

K052643

1/2

APR 11 2006

510(k) Summary

**1. Submission Applicant & Correspondent**

Name: Ceragenix Corporation  
Address: 1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

Phone No. (720) 946-6440

Contact Person: Carl Genberg, J.D.

**2. Name of Device:** EPICERAM® Skin Barrier Emulsion

Trade/Proprietary/Model Name: EPICERAM®

Common or Usual Name: Skin Barrier Emulsion

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

**Devices to Which New Device is Substantially Equivalent:**

- Sinclair Wound and Skin Emulsion™ - Sinclair Pharmaceuticals, Ltd (K024367, July 28, 2003);
- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) - Medix Pharmaceuticals Americas, Inc. (K964240, Jan. 22, 1997);
- Carrasyn® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing - Carrington Laboratories, Inc. (K961758, July 11, 1996); and
- Mimyx™ Cream - Steifel Laboratories, Inc. (K041342, July 19, 2005)

**3. Device Description:**

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use.

**4. Intended Use of the Device:**

The device is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve dry skin conditions and to relieve and to manage the burning, itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment.

K052643

2/2

**5. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

**6. Tests and Conclusions:**

Functional and performance testing has been conducted to assess the safety and effectiveness of EPICERAM™ Skin Barrier Emulsion and the results are satisfactory.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

**APR 11 2006**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ceragenix Corporation  
c/o Mr. Carl Genberg  
Senior Vice President, R&D  
1444 Wazee Street  
Denver, Colorado 80202

Re: K052643  
Trade/Device Name: EPICERAM™ Skin Barrier Emulsion  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: January 17, 2006  
Received: January 17, 2006

Dear Mr. Genberg:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 - Mr. Carl Genberg

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K052643

Device Name: EPICERAM™ Skin Barrier Emulsion

Indications for Use:

FOR TOPICAL DERMATOLOGICAL USE ONLY

EPICERAM® is a skin barrier emulsion to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis. EPICERAM® helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Apply Epiceram® in a thin layer to the affected skin areas 2 times per day (or as needed) and massage gently into the skin. If the skin is broken, cover Epiceram® with a dressing of choice.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *[Signature]*  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K052643

Prescription Use  X  OR Over-the-Counter Use \_\_\_\_\_

(Per 21 C.F.R. § 801.109)

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

Food and Drug Administration  
 Center for Devices and  
 Radiological Health  
 Office of Device Evaluation  
 Document Mail Center (HFZ-401)  
 9200 Corporate Blvd.  
 Rockville, Maryland 20850

September 26, 2005

CERAGENIX CORPORATION  
 1444 WAZEE STREET  
 DENVER, CO 80202  
 ATTN: CARL GENBERG

510(k) Number: K052643  
 Received: 26-SEP-2005  
 Product: EPICERAM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. 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/cdrh/oivd/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) 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 [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman  
 Supervisory Consumer Safety Officer  
 Office of Device Evaluation  
 Center for Devices and Radiological Health

247

DXK

Due Nov 25, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services  
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s):

K052643/A2

To: Division Director:

SU / DSORD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN])

No response necessary (e.g., hard-copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

*change of ownership*

**CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)**

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by:

*David Kane*

Date:

*November 17, 2011*

*Doc  
11/17*

K052643/AZ



FDA CDRH DMC

NOV - 9 2011

Received K22

November 3, 2011

Sent via Certified Mail, Return Receipt Requested

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – W066-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

RE: K052643  
Trade/Device name: EPICERAM™ Skin Barrier Emulsion  
Regulatory Class: Unclassified  
Product Code: FRO

To whom it may concern:

Please be advised that this letter is an add to file document and serves as notification that all right, title and ownership interest in and to the above-referenced 510(k) has been transferred from Ceragenix Corporation to PuraCap Pharmaceutical LLC.

If you have any questions, please feel free to contact the undersigned.

Sincerely,



James A. Skelton  
Chief Restructuring Officer

Cc: Puracap Pharmaceutical LLC

1444 Wazee Street  
Suite 210  
Denver, CO 80202

K052643/A1



DUPLICATE

www.ceragenix.com

7 February 2006

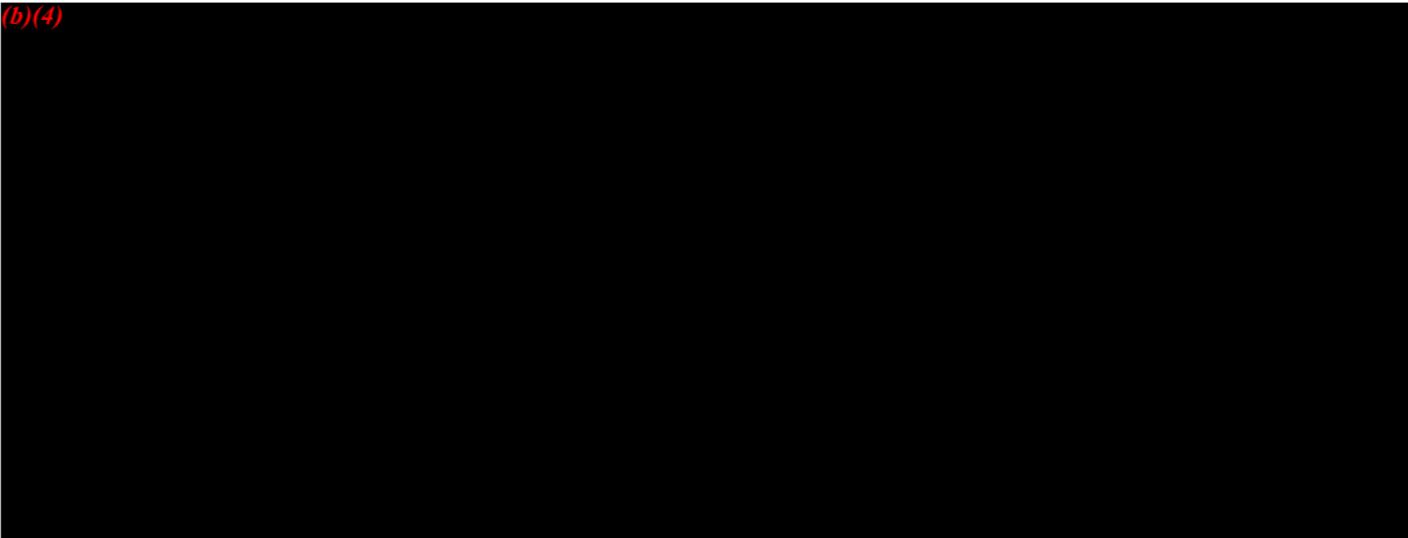
Dr. Dora Vega  
CDRH  
Division of General, Restorative and Neurological Devices  
9200 Corporate Boulevard, HFZ-410  
Rocville, MD 20850

RE: **K052643**  
Trade Name: Epiceram Skin Barrier Emulsion  
Dated: September 22, 2005  
Received: September 26, 2005

Dear Dr. Vega,

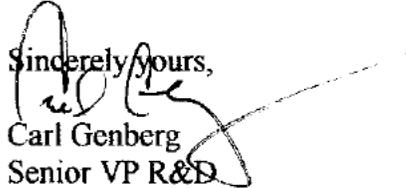
Thank you for your telephone call on Monday, February 6, 2006 regarding the above-referenced 510(k) notification. Pursuant to our discussion and agreement:

(b)(4)



Thank you for your consideration and expeditious review of our 510(k) notification.

Sincerely yours,

  
Carl Genberg  
Senior VP R&D  
Ceragenix Pharmaceuticals, Inc.  
(702) 451-0219  
(702) 241-3765 (cell)  
[cgenberg@ceragenix.com](mailto:cgenberg@ceragenix.com) (email)

1444 Wazee Street  
Suite 210  
Denver, CO 80202

p: 720.946.6440  
f: 303.534.1860

K29

## 510(k) Summary

### 1. Submission Applicant & Correspondent

Name: Ceragenix Corporation  
Address: 1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

Phone No. (720) 946-6440

Contact Person: Carl Genberg, J.D.

**2. Name of Device:** EPICERAM® Skin Barrier Emulsion

Trade/Proprietary/Model Name: EPICERAM®

Common or Usual Name: Skin Barrier Emulsion

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

### 3. Devices to Which New Device is Substantially Equivalent:

- Sinclair Wound and Skin Emulsion™ - Sinclair Pharmaceuticals, Ltd (K024367, July 28, 2003);
- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) - Medix Pharmaceuticals Americas, Inc. (K964240, Jan. 22, 1997); and
- Carrasyn® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing – Carrington Laboratories, Inc. (K961758, July 11, 1996).

### 4. Device Description:

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use which is specially formulated to treat xerotic skin conditions by maintaining a moist skin environment which is beneficial to the healing process.

### 5. Intended Use of the Device:

The device is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve xerotic skin conditions and to relieve and to manage the burning and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

**6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

**7. Tests and Conclusions:**

Functional and performance testing has been conducted to assess the safety and effectiveness of EPICERAM™ Skin Barrier Emulsion and the results are satisfactory.

## INDICATIONS FOR USE

**510(k) Number:** K052643

**Device Name:** EPICERAM™ Skin Barrier Emulsion

**Indications for Use:**

EPICERAM® is a skin barrier emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

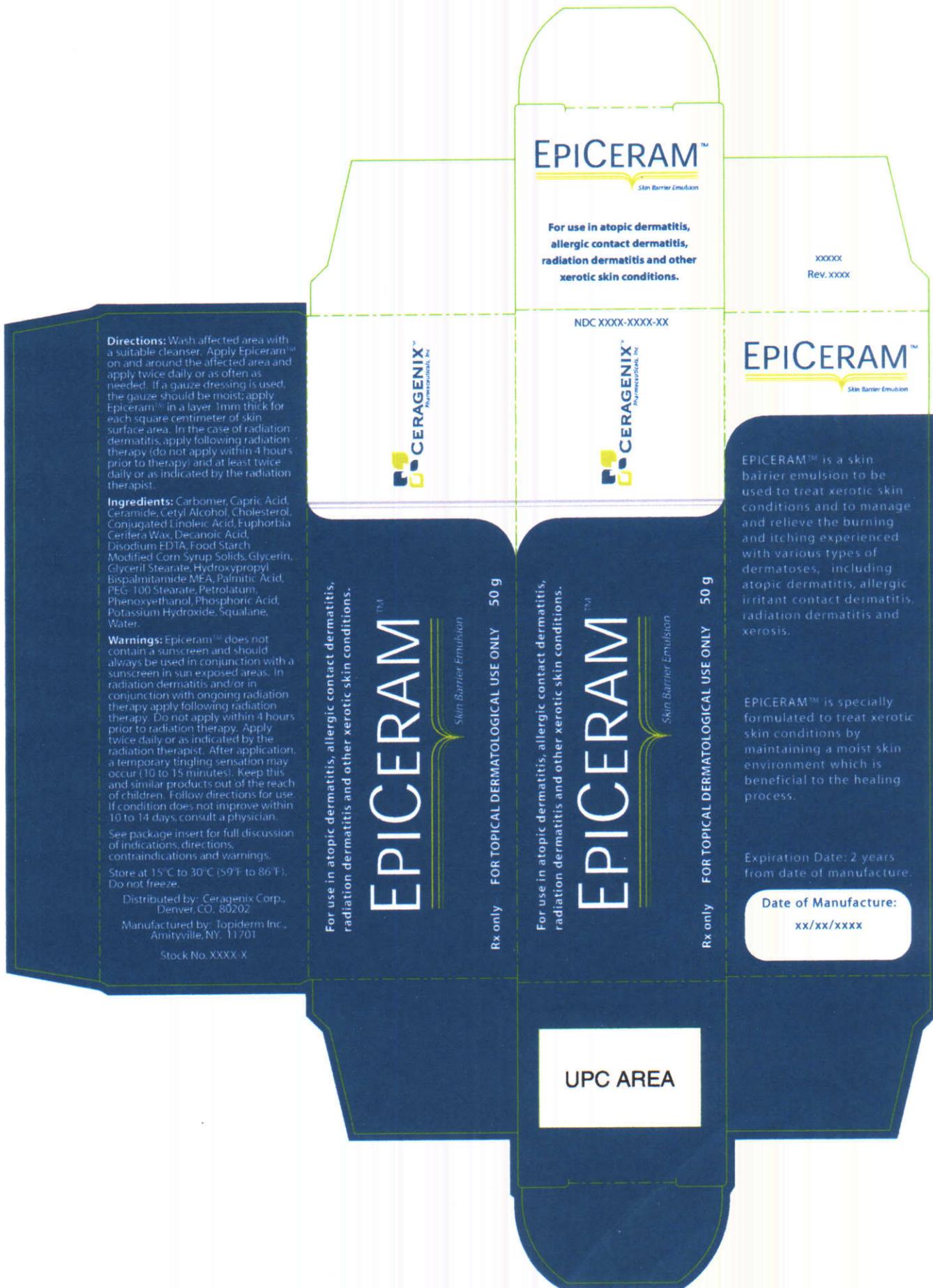
Prescription Use  X  AND/OR Over-the-Counter Use    
(Part 21 CFR 801 Subpart D)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



**Directions:** Wash affected area with a suitable cleanser. Apply EPICERAM<sup>TM</sup> on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist; apply EPICERAM<sup>TM</sup> in a layer 1mm thick for each square centimeter of skin surface area. In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

**Ingredients:** Carbomer, Capric Acid, Ceramide, Cetyl Alcohol, Cholesterol, Conjugated Linoleic Acid, Euphorbia Cerifera Wax, Decanoic Acid, Disodium EDTA, Food Starch, Modified Corn Syrup Solids, Glycerin, Glyceril Stearate, Hydroxypropyl Bispalmitamide MEA, Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Phosphoric Acid, Potassium Hydroxide, Squalane, Water.

**Warnings:** EPICERAM<sup>TM</sup> does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. In radiation dermatitis and/or in conjunction with ongoing radiation therapy apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

See package insert for full discussion of indications, directions, contraindications and warnings.

Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

Distributed by: Ceragenix Corp., Denver, CO, 80202

Manufactured by: Topiderm Inc., Amityville, NY, 11701

Stock No. XXXX-X

For use in atopic dermatitis, allergic contact dermatitis, radiation dermatitis and other xerotic skin conditions.

**EPICERAM<sup>TM</sup>**  
Skin Barrier Emulsion

Rx only FOR TOPICAL DERMATOLOGICAL USE ONLY 50 g

For use in atopic dermatitis, allergic contact dermatitis, radiation dermatitis and other xerotic skin conditions.

**EPICERAM<sup>TM</sup>**  
Skin Barrier Emulsion

Rx only FOR TOPICAL DERMATOLOGICAL USE ONLY 50 g

UPC AREA

**EPICERAM<sup>TM</sup>**  
Skin Barrier Emulsion

For use in atopic dermatitis, allergic contact dermatitis, radiation dermatitis and other xerotic skin conditions.

XXXXX  
Rev. XXXX

NDC XXXX-XXXX-XX



**EPICERAM<sup>TM</sup>**  
Skin Barrier Emulsion

EPICERAM<sup>TM</sup> is a skin barrier emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic irritant contact dermatitis, radiation dermatitis and xerosis.

EPICERAM<sup>TM</sup> is specially formulated to treat xerotic skin conditions by maintaining a moist skin environment which is beneficial to the healing process.

Expiration Date: 2 years from date of manufacture.

Date of Manufacture:

xx/xx/xxxx

# EPICERAM<sup>TM</sup>

Skin Barrier Emulsion

**For Topical Dermatological Use Only**

**Rx only**

## PRODUCT DESCRIPTION

EPICERAM<sup>TM</sup> is a skin barrier emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic irritant contact dermatitis, radiation dermatitis and xerosis.

## INDICATIONS FOR USE

EPICERAM<sup>TM</sup> is specially formulated to treat xerotic skin conditions by maintaining a moist skin environment which is beneficial to the healing process.

## CONTRAINDICATIONS

When an allergy to one of the ingredients is known:

## WARNINGS

EPICERAM<sup>TM</sup> does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. In radiation dermatitis and/or in conjunction with ongoing radiation therapy apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

## PRECAUTIONS AND OBSERVATIONS

For the treatment of any dermal wound, consult a physician.

- Use EPICERAM<sup>TM</sup> Skin Barrier Emulsion only as directed.
- EPICERAM<sup>TM</sup> Skin Barrier Emulsion is non-toxic, however it is for external use only and should not be ingested or taken internally.
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of EPICERAM<sup>TM</sup> Skin Barrier Emulsion may be continued during the anti-infective therapy.
- If condition does not improve within 10 to 14 days, consult a physician.
- EPICERAM<sup>TM</sup> Skin Barrier Emulsion does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas.
- In radiation dermatitis and/or in conjunction with ongoing radiation therapy, apply following radiation therapy.
- Do not apply within 4 hours prior to radiation therapy.
- Apply twice daily or as indicated by the radiation therapist.
- Following the application of EPICERAM<sup>TM</sup> Skin Barrier Emulsion a temporary tingling sensation may occur (10 to 15 minutes).
- Keep this and other similar products out of the reach of children.

## INSTRUCTIONS FOR USE

Wash affected area with a suitable cleanser. Apply EPICERAM<sup>TM</sup> on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist; apply EPICERAM<sup>TM</sup> in a layer 1mm thick for each square centimeter of skin surface area. In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

## INGREDIENTS

Carbomer, Capric Acid, Ceramide, Cetyl Alcohol, Cholesterol, Conjugated Linoleic Acid, Euphorbia Cerifera Wax, Decanoic Acid, Disodium EDTA, Food Starch Modified Corn Syrup Solids, Glycerin, Glyceril Stearate, Hydroxypropyl Bispalmitamide MEA, Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Phosphoric Acid, Potassium Hydroxide, Squalane, Water.

## HOW SUPPLIED

EPICERAM<sup>TM</sup> Skin Barrier Emulsion is available in a 50 g tube. NDC XXXX XXXX XX

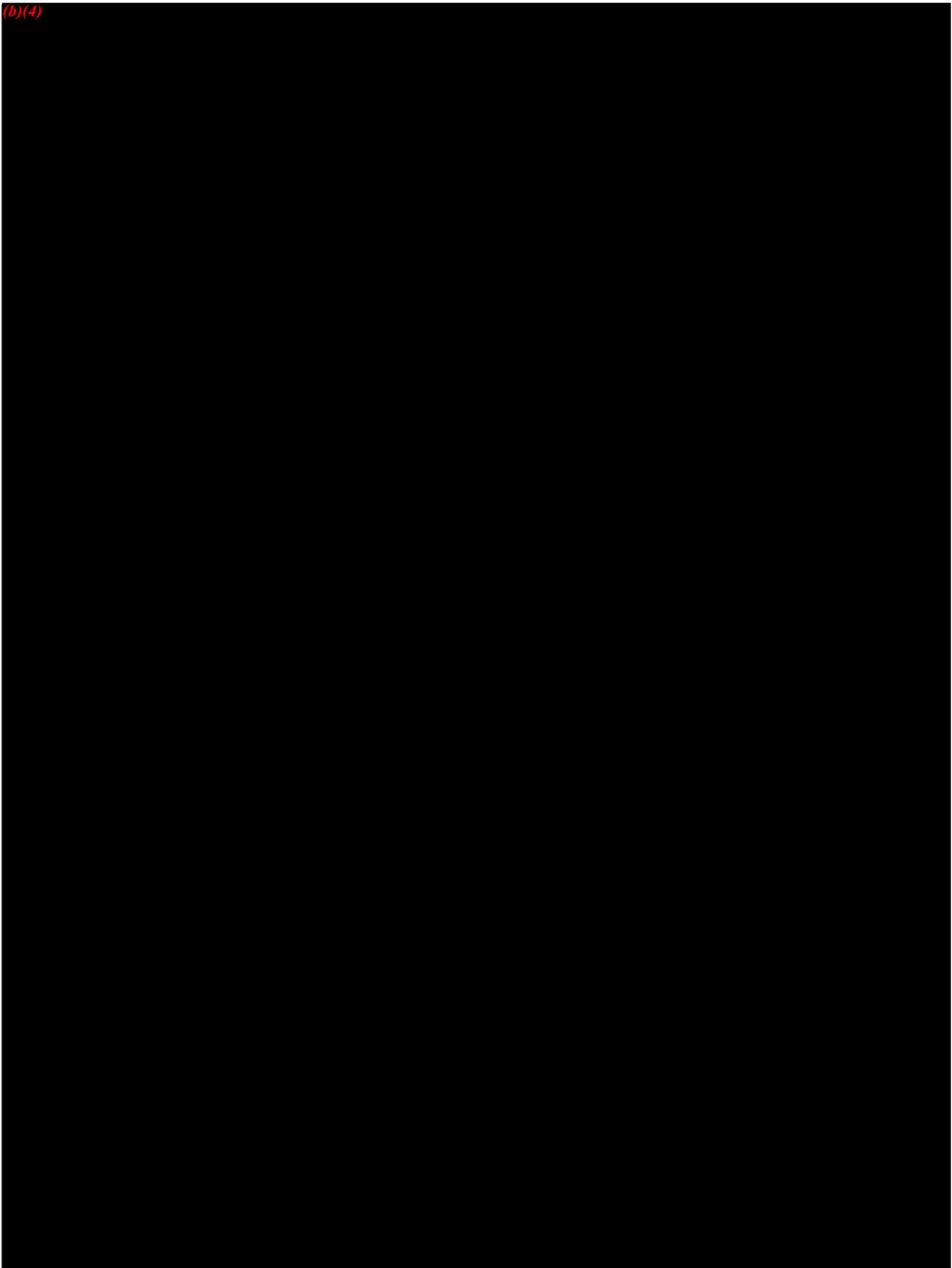
Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

Distributed by: Ceragenix Corp., Denver, CO. 80202      Manufactured by: Topicalerm Inc., Amityville, NY. 11701

**Rx ONLY - Prescription Medical Device; Federal law restricts this device to sale by or on the order of a physician.**



(b)(4)



(b)(4)

(b)(4)

# TECHNICAL DATA SHEET

Product: (b)(4) Al - Tube Laminate

Structure:

(b)(4)

Date:

Ju

## 1. Specification

(b)(4)

[Redacted content]

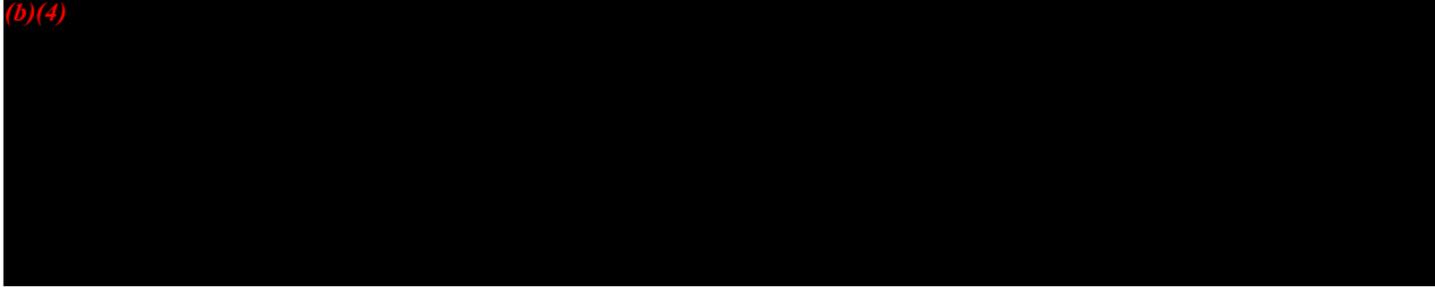
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EXPERCHEM LABORATORIES FAX-410-600-79201

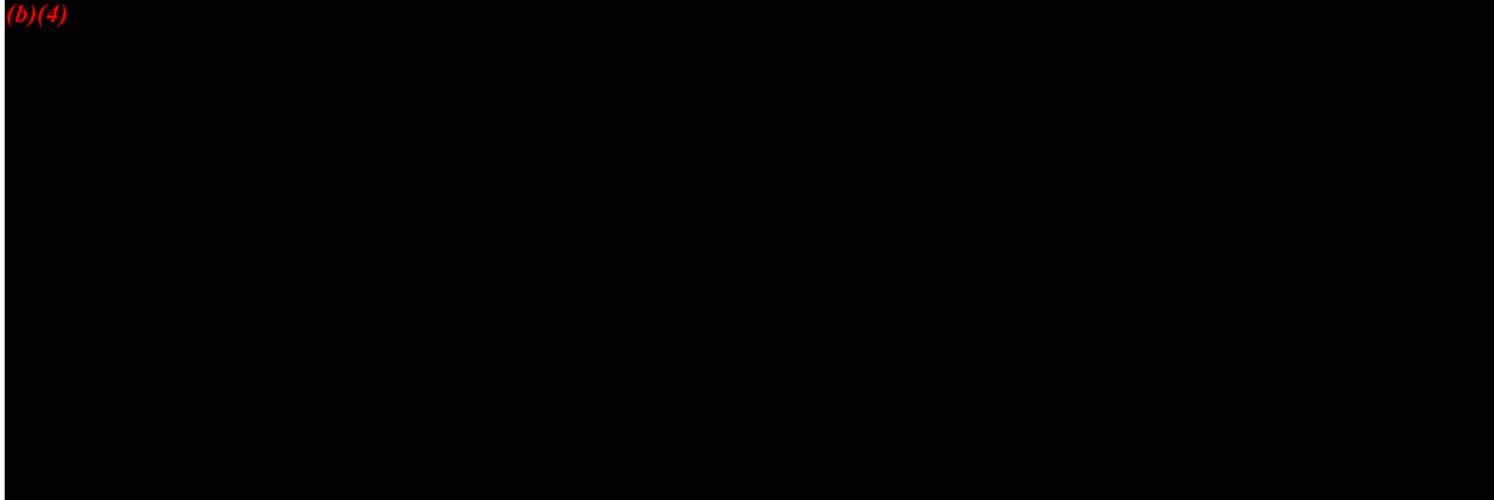
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November 5, 2001

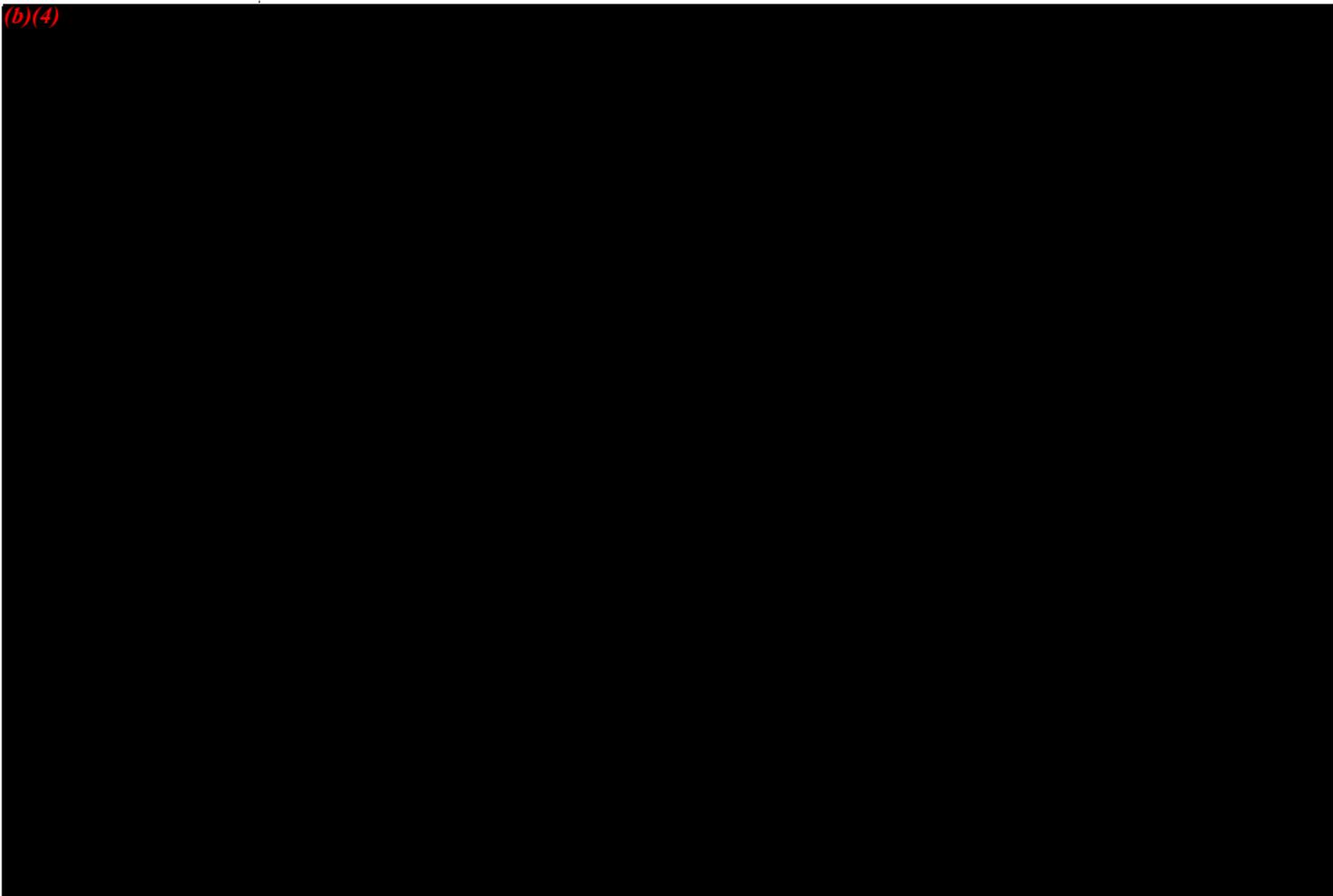
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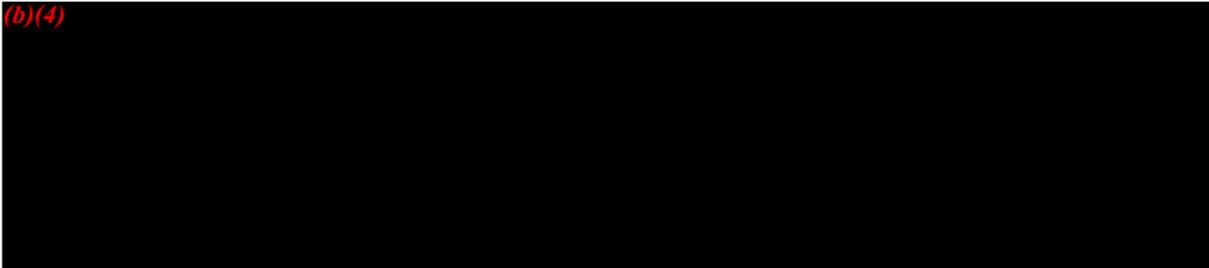
**RESULTS**

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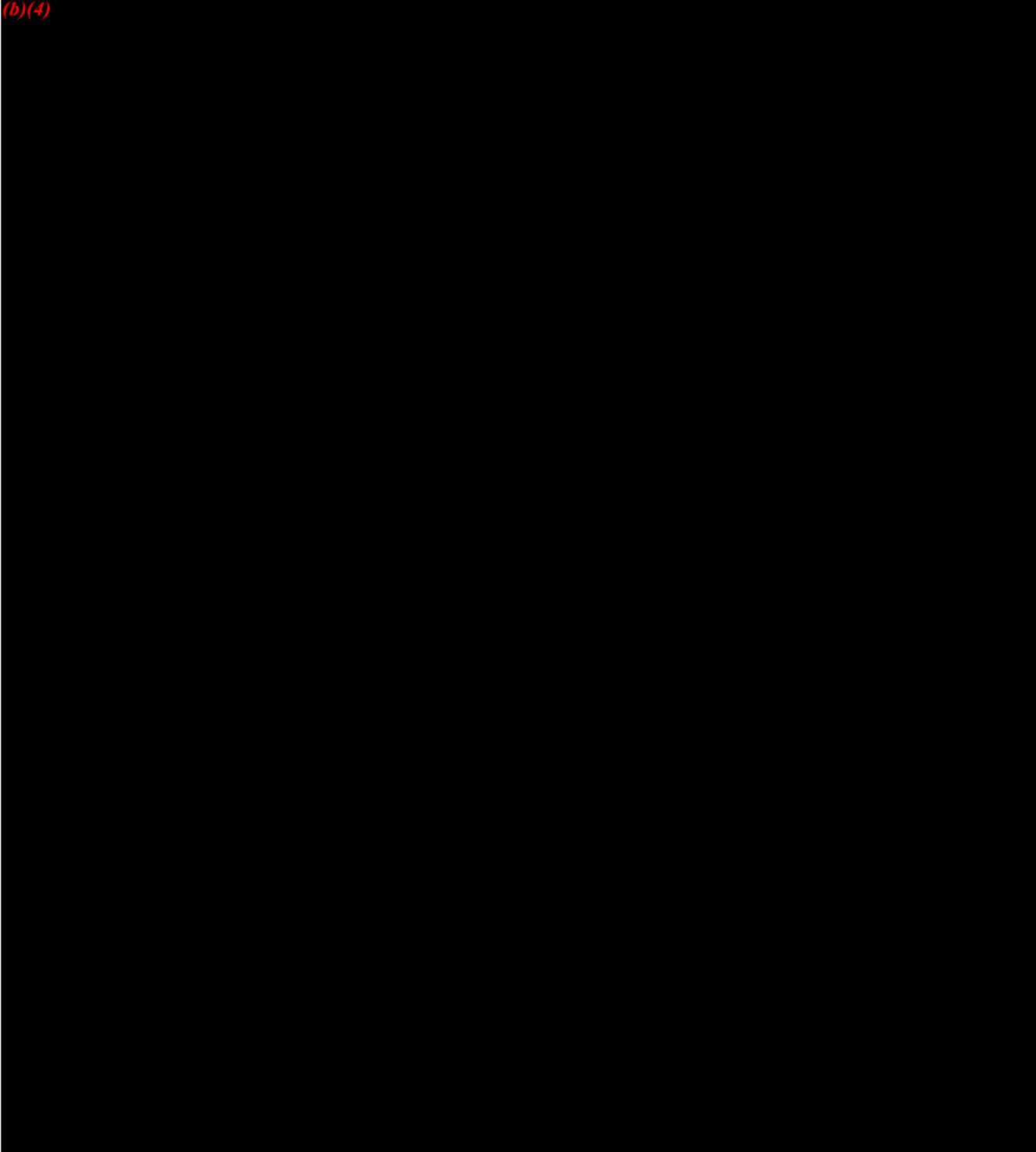
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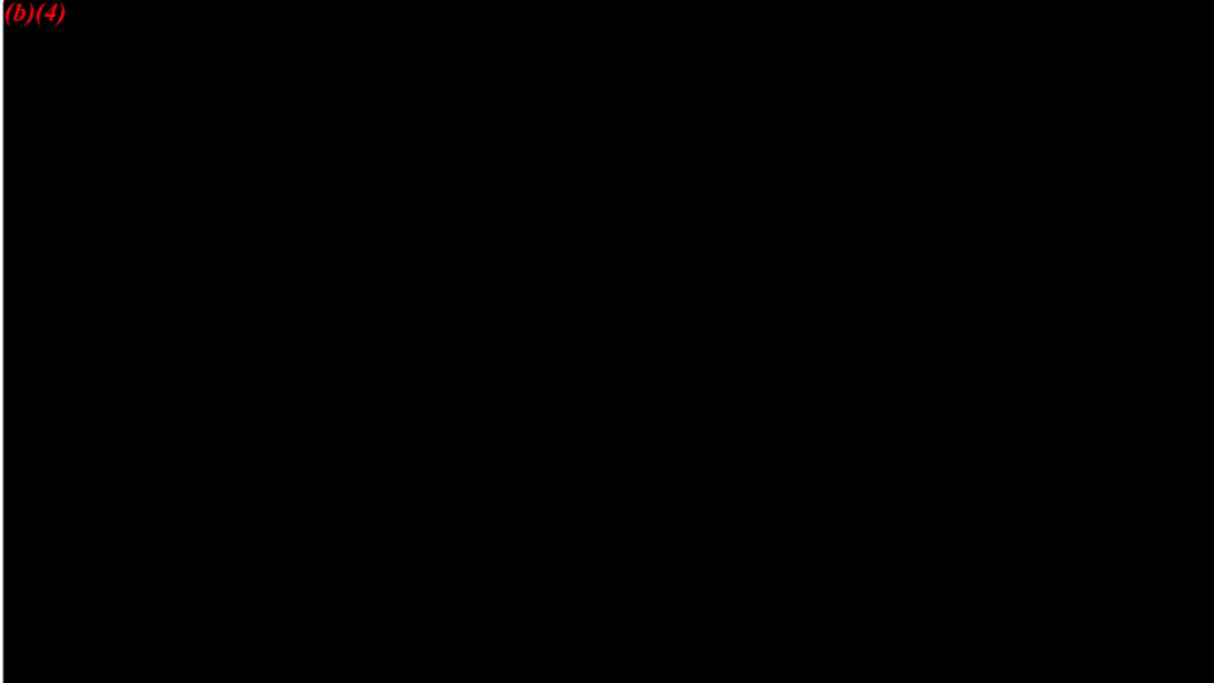
(b)(4)

A very large black rectangular redaction box covers the majority of the page, obscuring all text and graphics beneath it.

