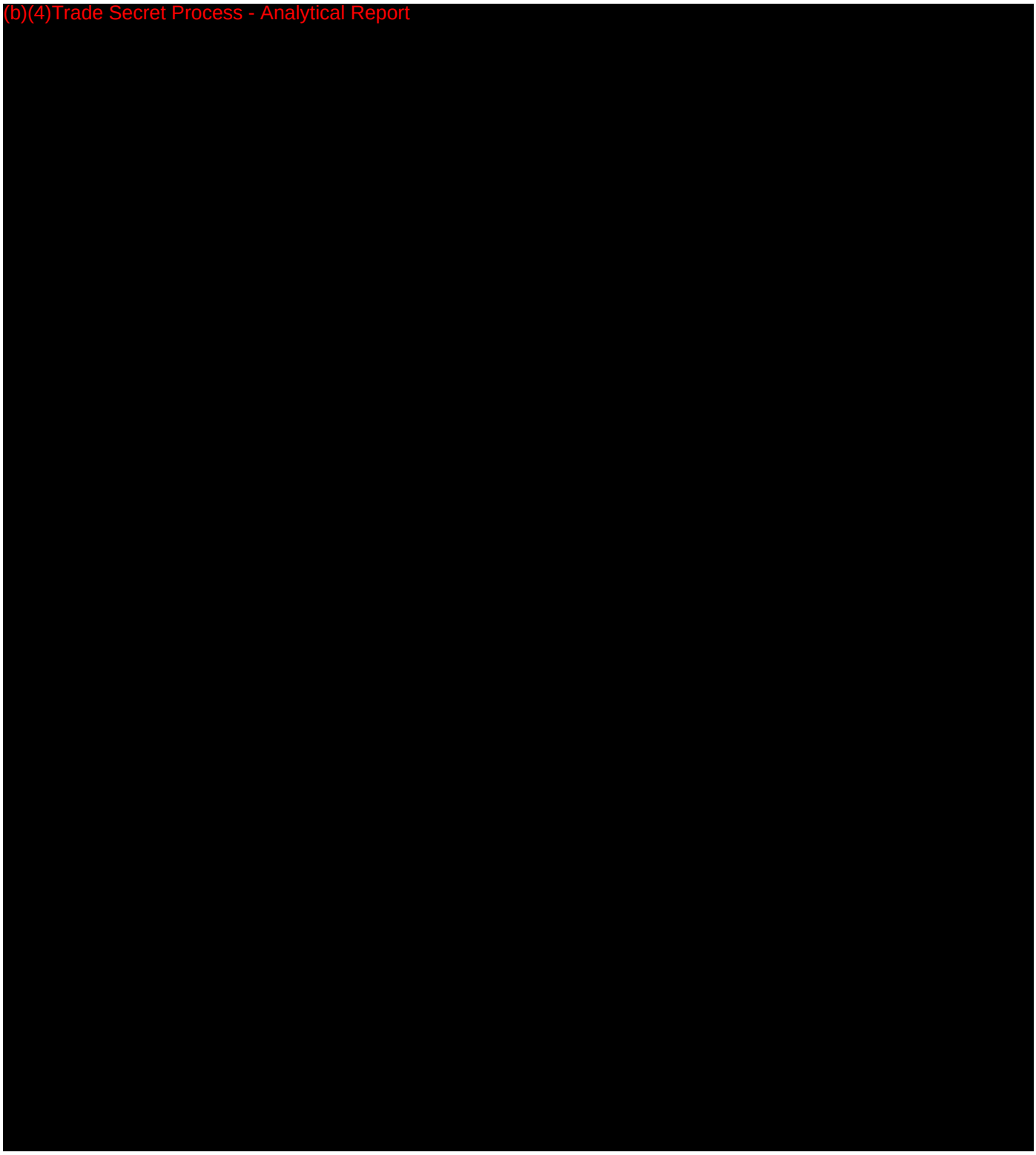

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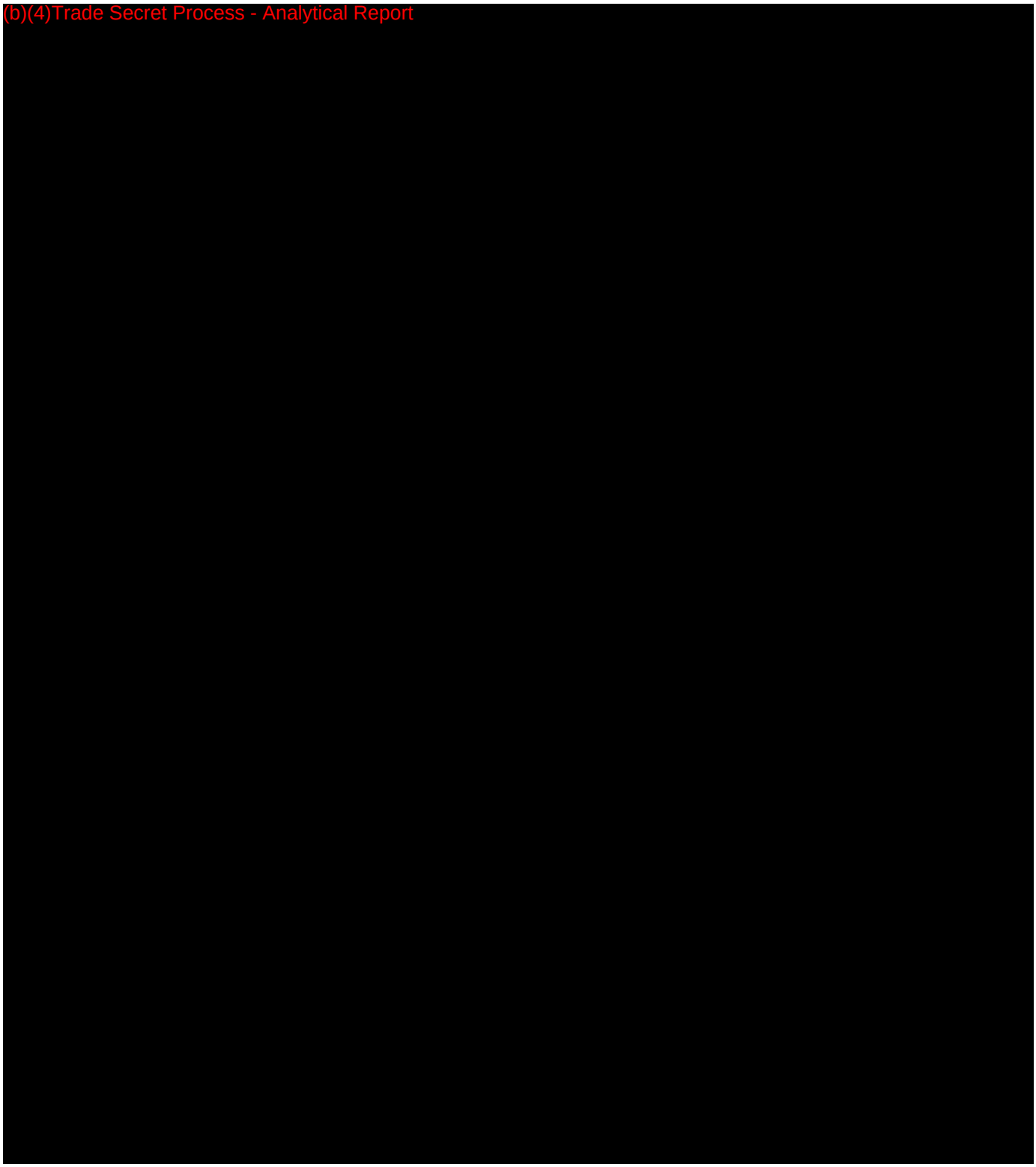

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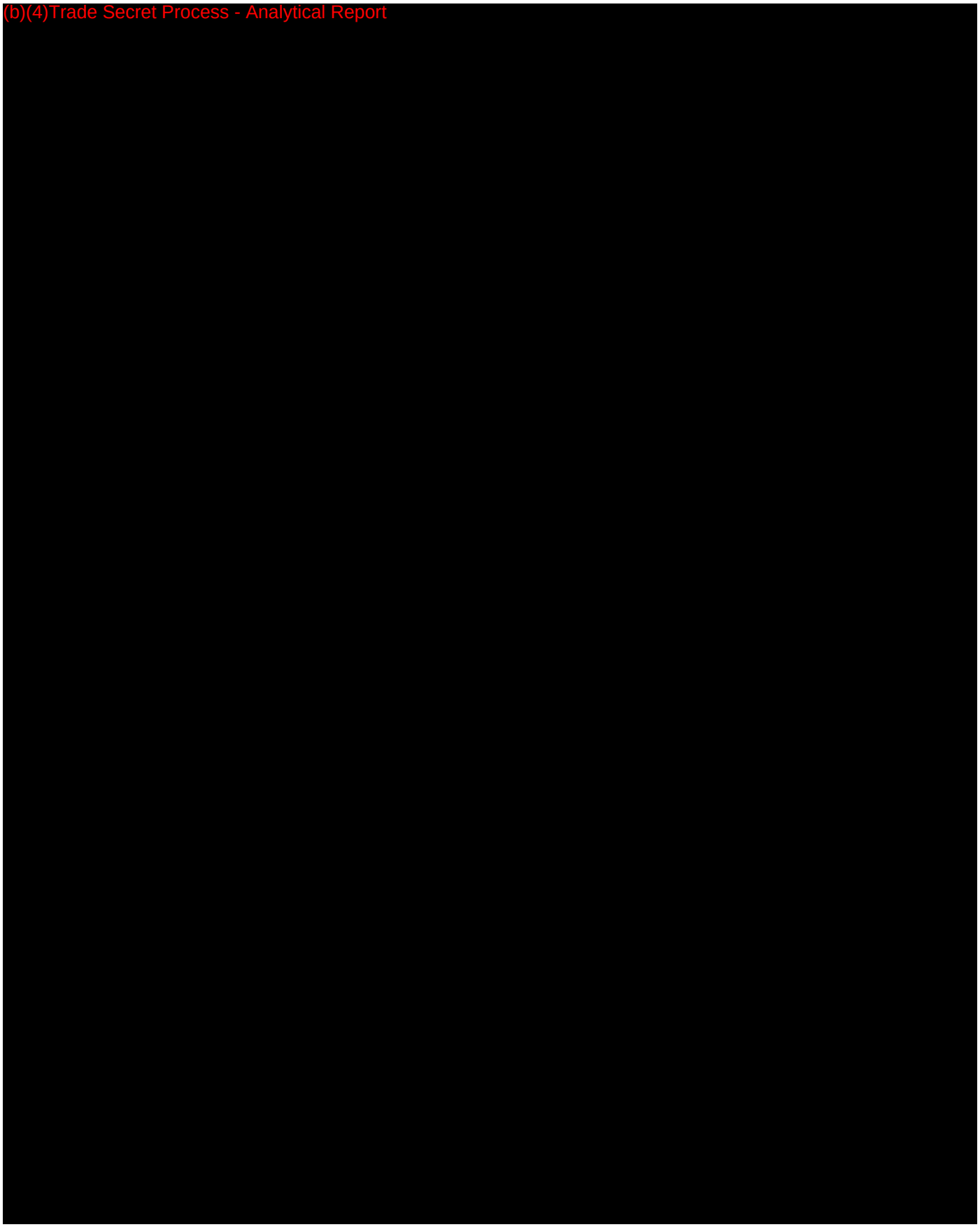