61

**Measurement of oxygen and water vapour permeation of tube laminate**

(b)(4)



## 510(k) Summary

### 1. Submission Applicant & Correspondent

Name: Ceragenix Corporation  
Address: 1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

Phone No. (720) 946-6440

Contact Person: Carl Genberg, J.D.

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## INDICATIONS FOR USE

**510(k) Number:** K052643

**Device Name:** EPICERAM™ Skin Barrier Emulsion

**Indications for Use:**

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Prescription Use  X  AND/OR Over-the-Counter Use    
(Part 21 CFR 801 Subpart D)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



www.ceragenix.com

FEB 11 2012 A 9:33

11 January 2006

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: K052643  
Trade Name: Epiceram Skin Barrier Emulsion  
Dated: September 22, 2005  
Received: September 26, 2005

Dear Mr. Melkerson:

By this letter we are requesting an additional extension of time (b)(4) [redacted]  
[redacted] res [redacted]  
2 [redacted] to [redacted].

Thank you for your consideration in this matter

Sincerely yours,

*Carl Genberg by LT*  
Carl Genberg  
Senior VP R&D  
Ceragenix Pharmaceuticals, Inc.

1444 Wazee Street  
Suite 210  
Denver, CO 80202  
p: 720.946.6440  
f: 303.534.1860

189 K17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

December 28, 2005

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

CERAGENIX CORPORATION  
1444 WAZEE STREET  
DENVER, CO 80202  
ATTN: CARL GENBERG

510(k) Number: K052643  
Product: EPICERAM

Extended Until: 13-JAN-2006

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 is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

K052643/191



www.ceragenix.com

21 December 2005

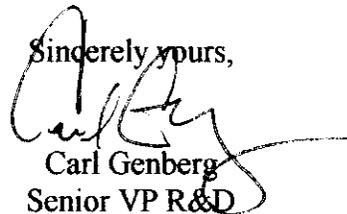
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Re: K052643  
Trade Name: Epiceram Skin Barrier Emulsion

Dear Mr. Melkerson:

We are in receipt of your letter dated November 21, 2005 (received by us on November 28, 2005) requesting additional information regarding the above-referenced 510k notification. We are in the process of assembling the requested information and respectfully request an extension of time to file our response on or before January 13, 2006.

Sincerely yours,

  
Carl Genberg  
Senior VP R&D

LS:1 10 15:57  
GMR/B

1444 Wazee Street  
Suite 210  
Denver, CO 80202

p: 720.946.6440  
f: 303.534.1860

K23

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Carl Genberg, J.D.  
Senior VP Research & Development  
Ceragenix Corporation  
1444 Wazee Street- Suite 210  
Denver, Colorado 80202

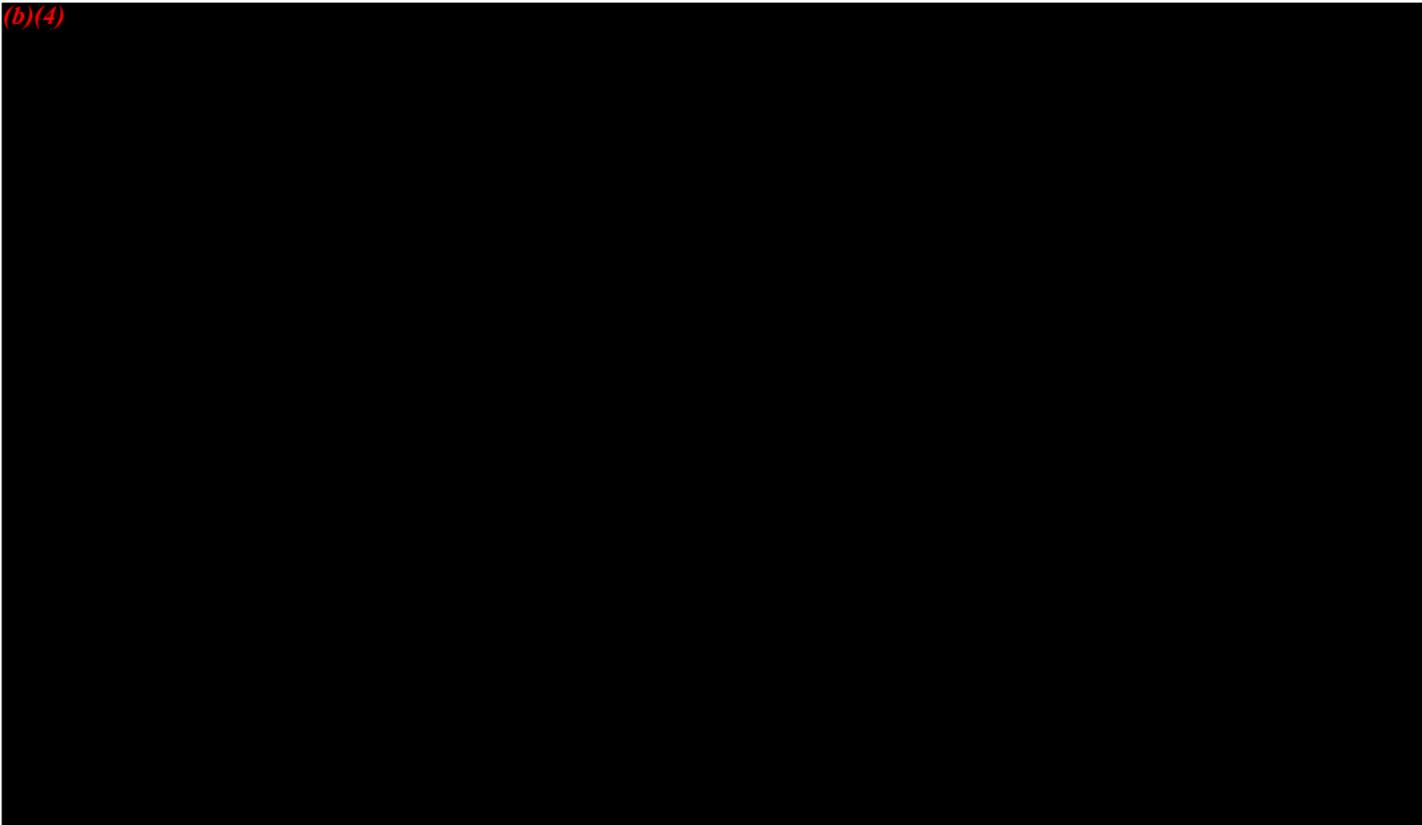
NOV 21 2005

Re: K052643  
Trade Name: Epiceram Skin Barrier Emulsion  
Dated: September 22, 2005  
Received: September 26, 2005

Dear Mr. Genberg:

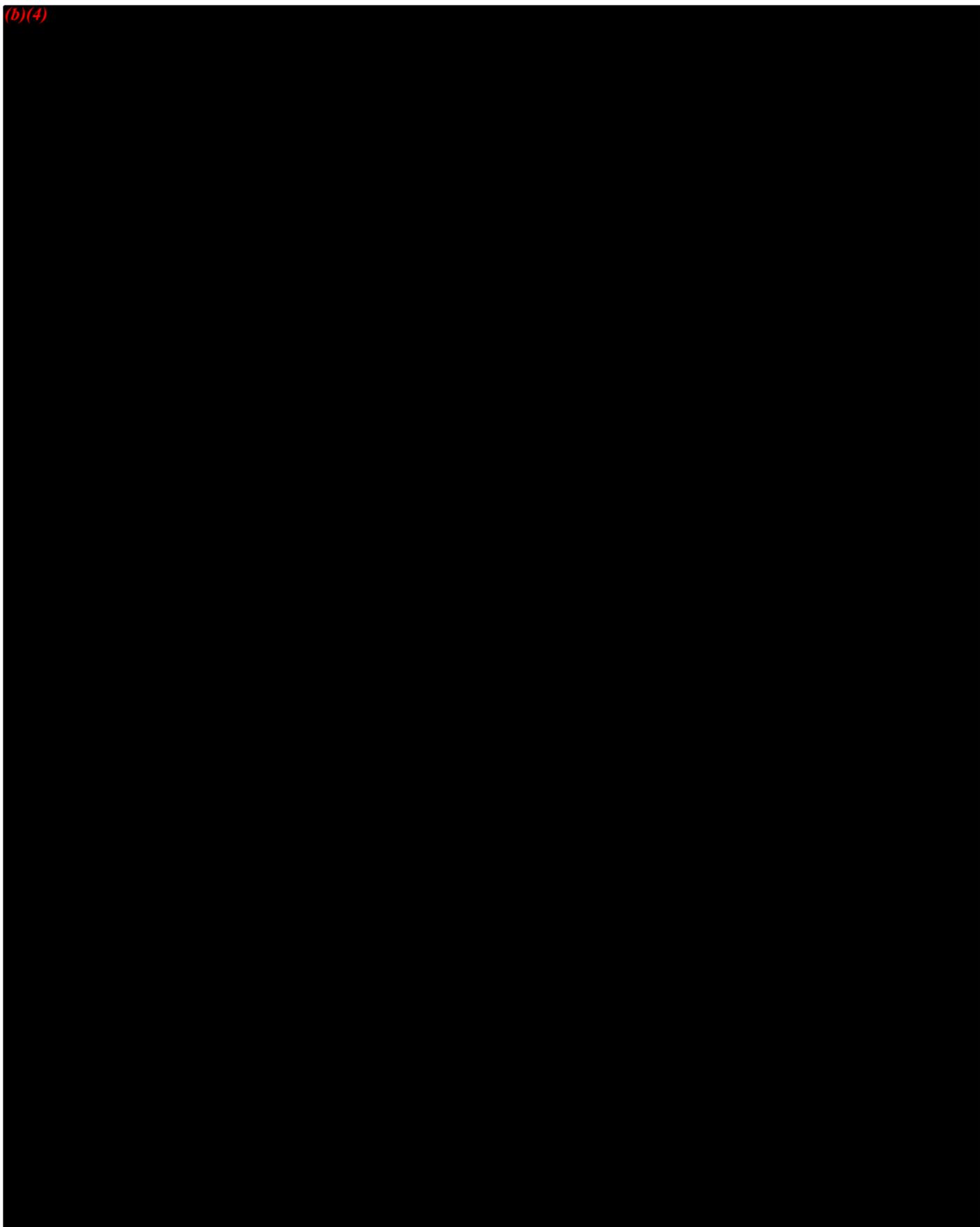
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we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

(b)(4)



Page 2 – Carl Genberg, J.D.

(b)(4)



Page 3 -- Carl Genberg, J.D.

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled *Use of Standards in Substantial Equivalence Determinations* located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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 Federal Food, Drug, and Cosmetic Act (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.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Pre-market Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment." 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/cdrh/mdufma/guidance/1219.html>.

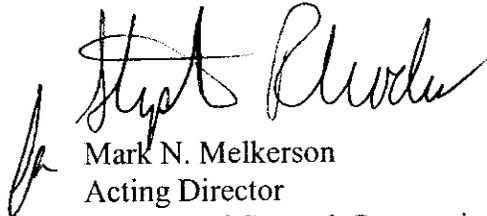
Page 4 – Carl Genberg, J.D.

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:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Dora Vega at (301) 594-3090 – ext 142. 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 at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K052-643

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005 (b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification number on	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a> . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.			
--> 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  CERAGENIX CORPORATION 1444 Wazee St, Ste 210 Denver CO 80202 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 412028516		2. CONTACT NAME Carl Genberg 2.1 E-MAIL ADDRESS cgenberg@ceragenix.com 2.2 TELEPHONE NUMBER (include Area code) 702-4510219 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 303-2659994	
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: <a href="http://www.fda.gov/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. 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).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
(b)(4)		PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)	
(b)(4)		21-Sep-2005	

(b)(4)

Close Window

[https://fdasfinapp8.fda.gov/OA\\_HTML/mdufmaCScdCfgItemsPopup.jsp?ordnum=6022608](https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?ordnum=6022608) 9/21/2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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 SU?  
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 248

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approval  
OMB No. 9010-0120  
Expiration Date: May 31, 2007.  
See OMB Statement on page 5.

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission  
22/05

(b)(4)

FDA Submission Document Number (if known)

**SECTION A TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Meeting</b></p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Ceragenix Corporation		Establishment Registration Number (if known) Applicant has yet to apply for a registration number	
Division Name (if applicable)		Phone Number (including area code) ( 303 ) 478-8965	
Street Address 1444 Wazee Street		FAX Number (including area code) ( 303 ) 265-9994	
City Denver	State / Province Colorado	ZIP/Postal Code 80202	Country USA
Contact Name Carl Genberg			
Contact Title Senior VP R&D		Contact E-mail Address cgenberg@ceragenix.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/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (specify):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	2	3	4	<input type="checkbox"/> 510 (k) summary attached	<input type="checkbox"/> 510 (k) statement
MGQ					
	6	7	8		

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

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K024367	1 Sinclair Wound and Skin Emulsion	1 Sinclair Pharamceuticals, Ltd.
2 K96420	2 BIAFINE Wound Dressing Emulsion	2 Medix Pharmaceuticals Americas, Inc.
3 K961758	3 Carrasyn Hydrogel Wound Dressing	3 Carrington Laboratories, Inc.
4	4	4
5	5	5
6	6	6

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
 Dressing, Wound & Burn, Hydrogel w Drug or Biologic

Trade or Proprietary or Model Name for This Device	Model Number
1 EPICERAM	1
2	2
3	3
4	4
5	5

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

1 K042589	2 RFD 2005-11	3	4	5	6
7	8	9	10	11	12

Data Included in Submission  
 Laboratory Testing       Animal Trials       Human Trials

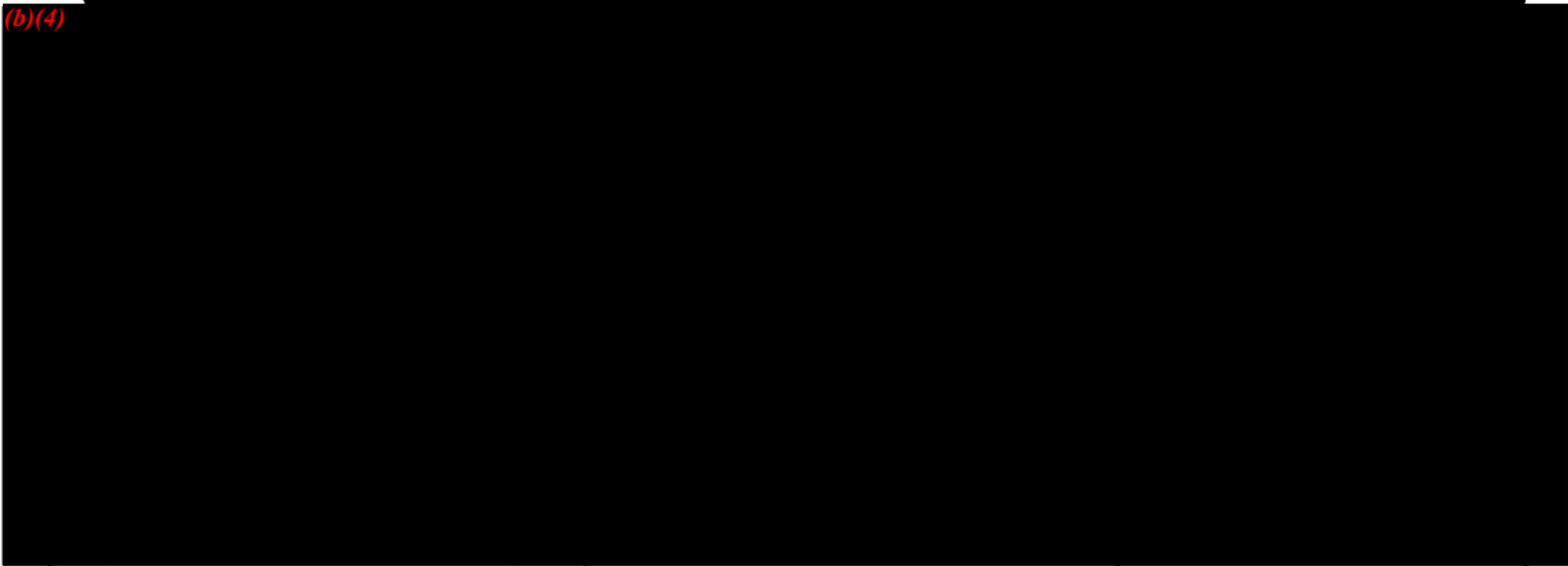
**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code MGQ	C.F.R. Section (if applicable)	Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery Panel		

Indications (from labeling)  
 in barrier emulsion to be used to reduce excessive transepidermal water loss in xerotic skin conditions and to manage and relieve the burning, itching and pain experienced in various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

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**



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) (     )	
Street Address		FAX Number (including area code) (     )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) (     )	
Street Address		FAX Number (including area code) (     )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

**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.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 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

253

510(k) NOTIFICATION FOR

EPICERAM™ Skin Barrier Emulsion

510K Number K052-643

(b)(4)

Dated:

22 September 2005

Submitted by:

Ceragenix Corporation  
1444 Wazee Street  
Suite 210  
Denver, CO 80202

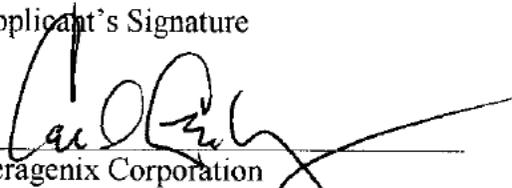
Contact Person:

Carl Genberg J.D.  
Senior VP Research & Development  
(702) 451-0219  
(303) 478-8965 (cell)  
(303) 265-9994 (fax)  
[cgenberg@ceragenix.com](mailto:cgenberg@ceragenix.com)

Manufactured by:

(b)(4)

Applicant's Signature

  
\_\_\_\_\_  
Ceragenix Corporation  
By Carl Genberg, J.D. its Senior VP R&D

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	Section 807.87(c) (Classification, Device, Panel)	2.3
	Section 807.87(d) (Applicable Performance Requirements)	2.4
	Section 807.87(e) (Proposed Labeling)	2.5
	Section 807.87(f) (Similarity to Predicate Devices)	2.6-2.17
	Section 807.87(g) (Modifications)	2.18
	Section 807.87(h) (510k Summary)	2.19
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### Exhibits

Exhibit A	510(k) Summary for Sinclair Wound and Skin Emulsion (K024367)
Exhibit B	Indications for Use for Sinclair Wound and Skin Emulsion (K024367)
Exhibit C	Biafine RE's "Table of Substantial Equivalence" (K963240)
Exhibit D	Biafine's Labeling for its Box and Tube
Exhibit E	Biafine's Labeling for its Package Insert
Exhibit F	Biafine's online product brochure ( <a href="http://www.biafine.com">www.biafine.com</a> )

- Exhibit G Applicant's Table of Substantial Equivalence
- Exhibit H Medline Abstract, Madison KC "Barrier function of the skin: la raison D'etre of the epidermis." Journal of Investigative Dermatology 2003 Aug;121(2):231-41
- Exhibit I Medline Abstract, Pilgram GS et al, "Aberrant lipid organization in stratum corneum of patients with atopic dermatitis and lamellar ichthyosis." Journal of Investigative Dermatology: 2001, Sept. 117(3):710-7
- Exhibit J McIntosh TJ, "Organization of Skin Stratum Corneum Extracellular Lamellae: Diffraction Evidence for Asymmetric Distribution of Cholesterol." Biophysical Journal 85:167501681 (2003)
- Exhibit K AMA Laboratories Report
- Exhibit L Chamlin, et al., "Ceramide-dominant barrier repair lipids alleviate Childhood atopic dermatitis: Changes in barrier function provide A sensitive indicator of disease activity." J Am Acad Dermatol. 2002 Aug; 47(2):198-208
- Exhibit M Medline Abstract. Schmuth M, et al., "Permeability barrier function of skin exposed to ionizing radiation." Arch Dermatol 2001 Aug; 137(8):1019-23
- Exhibit N Applicant's 510(k) Summary
- Exhibit O In vitro cytotoxicity protocol and results
- Exhibit P In vivo dermal irritation protocol and results
- Exhibit Q In vivo dermal irritation Table II (abraded skin results)
- Exhibit R In vivo dermal sensitivity protocols and results
- Exhibit S Proposed Labeling (Box and Tube) for EPICERAM™

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**1**

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**3**

**4**

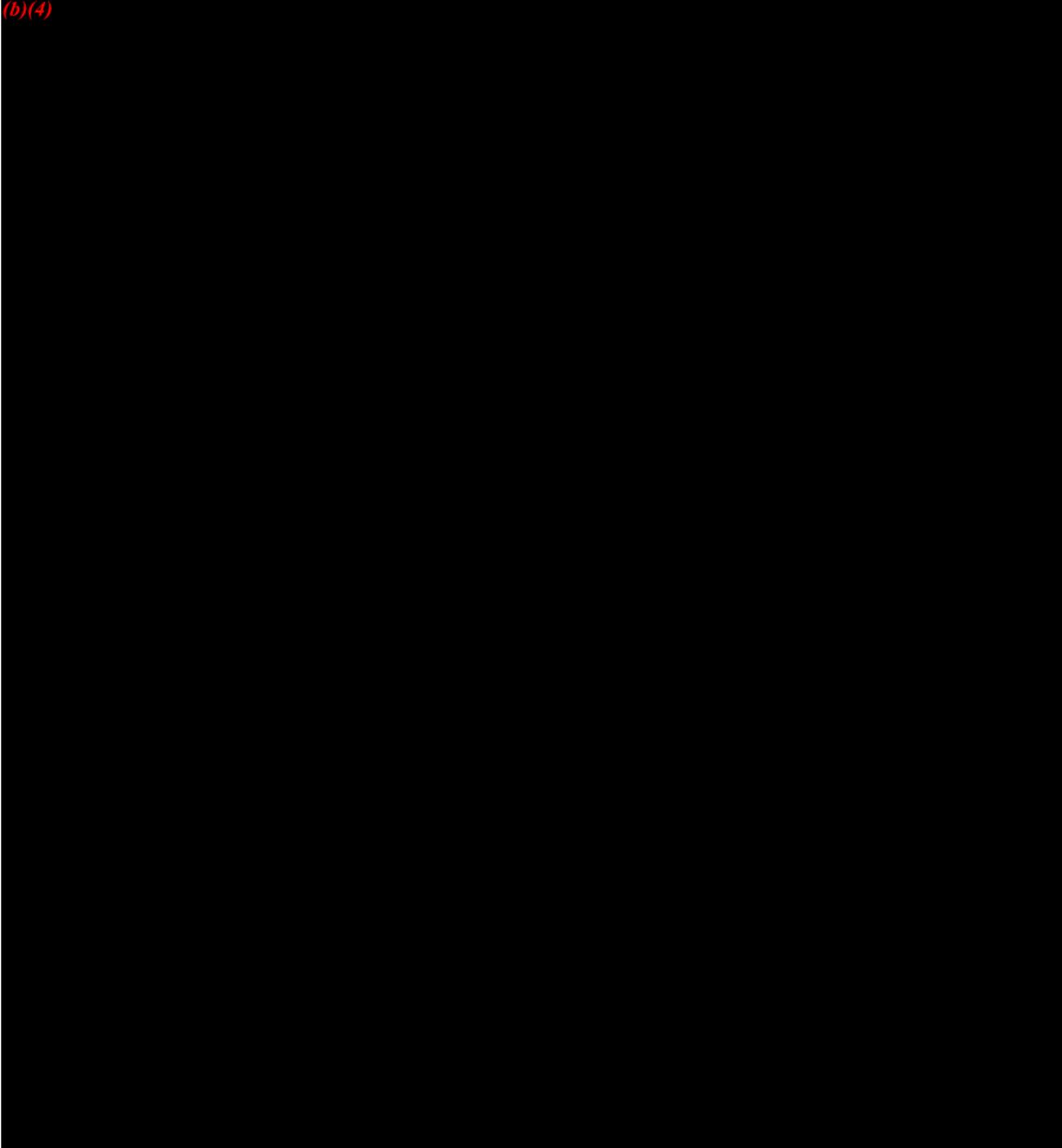
**5**

# EXHIBIT A

## Epiceram®

<u>Ingredient</u>	<u>Reference</u>	<u>%(w/w)</u>	<u>Grade</u>
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(b)(4)



## I. Introduction

This 510(k) application is being submitted by Ceragenix Corporation. This Application is confidential. The application seeks clearance for a skin barrier emulsion to be marketed under the tradename EPICERAM™ to be indicated for use in the treatment of xerotic skin conditions including atopic dermatitis, irritant contact dermatitis and radiation dermatitis.. The most recent of the three cited predicate devices is Sinclair Pharmaceuticals' Skin and Wound Emulsion (K024367), also a topical cream, which is "*indicated to manage and relieve the burning, itching and pain associated with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis.*" (See Exhibit B). This application is a significantly revised formulation of Epiceram that was the subject of application K042589 submitted by the Applicant (previously know as Osmotics Pharma) in September 2004.<sup>1</sup> The prior application was based on formulation (b)(4) which contained several botanical antioxidants (apigenin, curcumin, silymarin) as part of the formula. During the pendency of the review of K042589 application, the Applicant was advised by CDRH to file a Request for Designation ("RFD") with the Office of Combination Products ("OCP") to obtain a determination as to whether K042589 presented a combination device, and, if so, which center should be the lead agency. This recommendation to file a RFD was based on the view that the botanical antioxidants present in the (b)(4) formulation may possess "drug-like" activity. Applicant filed an RFD on (b)(4). Following discussions with the Office of Combination Products, Applicant advised the OCP that it would reformulate its Epiceram product to remove the botanical antioxidants from the formulation. A revised ingredient list was presented to the OCP and following input from both CDRH and CDER, the OCP advised Osmotics

(b)(4)

Pharma that the revised ingredient formulation obviated the need for a formal determination by the OCP and that the reformulated version of the product should be resubmitted to CDRH. This application is for the reformulated version of Epiceram based on the ingredient list previously submitted to the OCP. Any references in the Exhibits to "Epiceram," "Epiceram NV" or formula (b)(4) refer to the current EPICERAM™ formulation.

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 052643/S001

Reviewer: DONA VEGA, M.D., Ph.D.

Division/Branch: DGRND - PRSP

Device Name: EPICERAM

Product To Which Compared (510(K) Number If Known): K024367 (SINCUA) - K064240 (CARBASYN) - K041342 (BIAFINE) (MIMIX)

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>		If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>		If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>		If YES = <u>Go To 5</u>
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	N/A		If YES = Stop NE
5. Same Technological Characteristics?		<input checked="" type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		<input checked="" type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		<input checked="" type="checkbox"/>	If NO = <u>Go To 10</u> If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	N/A		If YES = Stop NE
9. Accepted Scientific Methods Exist?	N/A		If NO = Stop NE
10. Performance Data Available?	<input checked="" type="checkbox"/>		If NO = Request Data
11. Data Demonstrate Equivalence?	<input checked="" type="checkbox"/>		Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: "~~Epiceram is a skin barrier emulsion to be used to reduce excessive trans-epidermal moisture loss in xerotic skin conditions and to manage and relieve the burning, itching and pain experienced in various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.~~" *see indications for use form.*
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Epiceram is a non-sterile, viscous, lipid-rich emulsion intended for use in dermatoses of varied etiology to reduce loss of moisture and burning, itching and pain. It is composed by Carbomer, Capric acid, Ceramide, Cetyl alcohol, Cholesterol, Conjugated Linoleic acid, Corn syrup solid euphorbia cerifea wax, Decanoic acid, Disodium EDTA, Food starch modified, Glycerin, Glyceryl stearate, Hydroxypropyl Bispalmitate MEA (i.e., Ceramide), Palmitic acid, PEG-100 stearate, Petrolatum, Phenoxyethanol, Phosphoric acid, Potassium hydroxide, Squalane, and water. The sponsor provides the device formulation, specifications, degree of purity and level of contaminants, and biological functions of the formulation components, which satisfies FDA's request for AI (see Ceragenix Corporation's response, S001.)

**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED**

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:

Epiceram has few ingredients in common with the predicate Sinclair (e.g., Carbomer, Disodium EDTA and PEG-100 EDTA), and also with Biafine (e.g., Squalane). There are also some similar (i.e., chemically related) components, but it differs in a number of others. Despite of an overall non-identical device formulation, Epiceram shows a similar profile of biological functions with the predicates, which provides an acceptable level of assurance that the product may perform similarly to the predicate products.

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

The proposed device differs in formulation with the predicates however the level of assurance that the proposed device is as safe and effective as the predicates is supported by the Biocompatibility results to assess the in vivo performance of the device. In addition, the device formulation components have a long history of safety for medical use.

7. Explain how descriptive characteristics are not precise enough: The device characteristics were not adequately addressed in the original application however in S001, Ceragenix Corporation provides adequate response to the FDA's concerns regarding the product characteristics and formulation, which satisfies the FDA's concern.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

As a summary of the above mentioned concerns and information provided by the sponsor, there is an acceptable level of assurance that the proposed device is as safe and effective as the predicate devices in this application.

ATTACH ADDITIONAL SUPPORTING INFORMATION

**5 1 0 (K) M E M O R A N D U M**

**TO:** The Records  
Stephen Rhodes, Branch Chief, PRSB

**FROM:** Dora Vega, M.D., Ph.D.  
ODE / DGRND  
Plastic and Reconstructive Surgery Devices Branch, HFZ-410

**DATE:** March 23, 2006

**SUBJ:** **K052643** – Supporting Information for SE determination  
Epiceram  
Ceragenix Corporation, Inc.

**Procode:** FRO  
**Class:** Unclassified  
**Regulation Name:** Dressing

**Reason for this memo:** To support the review recommendation for SE for Epiceram Skin Barrier Emulsion with the predicates to obtain Branch concurrence.

**Reviewer's Comments:**

The product's current Indications for Use are: Epiceram is a Skin Barrier Emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis and radiation dermatitis."

Although we require that devices cleared as wound dressings have "wound" and/or "dressing" in the product name and/or IFU, predicates intended for the treatment of both, "dermatoses" and "wounds" carry the term "wound" in the product's name and IFU are treated as "wound dressings," from the regulatory point of view. The fact that "dermatoses" are not specifically considered "wounds," but skin conditions that mostly occur with intact skin supports this understanding. However, dermatoses also characterize by transient small multiple wounds due to excessive skin dryness and itching, which makes the current regulatory product names more controversial.

The limit for the right wording become even more controversial when we realize that "dermatoses" are a group of skin conditions of varied etiology, and characterized by a common spectrum of signs and symptoms such as excessive dryness and itching, which cause temporally

small wounds including micro-abrasions, skin cracking and scalding.

Regarding the concern for "xerotic skin conditions" and "xerosis," the term "skin xerosis" is used to define excessively abnormal skin dryness such as in dermatoses (e.g., atopic dermatitis, irritant contact dermatitis, radiation dermatitis), K052643/S001, Section "Reviewer Comments.") The medical expression "xerotic skin" does not apply to any particular medical entity, but a number of skin conditions of varied etiology characterized by atypical dry skin.

The Indications for Use statement that refers to "dermatoses" in the predicate Sinclair Wound Dressing state that the product "helps to relieve dry skin by maintaining a moist wound & skin environment."

"MimiX Cream" –cleared name for the originally proposed Impruv A.I. Cream and Wound Emulsion, K041342- was not proposed as predicate in the original Epiceram submission, but it was found as the most appropriated predicate for Epiceram in Supplement S001 because it was only intended for dermatoses and has a similar overall profile of the biological functions for the formulation components.

MimiX Cream -the first product cleared for "dermatoses"- was found SE for the Indication for Use statement that refers to specific "dermatoses" in the predicate Sinclair Wound Dressing despite that it MimiX was not strictly considered as a wound dressing. MimiX's IFU are: "for use to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and allergic contact dermatitis."

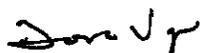
The clearance of Sinclair required clinical data, but not to support identical claims to those for Epiceram. The objective of the Sinclair's study, Caputo and Veraldi, on atopic dermatitis consisted in the assessment of pain relief and relief of itching, but not the device effects on the patient skin dryness. Also, the clinical trial performed by Inocenti on pediatric patients with contact dermatitis supporting Sinclair's clearance was also aimed to assess relief of pain and itching. Notice that "pain" was a claim in the original Epiceram IFU statement, but it was removed in S001, which are not the main symptom in dermatoses.

Epiceram Skin Emulsion is not a sterile device, similar to the predicate MimiX Cream. MimiX Cream provided the results from the Antimicrobial testing to quantify bioburden in the device in accordance to USP <51>. Ceragenix Corporation provided the results from the microbial assessment for Epiceram in S001 at the FDA's request, Appendix E concludes that "all samples tested were free from the listed microbial species listed in USP <51> current issue," which provides an acceptable level of assurance that the Epiceram is safe as the equivalent MimiX predicate from the sterility point of view.

In addition, other predicates such as Sinclair Wound Dressing, K024367, and Biafine Wound dressing, K964240 also intended for treatment of "wounds," provided similar bioburden testing (i.e., assessment of an acceptable level of bioburden) to Epiceram despite that they were intended also for treatment of evident damaged skin, which involves a higher safety risks for infections that for skin dermatoses. The current wound dressing guidance recommends that dressings that are not sterile need preservative testing however, this guidance is currently not available yet for the Industry.

Regarding the reformulated version of Epiceram Skin Barrier Emulsion at the FDA's request, K042589, Ceragenix Corporation filed the RFD #2005-11 on April 6, 2004, which based on the input of CDRH, CDER and the OCP recommended "A revised ingredient list –to remove botanical antioxidants," [from Epiceram] should be submitted to CDRH, (Section 1, page 1.1, original Epiceram submission, K042589.) Following assignation for the primary jurisdiction of the product to CDRH, a consult with CDER was requested. However, in the CDER's recommendation the reviewer concludes that "the ceramide is an active ingredient and therefore this product is a drug product," (see CDER review memo enclosed in the file.)

Based on this statement and the antecedents of RFD Inter-center concurrence for primary jurisdiction to CDRH, I consulted with Eugene Berk, CSO/Device Status & Jurisdiction, OC, before I proceeded to S001 review submitted on January 2006, PRSB (enclosed e-mails, dated November 14, 2005), which resulted in no Branch concurrence for the reasons described in this memo.



Dora Vega, M.D., Ph.D.  
Division of General, Reconstructive,  
and Neurological Devices (HFZ-410)  
Plastic and Reconstructive Surgery Devices Branch

Date: March 23, 2006.

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?	N/A	✓
2. Did we grant expedited review?	N/A	✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	✓
4. If, not, has POS been notified?	N/A	✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.	N/A	

INDICATIONS FOR USE STATEMENT

Page 1 of 1

510(k) Number: K052643

Device Name: EPICERAM™ Skin Barrier Emulsion

Indications for Use:

FOR TOPICAL DERMATOLOGICAL USE ONLY

EPICERAM® is a skin barrier emulsion to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis. EPICERAM® helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Apply Epiceram® in a thin layer to the affected skin areas 2 times per day (or as needed) and massage gently into the skin. If the skin is broken, cover Epiceram® with a dressing of choice.

-----  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  X

OR

Over-the-Counter Use \_\_\_\_\_

(Per 21 C.F.R. § 801.109)

## 510(k) Summary

### 1. Submission Applicant & Correspondent

Name: Ceragenix Corporation  
Address: 1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

Phone No. (720) 946-6440

Contact Person: Carl Genberg, J.D.

2. Name of Device: EPICERAM® Skin Barrier Emulsion

Trade/Proprietary/Model Name: EPICERAM®

Common or Usual Name: Skin Barrier Emulsion

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

### Devices to Which New Device is Substantially Equivalent:

- Sinclair Wound and Skin Emulsion™ - Sinclair Pharmaceuticals, Ltd (K024367, July 28, 2003);
- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) - Medix Pharmaceuticals Americas, Inc. (K964240, Jan. 22, 1997);
- Carrasyn® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing – Carrington Laboratories, Inc. (K961758, July 11, 1996); and
- Mimyx™ Cream – Steifel Laboratories, Inc. (K041342, July 19, 2005)

### 3. Device Description:

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use.

### 4. Intended Use of the Device:

The device is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve dry skin conditions and to relieve and to manage the burning, itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment.

**5. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

**6. Tests and Conclusions:**

Functional and performance testing has been conducted to assess the safety and effectiveness of EPICERAM™ Skin Barrier Emulsion and the results are satisfactory.

**510 (K) MEMORANDUM**

**TO:** K052643/S001

**FROM:** Dora Vega, M.D., Ph.D.  
ODE / DGRND  
Plastic and Reconstructive Surgery Devices Branch, HFZ-410 *S. Rhode 2/22*

**DATE:** February 8, 2006

**SUBJ:** Epiceram  
Ceragenix Corporation, Inc.  
Carl Genberg. Ph: (702) 451-0219.

**Procode:** FRO

**Class:** Unclassified

**Regulation Number:**

**Regulation Name:** Wound and Burn Dressing

**Recommendation:** Review of the information provided in this supplement allows determine substantial equivalency between Epiceram and the predicates MimiX Cream, K041342, Sinclair Wound and Skin Emulsion, K024367; and Biafine Wound Dressing Emulsion, K964240.

**Reason for this application:** Ceragenix provides response for AI, FDA's letter dated November 21, 2005.

**Reviewer's Comments / Review Summary:** Epiceram is a non-sterile emulsion proposed to be used on inflammatory / allergic processes of intact skin such as dermatoses of varied etiology (e.g., atopic dermatitis, contact dermatitis and radiation dermatitis and xerosis\*).

(\*) The term skin xerosis is used to define excessive or abnormal dryness of the skin such as skin dermatoses of varied etiology (e.g., atopic dermatitis, irritant contact dermatitis, radiation dermatitis.) The term "xeroderma" does not apply to any particular medical disease, but a sign of abnormally dried skin. Xerotix skin is the affected area of skin characterized by xerosis.

**Note:** that in the original application, Ceragenix Corporation provided Sinclair Wound and Skin Emulsion, K024367; and Biafine Wound Dressing Emulsion, K964240 as the predicates for the subject device. However, during the review process, it was concluded that the most adequate predicate device for Epiceram's clearance was MimiX Cream, which also showed SE with used Sinclair Wound and Skin Emulsion (see clarification from Ceragenix, fax dated February 21, 2006.)

The intended use for Epiceram is substantially equivalent to MimiX Cream, K041342. However, only the intended use for skin dermatoses on the IFU statement from the predicates Sinclair, K024367, and Biafine, K964240 is seen SE to the proposed intended use of Epiceram. The additional intended use of these predicate devices in "wounds" is seen as not SE. The device technology of the subject device is similar to the predicates at certain extent. The predicates MimiX Cream, Sinclair and Biafine are coded as MGQ - CFR 878.4022, Wound and Burn Dressing, Hydrogel, (information from IMAGE.) However, Epiceram is coded as FRO - Unclassified in this application by PRS-Branch advice given that the product is not strictly a "wound dressing." Epiceram's labeling has been amended to remove the term "wound" at the FDA's request (see Ceragenix Corporation's response S001 and enclosed sponsor's email dated February 7, 2006).

## **REVIEW:**

**Device Summary:** Epiceram is a non-sterile, viscous, lipid-rich emulsion intended for use in dermatoses of varied etiology to reduce loss of moisture (i.e., skin dryness), burning, and itching.

(b)(4)

### **1. Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

#### **Subject Device**

"Epiceram is a skin barrier emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning, and itching experienced in various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis."

#### **Predicate device(s)**

During the review process, it was concluded that the main predicate in this application was MimiX Cream, which is intended "for use to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and allergic contact dermatitis."

One of the originally proposed predicate for Epiceram was Sinclair Wound and Skin Emulsion cleared in K024367, which also served as predicate for Mimix' marketing. The intended use of Sinclair Wound and Skin Emulsion is to "manage and relieve the burning, itching and pain experienced with various types of dermatoses including radiation dermatitis, atopic and allergic dermatitis." However, Sinclair Wound and Skin Emulsion also is intended for use to relieve the pain of first and second degree burns."

Sinclair Wound and Skin Emulsion claims help to relieve dry skin (i.e., clinically defined as xeroderma (\*)) by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Biafine Wound Dressing Emulsion, K964240 was also an additional predicate in this application. Biafine Wound Dressing Emulsion intended use is for "dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, first and second degree burns, including sunburns, and radiation dermatitis."

Lastly, Carrasyn Hydrogel Wound Dressing, K961758, which is intended for use for management and relief of pain is proposed as an additional predicate.

#### **Discussion of whether the intended use/indications are the same**

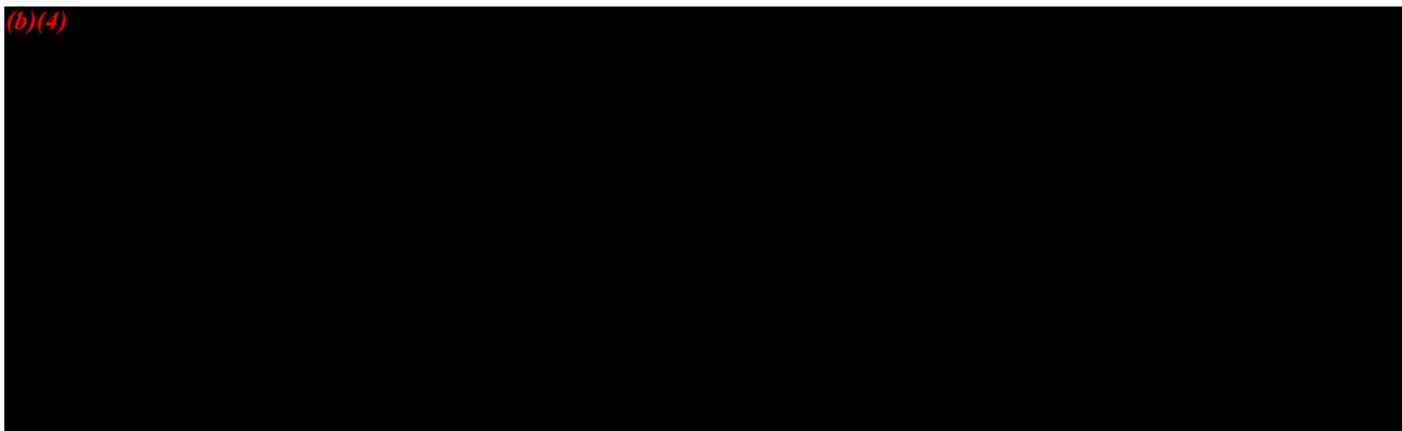
The amended Epiceram IFU statement (S001) shows SE indications for use that the predicate Sinclair Wound and Skin Emulsion (i.e., "for use to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and allergic contact dermatitis.") Epiceram claims to reduce excessive trans-epidermal moisture loss in xerotic skin conditions - dermatoses has also been removed from the IFU and other sections of the device labeling at the FDA's request. No claims regarding the use of the device for wounds such as minor abrasions, ulcers, and burns are made for Epiceram in this application.

Epiceram has limited similarity with the IFUs for Biafine Wound Dressing Emulsion, which is indicated for the "management of superficial wounds, minor abrasions, dermal ulcers, donor sites, first and second degree burns, including sunburns, and radiation dermatitis," as well as with Carrasyn Hydrogel (intended for use for management and relief of pain.)

In summary, Epiceram shows substantially equivalent indications for use to the predicates MimiX Cream and Sinclair Wound and Skin Emulsion, and similar, but not identical to the Biafine intended use.

#### **2. Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device and Predicate(s)**

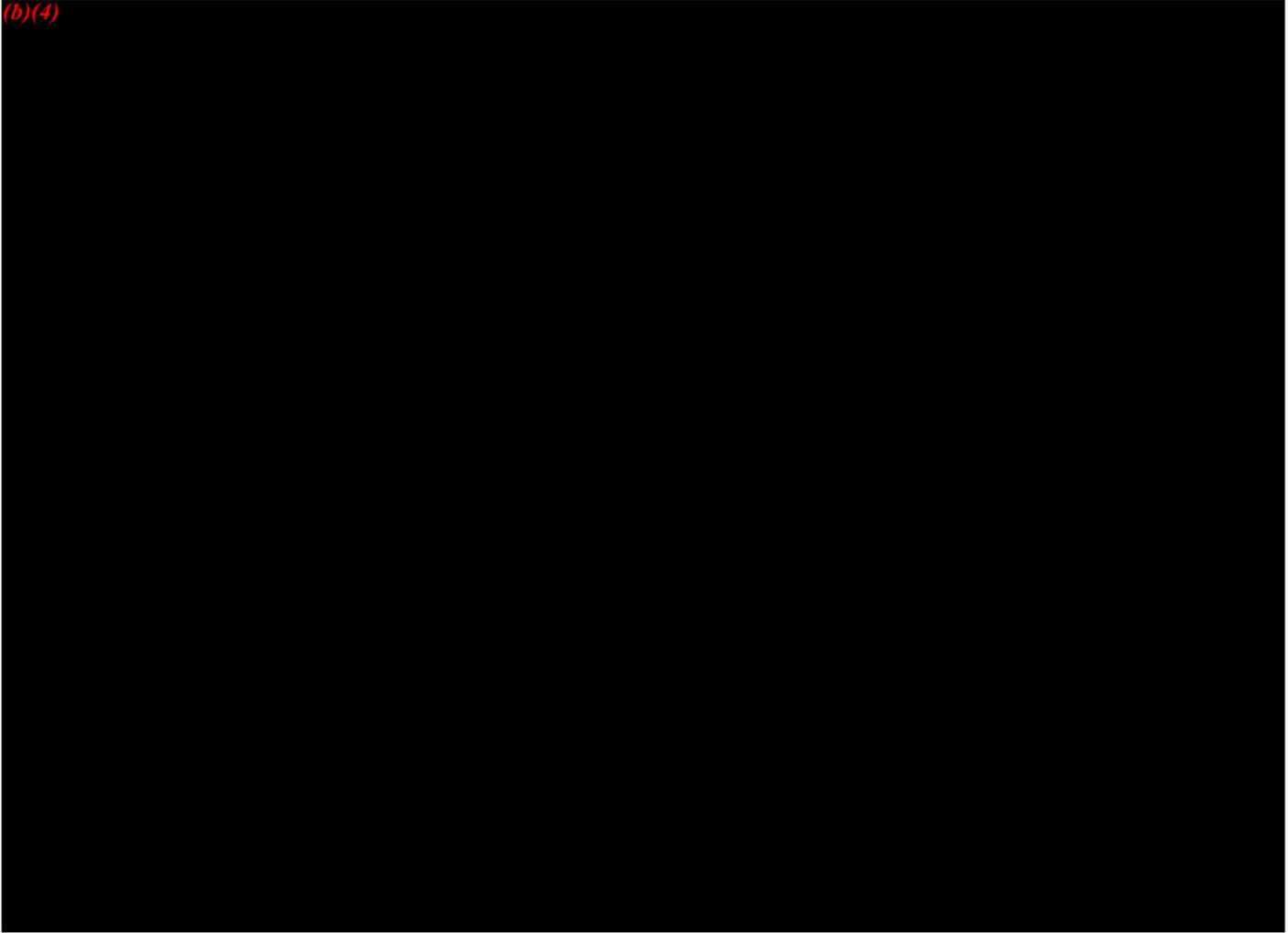
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(b)(4)

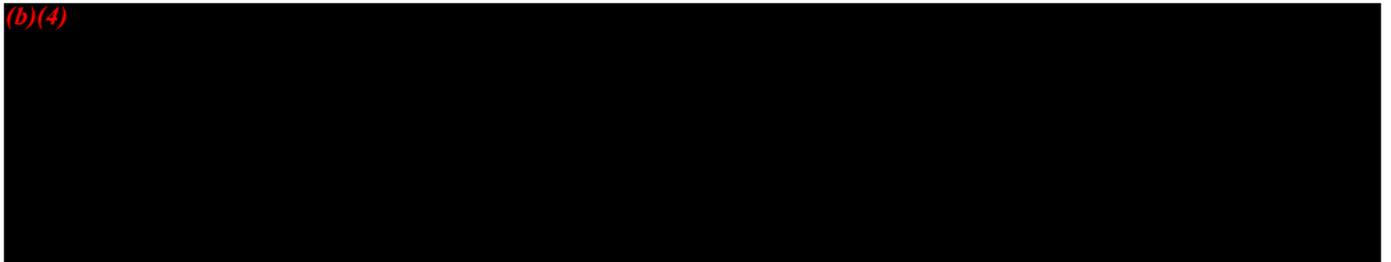


(b)(4)



**Discussion of whether the subject device has a significant change in technological characteristics**

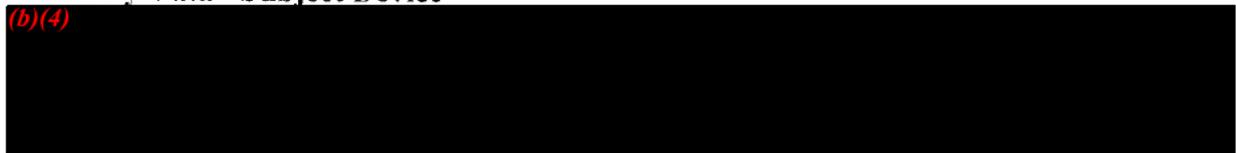
(b)(4)



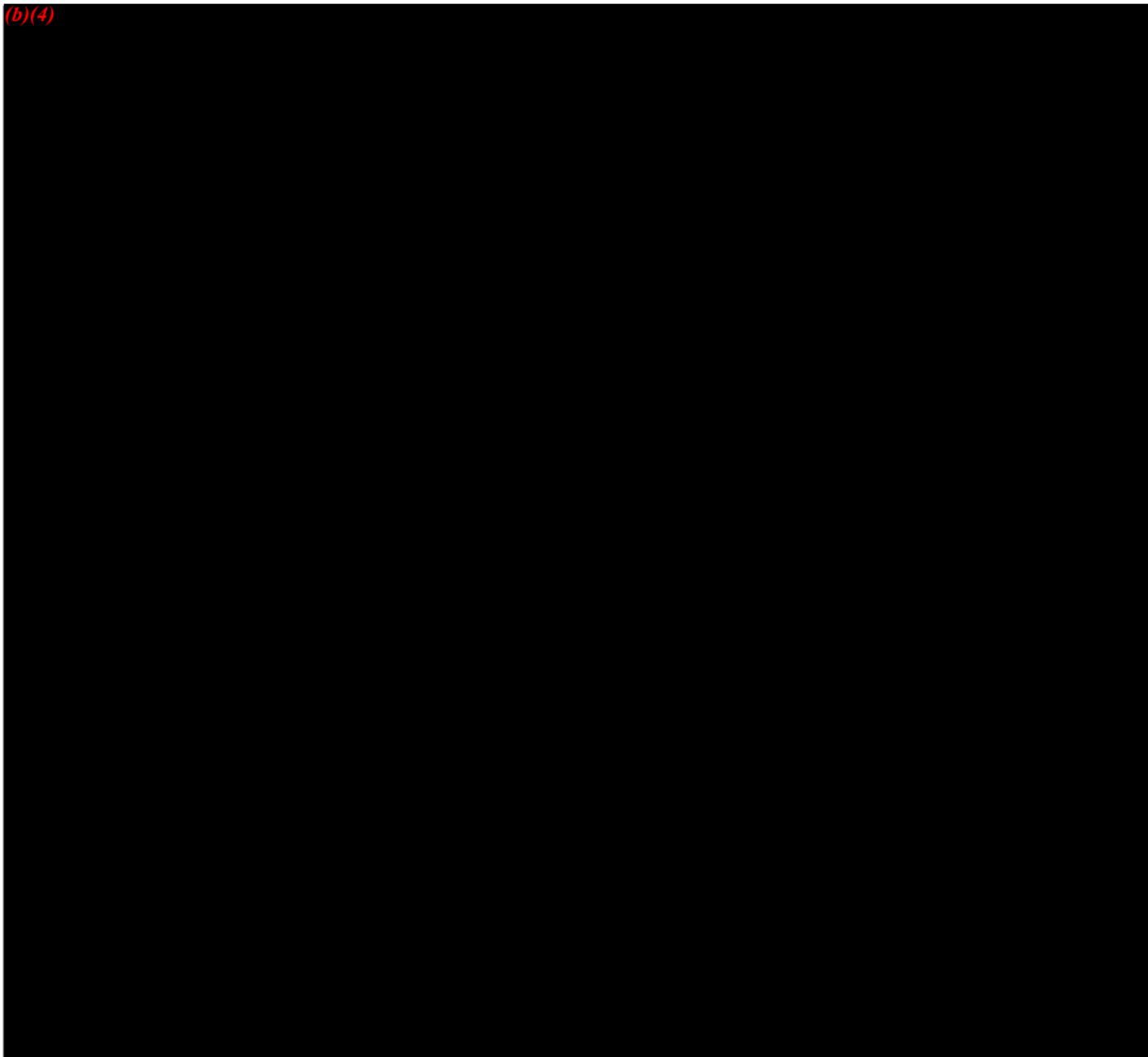
**3. Comparative Data (in vitro, animal and/or clinical)**

**Safety Data - Subject Device**

(b)(4)



(b)(4)



**Safety Data - Predicate Device(s)**

The original Biafine submission requested the results from the Irritation and Sensitization tests for the clearance of the product (information from IMAGE). The clearance of the product was also supported by a clinical study that enrolled (b)(4) patients randomized in (b) groups of treatment. Notice that the intended use of Biafine included wounds superficial wounds, minor abrasions, dermal ulcers, donor sites, first and second degree burns, including sunburns, which is not the intended use for the subject device in this application (i.e., skin dermatoses with "intact skin.") . The clearance of Biafine for the IFU for the treatment of wounds (i.e., "damaged skin") required the results of a clinical study.

Overall, the biocompatibility testing provided for Epiceram is seen substantially equivalent to the predicates MimiX and Sinclair Given that the intended use for Epiceram is for "dermatoses," the wording indicating "damaged skin" (i.e., "wound") has been removed

from the product labeling (see Ceragenix's response to the FDA's request, e-mail dated February 7, 2006.)

**Effectiveness Data – Subject Device**

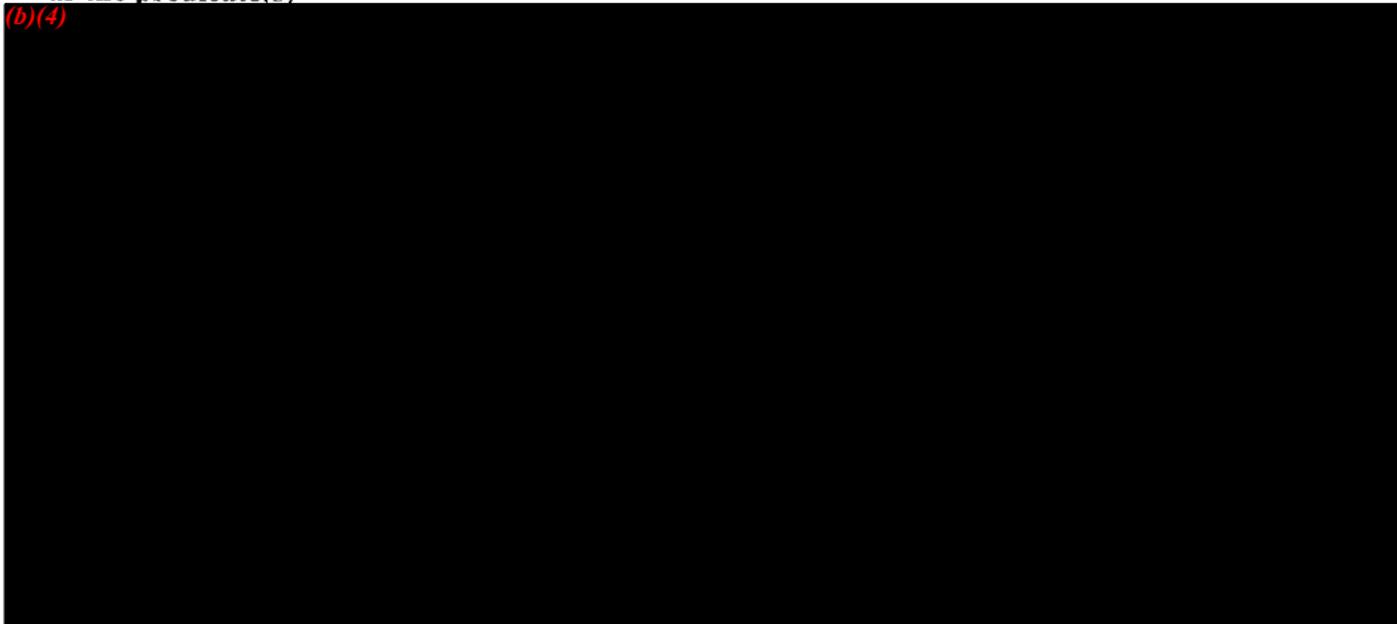
The sponsor reports the results from a Tran-Epidermal Moisture Loss (TEML) study that comprised 5 patients, which is seen as insufficient to support the product claim on reduction of the trans-epidermal moisture/water loss as discussed in the listing of deficiencies in this Memo. Ceragenix Corporation was consulted and ultimately decided withdrawal of this claim for the product.

**Effectiveness Data – Predicate Device(s)**

No clinical trials were required for the clearance of the predicates Mimix and Sinclair, with which Epiceram shows SE for the IFU (information from IMAGE), and biological functions of the device formulation. The predicate Biafine Wound Dressing Emulsion provided the results from a clinical evaluation given that it was intended for "open wounds" (see IFU statement, above.)

**Discussion of whether the data demonstrate that the subject device is as safe and effective as the predicate(s)**

(b)(4)



**4. Does the product contain drugs or biologicals?**

(b)(4)

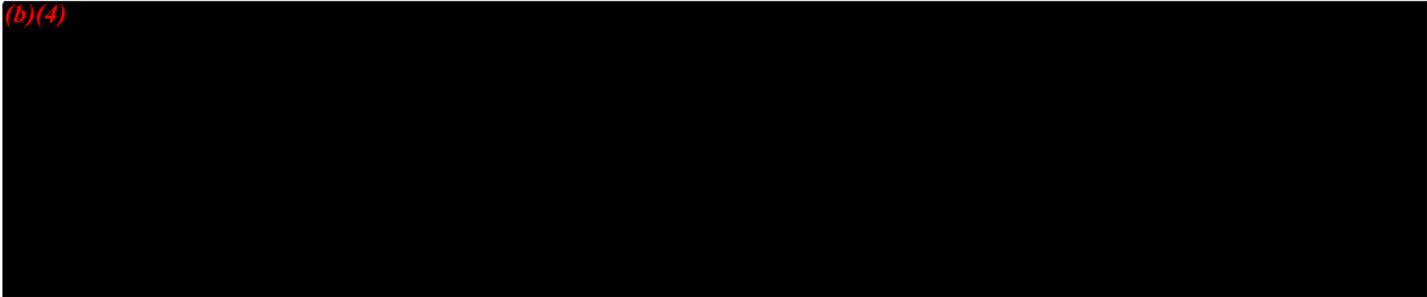


**5. Sterilization**

(b)(4)



(b)(4)



**6. Packaging**

Additional information regarding Epiceram packaging conformation including the device materials, dimensions, and packaging testing performance was adequately provided in response to the deficiencies listed in this memo (sponsor's response S001, and enclosed e-mail dated February 7, 2006.) Briefly, the product package dimensions, labeling and the expiration date for the product were provided in Exhibits I, J, and K in the sponsor's response, S001. The device packaging performance was not submitted, but when consulted, Ceragenix Corporation states that the product won't be marketed until the stability testing is provided to support the expiration date of the product (enclosed Ceragenix's letter dated February 7, 2006, enclosed in this file.)

**7. Labeling**

OTC and / or Prescription: The proposed device is to be a prescription product. The directions for use and labeling sections of Epiceram are seen as SE to those of the predicate Sinclair.

**8. Claims**

Epiceram's claim to reduce trans-epithelial moisture loss is not adequately supported by data in this application, therefore, it has been withdrawn from the application at the FDA's request (see listing of deficiencies in this memo, and e-mail dated February 7, 2006.) Also a claim on pain has been withdrawn. No additional claims are made for the device.