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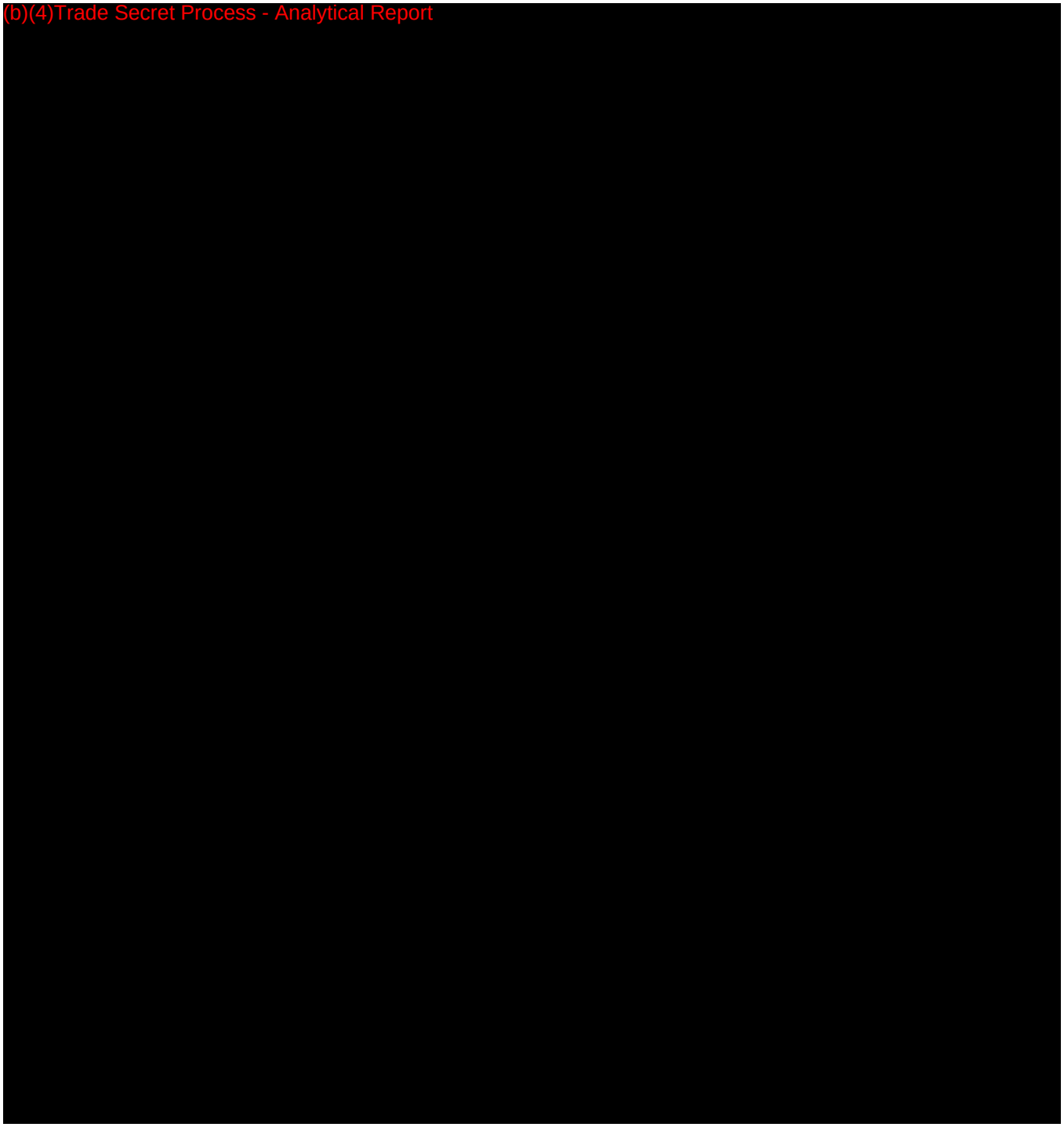

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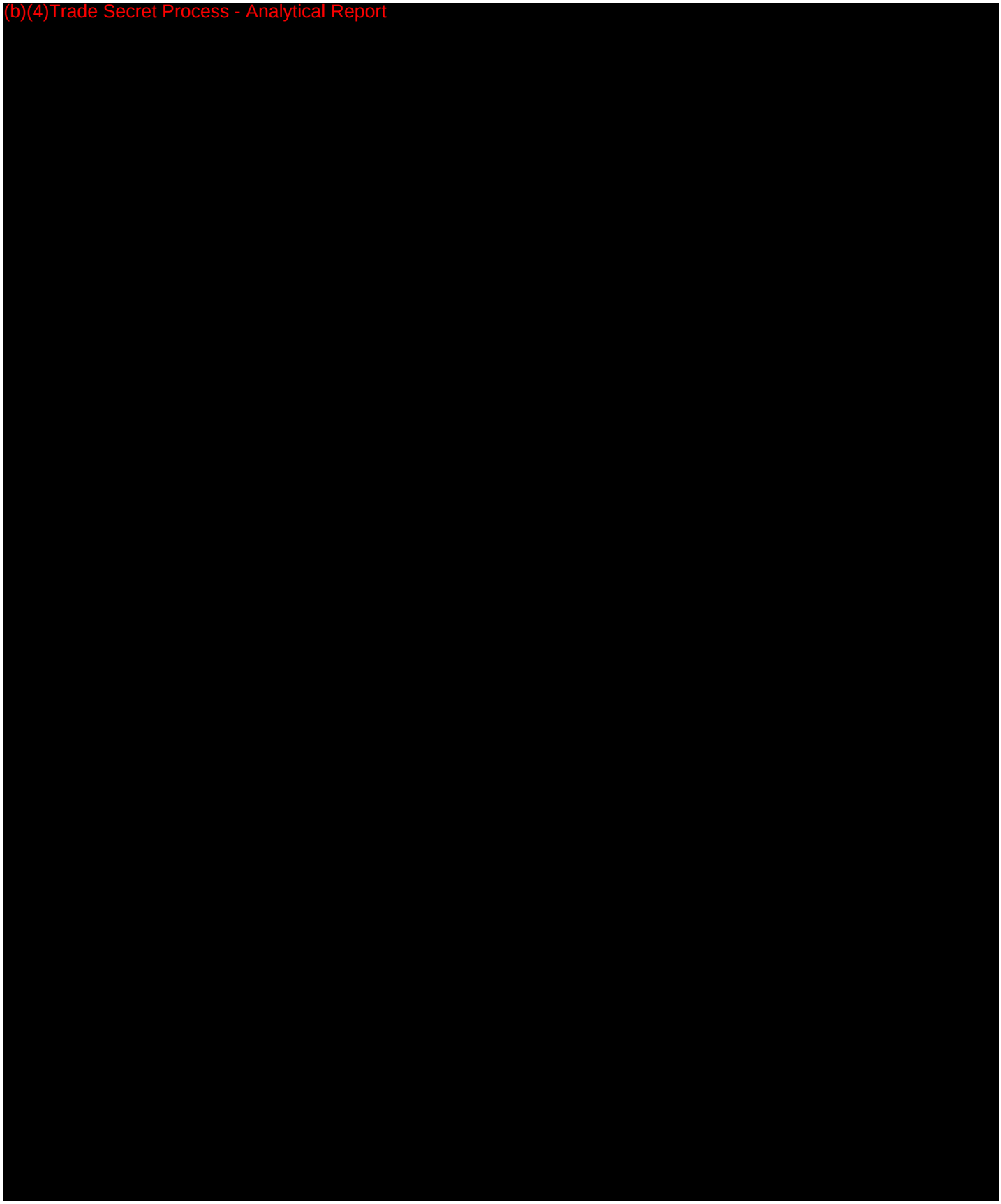

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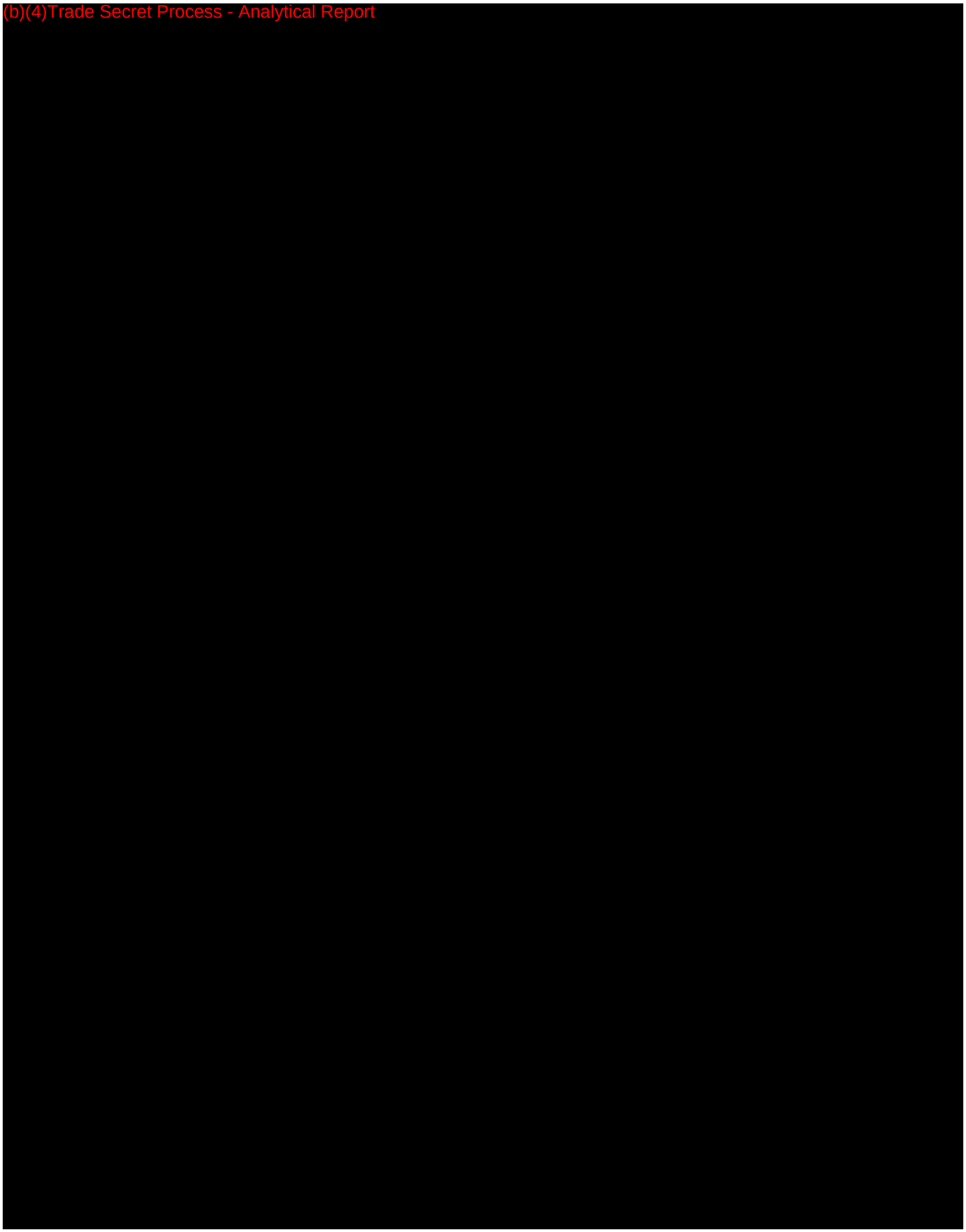