**9. Has sponsor provided all administrative requirements?**

- Truthful and Accurate Statement: Yes
- 510(k) Summary or Statement: Yes
- Indication for Use Form: Yes (provided in Supplement 001.)

A statement of the intended use for Epiceram was provided in Section III. Indications for Use, page 31, which reads "Epiceram is a skin barrier emulsion to be used to treat xerotic skin conditions and to manage and relieve the burning, itching and pain experienced in various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis."

The proposed device is an Un-classified device and its description is provided in Section 2, page 2.6.

The predicate devices in this application are: MimiX Cream, K041342, Sinclair Wound and Skin Emulsion, K024367; Biafine Wound Dressing Emulsion (K964240), and Carrasyn Hydrogel Wound Dressing, K961758.

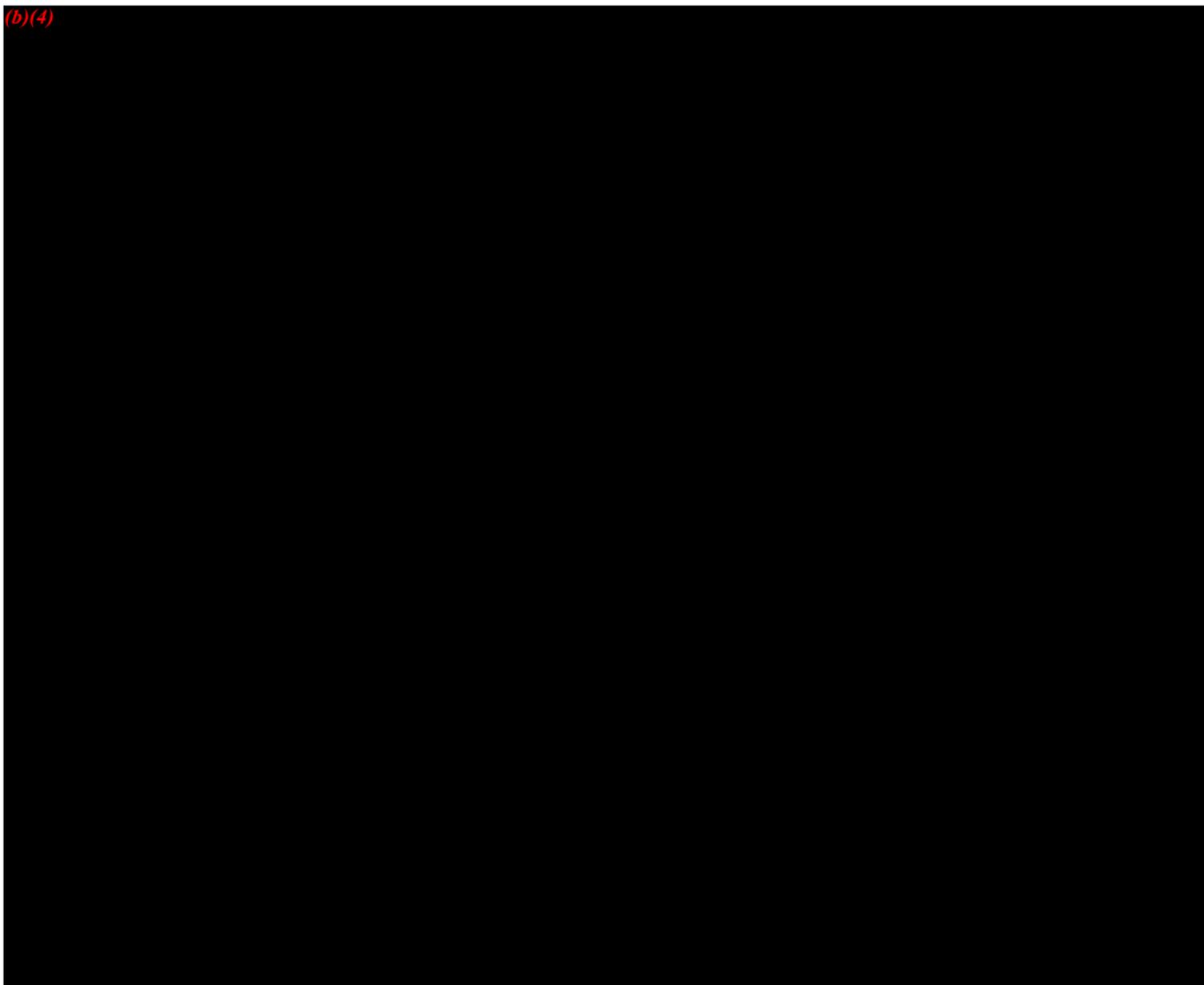
**Antecedents of contact with the sponsor:** The chemical and biological/cell functions of the

device formulation components were requested to Mr. Carl Genberg, Ceragenix Corporation, Inc, by phone on October 27, 2005, and provided in the file. Also, amendment in the device labeling, packaging specifications and assessment of the stability testing to support the expiration date of the product have been communicated over the phone to Mr. Carl Genberg. In letter dated February 7, 2006, Ceragenix provides adequate response to the FDA's concerns. In fax dated February 21, 2006, Ceragenix Corporation provides clarification regarding the previously proposed MimiX as predicate for Epiceram in this application.

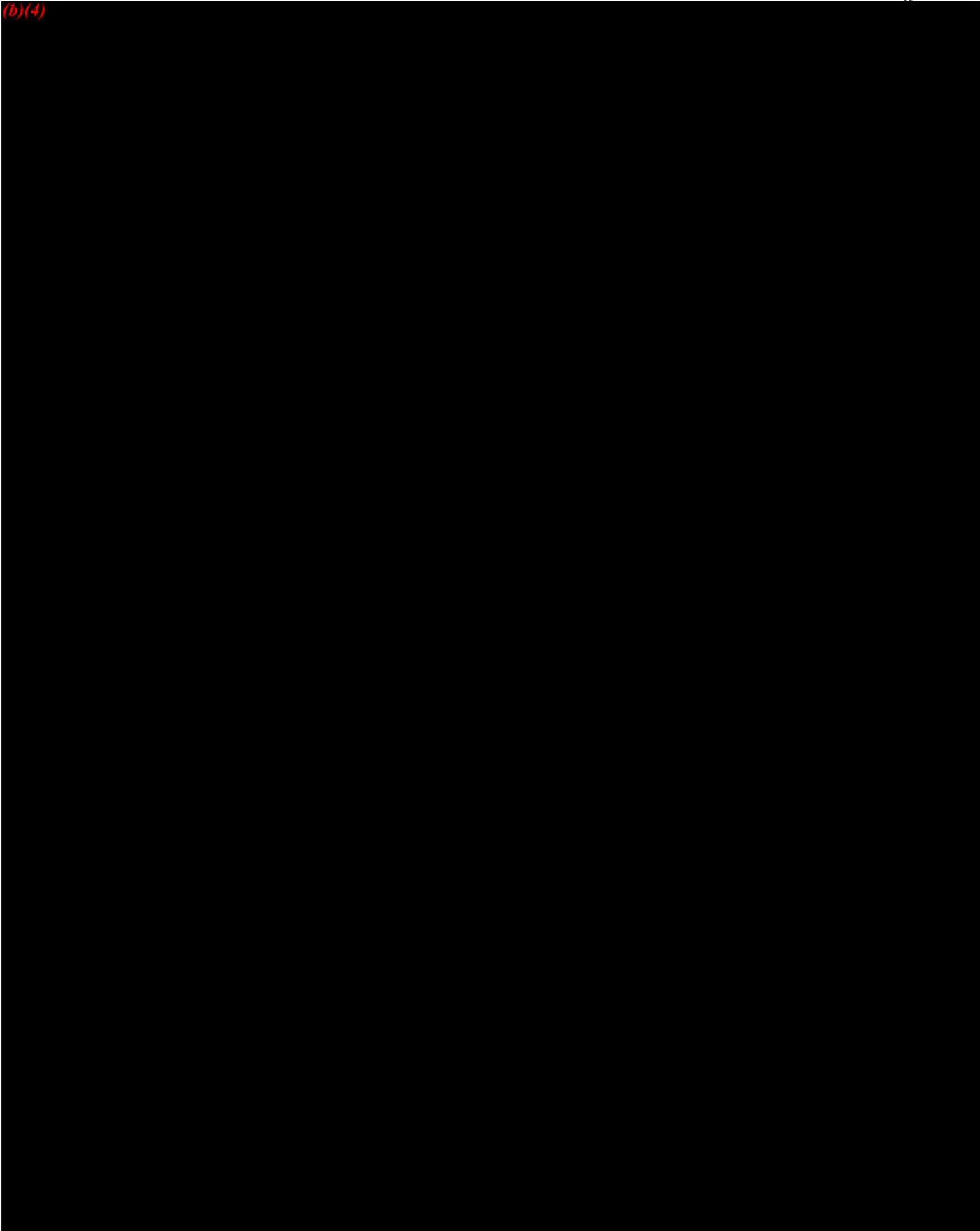
**Recommendation:** I found Epiceram SE to the predicates devices MimiX and Sinclair. I base my recommendation in the equivalency determined for its intended use, device technology (e.g., formulation of the device and biological functions, SE IFU, safety (e.g., Biocompatibility testing), sterility, packaging and device labeling.

**Deficiencies:**

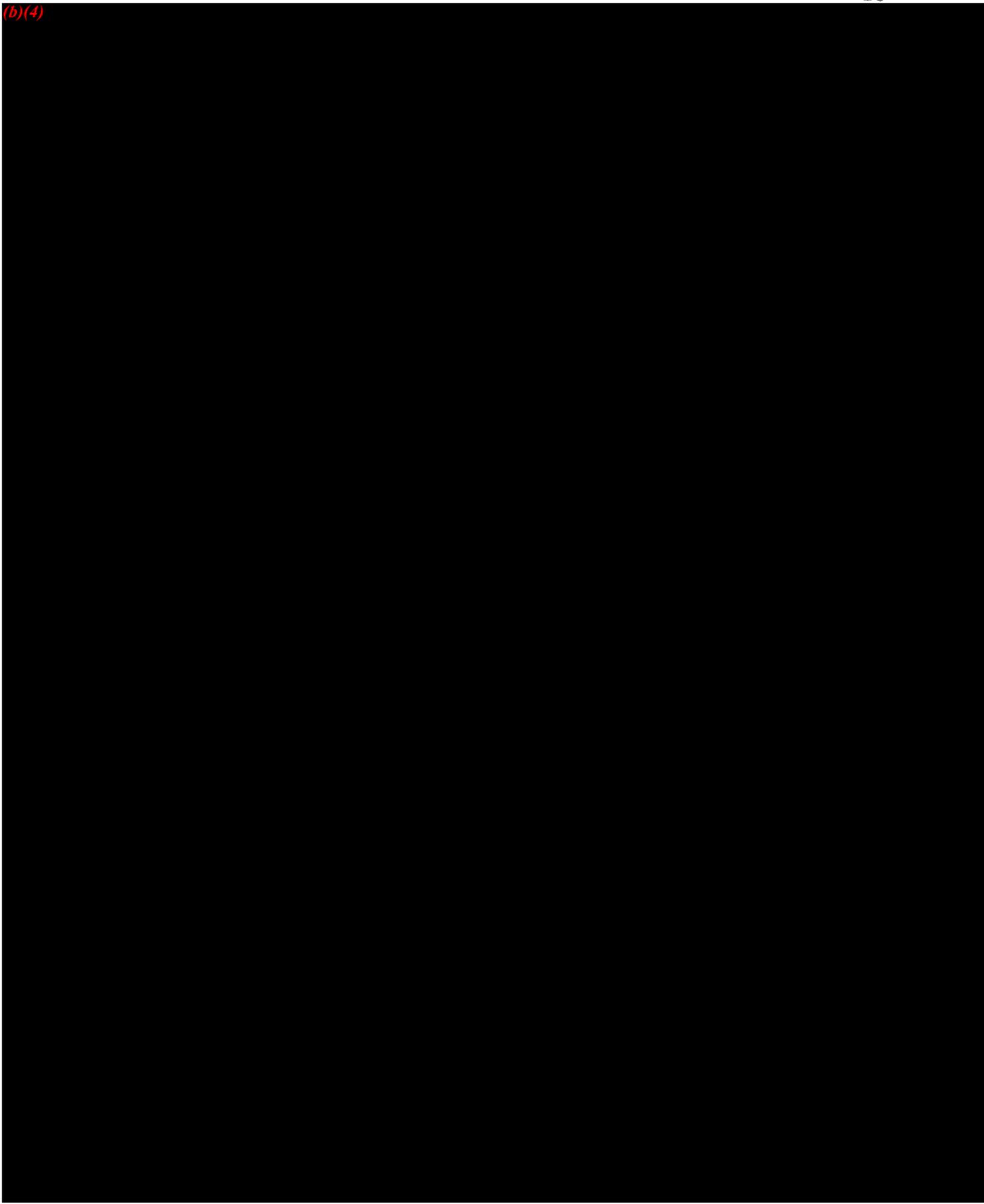
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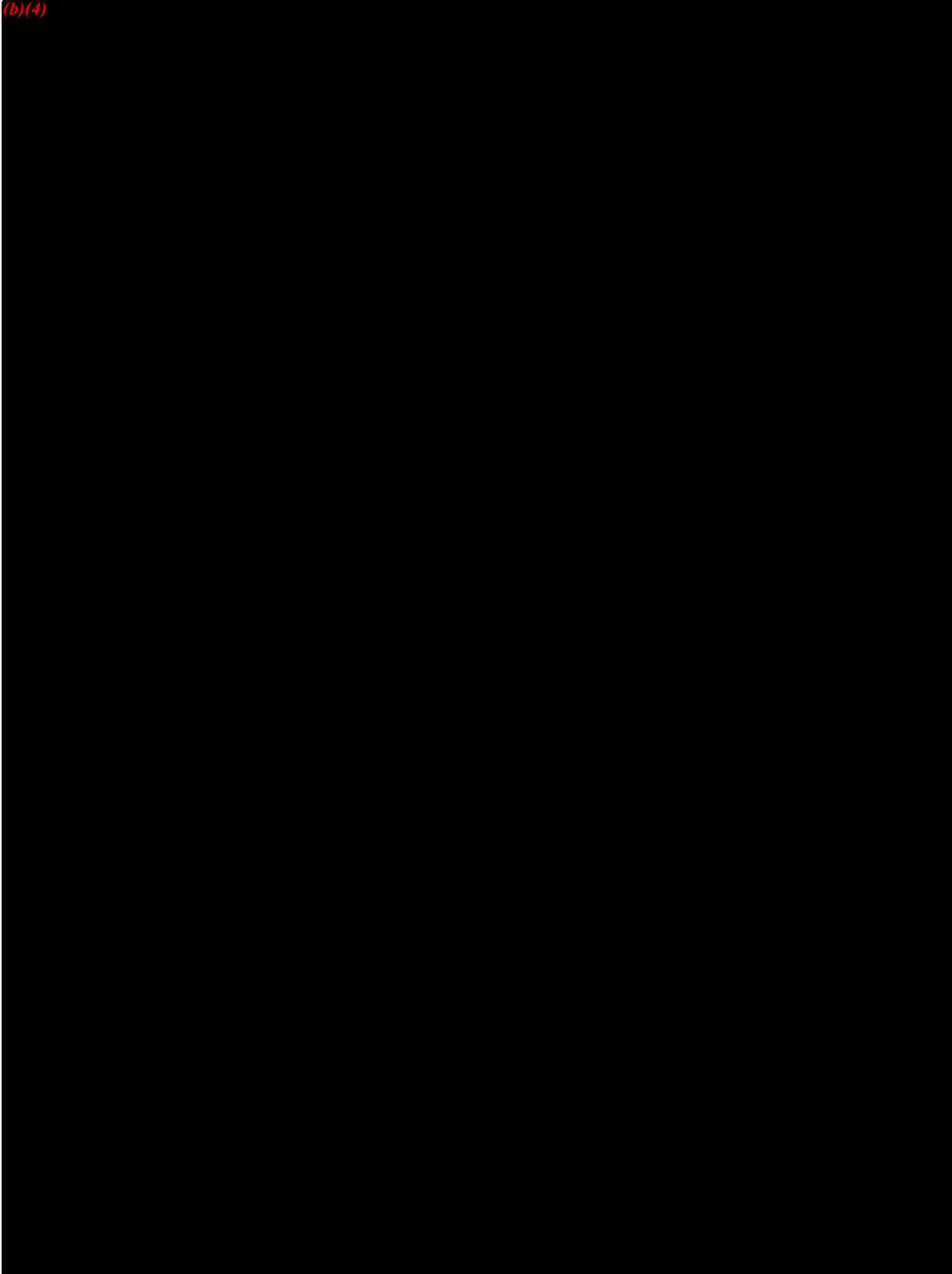
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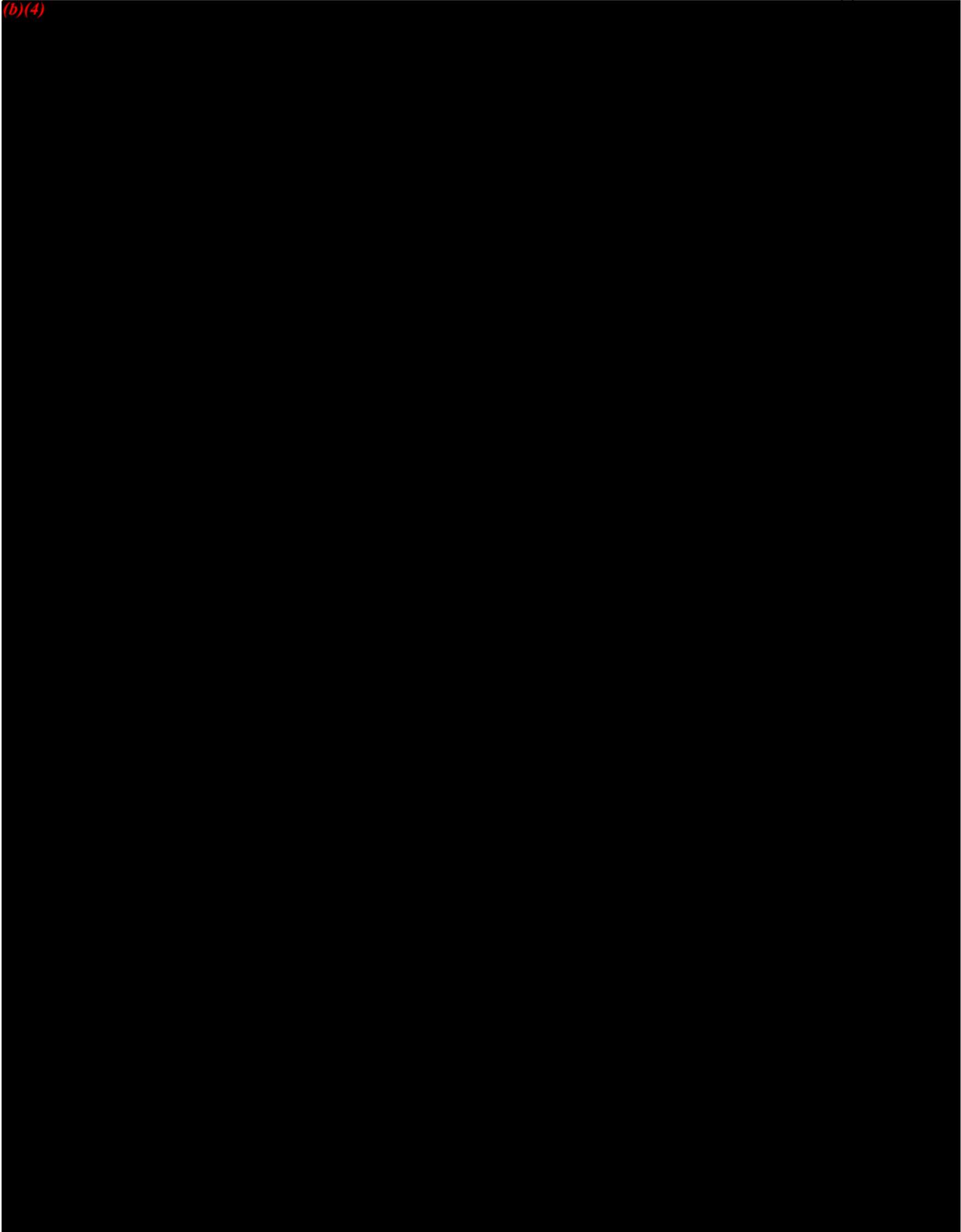
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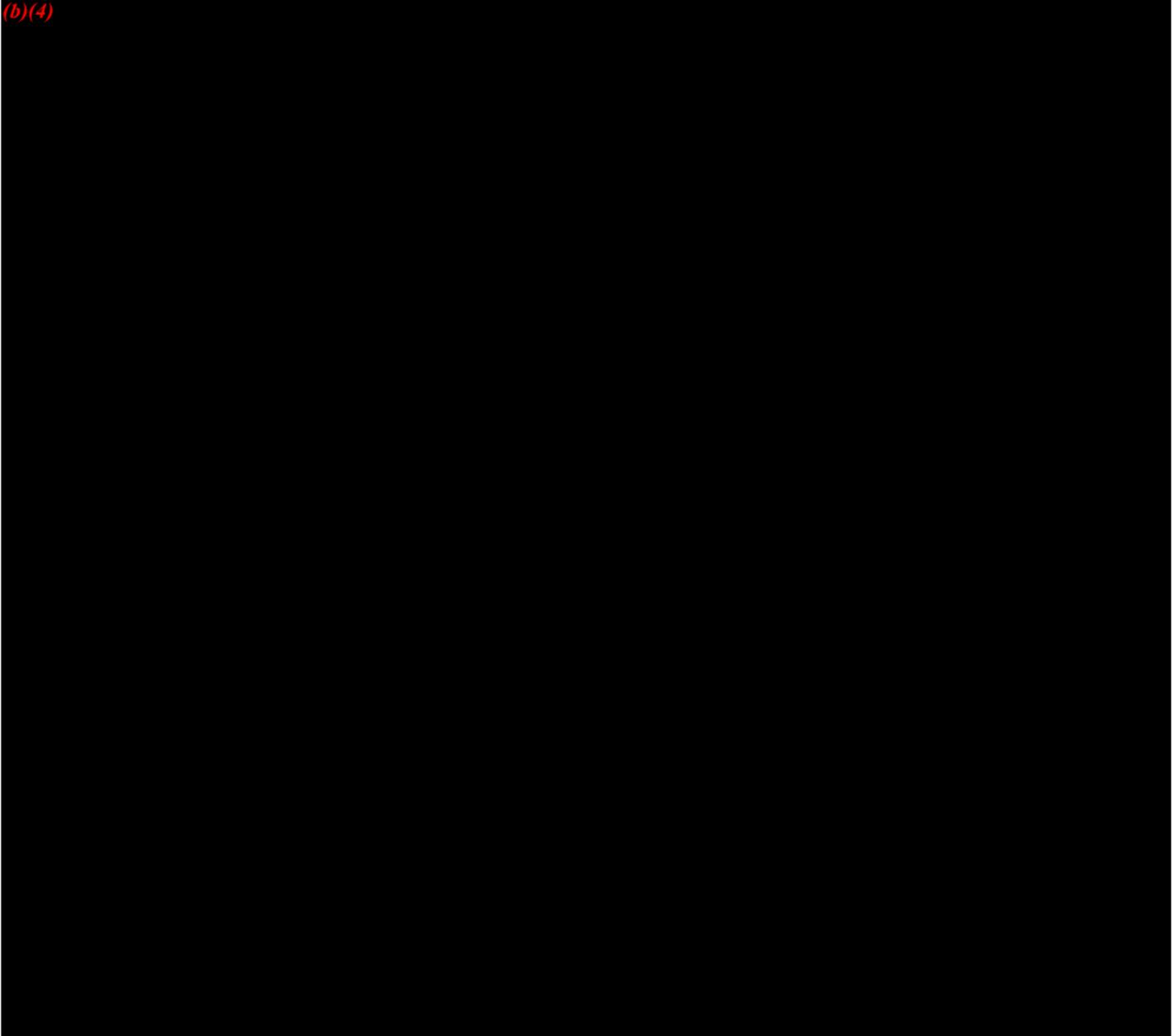
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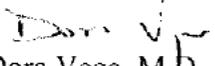


(b)(4)



(b)(4)



  
Dora Vega, M.D., Ph.D.  
Division of General, Reconstructive,  
and Neurological Devices (HFZ-410)  
Plastic and Reconstructive Surgery Devices Branch

Date: February 8, 2006.

# EXHIBIT B

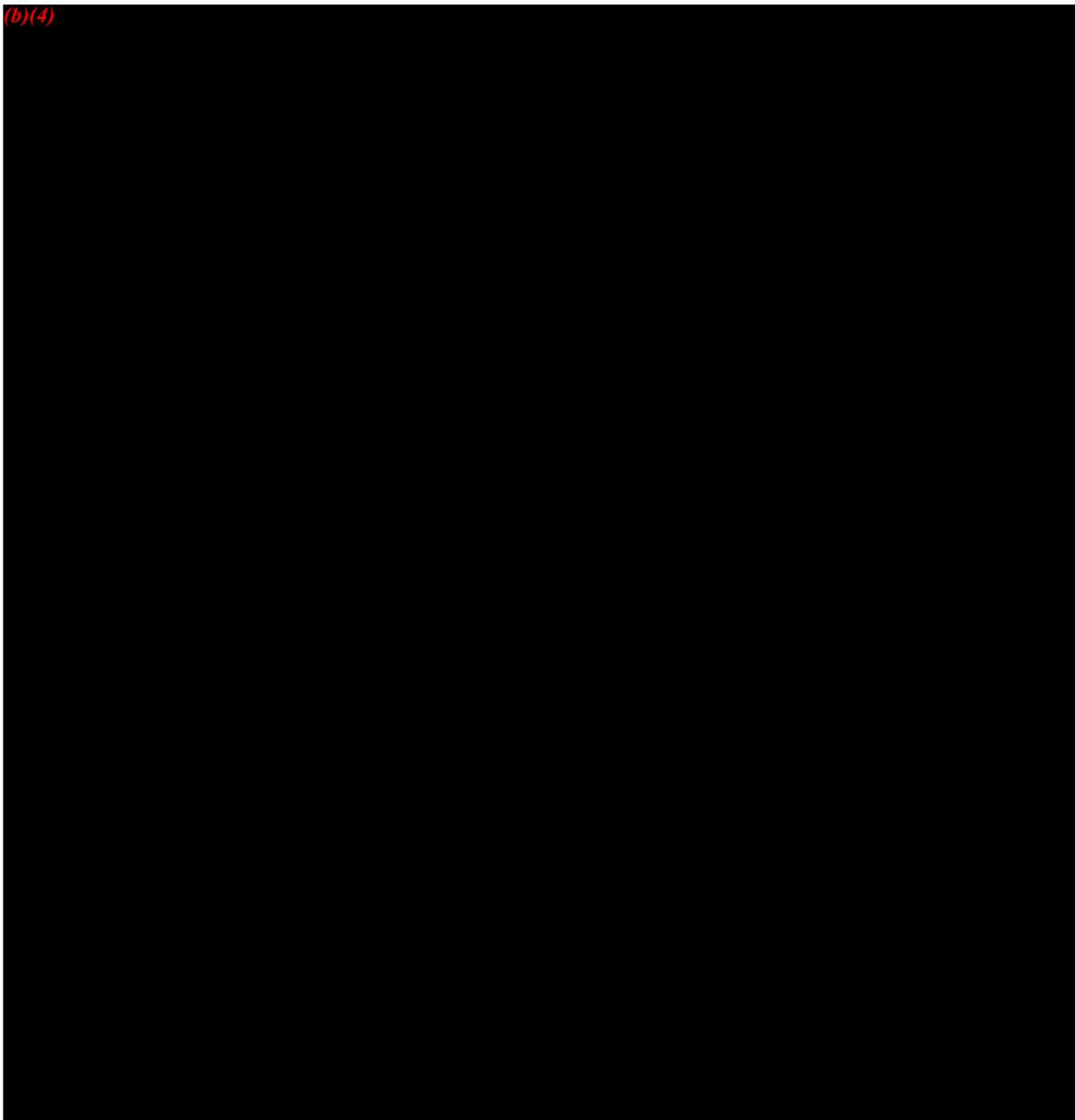
## Certificates of Analysis for Ingredients With Supplier Identification

See attached

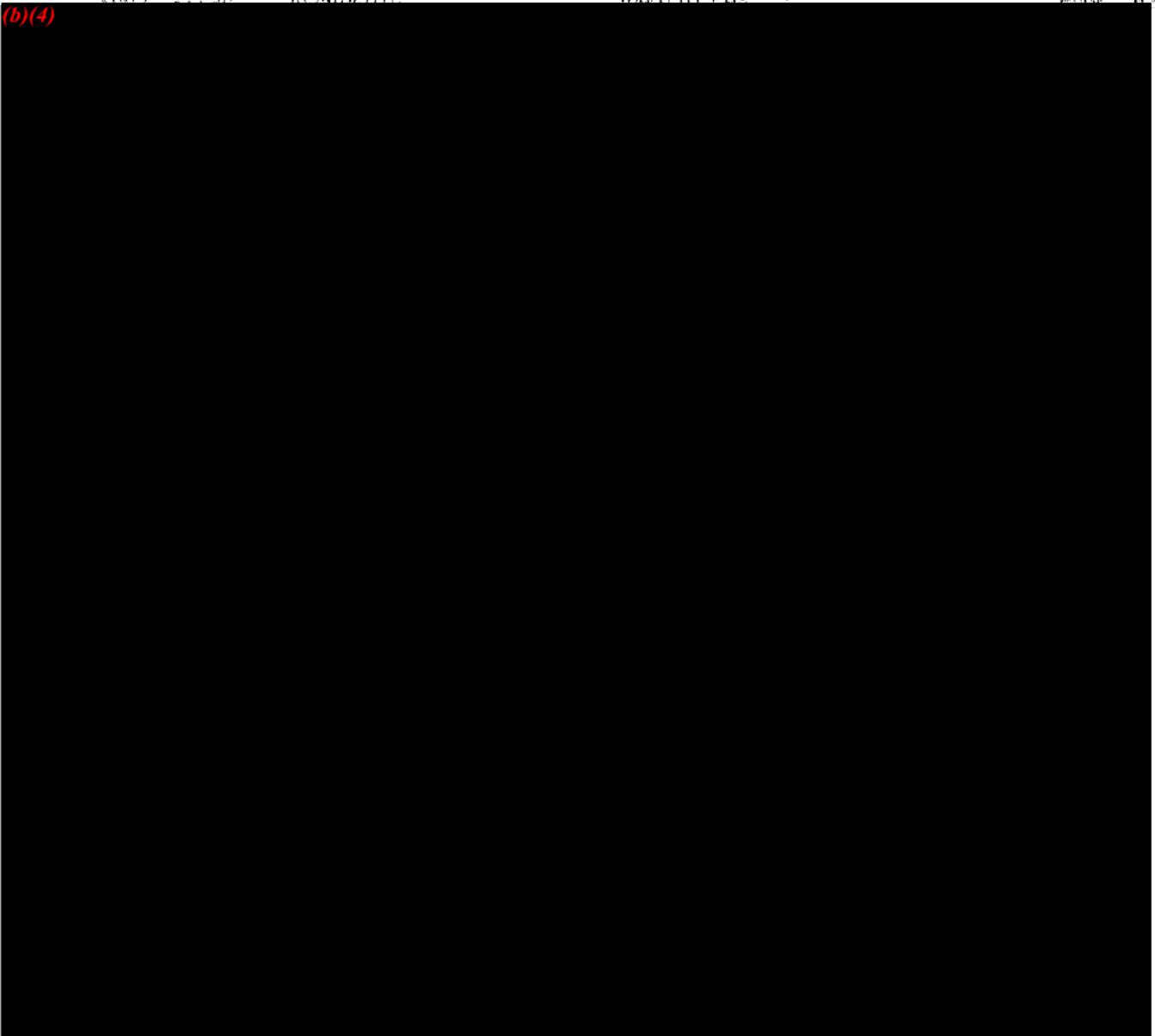
**Ingredient**

**Supplier**

(b)(4)



(b)(4)