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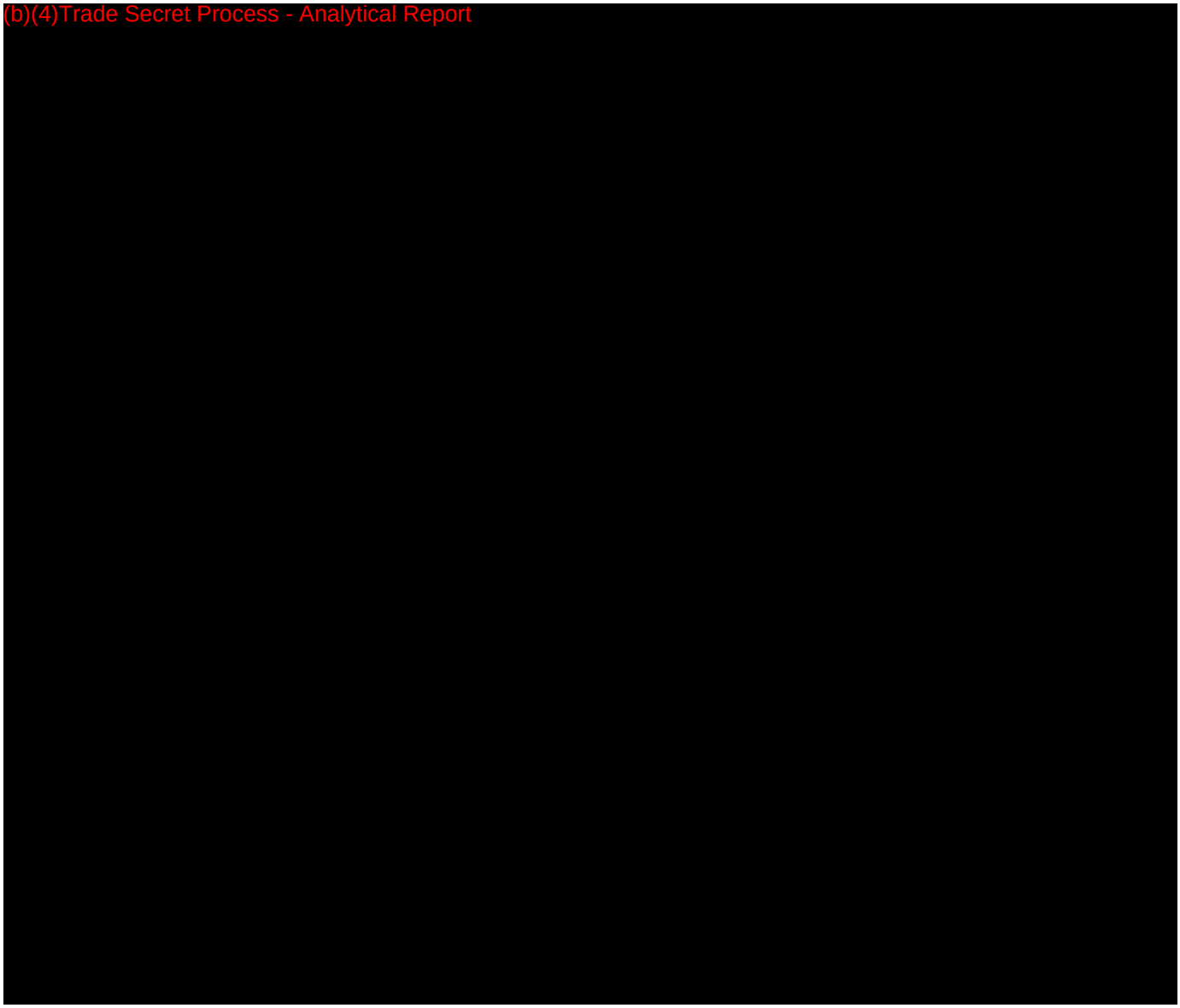

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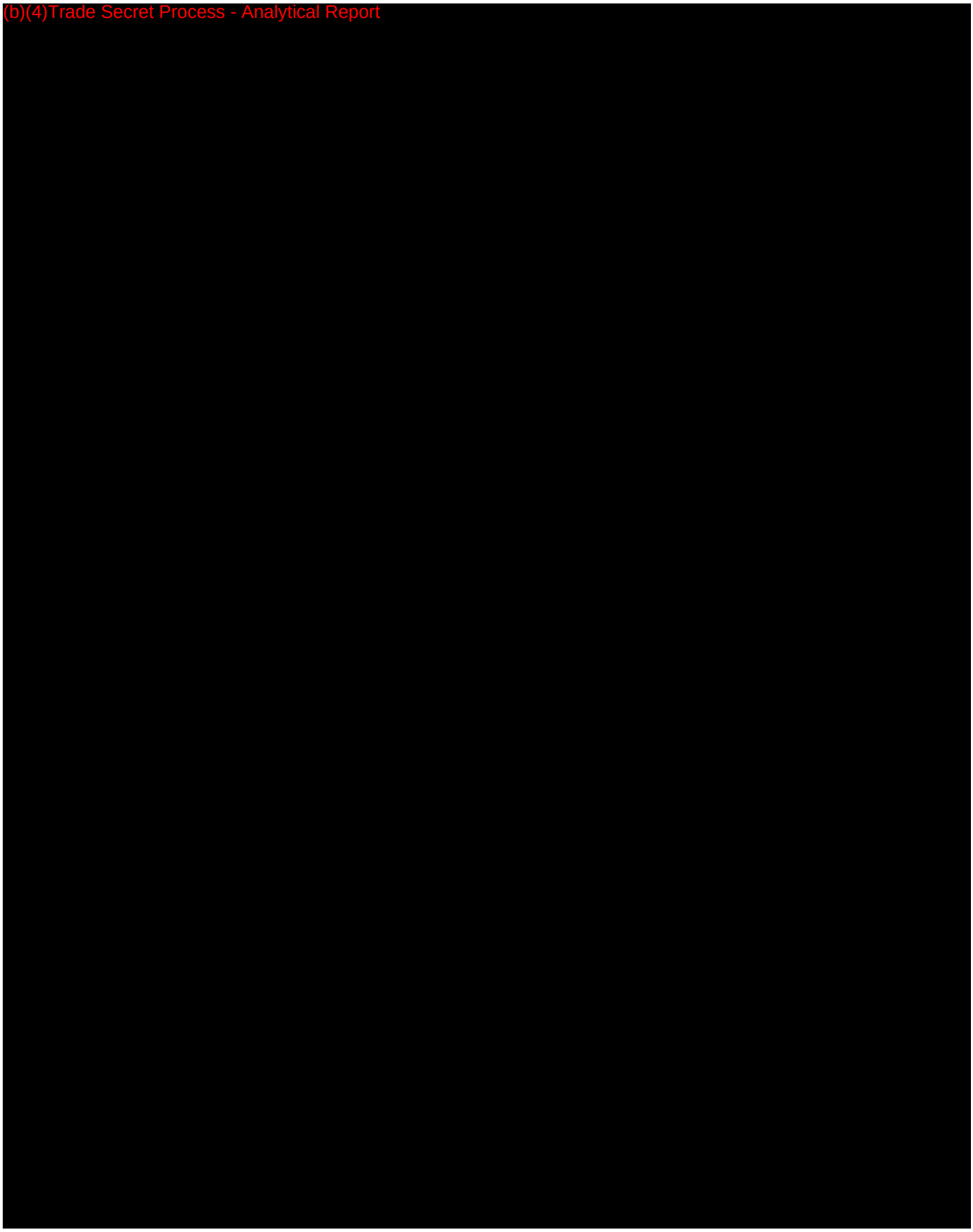

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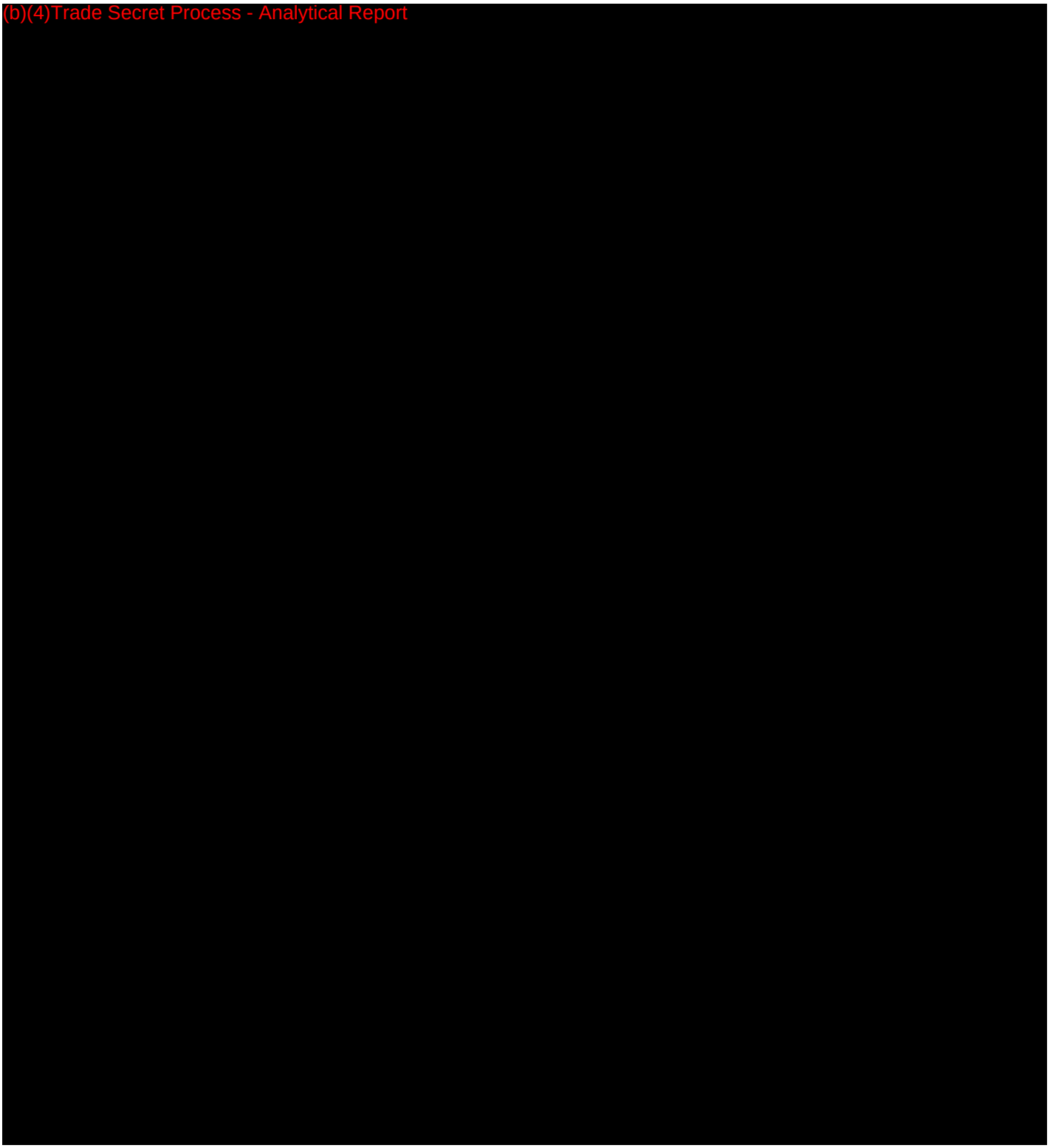