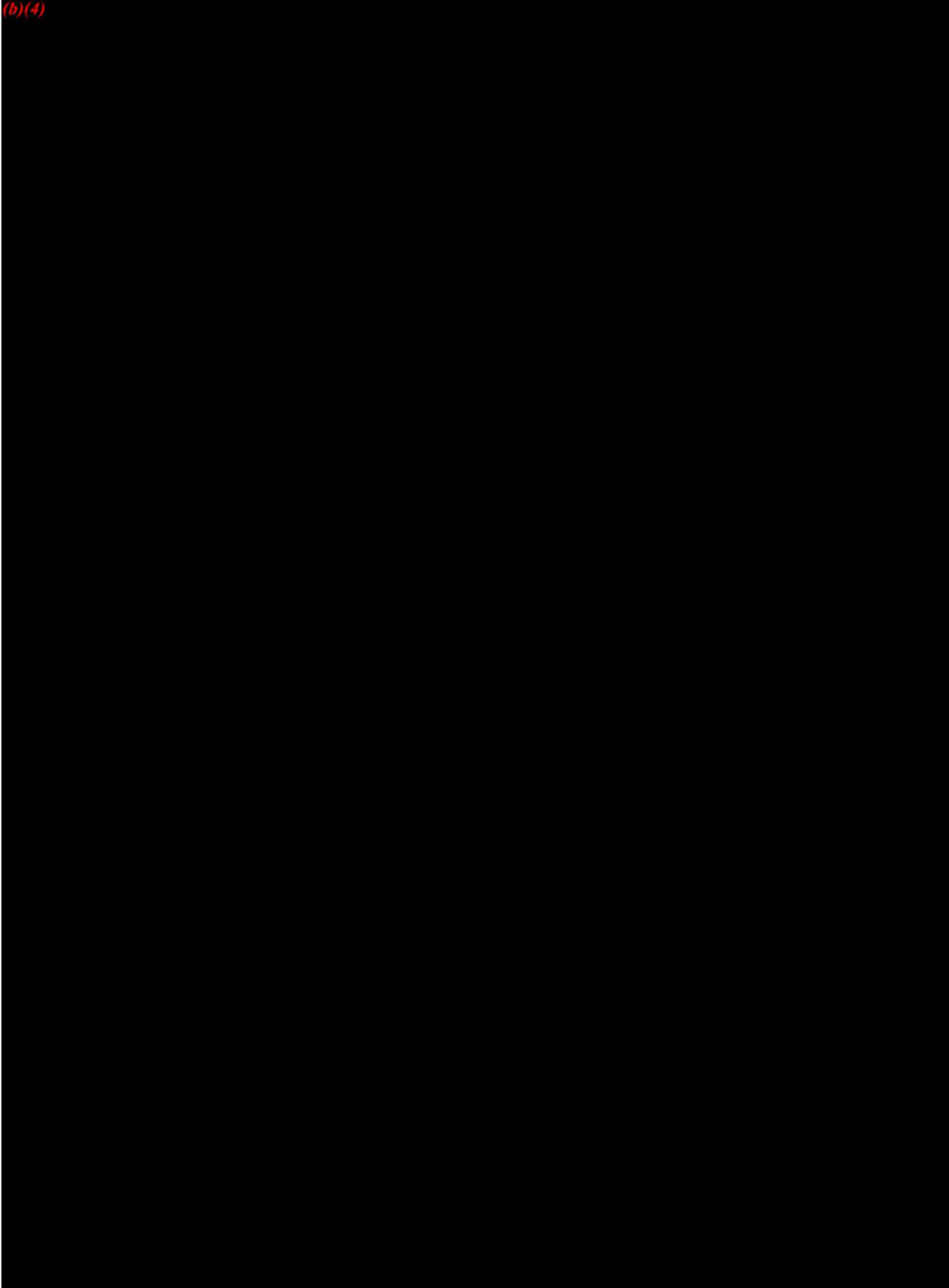


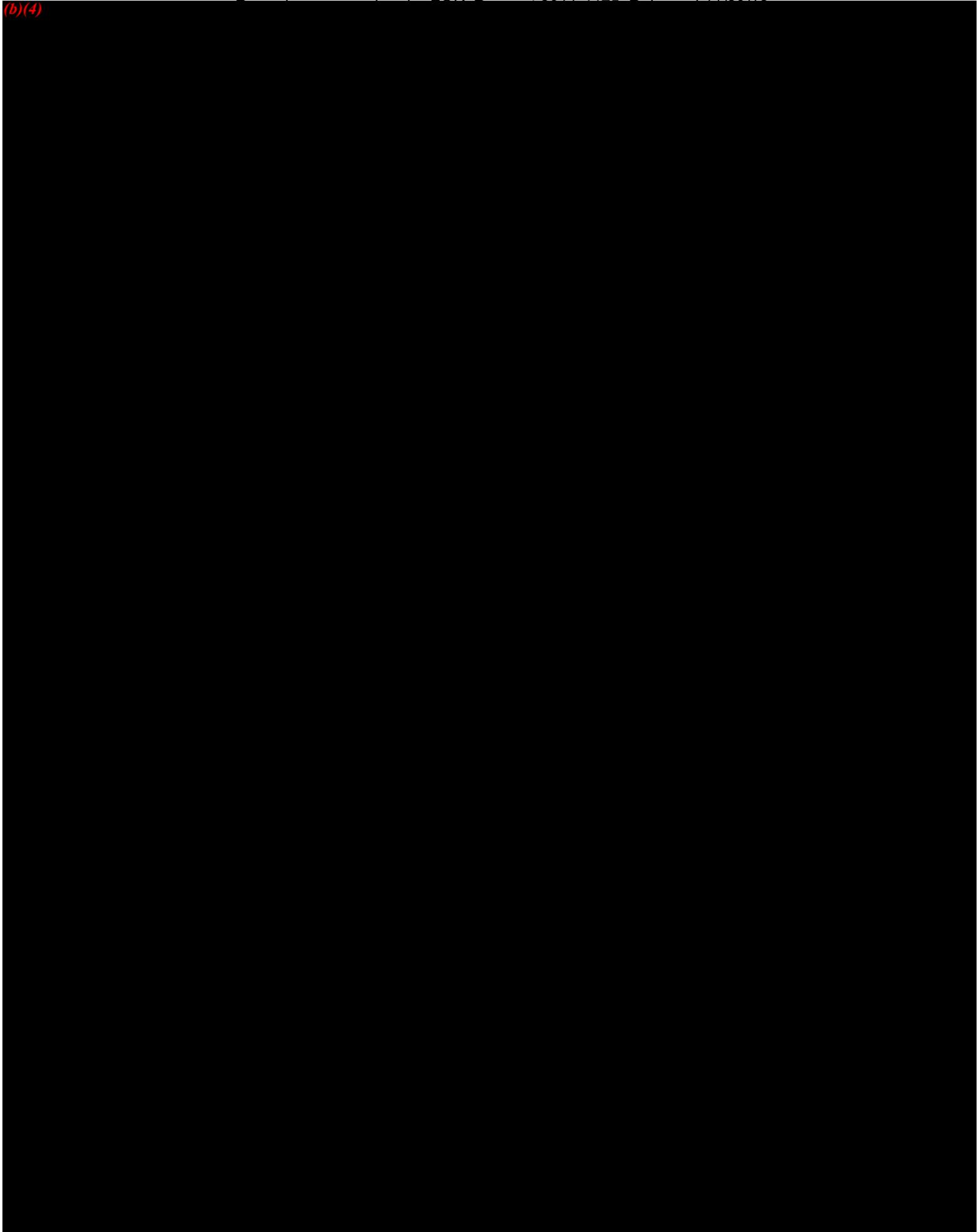
*[Handwritten signature]*

Manager

Quality Assurance Team

(b)(4)





FROM :

FAX NO. :

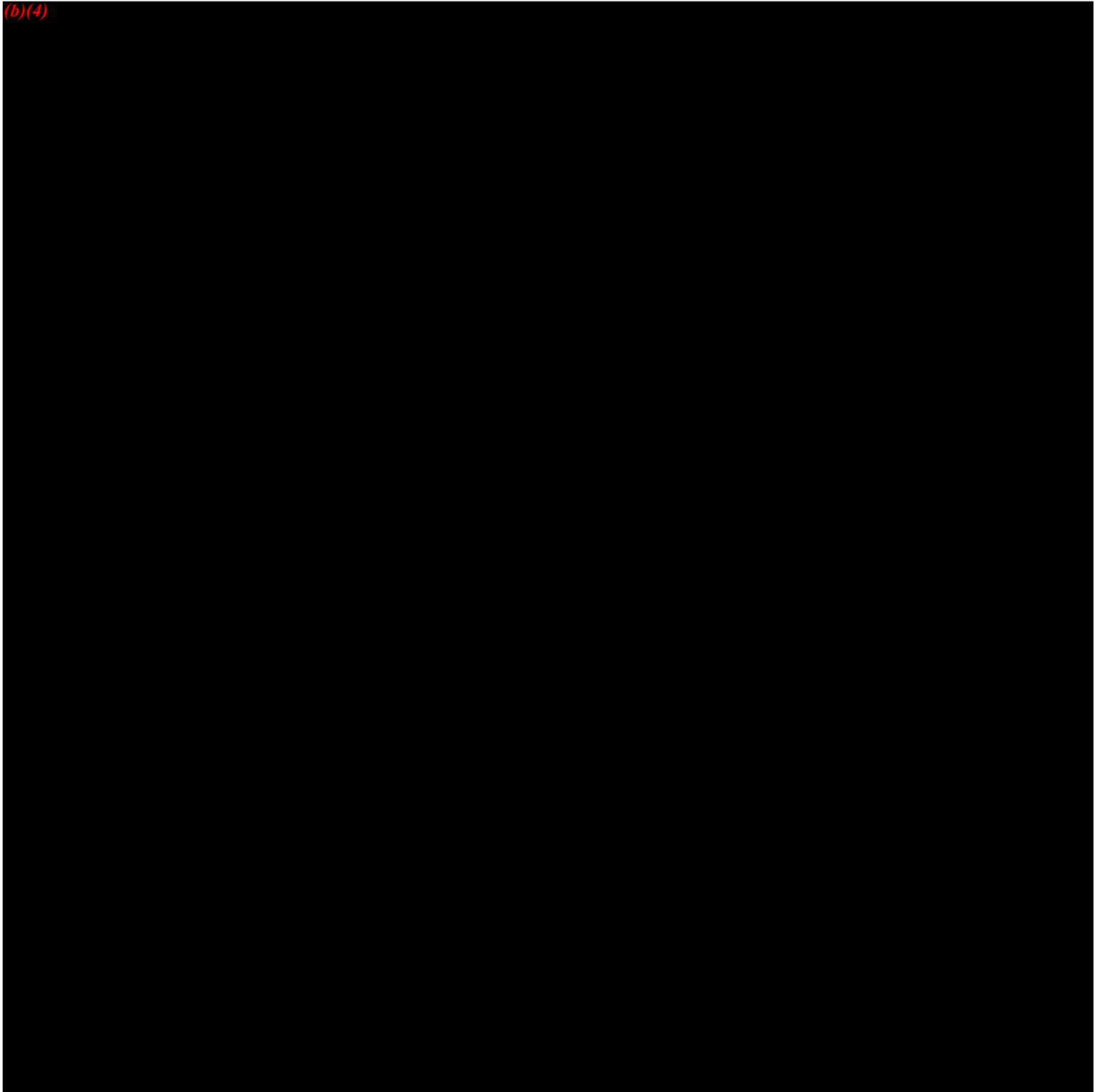
Sep. 04 2005 11:19PM P2

(b)(4)



### CERTIFICATE OF ANALYSIS

(b)(4)



FROM :

FAK NO. :

Sep. 04 2005 11:19PM P3

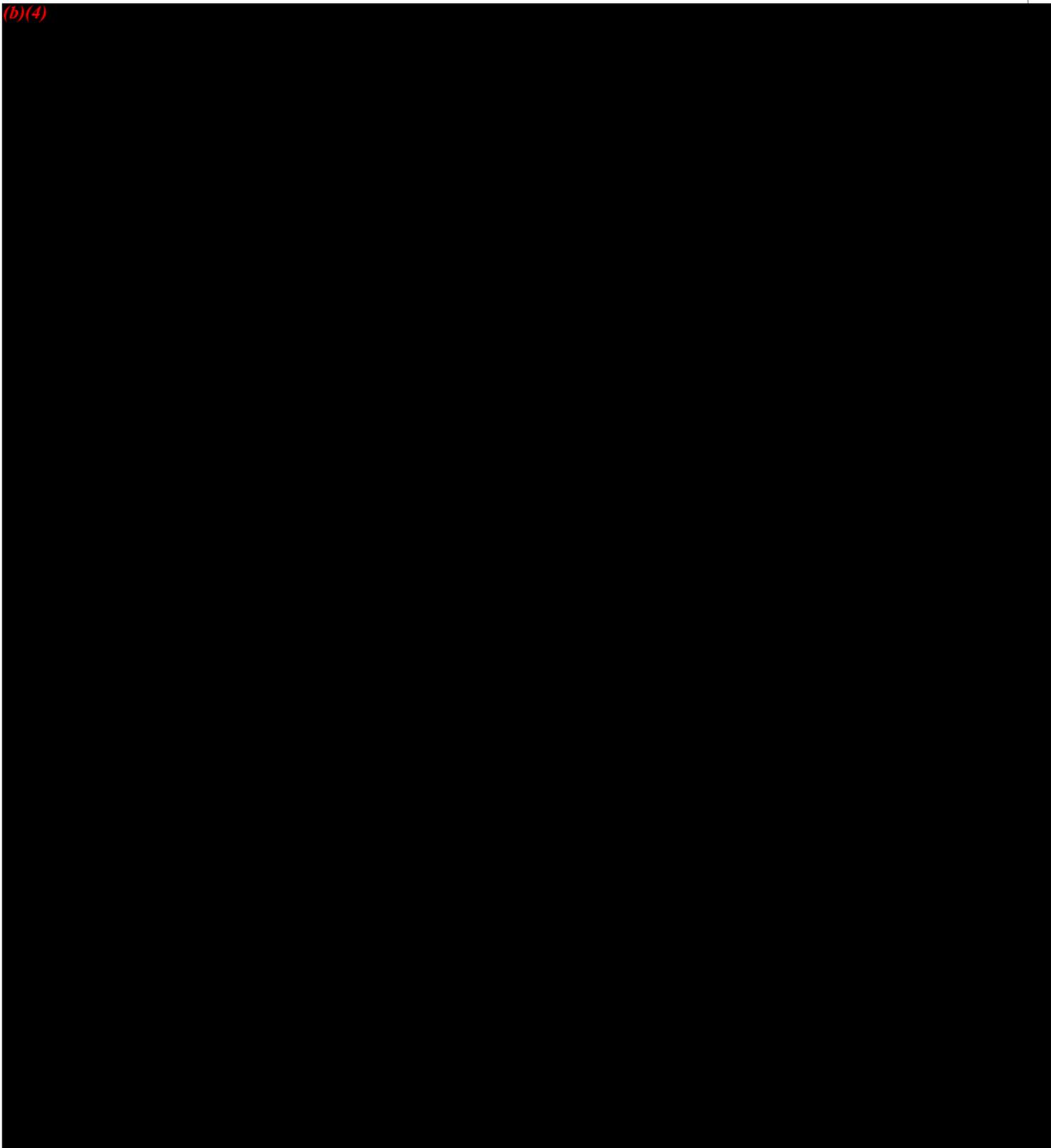
DEC-12-2005 15:31

TOPIDERM, INC.

631 226 8588 P.09

CERTIFICATE OF ANALYSIS

(b)(4)



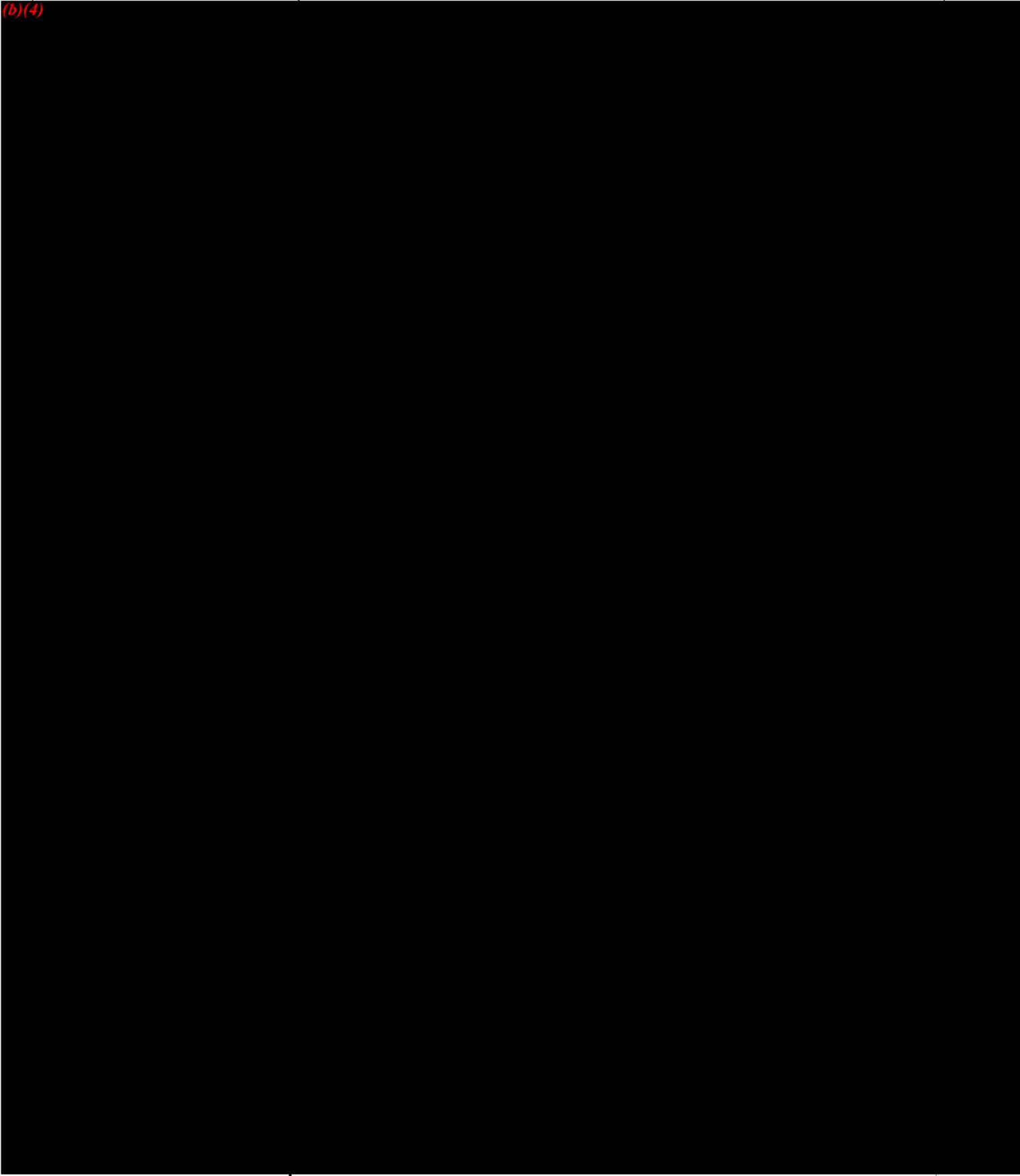
FROM :  
DEC-12-2005 15:31

(b)(4)

FAX NO :

Sep. 04 2005 11:20PM P4  
631 226 8588 P.11

(b)(4)



(b)(4)

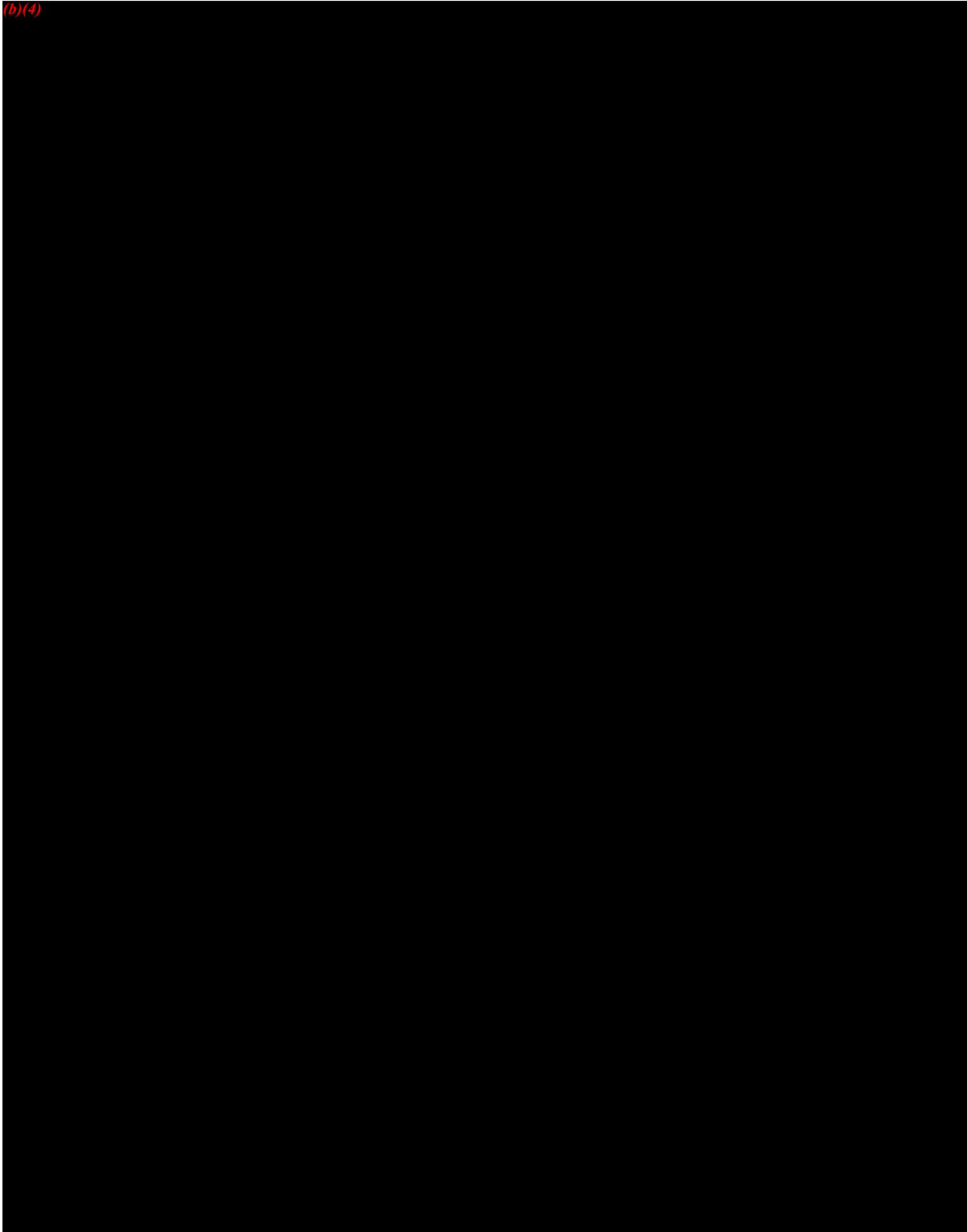
CERTIFICATE OF ANALYSIS

(b)(4)

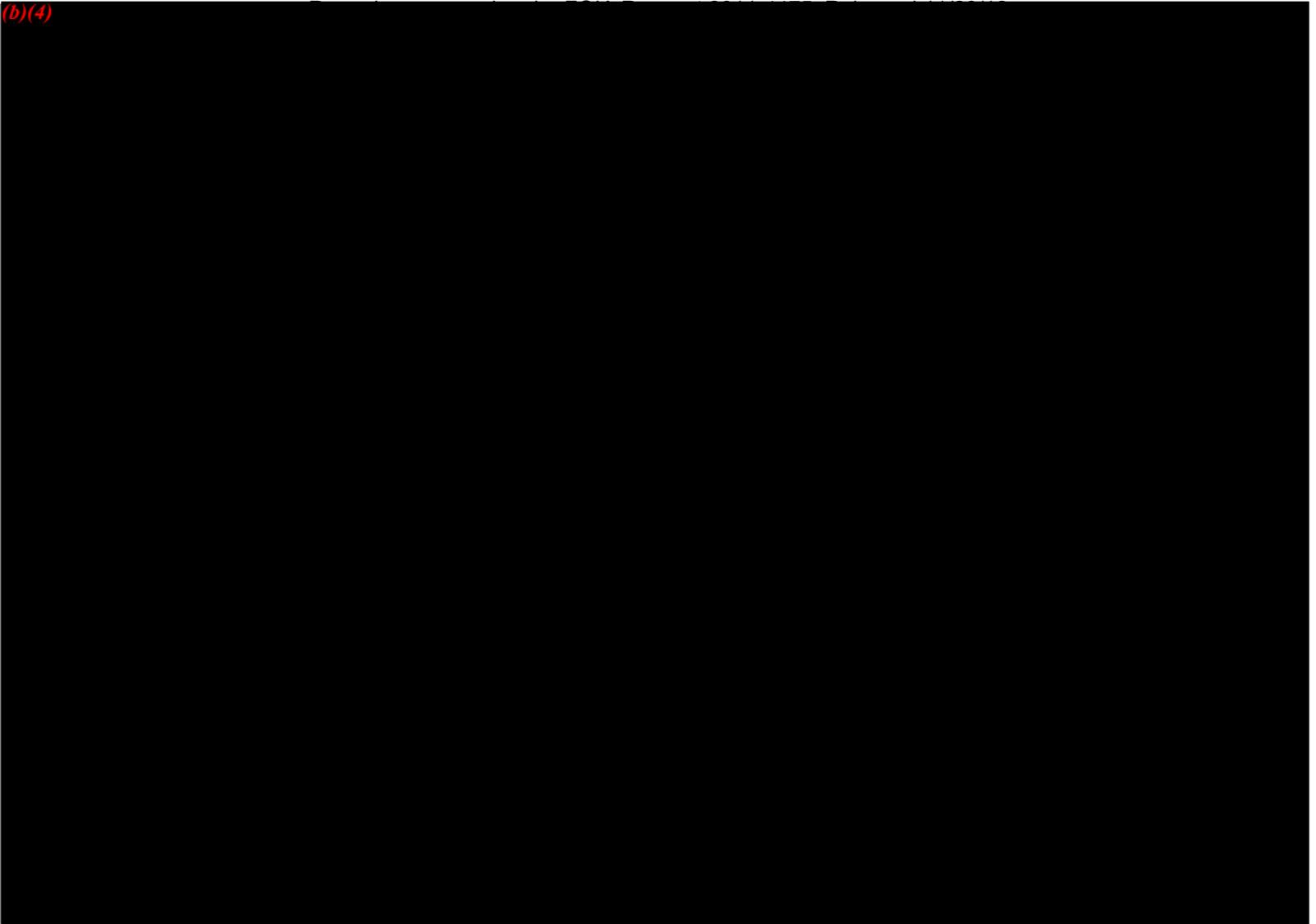
TEST RESULT

(b)(4)

The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantee since the conditions of use are beyond our control.



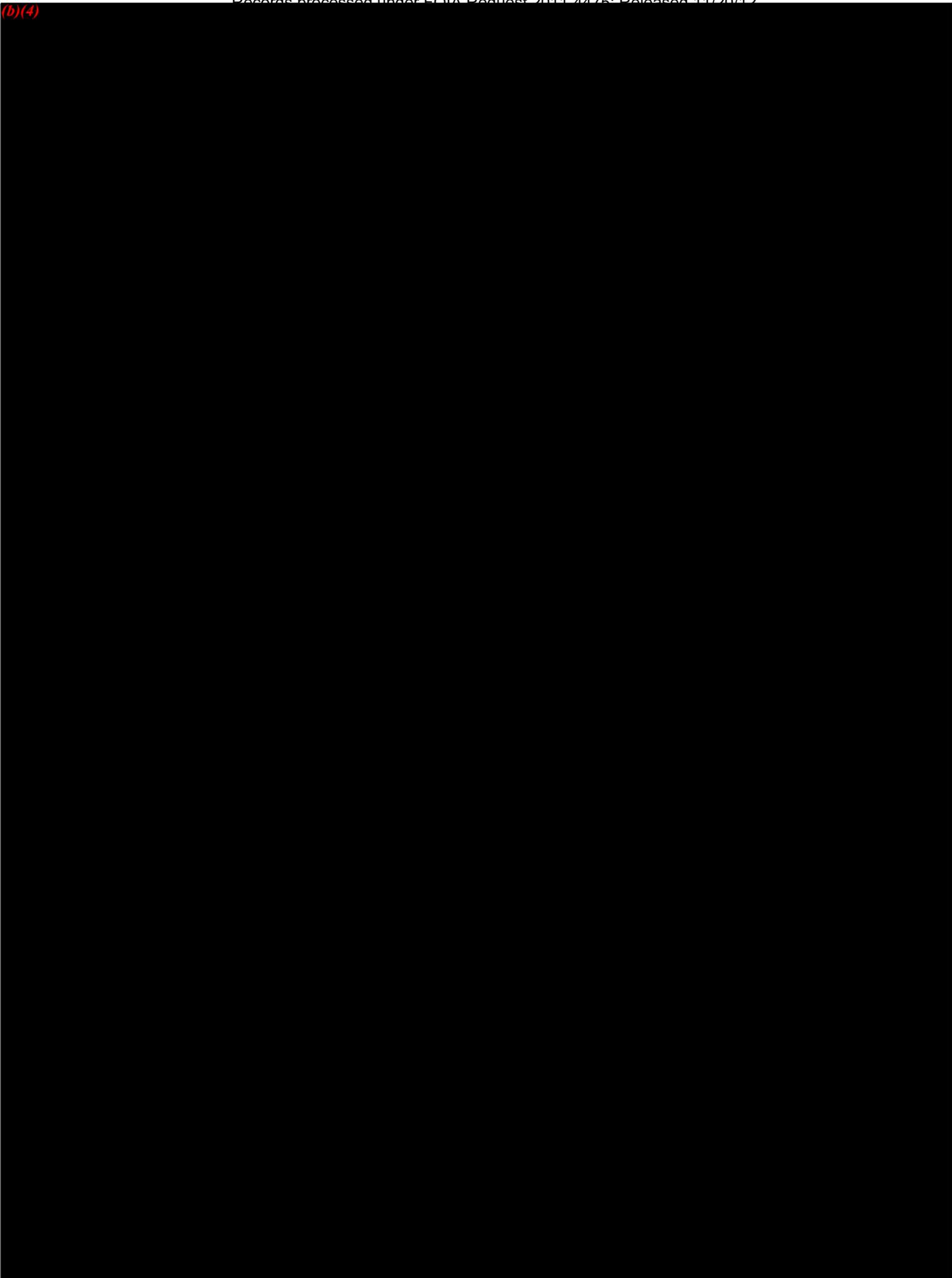
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(b)(4)



(b)(4)