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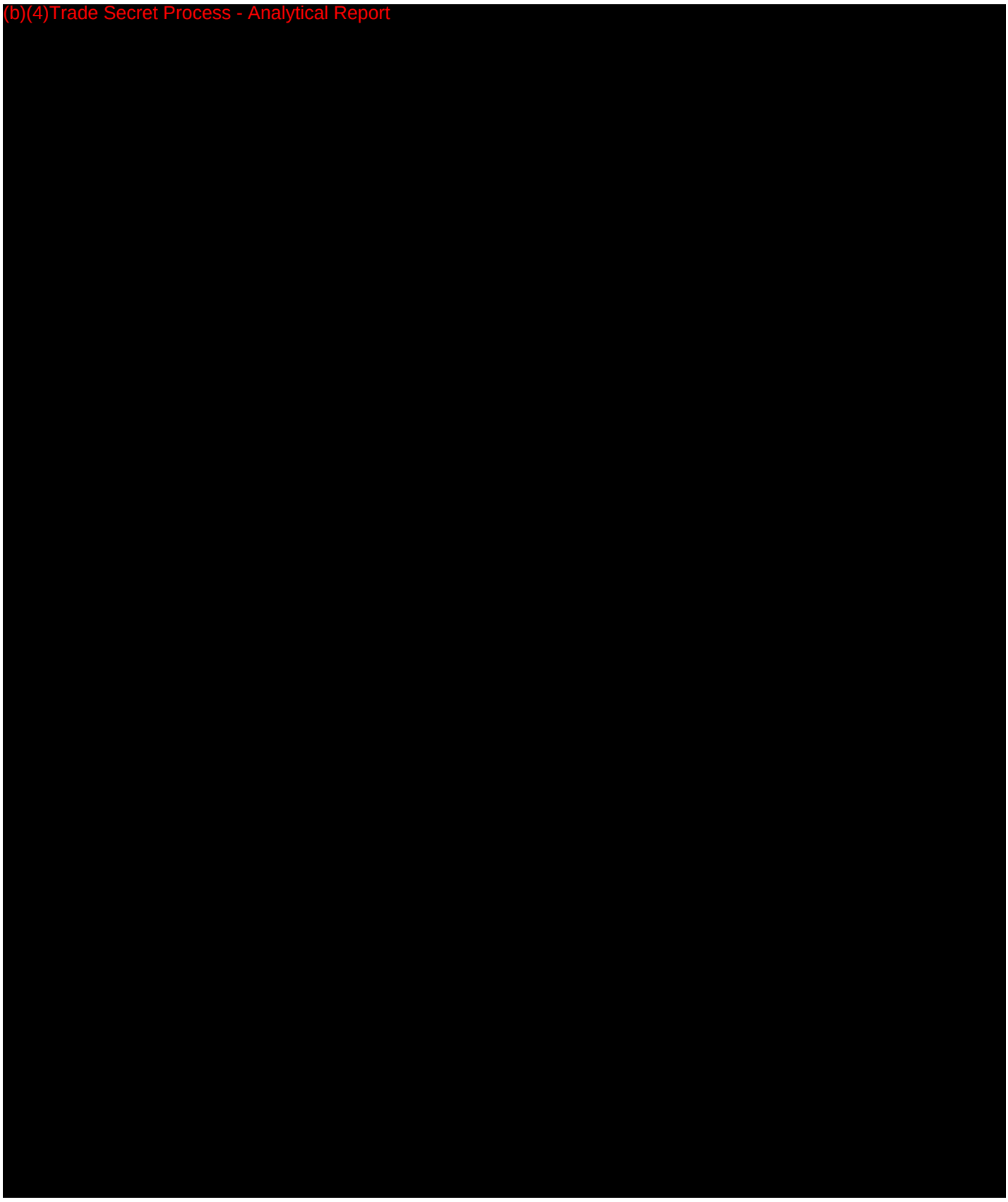

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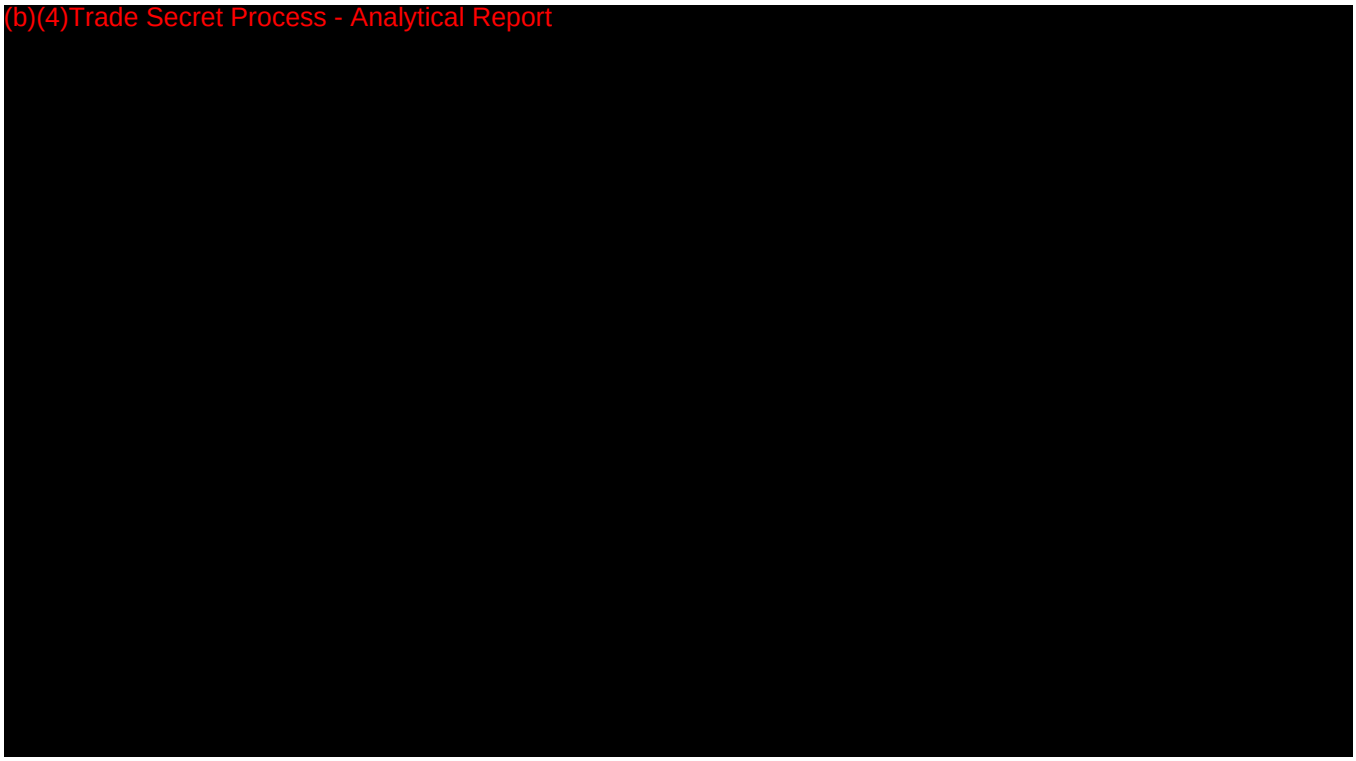

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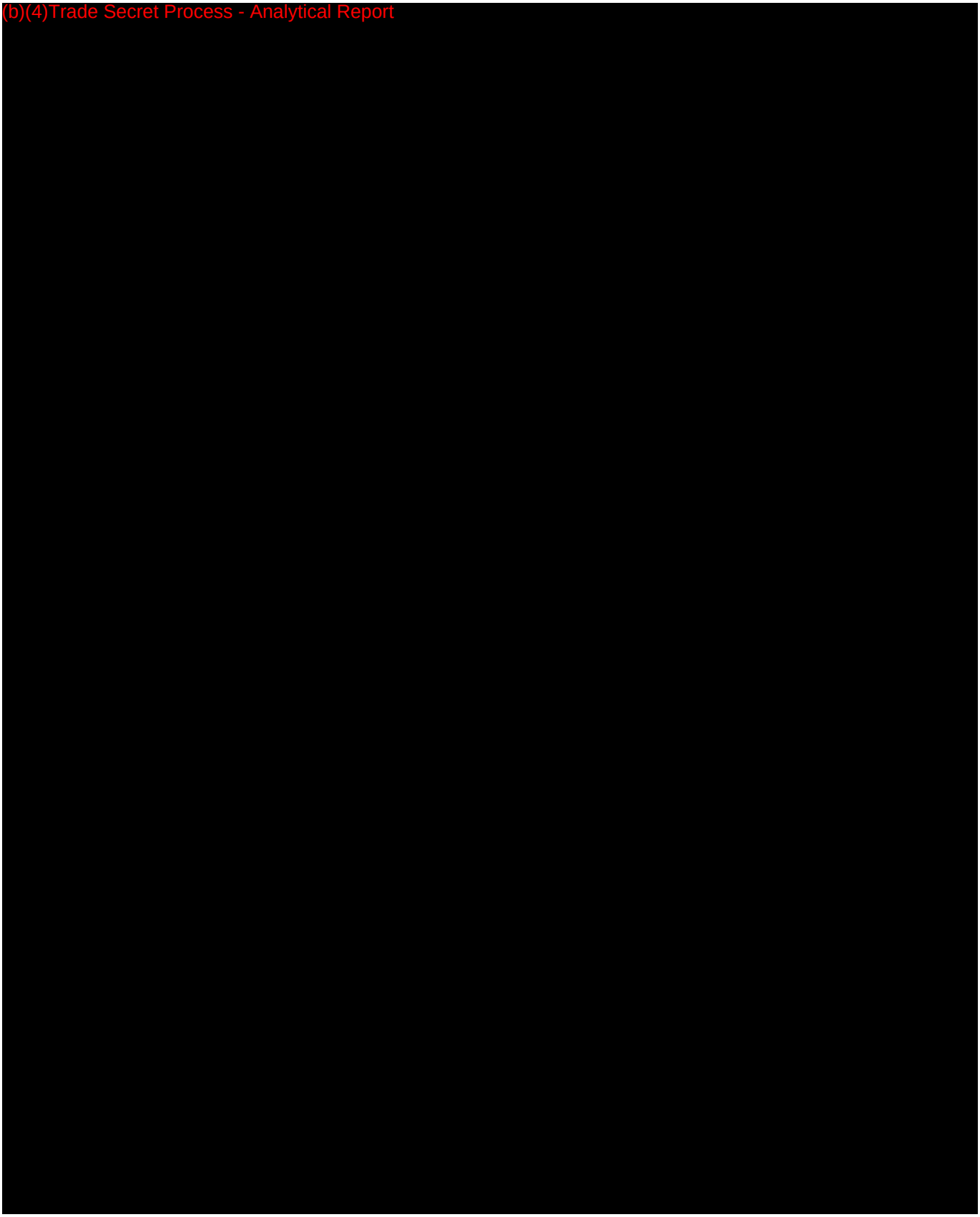

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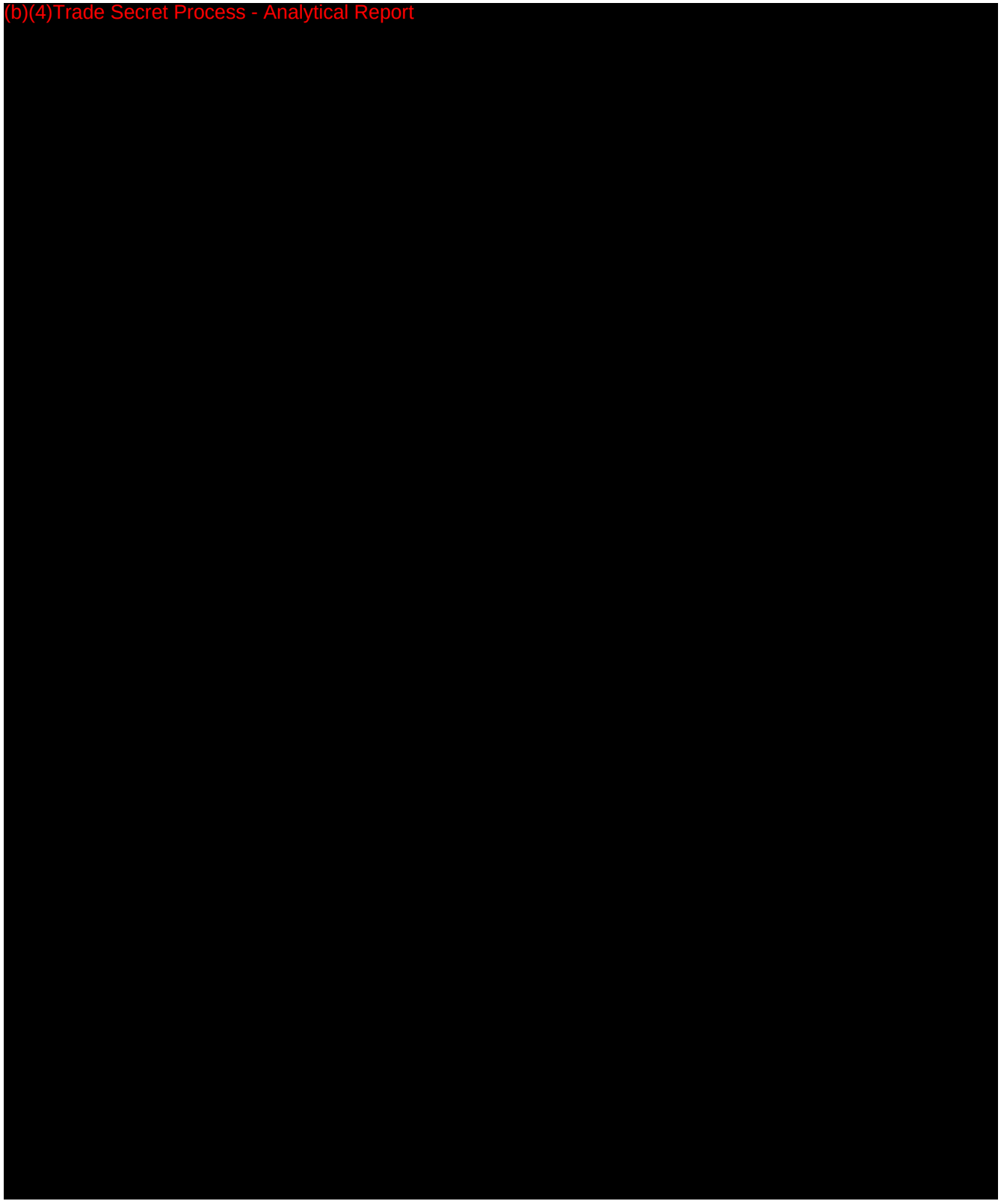

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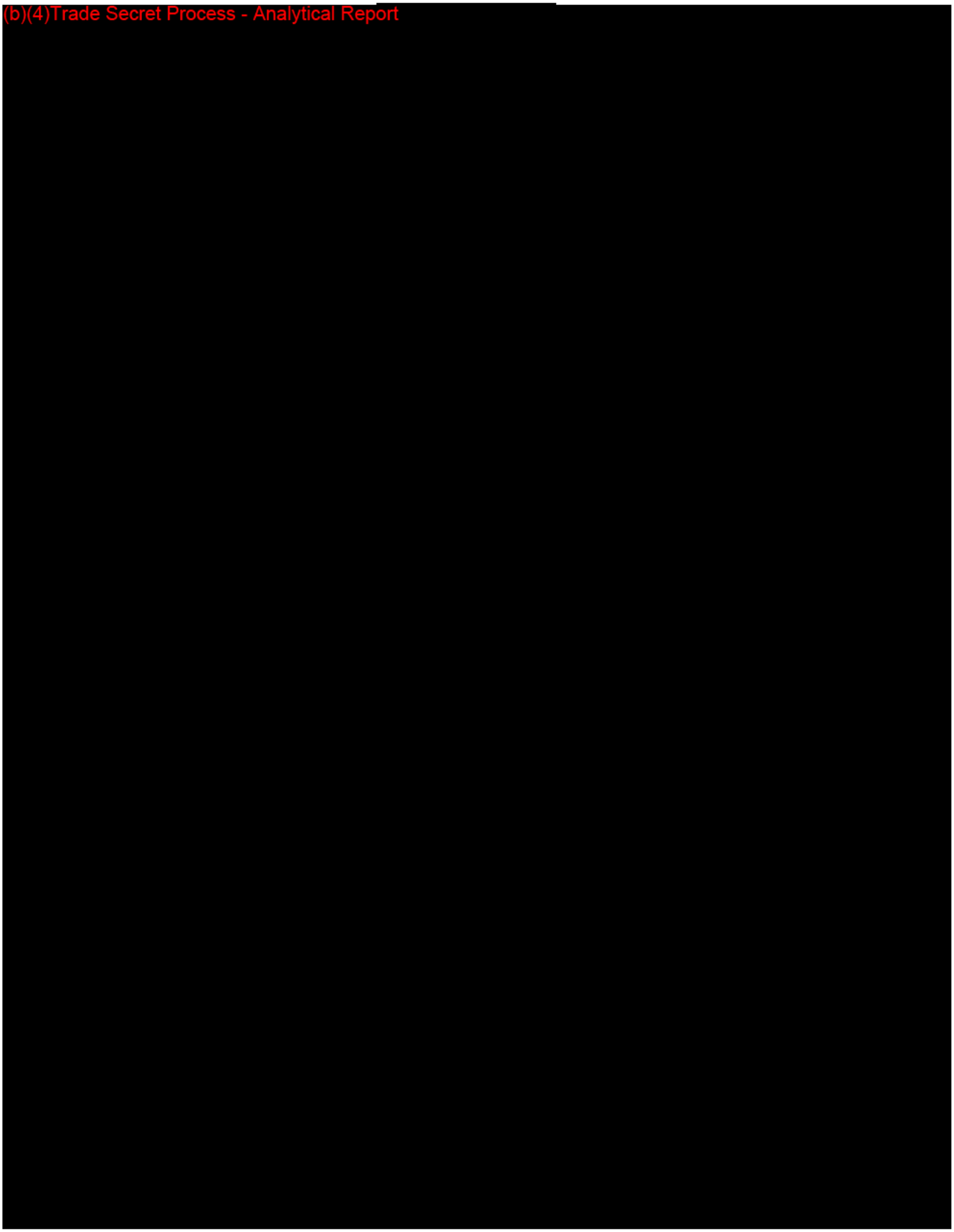

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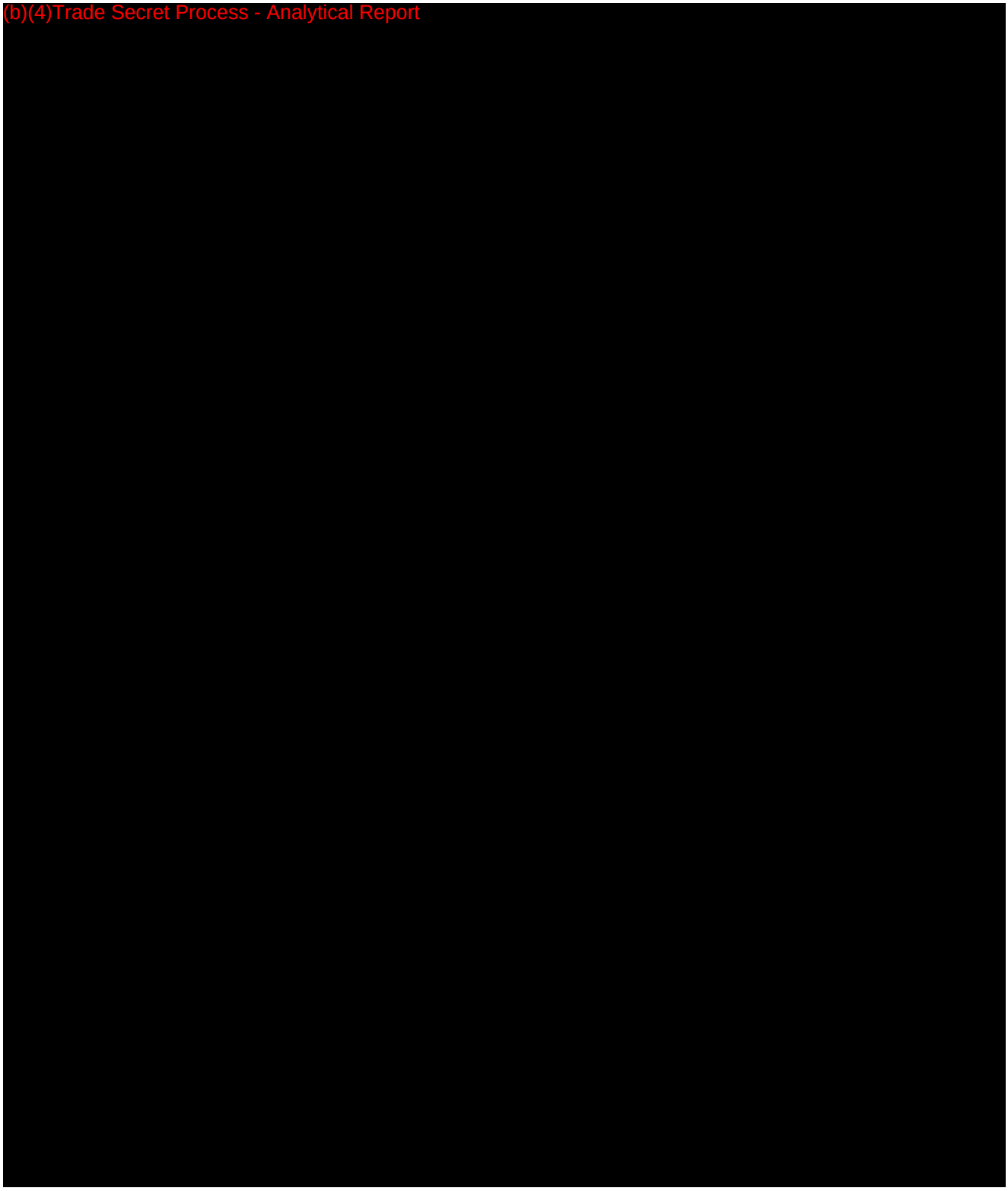