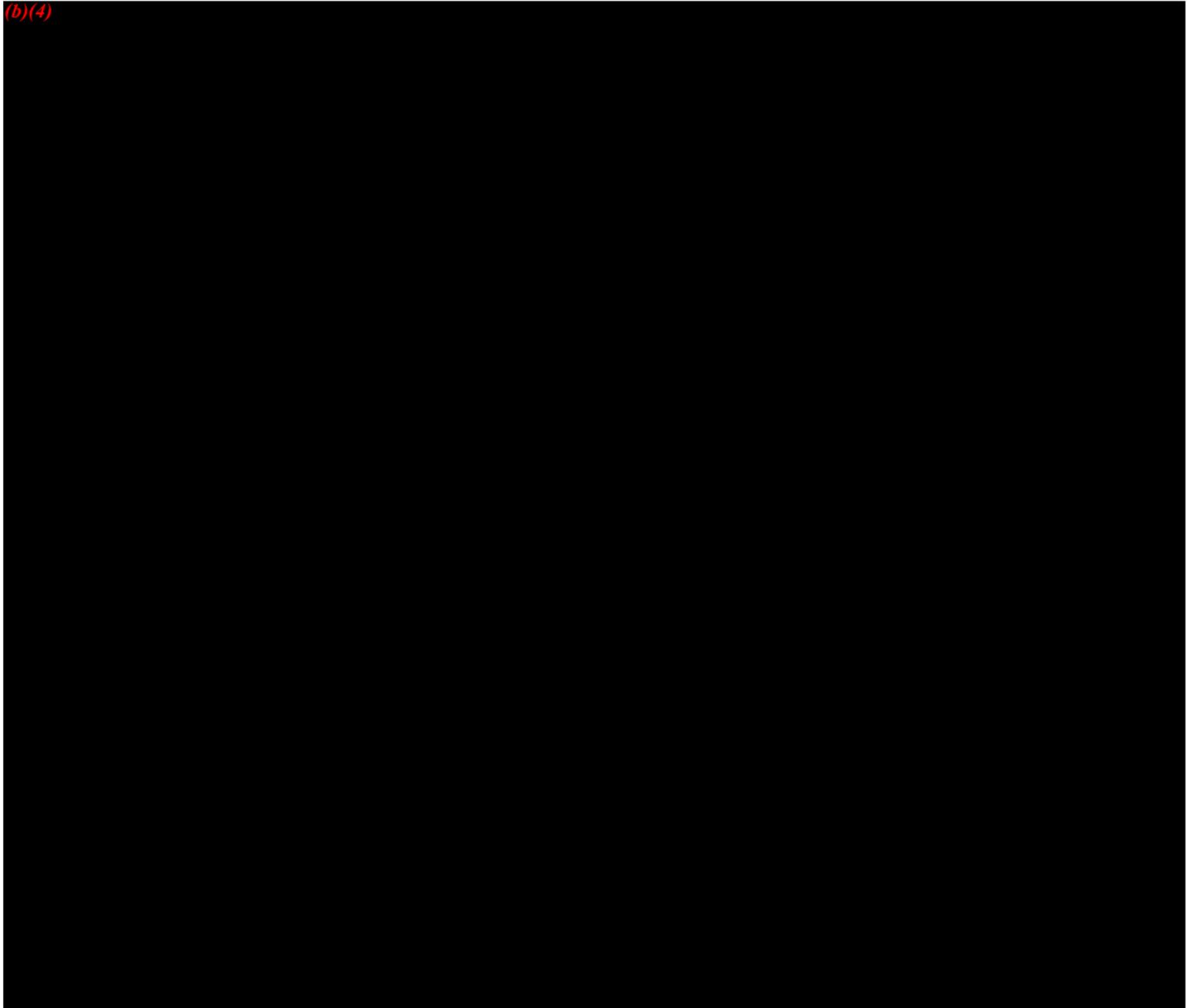
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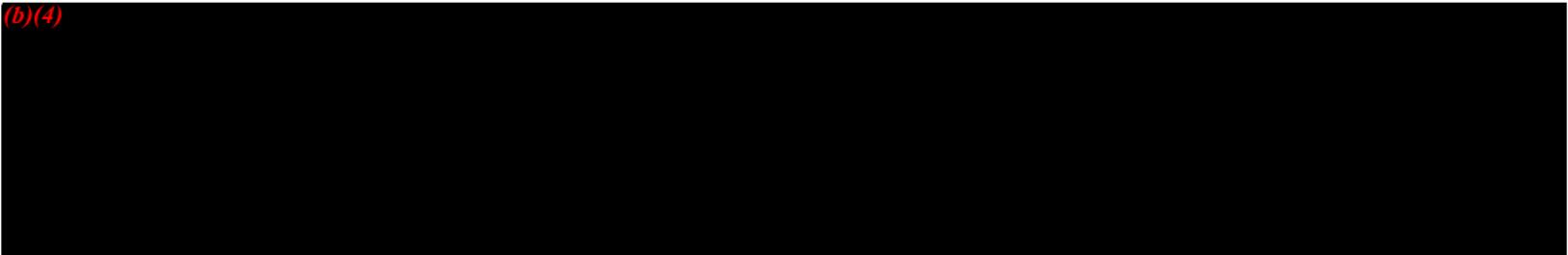
# ULTRAPURE L WHITE PETROLATUM USP

## SPECIFICATIONS

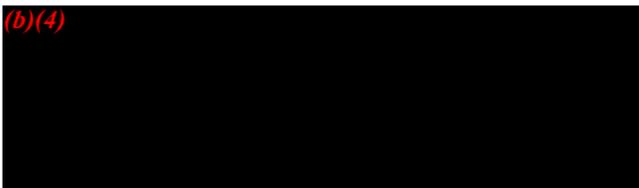
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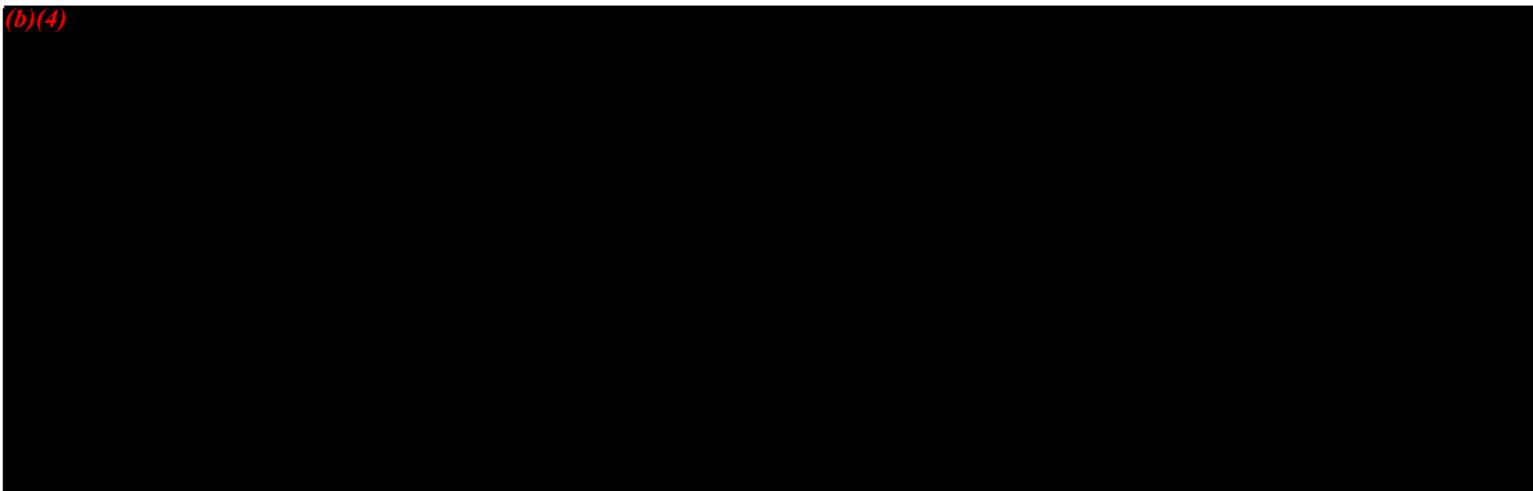
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CERTIFICATE OF ANALYSIS



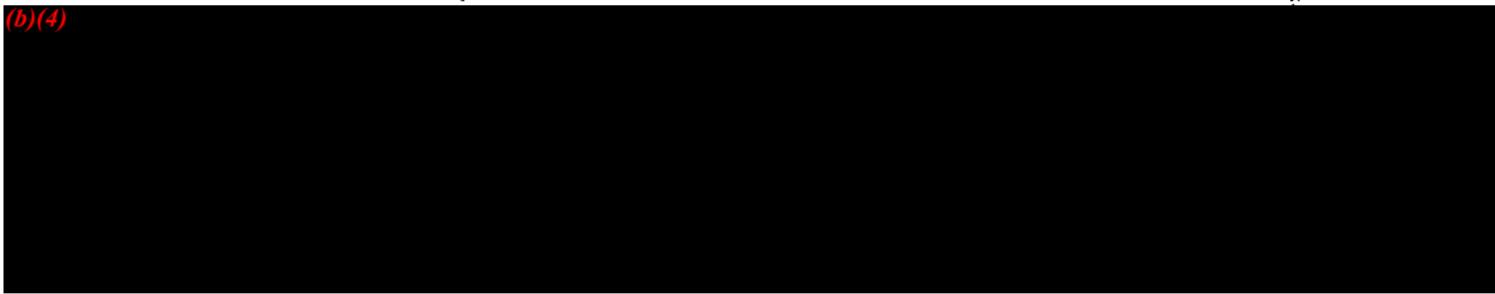
ATTN:  
FAX NO:



Sincerely Yours,

J. E. McCormick  
Quality Assurance Chemist

(b)(4)

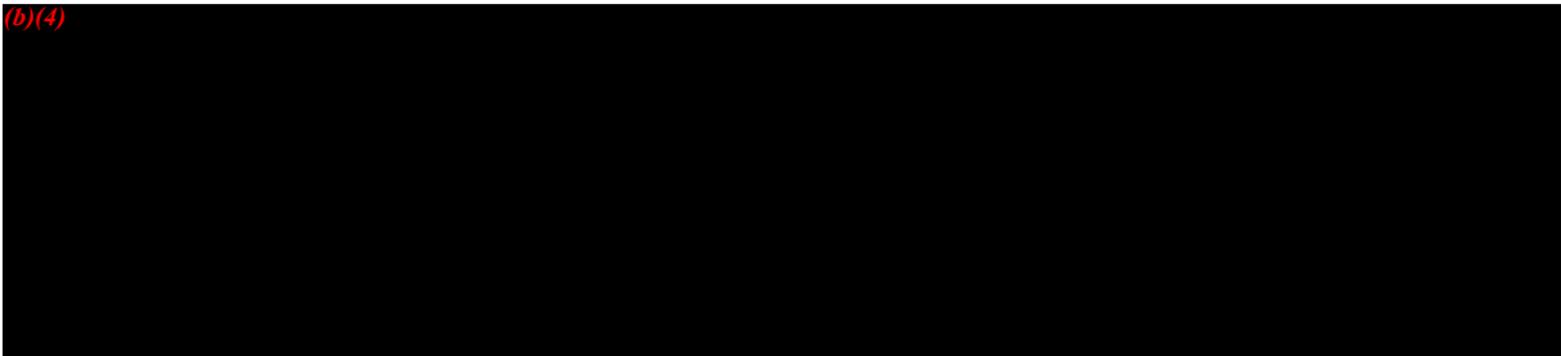


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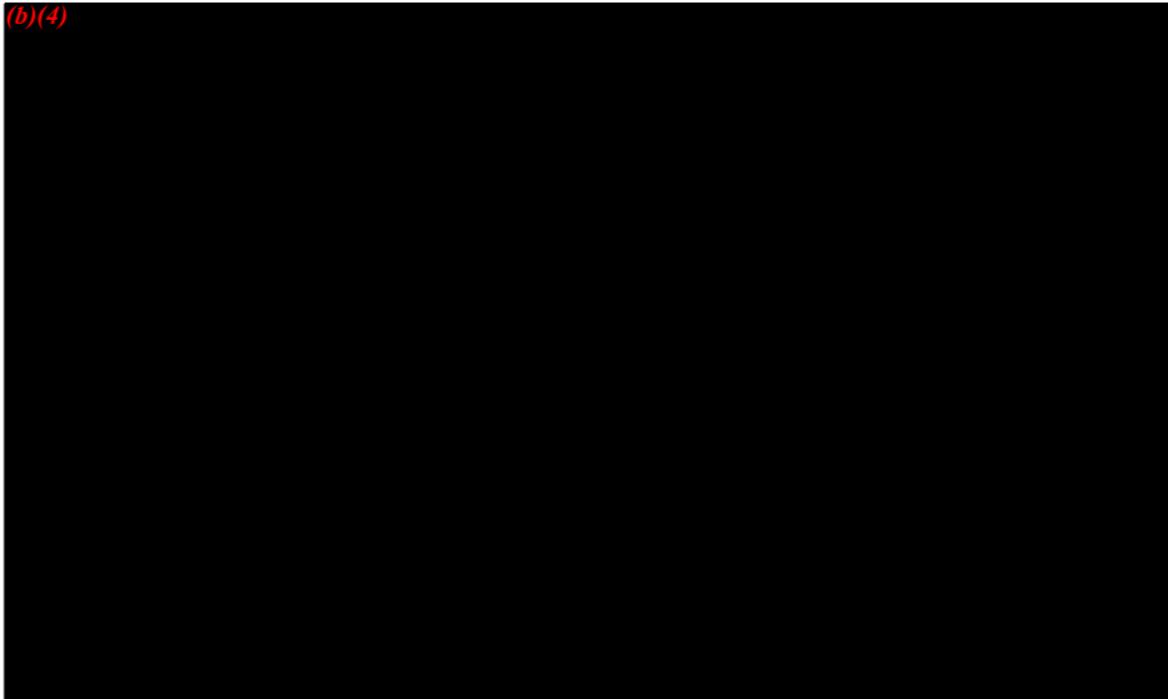
Sep. 04 2005 11:23PM P11

(b)(4)

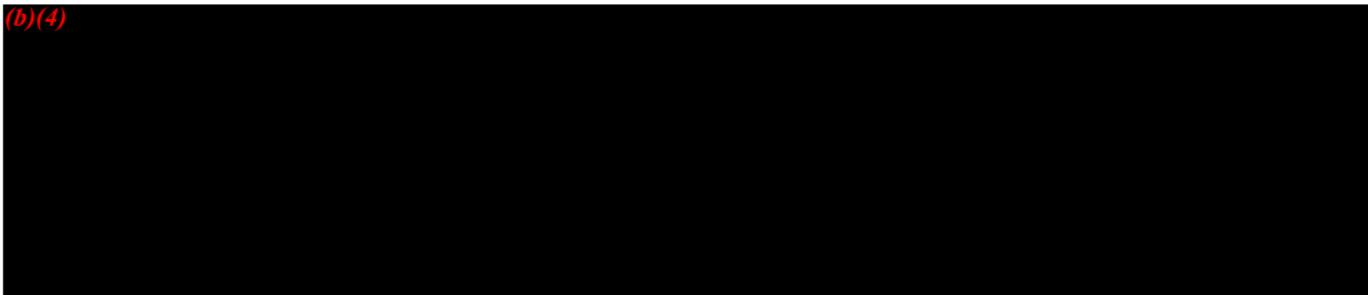


## Certificate of Analysis

(b)(4)

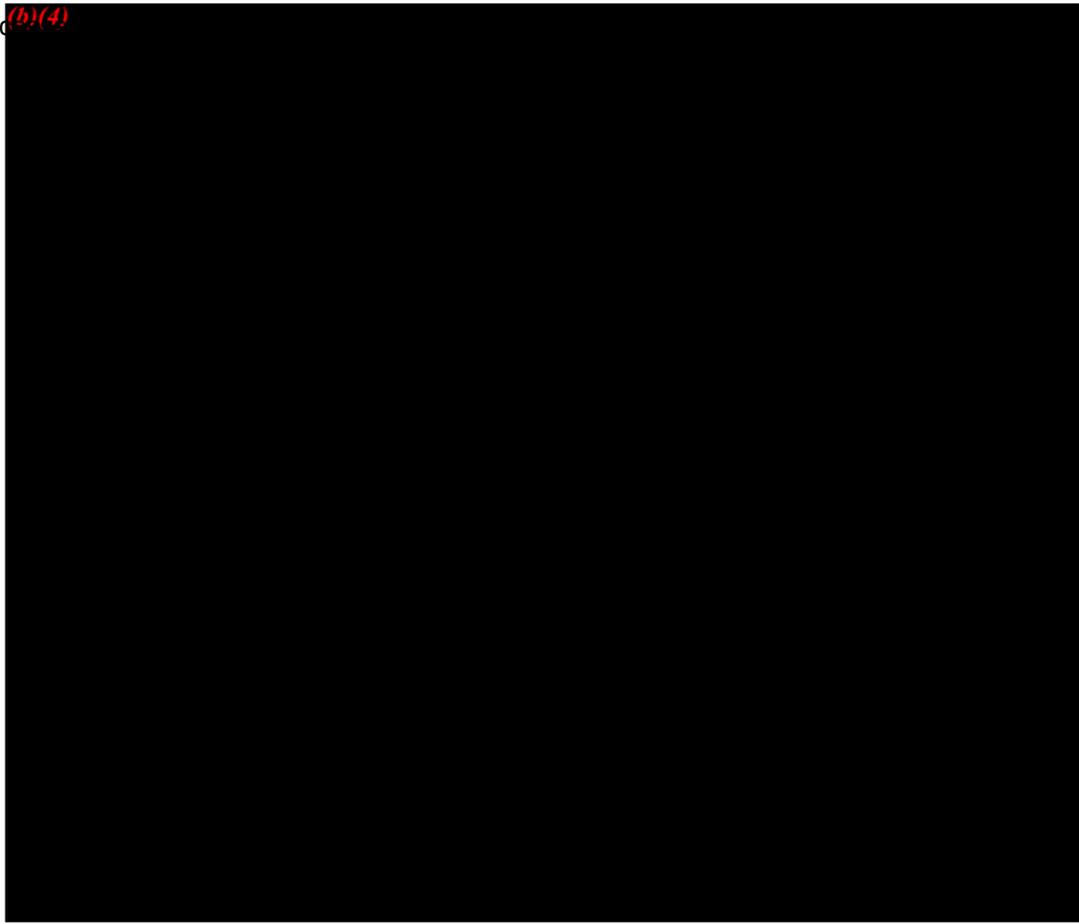


(b)(4)



FROM :

Records produced (b)(4)



**II. Information required by relevant C.F.R. Sections**

807.87(a) The device name, including both the trade or proprietary name and the common or usual name of the device.

Proprietary Name:	EPICERAM™
Common Name:	Skin Barrier Emulsion

807.87(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

This application is being submitted by Ceragenix Corporation. Ceragenix Corporation has not applied for an establishment registration number as of yet. (b)(4)

[REDACTED]

[REDACTED] n [REDACTED].

807.87(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

Classification Regulation: None

Classification: Unclassified

Classification Name: Dressing, wound and burn, hydrogel w/drug and/or biologic

Product Code: MGQ

Classification Panel: General and Plastic Surgery

807.87(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

No performance standards or special controls have been established under Section 514 of the Act.

807.87(e) Proposed labels, labeling and advertisements sufficient to describe the device, its intended use and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

See Exhibit S for proposed labeling of the EPICERAM™ box and tube. Attached are also copies of the labeling for one of the predicate devices, Biafine Wound Dressing Emulsion, including the box and tube (Exhibit D), package insert (Exhibit E), and an online brochure (Exhibit F).

807.87(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

A. Device Description

1. Indications for Use

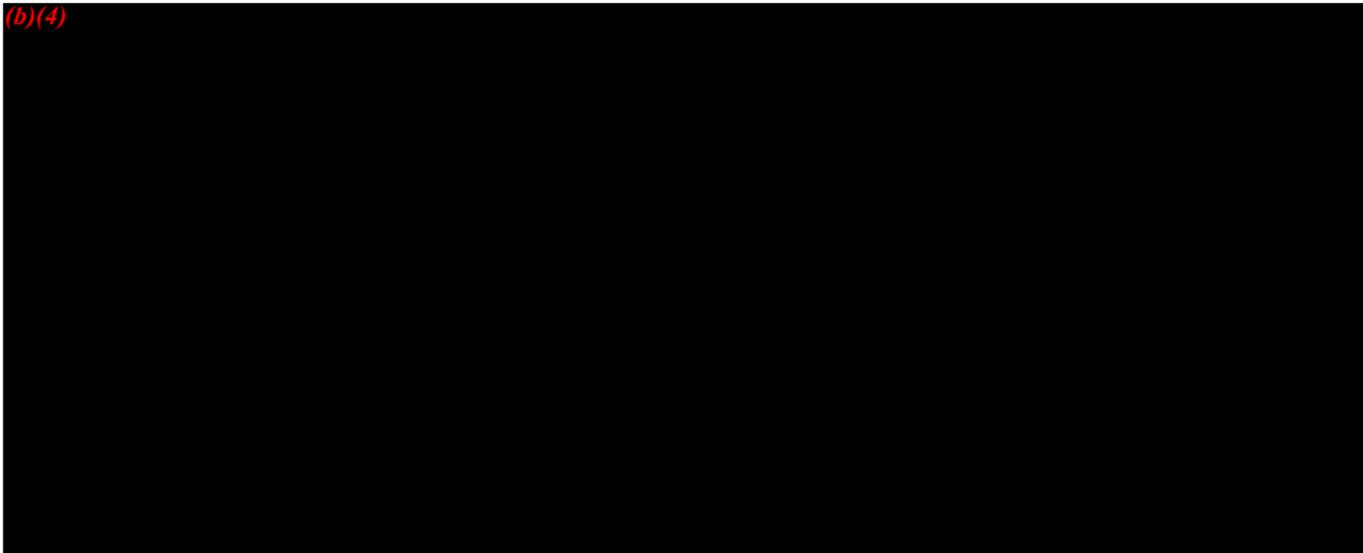
EPICERAM™ is a skin barrier emulsion to be used to reduce excessive moisture loss through the outer layers of the skin in xerotic skin conditions and to manage and relieve the burning, itching and pain experienced various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

2. Technological Characteristics

The skin is the largest organ in the human body. The outer layer of the skin, the epidermis, contains a thin layer of lamellar bilayers composed of an oil/water emulsion of epidermal lipids (ceramides, cholesterol and free fatty acids) which through phase behavior form a flexible vapor permeable membrane that act as a physical barrier to reduce excessive moisture loss from the lower layers of the skin. (See Exhibit J). This physical barrier, found in the stratum corneum, is about the thickness of a half a sheet of ordinary notebook paper. While normal, healthy skin has a fully formed skin barrier, persons who suffer from atopic dermatitis (eczema) as well as irritant contact dermatitis, radiation dermatitis and other dermatoses all have poor skin barrier function (See Exhibits H, I, K, L & M).

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use which helps to form a mechanical barrier in the outer layers of the skin to reduce excessive moisture loss. (b)(4)

(b)(4)



## **B. Comparison to Legally Marketed Devices**

EPICERAM™ is substantially equivalent to the following predicate devices:

- 1) SINCLAIR Wound and Skin Emulsion (K024367, July 28, 2003);
- 2) BLAFINE® Wound Dressing Emulsion (Radiodermatitis Emulsion) (K964240, Jan. 22, 1997); and
- 3) CARRASYN® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing (K961758, July 11, 1996).

The three predicates and EPICERAM™ are all oil in water emulsions (1) that have the consistency of a cream or gel; (2) that are topical preparations applied to the skin; (3) that contain waxy ingredients; (4) whose primary purpose is to provide a moist environment necessary to the healing process; and (5) that are indicated for the same purpose. Applicant's Table of Substantial Equivalence is attached as Exhibit G.

According to its Indications for Use Statement, Sinclair Wound and Skin Emulsion *“is indicated to manage and relieve the burning, itching and pain associated with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis.”* (See 510(k) Summary for Sinclair Wound and Skin Emulsion, attached as Exhibit A, and the corresponding Indications for Use Statement, attached as Exhibit B). The intended use for EPICERAM™ is nearly identical to that of the Sinclair Wound and Skin Emulsion. Similarly, Biafine Wound Dressing Emulsion (RE) is intended to be used as a wound dressing for the following indications: superficial wounds, minor abrasions, leg ulcers, donor sites, 1<sup>st</sup> and 2<sup>nd</sup> degree burns, including sunburns, for dermal ulcers, including full thickness wounds and pressure sores, and radiation dermatitis. (See Biafine’s “Table of Substantial Equivalence” obtained from 510(k) filing K963240, attached as Exhibit C, and Biafine’s Box and Tube Labeling, attached as Exhibit D, Package Insert, attached as Exhibit E, and online brochure obtained from [www.biafine.com](http://www.biafine.com), attached as Exhibit F). As EPICERAM™ is intended for various types of dermatoses, as are the predicate devices, the intended use for EPICERAM™ is substantially equivalent to the intended use of these predicates.

EPICERAM™ is also substantially equivalent to the predicate devices in terms of design, technology and function. The primary function of the outer layer of the skin (the epidermis) is to protect the body against excessive water loss. This is accomplished by means of the skin’s barrier function which is composed of various lipids that form a semi-permeable membrane. (See Madison, KC “Barrier function of the skin: ‘la raison d’etre of the epidermis.’” Abstract from the Journal of Investigative Dermatology. 2003Aug; 121(2): 231-41, attached as Exhibit H) (“There are several skin diseases in which the lipid composition in the intercellular matrix of

the stratum corneum is different from that of healthy human skin. It has been shown that patients suffering from atopic dermatitis have a reduced ceramide content in the stratum corneum...”).

Changes in the composition of the lipids in the epidermis have been associated with atopic dermatitis and other inflammatory skin disorders which are characterized by dry skin. (See Pilgram GS, et al. “Aberrant lipid organization in stratum corneum of patients with atopic dermatitis and lamellar ichthyosis.” Abstract from the Journal of Investigative Dermatology: 2001, September; 117(3): 710-7, attached as Exhibit I).

The use of X-ray crystallography has shown that various lipids when combined in vitro are able to spontaneously form the lipid bilayers that form the barrier function in the living skin. (McIntosh, TJ, “Organization of Skin Stratum Corneum Extracellular Lamellae: Diffraction Evidence for Asymmetric Distribution of Cholesterol.” Biophysical Journal 85:1675-1681 (2003), attached as Exhibit J).

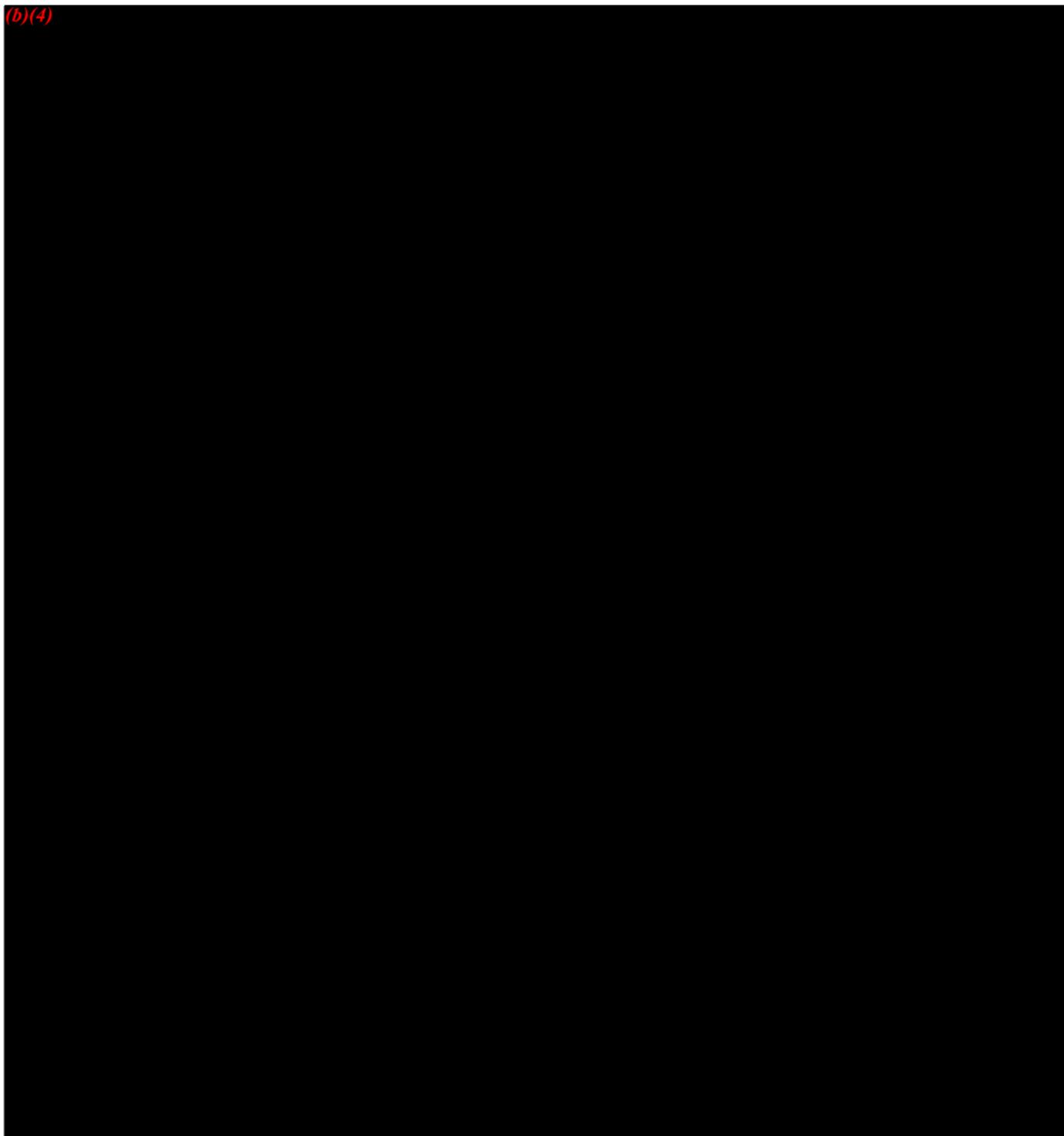
All of the predicate devices contain various lipids which are known to be important in forming a protective mechanical barrier on the surface of the skin, which reduces transepidermal water loss. For example, Biafine Wound Dressing Emulsion (RE) contains stearic acid as well as avocado oil. Avocado oil consists mainly of glycerides of the oleic and linoleic acid, as well as of the palmitoleic acid characteristic for this oil. EPICERAM™, like Biafine Wound Dressing Emulsion (RE), also contains linoleic acid (in the form of conjugated linoleic acid. The following table compares the functional activities of the key ingredients in Biafine Wound Dressing Emulsion (RE) and EPICERAM™

<b>BIAFINE INGREDIENTS (SEE EXHIBIT F)</b>	<b>COMPARABLE EPICERAM™ INGREDIENTS</b>	<b>INGREDIENT FUNCTION (SEE EXHIBIT F)</b>
Demineralized Water	(b)(4)	Provides hydration
Liquid Parrafin		Protection against skin maceration
Monostearyl Stearate		Emollient properties maintain healthy skin
Stearic Acid		Lipids which replenish the skin's natural barrier function
Propylene Glycol		Maintains emulsion properties.
Parrafin Wax		Ensures consistency of the emulsion
Squalene		Healing, moisturizing and stimuli protection
Avocado Oil		Natural lipid protects and regenerates the skin
Trolamine/Sodium Alginate		Used to stimulate macrophage proliferation
Trichanolamine		Maintains the proper pH balance
Cetyl Palmitate		Surfactant with emollient properties
Methylparaben, Propylparaben		Product base preservative
Sorbic Acid		Assists in maintaining pH balance
Yerbatone		Masks odors associated with skin breakdown )

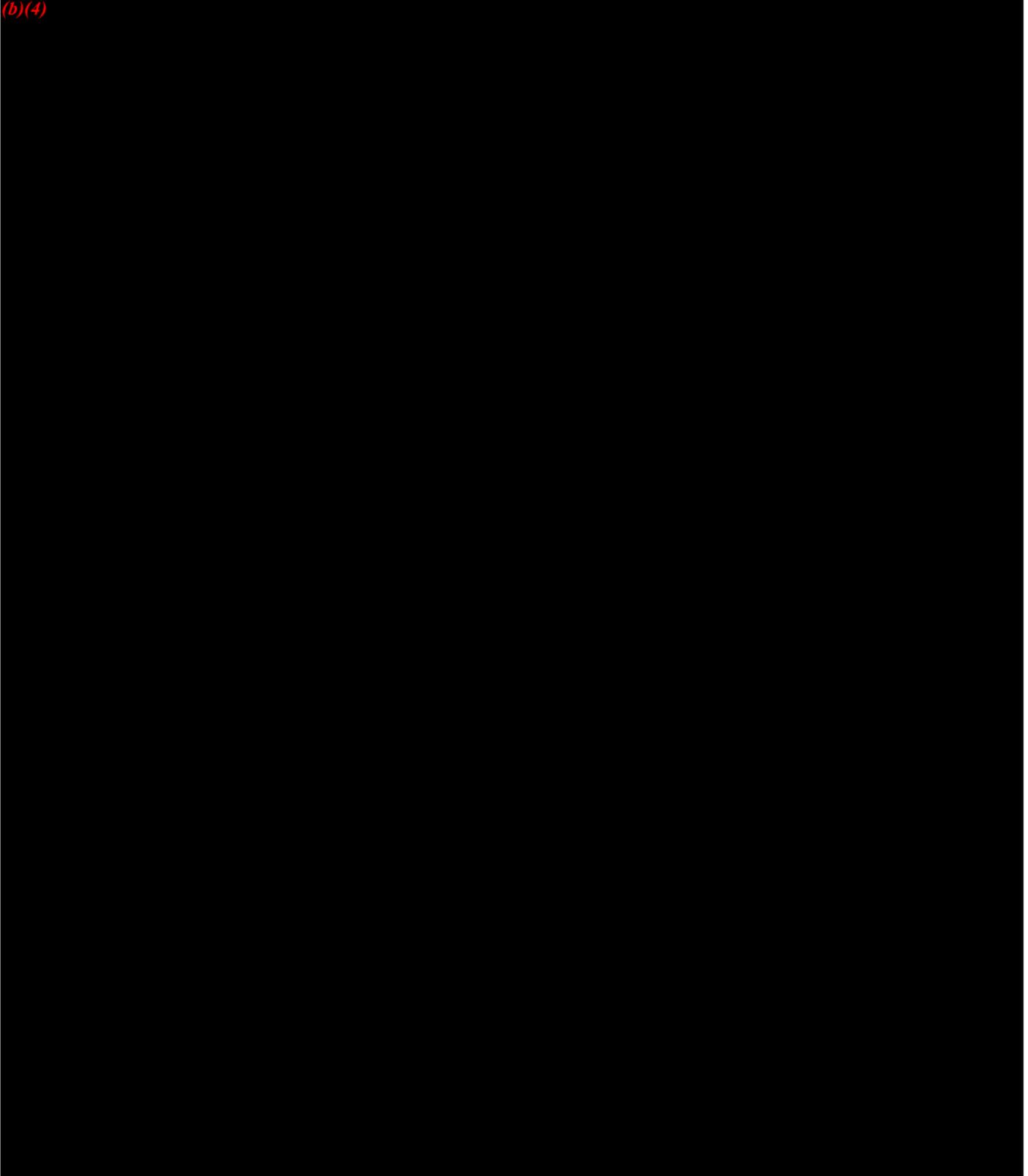
To test whether EPICERAM™ in fact does help reduce transepidermal moisture loss when applied to a disrupted skin barrier, Ceragenix sponsored a study conducted (b)(4)

(b)(4) on persons suffering from moderate-to-severe atopic dermatitis (eczema). A full and complete copy of the report is attached at Exhibit K.