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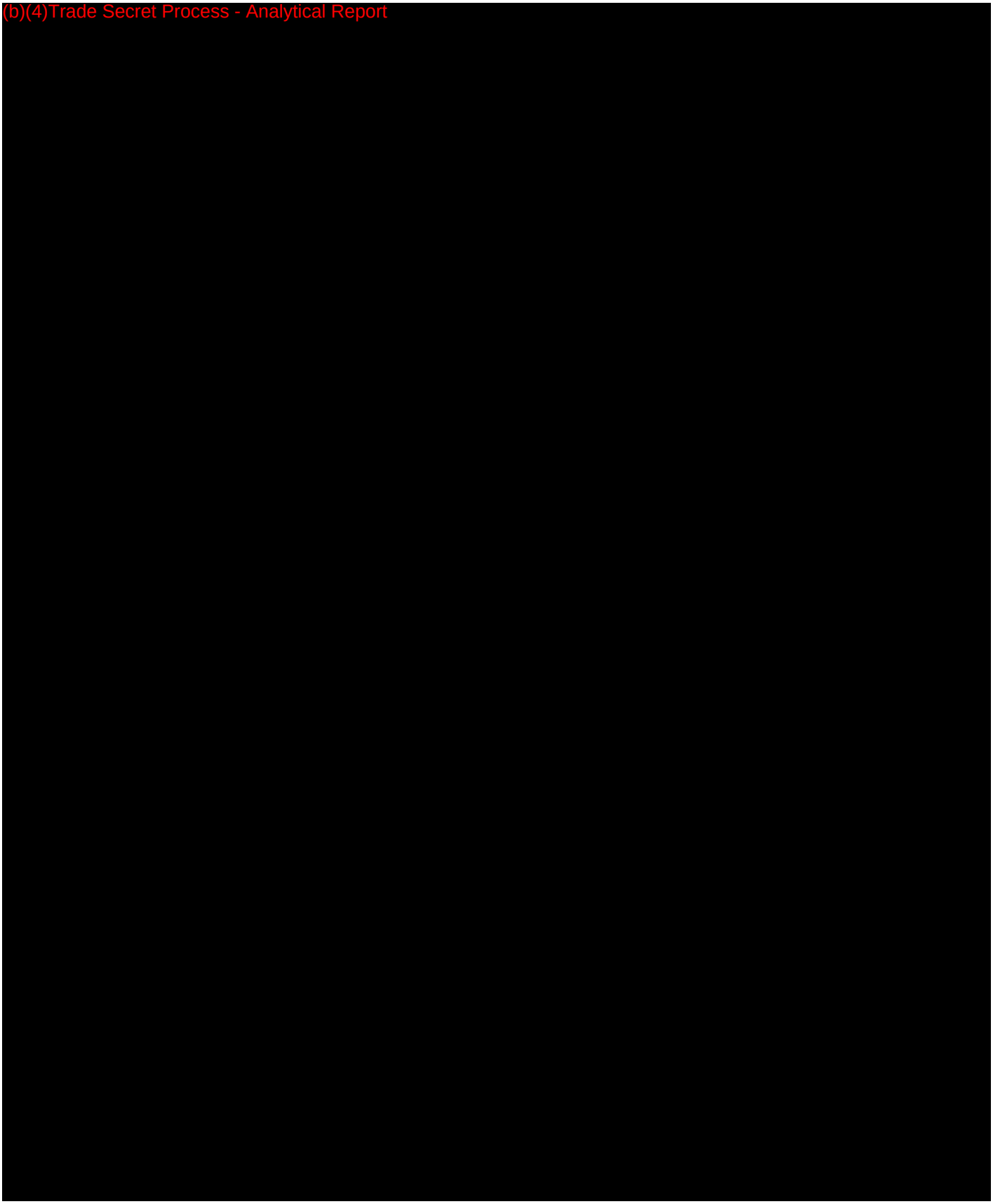

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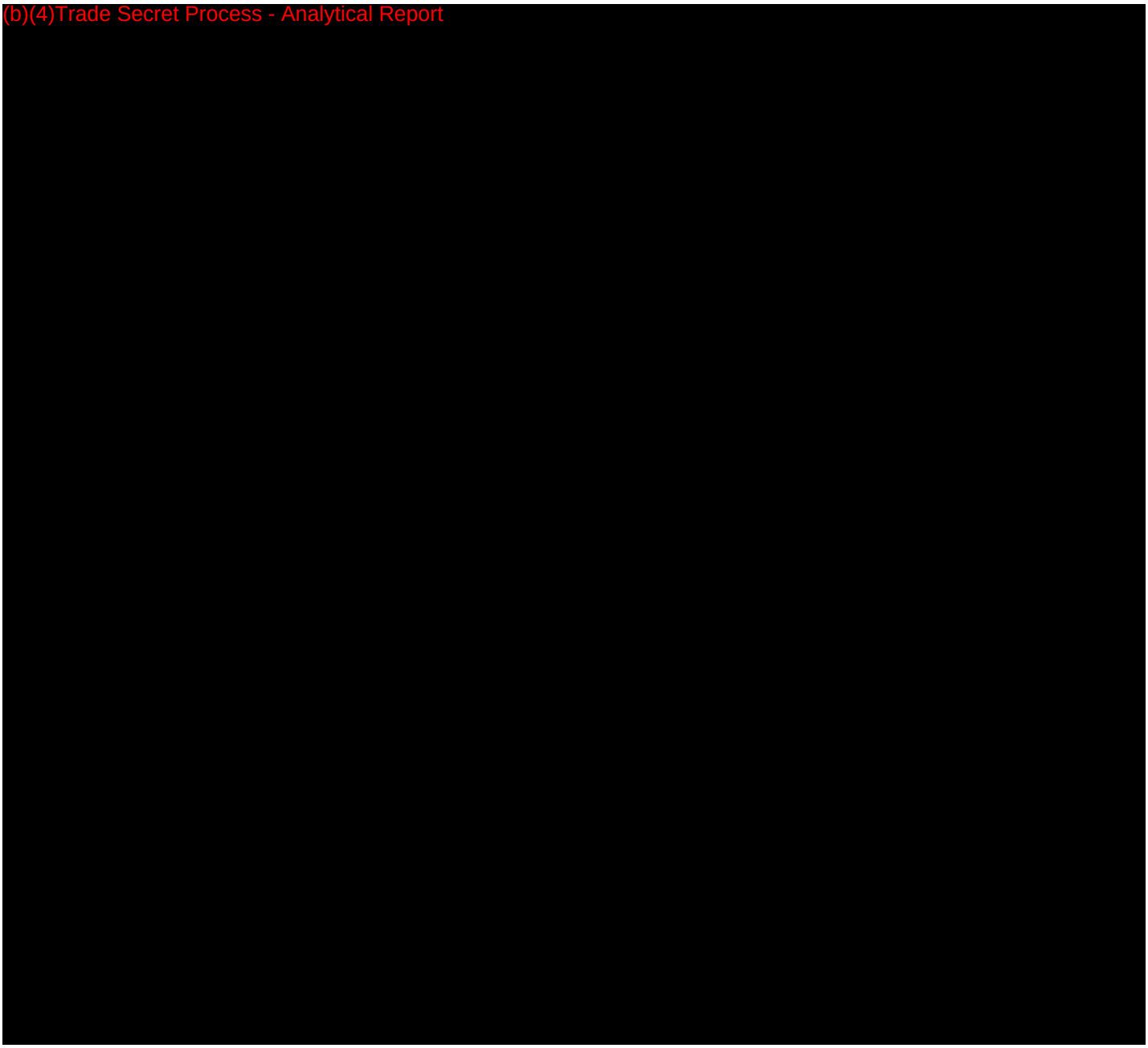

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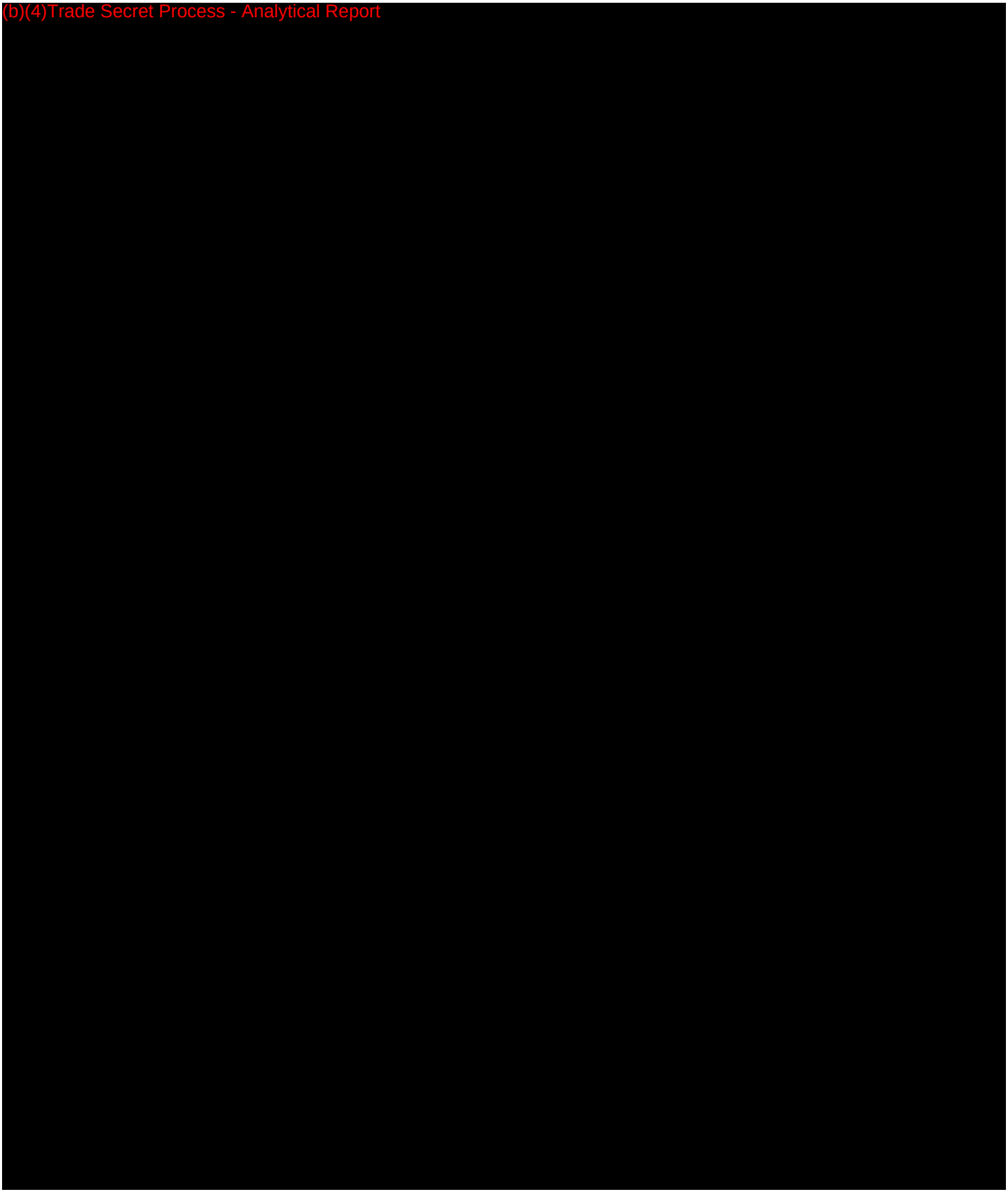

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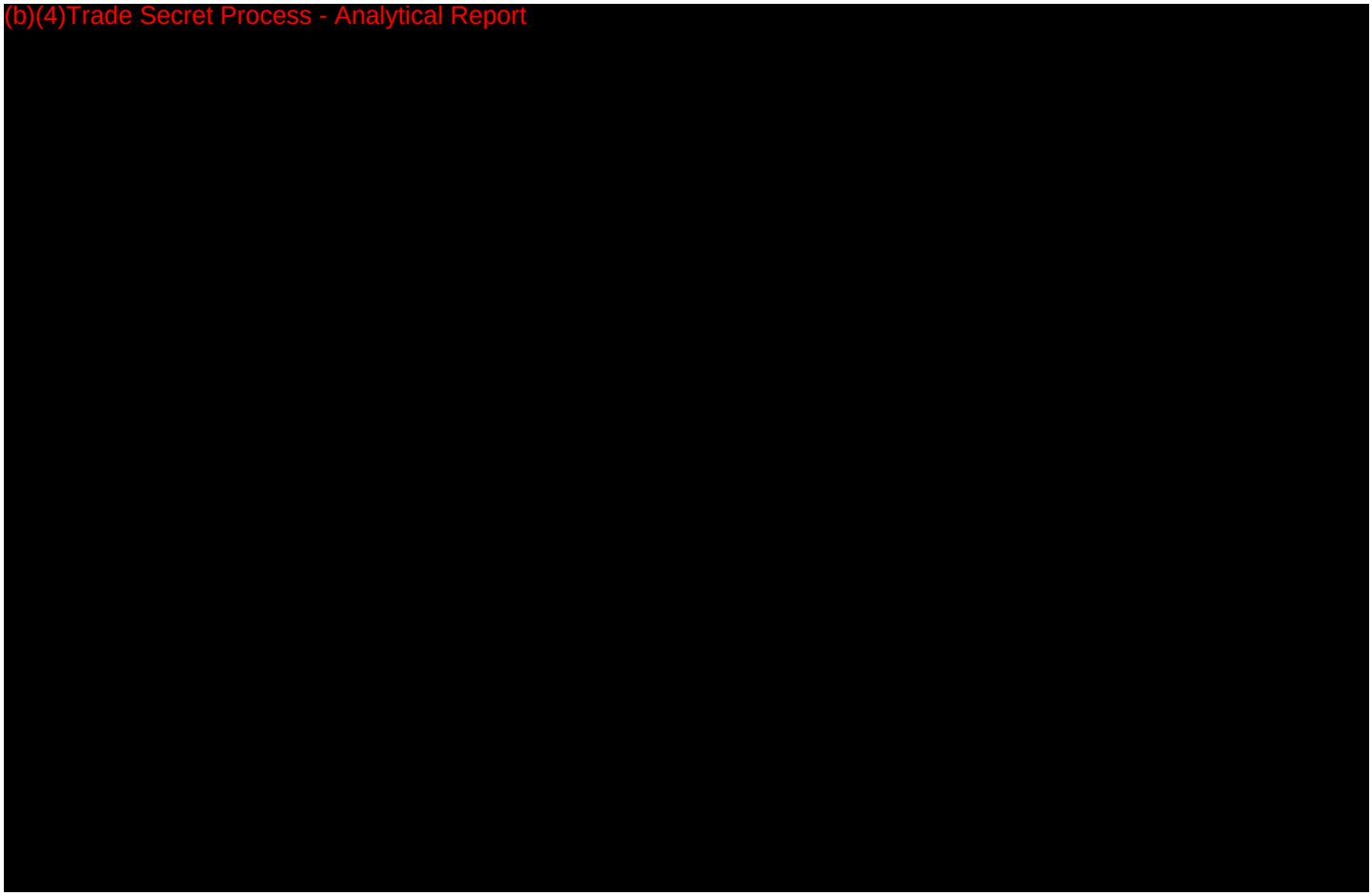

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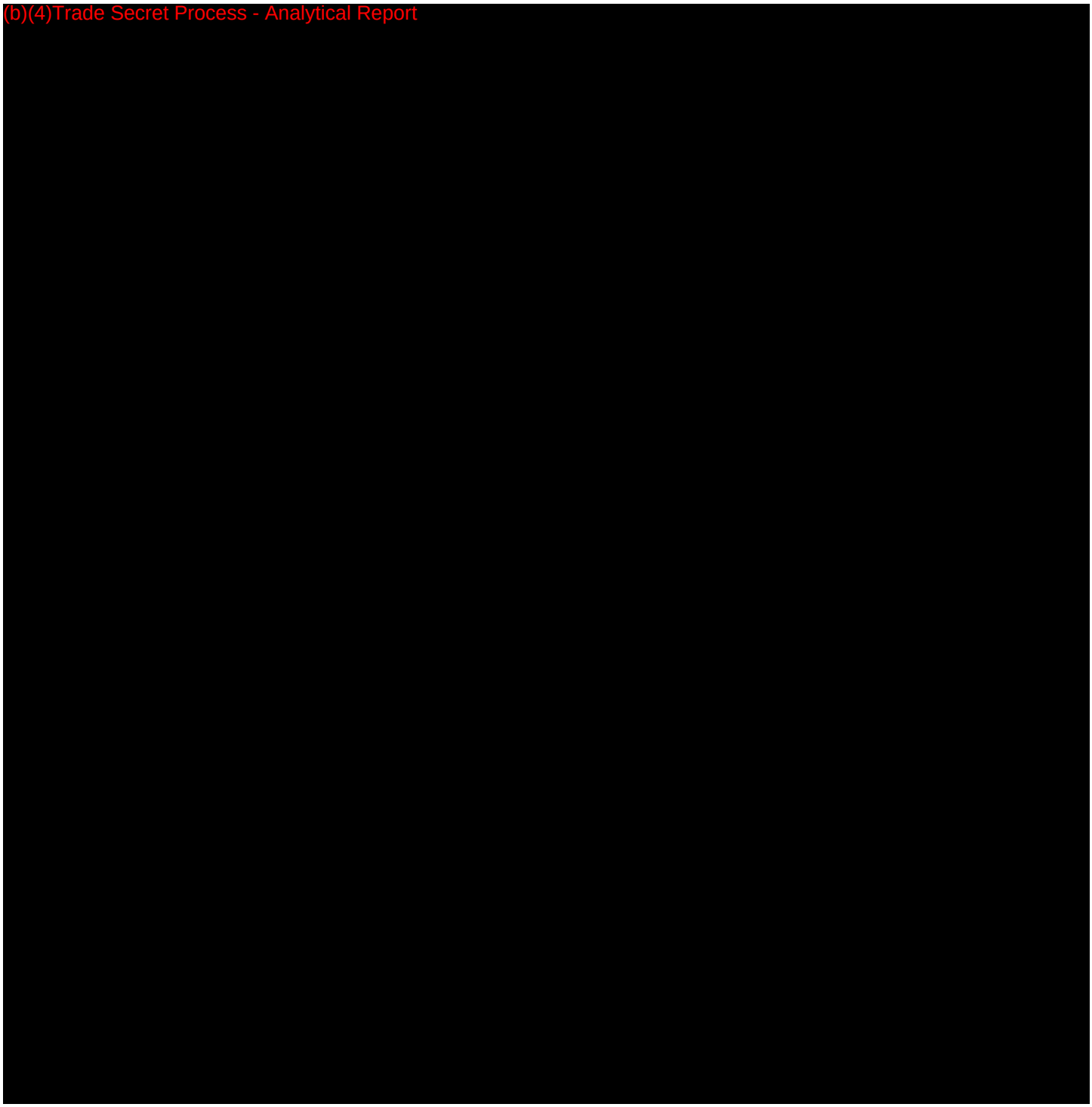

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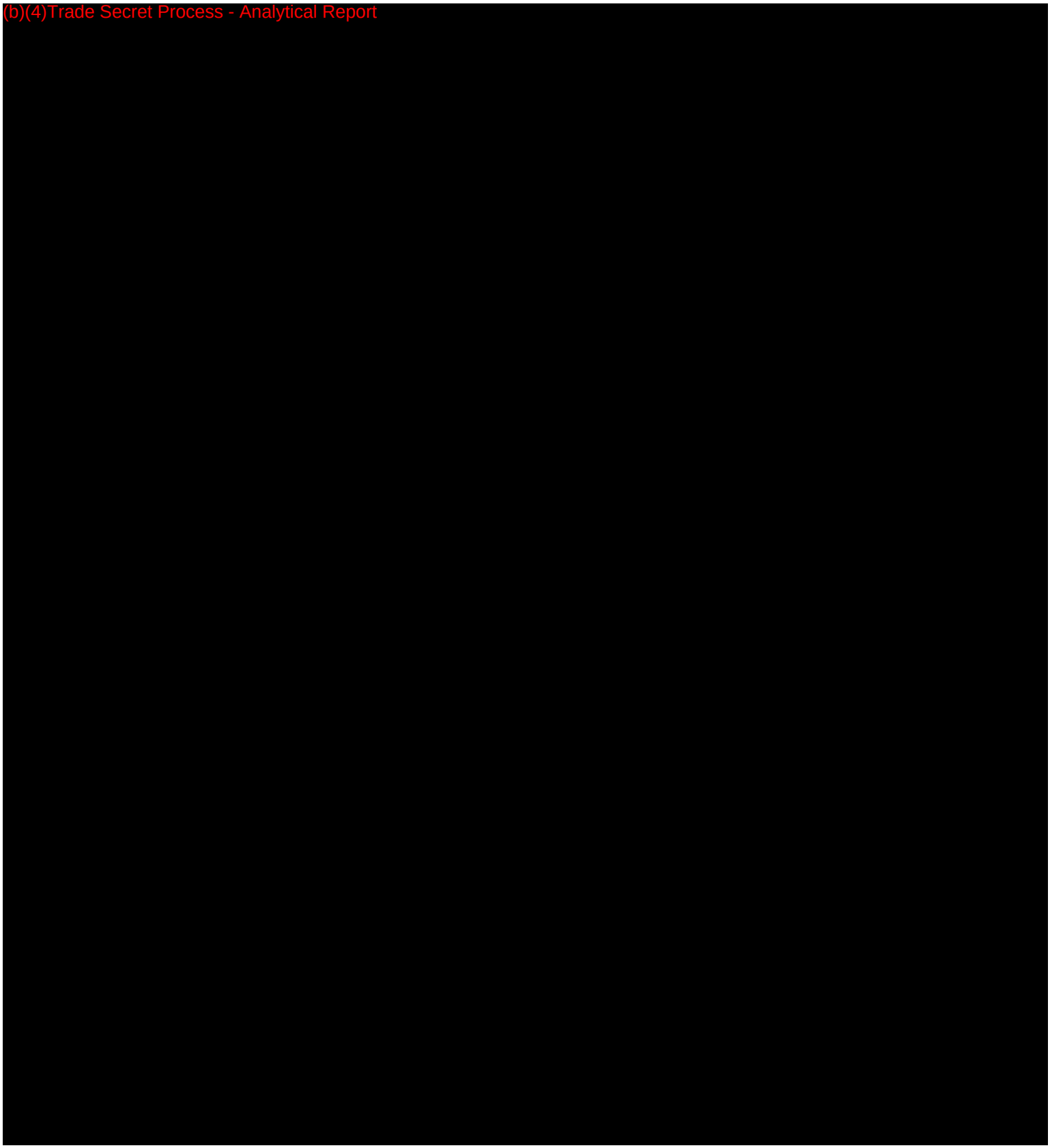