(b)(4)

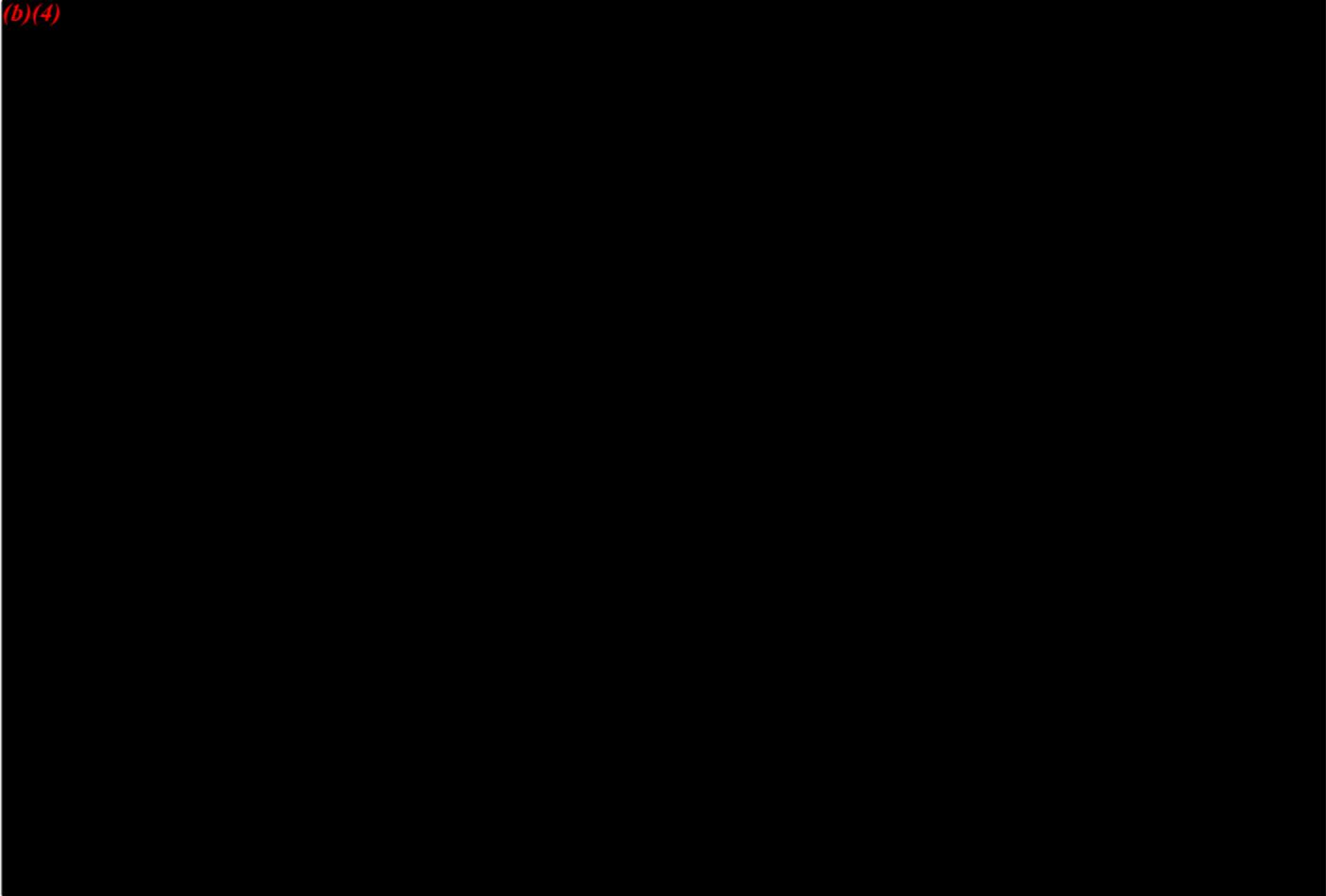


(b)(4)



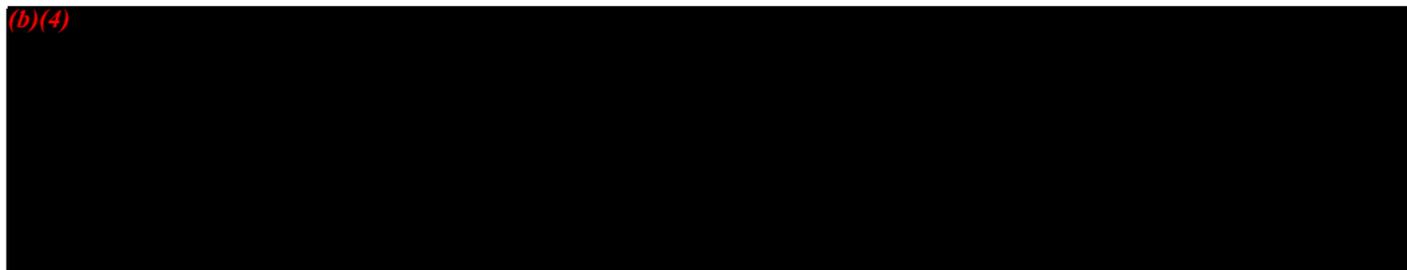
**Transepidermal Moisture Loss (TEML) – Evaporimeter**

(b)(4)



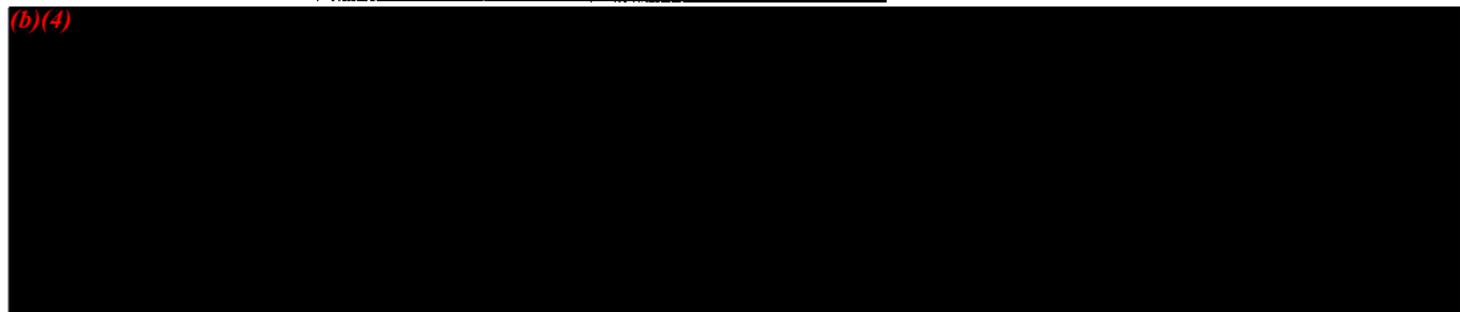
**Discussion and Conclusions:**

(b)(4)

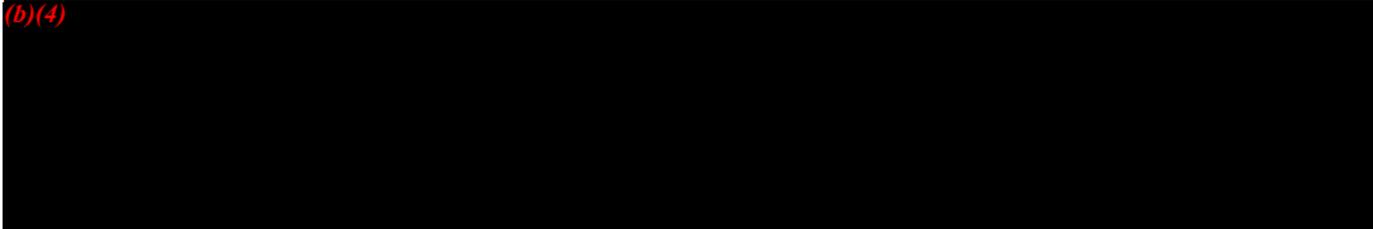


**Transepidermal Moisture Loss (TEML) – Evaporimeter**

(b)(4)

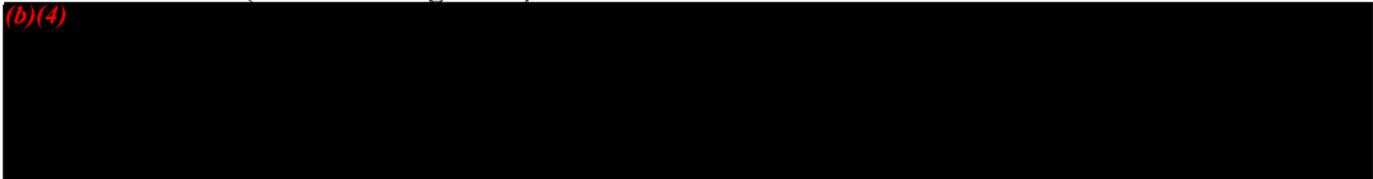


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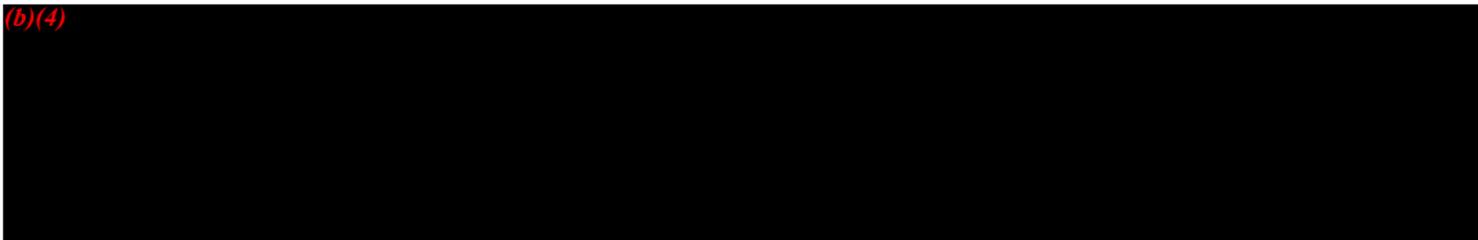
**Itch – VAS (Visual Analog Scale)**

(b)(4)

A black rectangular redaction box covering the content of the Itch – VAS section.

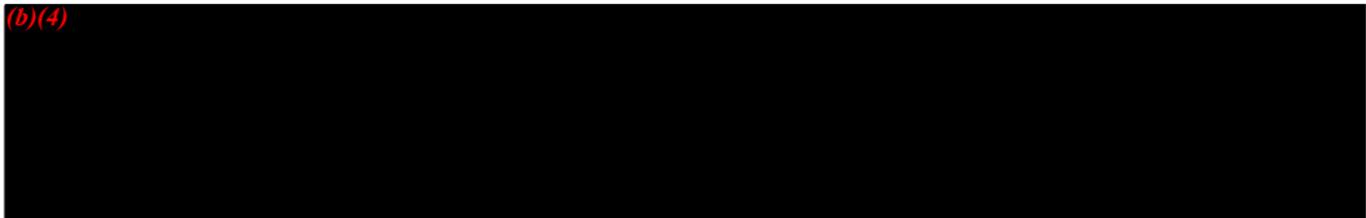
**Itch – Wong-Baker Scale**

(b)(4)

A large black rectangular redaction box covering the content of the Itch – Wong-Baker Scale section.

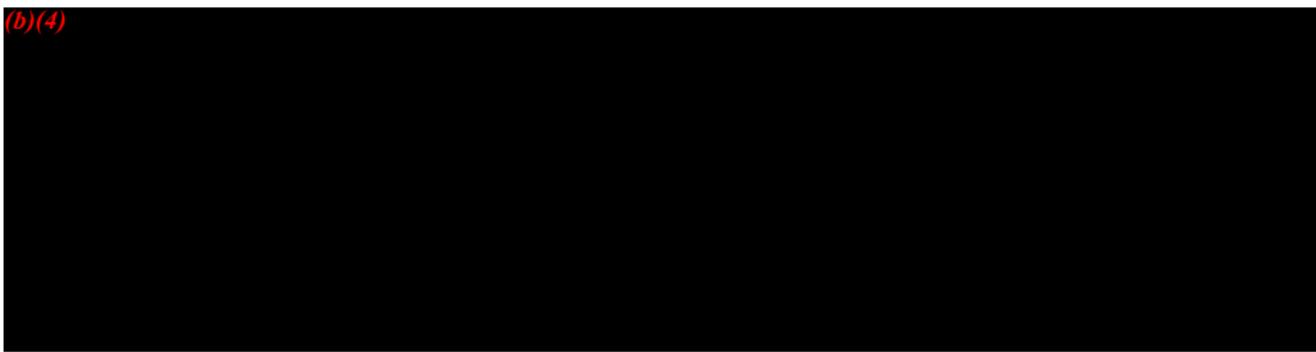
**Dry Skin – VAS (Visual Analog Scale)**

(b)(4)

A black rectangular redaction box covering the content of the Dry Skin – VAS section.

**Dry Skin – Wong-Baker Scale**

(b)(4)

A large black rectangular redaction box covering the content of the Dry Skin – Wong-Baker Scale section.

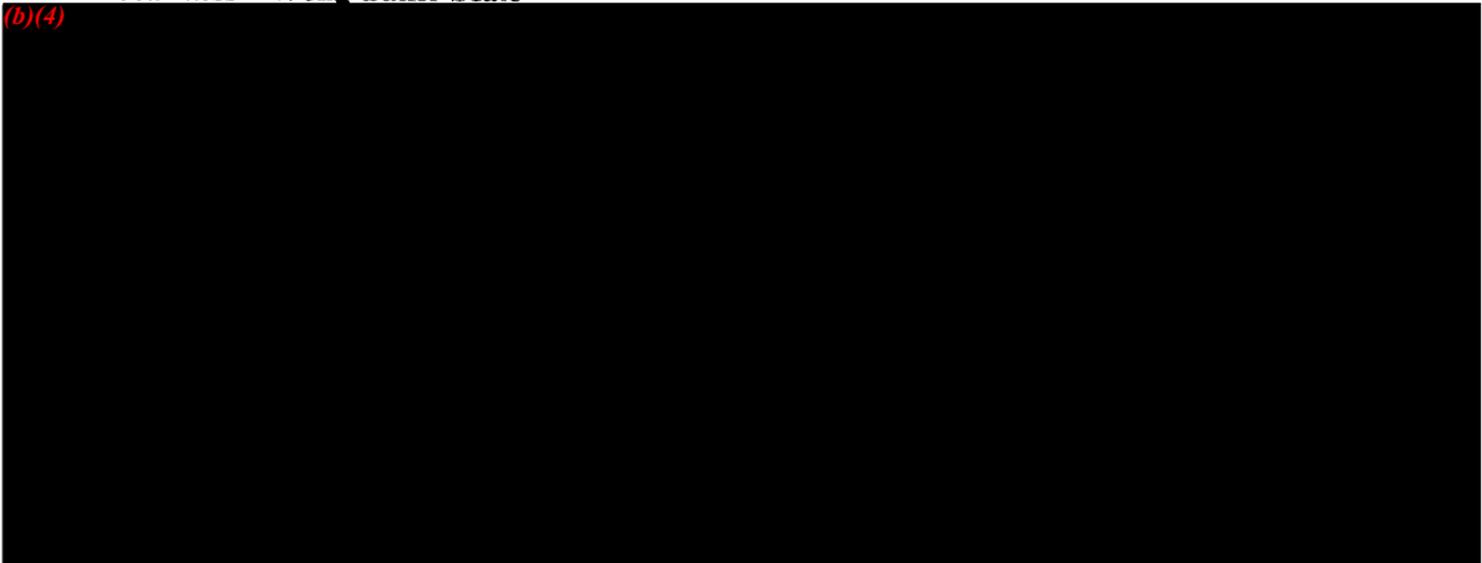
**Scaliness – VAS (Visual Analog Scale)**

(b)(4)

A large black rectangular redaction box covering the content of the Scaliness – VAS (Visual Analog Scale) section.

**Scaliness – Wong-Baker Scale**

(b)(4)

A large black rectangular redaction box covering the content of the Scaliness – Wong-Baker Scale section.

**Irritation/Inflammation – Wong-Baker Scale**

(b)(4)

A large black rectangular redaction box covering the content of the Irritation/Inflammation – Wong-Baker Scale section.



As EPICERAM™ and all of the predicate devices share in common the use of lipids and other waxy ingredients to help create a skin barrier to reduce water loss through the epidermis (thereby creating a “moist environment” to allow healing to occur), EPICERAM™ does not raise any new safety or effectiveness questions. (See discussion in Section V, Biocompatibility Testing).

We have attached a Table of Substantial Equivalence (Exhibit G) to fully compare the intended use, directions for use, ingredients, contraindications and warnings or precautions for EPICERAM™, SINCLAIR Wound and Skin Dressing, and BIAFINE® Wound Dressing Emulsion (RE).

807.87(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or is the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

EPICERAM™ is a new device. This section is not applicable.

807.87(h) A 510(k) summary as described in Section 807.92 or a 510(k) statement as described in Section 807.93.

Attached as Exhibit N is Applicant's 510(k) Summary.

(b)(4)

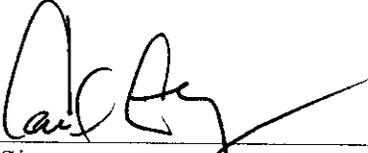


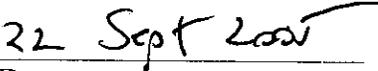
2.20

279

807.87(k) Statement of Truthfulness

I certify that in my capacity as Senior Vice-President of Research & Development of Ceragenix Corporation that I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

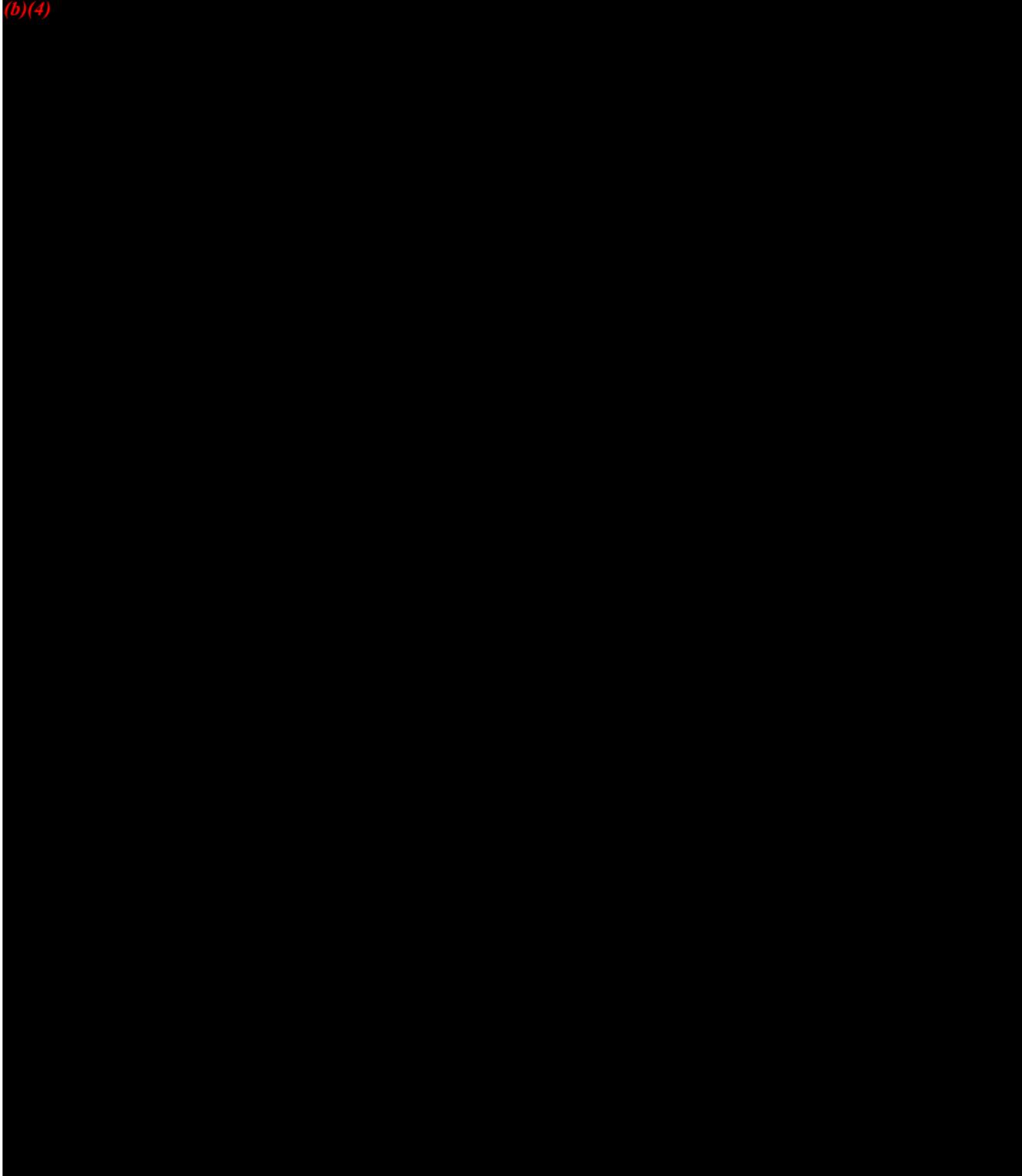
  
\_\_\_\_\_  
Signature  
Carl Genberg, J.D.

  
\_\_\_\_\_  
Date

## EXHIBIT C

### Function of Ingredients in Epiceram

(b)(4)



### **III. INDICATION FOR USE**

EPICERAM<sup>TM</sup> is a skin barrier emulsion to be used to reduce excessive transepidermal moisture loss in xerotic skin conditions and to manage and relieve the burning, itching and pain experienced various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

**DIRECTIONS:** Wash affected area with a suitable wound cleanser or disinfectant. Apply EPICERAM<sup>TM</sup> on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist, apply EPICERAM<sup>TM</sup> in a thin layer (1mg/cm<sup>2</sup>). In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

**CONTRAINDICATIONS:** When an allergy to one of the ingredients is known.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

OCTOBER 27, 2005

From: Reviewer(s) - Name(s) DOMA VEGA, MD., PhD. DKK

Subject: 510(k) Number K052643

To: The Record - It is my recommendation that the subject 510(k) Notification AE letter

"ON HOLD"  
for AE.

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party? (CDER)  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

Truthful and Accurate Statement  Requested  Enclosed

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices N

The indication for use form -(Requested)

Combination Product Category (Please see algorithm on H drive 510k/Boilers) \_\_\_\_\_

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

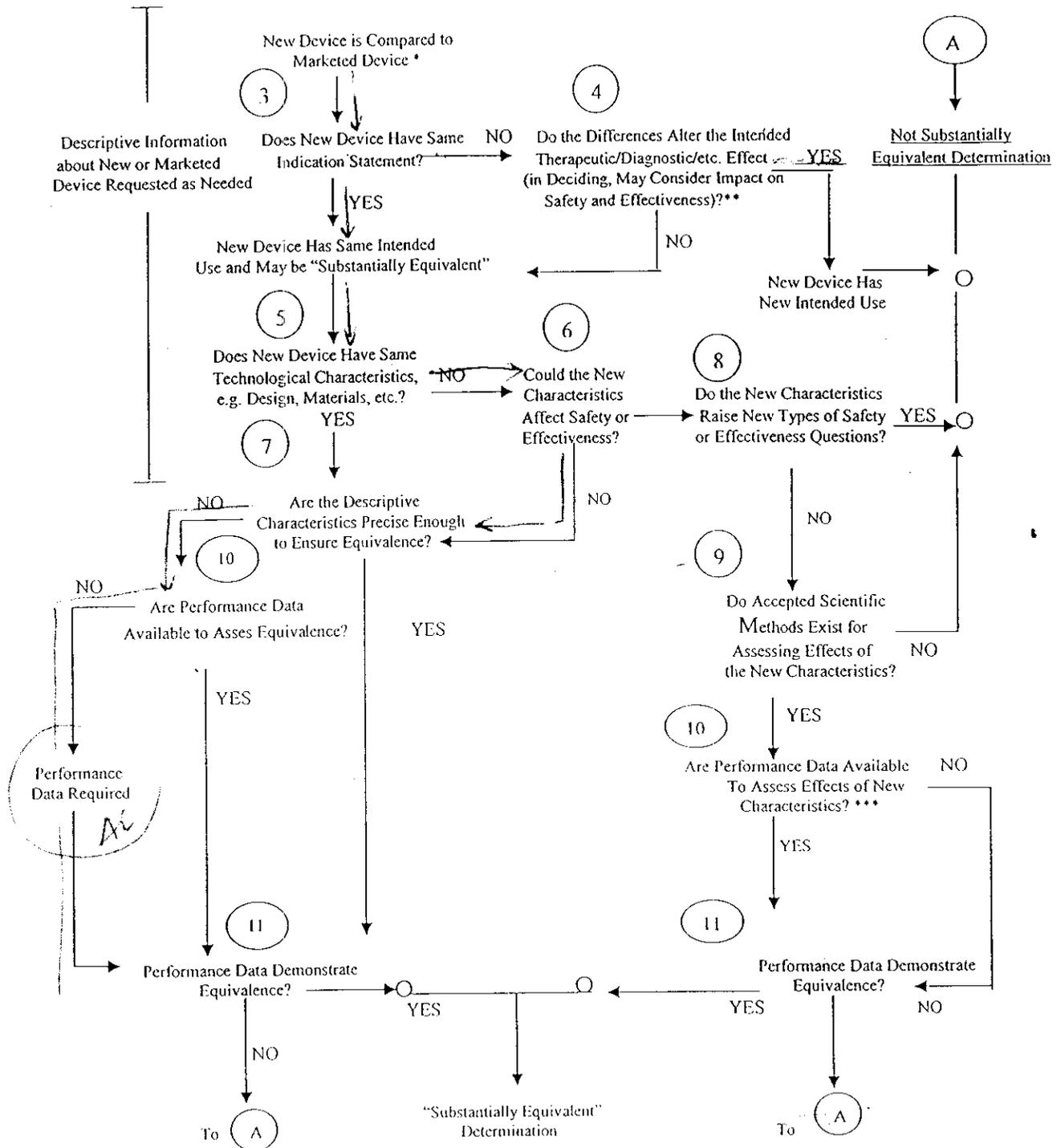
Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

21CFR 878.4022 - MEG. UNCLASSIFIED. - WOUND & BURN DRESSING - HYDROGEL.

Review: Steph Pluch PR 56 11/18/05  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (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.

(3)

**Internal Administrative Form**

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N/A	
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?	N	✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

203

(4)

**SCREENING CHECKLIST  
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K052643

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

**Section 1: Required Elements for All Types of 510(k) submissions:**

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		✓
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		✓
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	(not provided in the form format)
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		✓
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		N/A
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	✓	✓
510(k) Kit Certification ***		

- \* - May not be applicable for Special 510(k)s.
- \*\* - Required for Class III devices, only.
- \*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

(5)

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	N/A	
A description of the modified device and a comparison to the sponsor's predicate device.	N/A	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	N/A	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	N/A	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	N/A	
c. A Declaration of Conformity with design controls that includes the following statements:	N/A	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

(6)

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

\* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:		N/A (NON-STER)
i) sterilization process		N/A
ii) validation method of sterilization process		N/A
iii) SAL		N/A
iv) packaging		✓
v) specify nitrogen free		N/A
vi) ETO residues		N/A
vii) radiation dose		N/A
viii) Traditional Method or Non-Traditional Method		N/A
c) Software Documentation:		N/A

*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No  
 Reviewer: DONA VEGA, M.D., Ph.D.  
 Concurrence by Review Branch: \_\_\_\_\_  
 Date: \_\_\_\_\_

(7)

The deficiencies identified above 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/cdrh/modact/leastburdensome.html>

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REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 052643

Reviewer: DONA VEGA, MD, PhD

Division/Branch: DERND - PRSB

Device Name: EPICERAM

Product To Which Compared (510(K) Number If Known): K024367 (Sunclon), K964240 (BIAFINE), and K90752 (CARASYN)

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	N/A		If YES = Stop <u>NE</u>
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If YES = Go To <u>8</u>
7. Descriptive Characteristics Precise Enough?	N/A		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		✓	If YES = Stop NE
9. Accepted Scientific Methods Exist?	✓		If NO = Stop NE
10. Performance Data Available?		✓	If NO = <u>Request Data</u>
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Posted on: Monday, 26 September 2005, 09:01 CDT

E-mail this to a friend    Printable version    Discuss this story in the forum

Change

## Ceragenix Submits 510(K) Application to FDA for Epiceram(TM), a Skin Barrier for Treatment of Eczema and Other Skin Disorders

Ceragenix Pharmaceuticals, Inc. ("Ceragenix" or the "Company") (OTCBB: CGXP), a development stage biopharmaceutical company, announced that Ceragenix Corporation, its wholly owned subsidiary, has submitted a 510(k) application to the United States Food and Drug Administration ("FDA"). The application seeks marketing clearance for Epiceram(TM), a topical cream intended for use in alleviating itching and burning of atopic dermatitis (eczema), irritant contact dermatitis, radiation dermatitis and xerotic skin conditions. If approved by the FDA, Epiceram(TM) will be the Company's first commercial product.

Atopic dermatitis, also known as eczema, is a common skin disorder that afflicts over 15 million Americans and is typified by intense itching and skin inflammation. For many years the therapeutic options were limited to use of varying strengths of topical corticosteroids and use of moisturizers. While topical corticosteroids are helpful in reducing skin inflammation, recent research reported at the International Symposium on Atopic Dermatitis (ISAD) has shown that use of potent topical corticosteroids can lead to a disruption in the skin's barrier leading to further flares. Research by Dr. M.J. Cork (University of Sheffield, UK) and others have shown that a substantial portion of people with eczema have a defect in their skin's barrier function. This porous skin barrier allows external triggers such as allergens and irritants to pass through the skin's surface and induce an inflammatory response.

Dr. Peter M. Elias, Professor of Dermatology at UCSF and Ceragenix's Chief Scientific Officer, commented that "fortifying the skin's barrier to block such external triggers from passing through the surface of the skin and inducing inflammation is an important alternative approach to alleviating the symptoms of atopic dermatitis and other skin disorders."

The National Institute of Health has recently awarded Dr. Elias a \$1.2 million research grant to study the role of the skin's barrier function in maintaining health. According to Steven Porter, Ceragenix's Chairman and CEO "The submission of our 510(k) application for Epiceram(TM) marks an important milestone in our company's history and we look forward to reporting our progress on this and on other fronts during the months ahead."

### About Ceragenix

Ceragenix is a development stage biopharmaceutical company focused on dermatology and infectious disease. Ceragenix's patented Barrier Repair Technology, invented by Dr. Peter Elias and licensed from the University of California, is the platform for the development of two prescription topical creams- Epiceram(TM) and NeoCeram(TM) that form human-identical skin barriers. Defects in the skin's barrier function play critical roles in the pathogenesis of skin diseases such as eczema, irritant contact dermatitis and other common skin disorders. The Company's patented Cationic Steroid Antibiotic (CSA) technology provides the basis for its novel antimicrobial medical device coating that may be attached to various medical devices to provide potentially long duration antimicrobial activity. Ceragenix also plans to develop CSAs for use as topical and systemic antibiotic therapies in the treatment of skin infections (MRSA), burn wound infections, eye infections and other indications.