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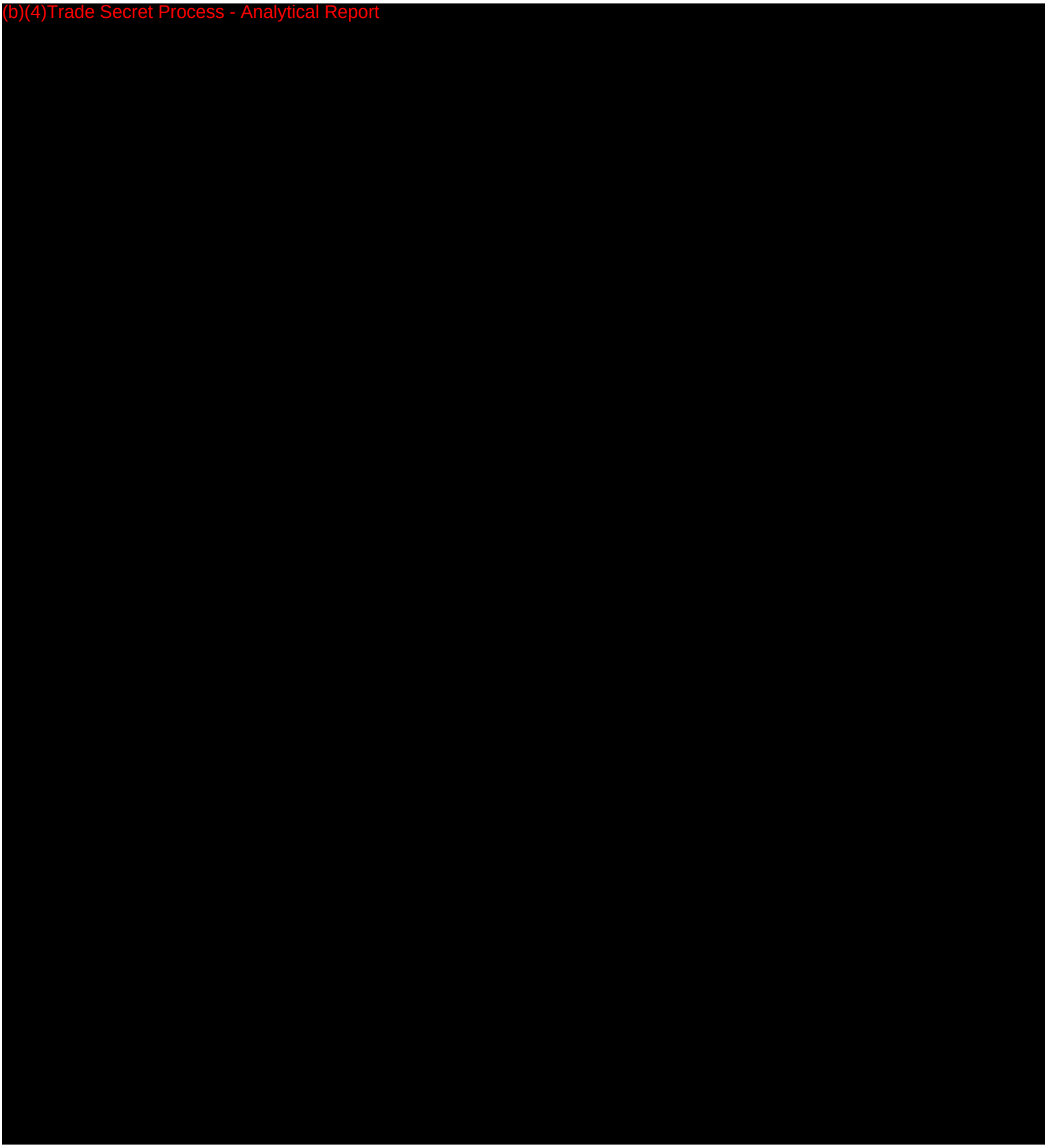

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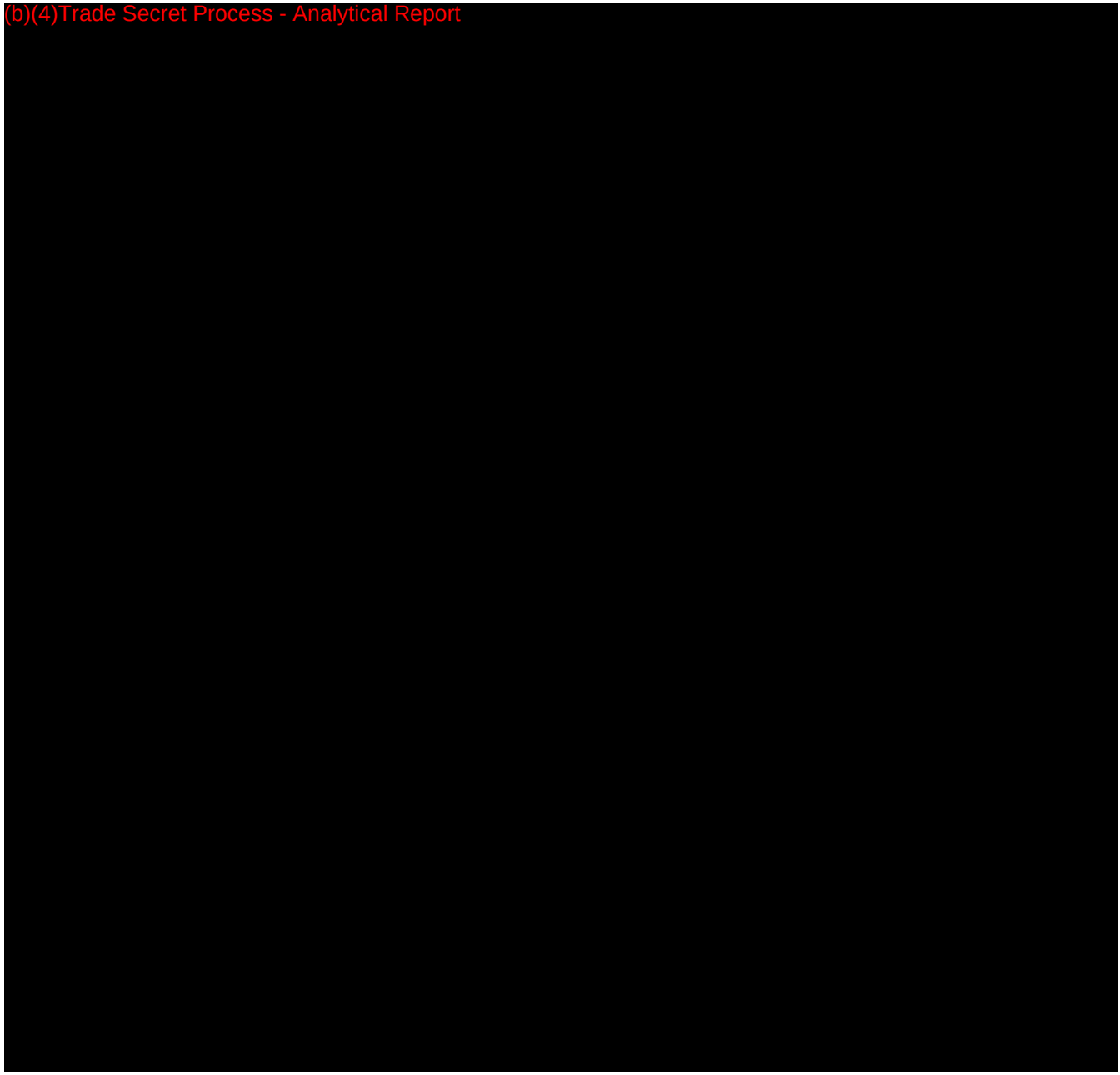

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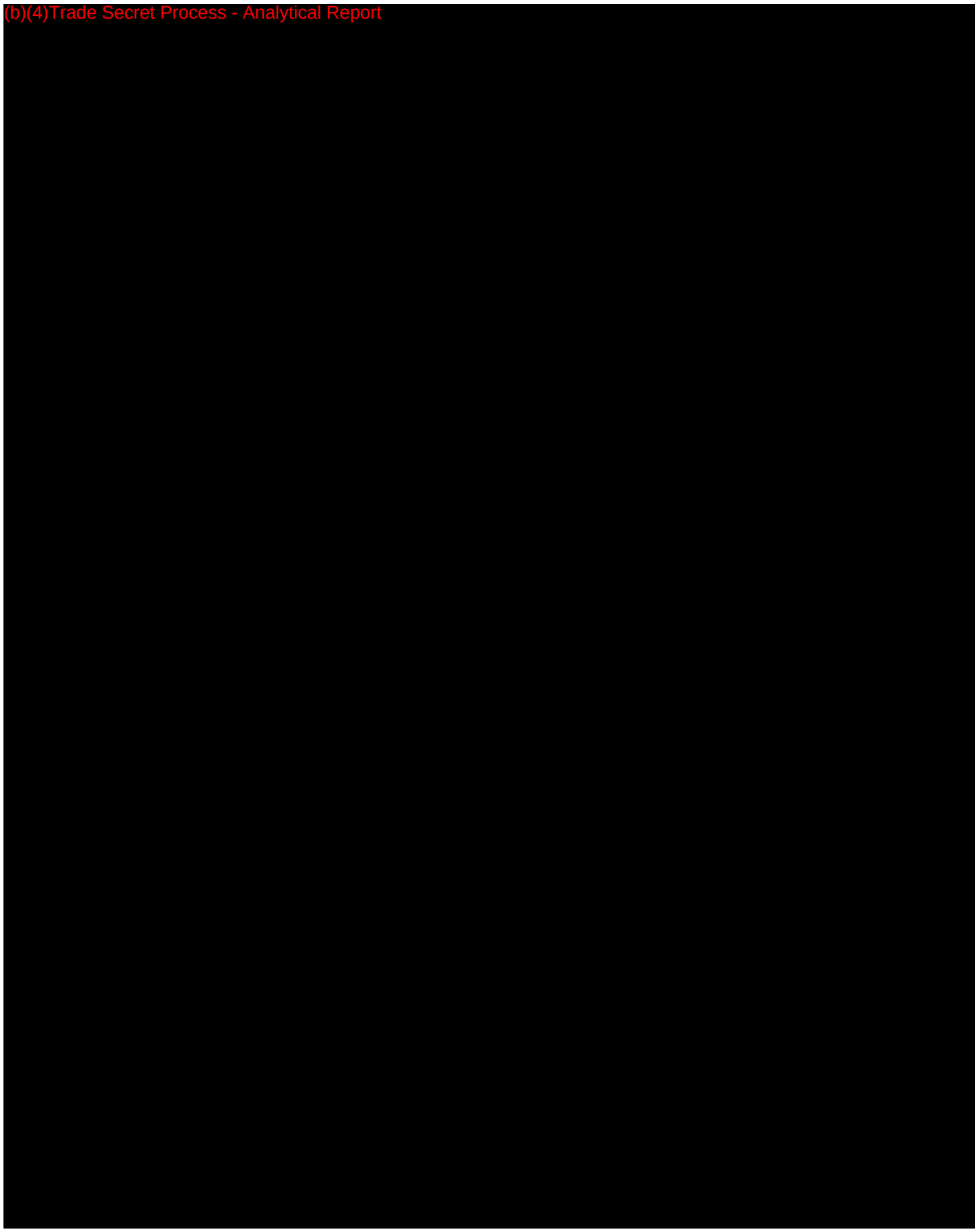

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Wound Management
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PREMARKET NOTIFICATION TRUTHFUL AND ACCURACY STATEMENT

I certify that, in my capacity as Director of Regulatory Affairs and Quality, North America of Smith & Nephew Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature:

Name: Terry McMahon Director of Regulatory Affairs and Quality, North America

Date: 12/12/2011