### FORWARD-LOOKING STATEMENTS

This press release may contain forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, the following: the Company's ability to raise capital in a timely manner, the ability of the Company to raise sufficient capital to finance its planned pharmaceutical activities, the FDA concurring with the Company that the 510(k) application is the appropriate approval process for Epiceram(TM), the necessary marketing clearance approvals from the FDA, successful clinical trials of the Company's planned products, the Company's ability to commercialize its planned products, market acceptance of the Company's planned products, and the Company's ability to successfully compete in the marketplace. Although management believes that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the forward-looking statements will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements, the information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved. For further information, please see the company's filings with the SEC, including its Forms SB-2, 10-KSB, 10-Q and 8-K. The Company assumes no obligation to update its forward-looking statements to reflect actual results or changes in factors affecting the Company's business.

Source: Business Wire

Ads by Google

**Vega, Dora**

**From:** Vega, Dora  
**Sent:** Friday, October 28, 2005 2:31 PM  
**To:** Luke, Markham C  
**Cc:** Rhodes, Stephen; Hill, Ayanna Y  
**Subject:** FW: Epiceram K052643

FYI

Markham,

I requested additional information regarding the product formulation for Epiceram including the chemical and biological functions of the individual ingredients. I share with you the information they provided.

Regards,  
Dora.

-----Original Message-----

**From:** Carl Genberg [mailto:cgenberg@ceragenix.com]  
**Sent:** Friday, October 28, 2005 2:06 PM  
**To:** dxv@cdrh.fda.gov  
**Cc:** jng@hpm.com  
**Subject:** Epiceram K052643

Dear Dr. Vega,

Thank you for your phone call of Thursday, October 27th. I have attached a document that contains an introductory overview to the formulation of Epiceram as well as the requested Table of Ingredients with corresponding functions. Please advise if you require any additional information.

Sincerely yours,

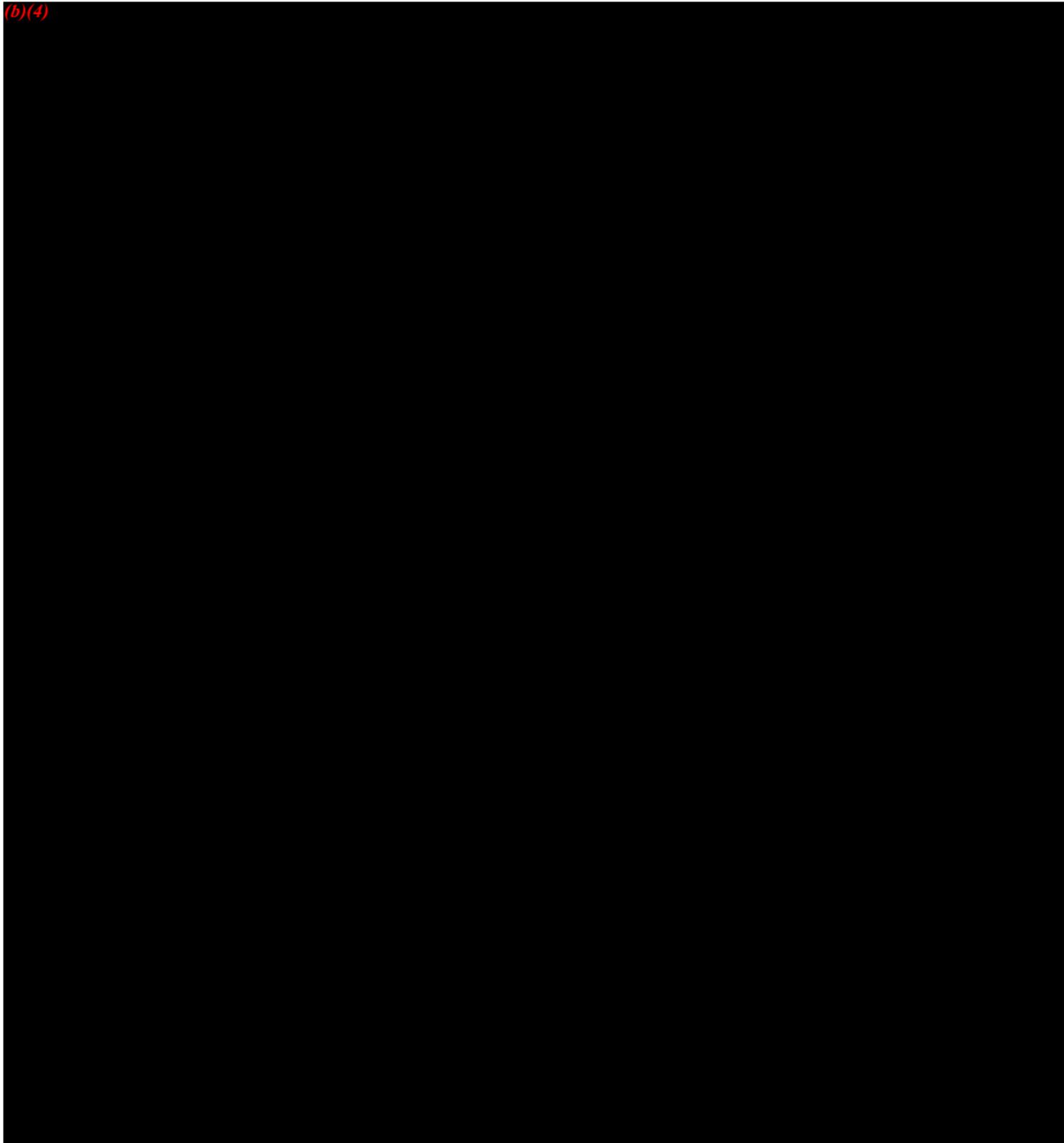
Carl Genberg  
Senior VP R&D  
Ceragenix Pharmaceuticals, Inc.  
cgenberg@ceragenix.com  
(702) 451-0219 (direct line)  
(303) 478-8965 (cell)  
(303) 265-9994 (fax)

10/28/2005

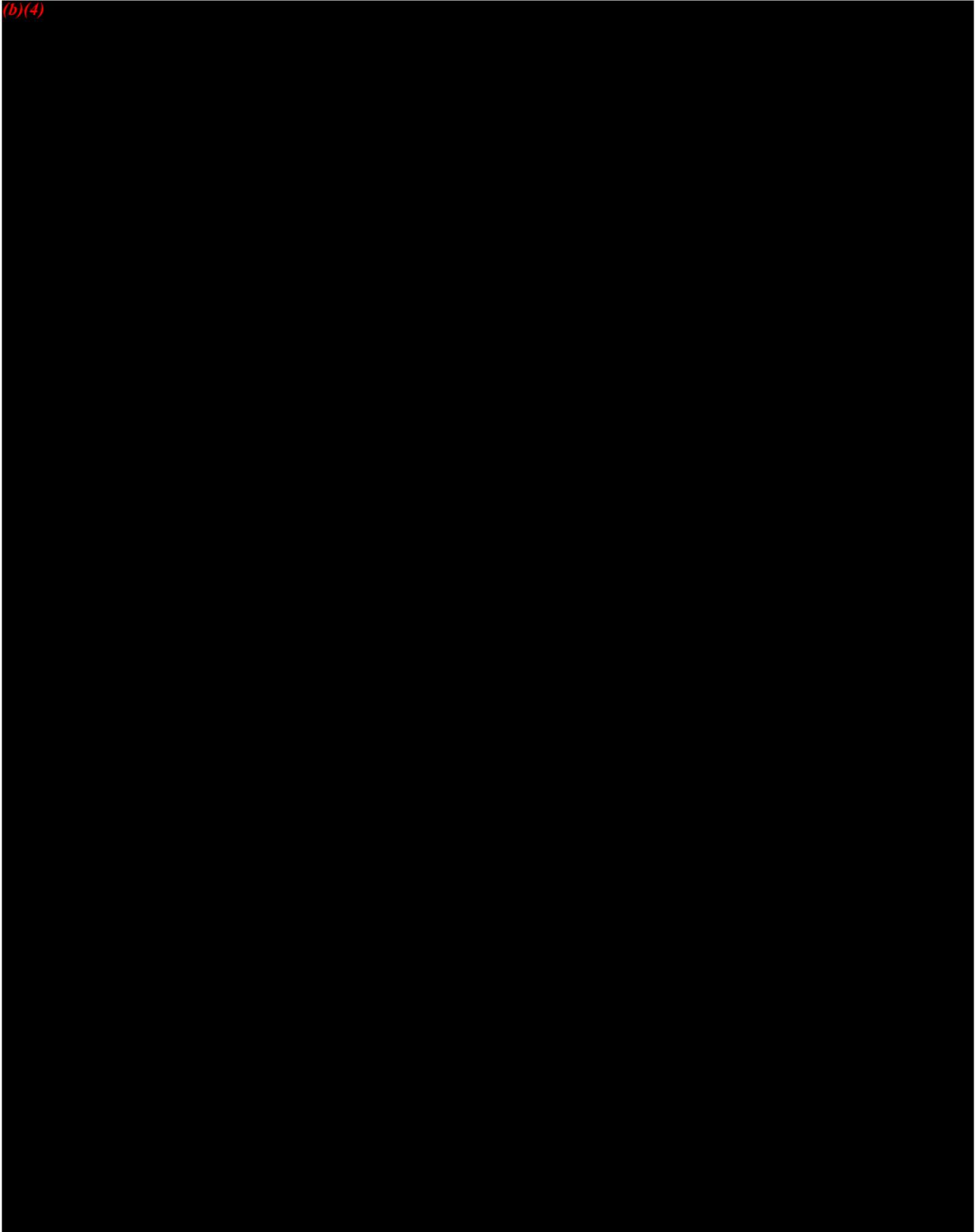
*Additional info requested by Dr.  
(Fernando H. Cohen)*

**EPICERAM™ K052643**  
**STATEMENT OF INGREDIENTS AND FUNCTION**

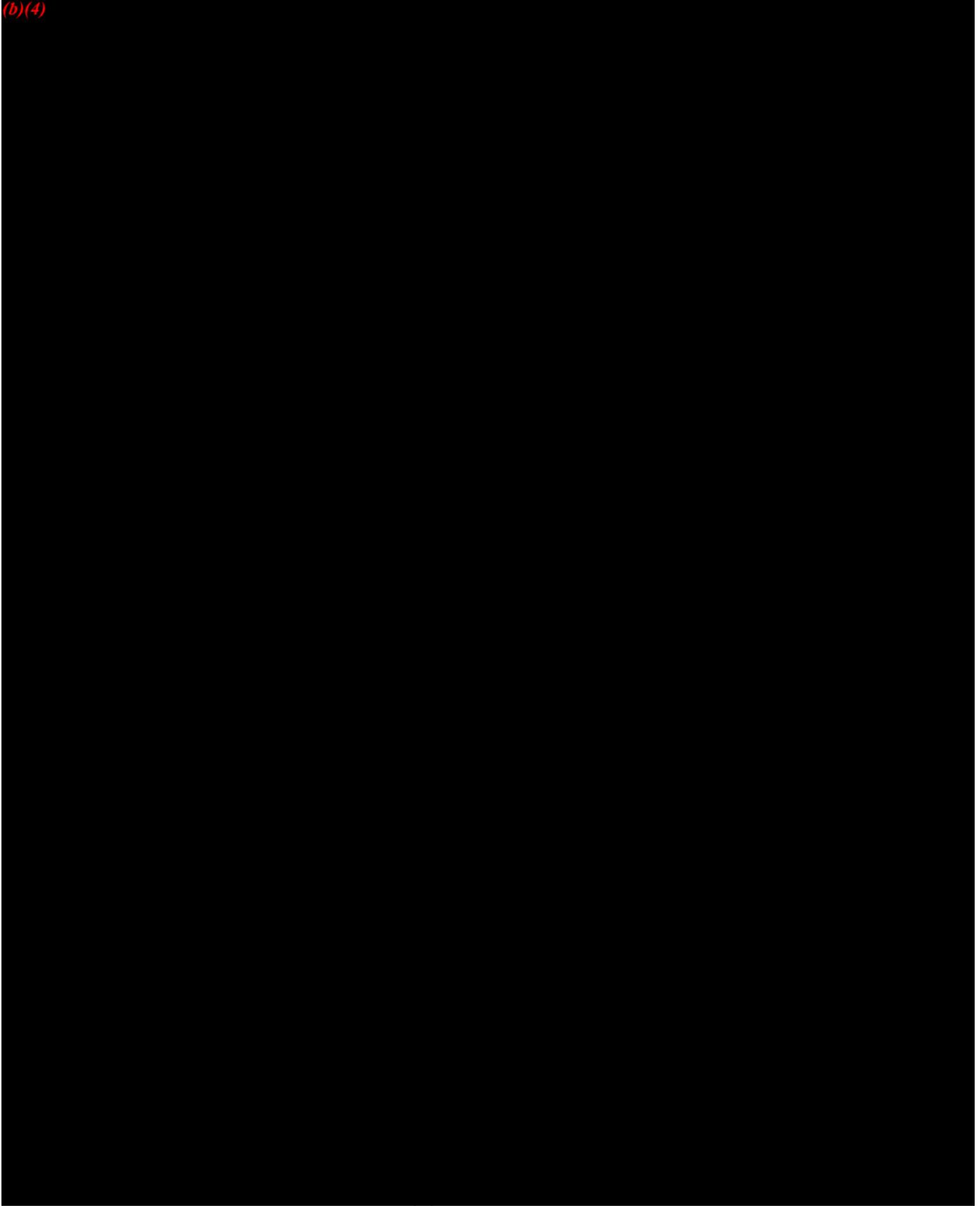
October 28, 2005



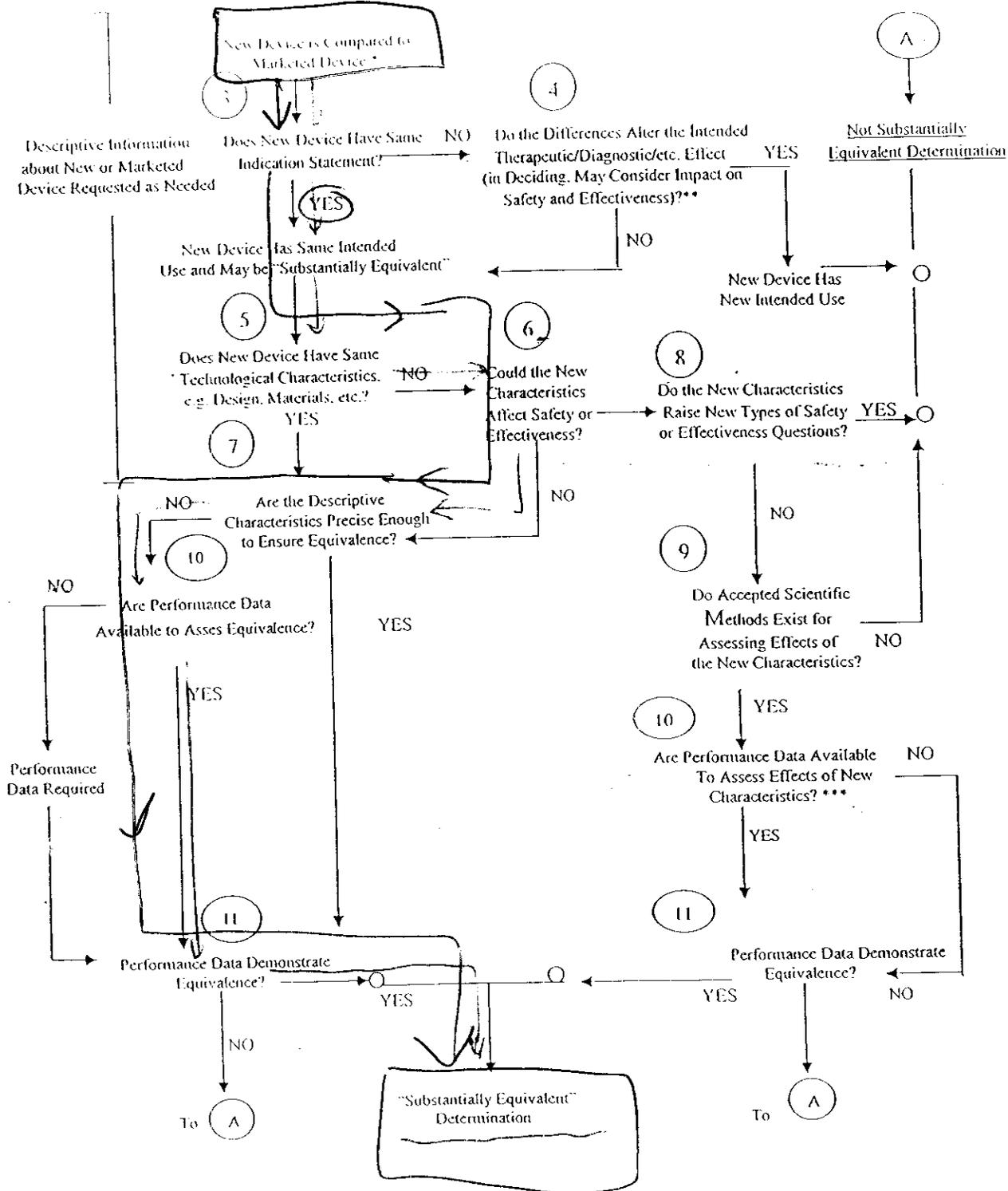
(b)(4)



(b)(4)



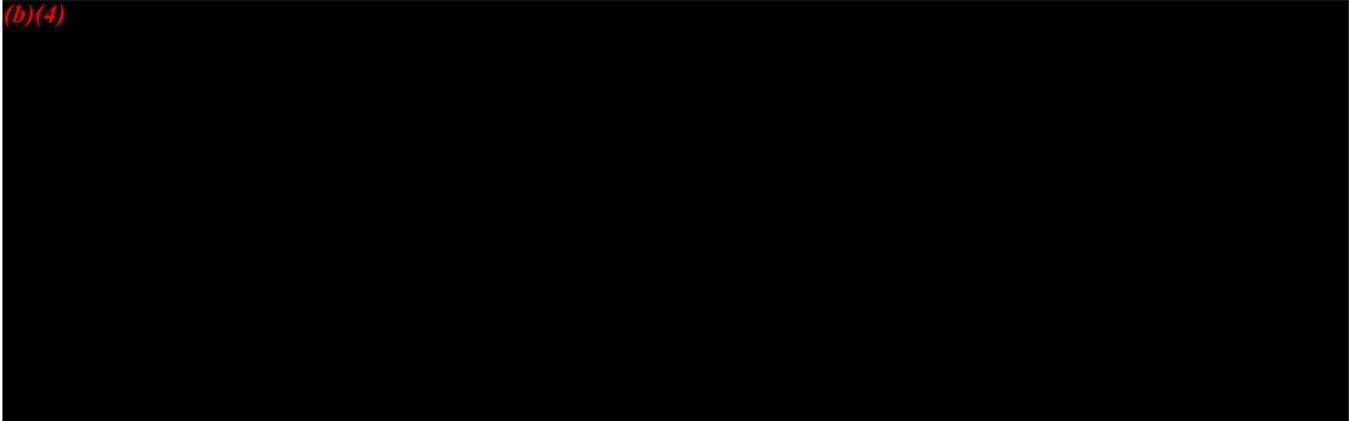
### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- \* 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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**IV. List of Ingredients**

(b)(4)

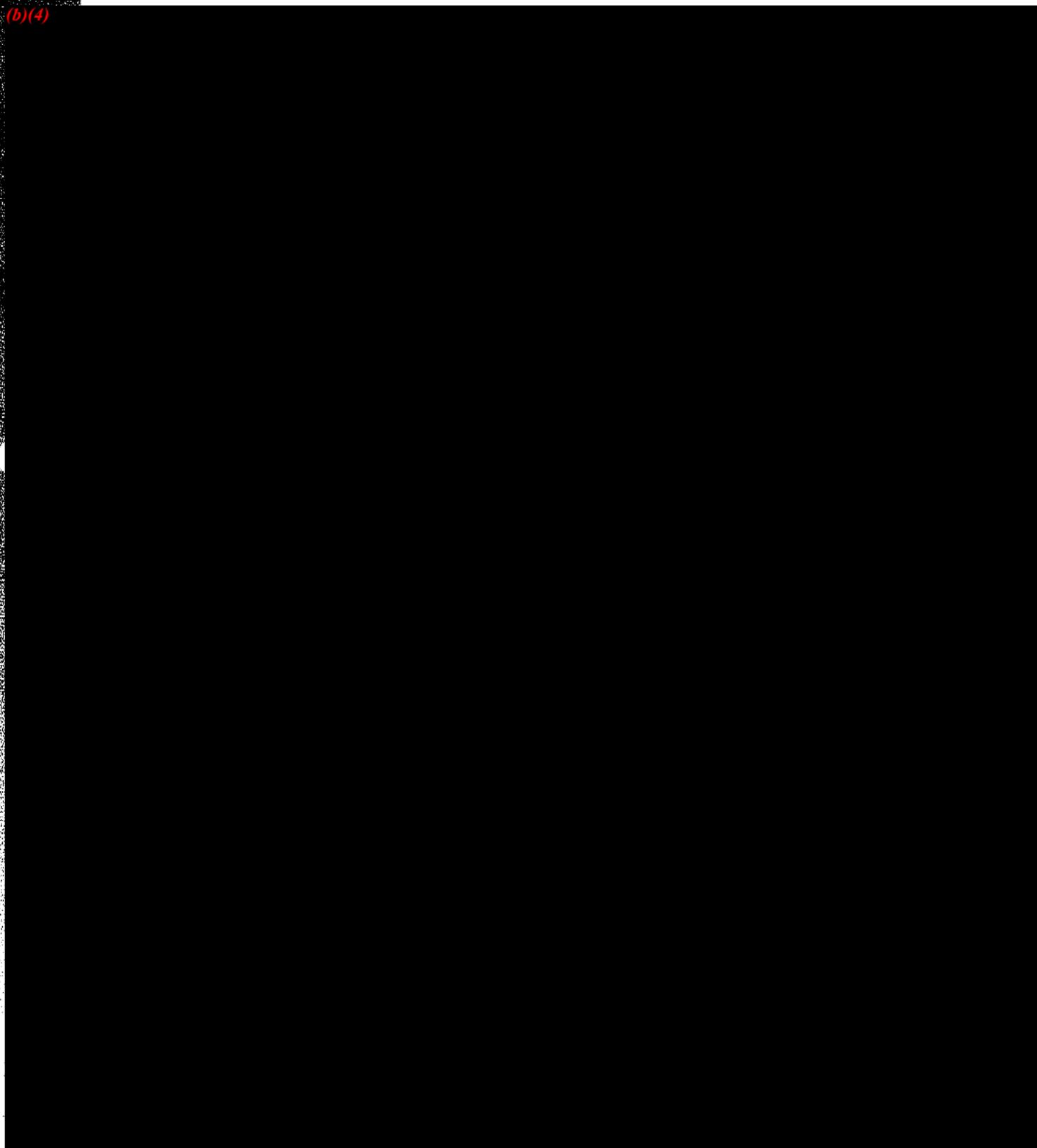


(b)(4)

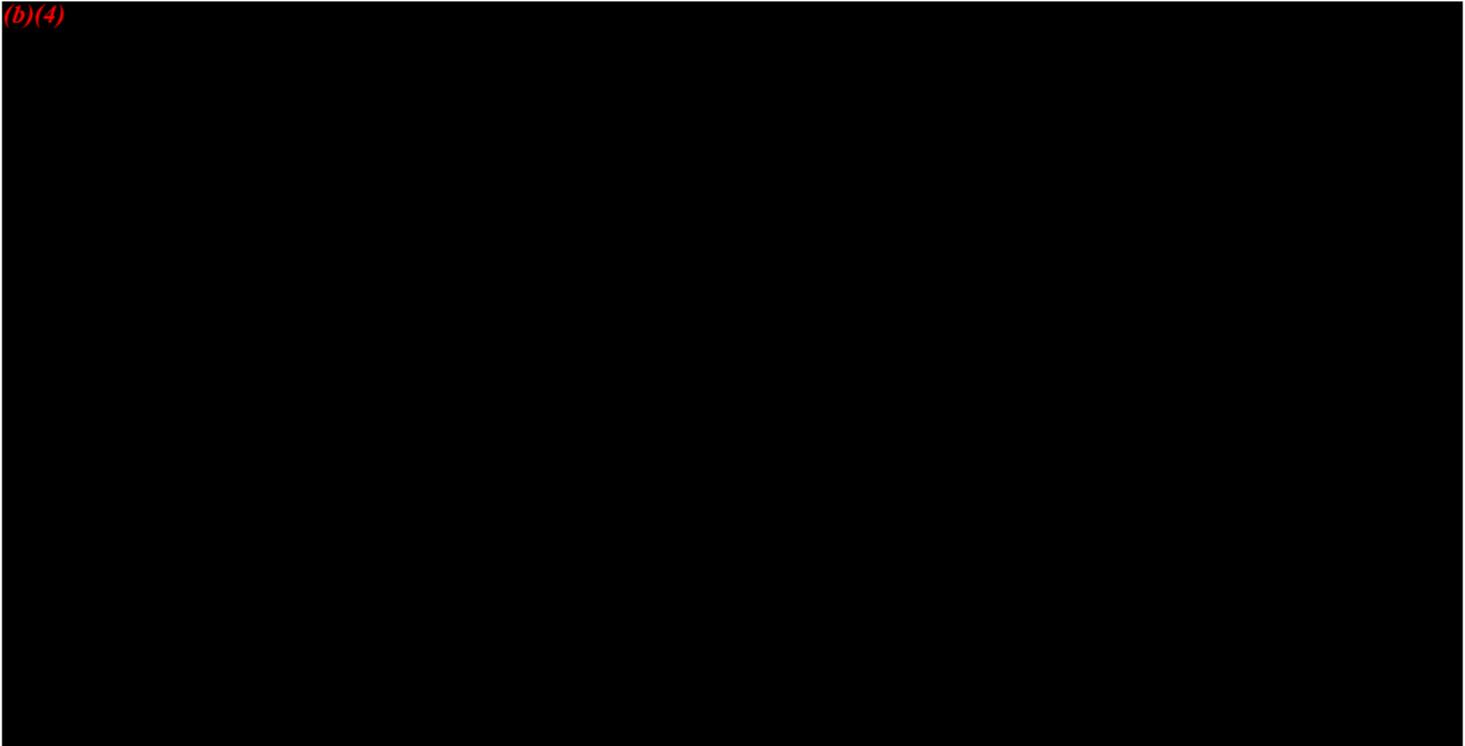
(b)(4)

MICROBIAL LIMITS USP <61> REPORT

(b)(4)



**V. Biocompatibility Testing**



Attachment 6

K024367

510(k) Summary  
JUL 28 2003

December 30, 2002

**1. Submission Applicant & Correspondent:**

Name: Sinclair Pharmaceuticals, Ltd.  
Address: Borough Road  
Godalming  
Surrey  
GU7 2AB  
United Kingdom

Phone No.: 1-972-939-2442  
Contact Person: Michael Killeen

**2. Name of Device:**

**SINCLAIR WOUND AND SKIN EMULSION™**

Trade/Proprietary/Model Name:

**SINCLAIR WOUND AND SKIN EMULSION™**

Common or Usual Name:

Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

Classification Names:

Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

**3. Devices to Which New Device is Substantially Equivalent:**

- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) in 510(k) K964240, from Medix Pharmaceuticals Americas Inc. and
- Carrasyn® Hydrogel Wound Dressing 510(k) K961758, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing.

**4. Device Description:**

**Sinclair Wound and Skin Emulsion** is a non sterile viscous emulsion / gel formulation, which is presented for both Prescription (requires physician diagnosis of disease state) and over-the-counter (OTC) use.

**5. Intended Use of the Device:**

The prescription product requires a physician to diagnose the disease state, while the OTC product is indicated for general symptoms such as burning and itching in minor skin irritations and minor burns. This formulation, when applied to the burn, injured tissue or skin, forms a protective barrier that helps to keep the wound moist.

**6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses.

**7. Tests and Conclusions:**

Functional and performance testing has been conducted to assess the safety and effectiveness of **SINCLAIR WOUND AND SKIN EMULSION™** and all results are satisfactory.

K024367

<b>Attachment 3 - Indications for Use Statement</b>	
<b>510(k) Number</b> NA	
<b>Device Name</b>	<b>SINCLAIR WOUND AND SKIN EMULSION™</b>
<b>Indications for Use</b>	<p style="text-align: center;"><b>FOR TOPICAL DERMATOLOGICAL USE ONLY</b></p> <p><b>Description Rx Product:</b> Under the supervision of a healthcare professional, Sinclair Wound and Skin Emulsion is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis. Sinclair Wound and Skin Emulsion may be used to relieve the pain of first and second degree burns. Sinclair Wound and Skin Emulsion helps to relieve dry waxy skin by maintaining a moist wound &amp; skin environment, which is beneficial to the healing process.</p> <p><b>Directions For Use (Rx and OTC):</b> Apply <b>Sinclair Wound and Skin Emulsion</b> to the affected skin areas 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover <b>Sinclair Wound and Skin Emulsion</b> with a dressing of choice.</p> <p><b>Description OTC Product:</b> Sinclair Wound and Skin Emulsion helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation. Sinclair Wound and Skin Emulsion may also be used to soothe minor burns, including sunburn.</p>
PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED	
Concurrence of CDRH, Office of Device Evaluation (ODE)	
<p><u>Miriam C. Provost</u> (Division Sign-Off) Division of General, Restorative and Neurological Devices</p>	
Prescription Use (per 21 CFR 801.109)	510(k) Number <u>K024367</u> OR Over-The Counter Use _____

Sinclair Pharmaceuticals Ltd  
K024367

510(k) Submission for Sinclair Wound and Skin Emulsion

**INDICATIONS FOR USE STATEMENT**

Page 1 of 1

**510(k) Number:**           **K052643**

**Device Name:**            **EPICERAM™ Skin Barrier Emulsion**

**Indications for Use:**

EPICERAM® is a skin barrier emulsion to be used to treat xerotic skin conditions by reducing excessive transepidermal water loss through the outer layers of the skin and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X                             OR           Over-the-Counter Use           

(Per 21 C.F.R. § 801.109)

## Table Of Substantial Equivalence

INTENDED USE	INTENDED USE	INTENDED USE
<p><b>BIAFINE®</b> is intended to be used as a wound dressing for the following indications:</p> <ul style="list-style-type: none"> <li>• superficial wounds</li> <li>• minor abrasions</li> <li>• leg ulcers</li> <li>• donor sites</li> <li>• 1st and 2nd degree burns, including sunburns</li> <li>• for dermal ulcers, including full thickness wounds and pressure sores, consult a physician</li> </ul>	<p><b>CARRASYN®</b> is intended to be used as a wound dressing for the following indications:</p> <ul style="list-style-type: none"> <li>• dressing and management of pressure ulcers stages 1-IV</li> <li>• stasis ulcers</li> <li>• 1st and 2nd degree burns</li> <li>• cuts, abrasions, irritation of the skin</li> <li>• skin conditions associated with peristomal care</li> </ul>	<p><b>DuoDERM® CGF®</b> is intended to be used as a wound dressing for the following indications:</p> <ul style="list-style-type: none"> <li>• dermal ulcers including full thickness wounds</li> <li>– pressure sore management</li> <li>– leg ulcer management</li> <li>– superficial wounds – e.g., minor abrasions</li> <li>• donor sites</li> <li>• 2nd degree burns</li> </ul>
DIRECTIONS	DIRECTIONS	DIRECTIONS
<p>Wash affected area with a suitable wound cleanser or disinfectant. Apply <b>BIAFINE®</b> on and around the affected area and reapply as often as needed. If a gauze dressing is used, the gauze should be moist; apply <b>BIAFINE®</b> in thick layers (1/4 to 1/2 inch thick). <b>BIAFINE®</b> can be washed away with a saline solution without causing damage to the newly formed tissue. <b>BIAFINE®</b> helps to isolate the affected area from harmful germs and external contamination.</p>	<p>Flush wound with a suitable wound cleanser such as Ultra-Klear™ or Cara-Klear™. Apply <b>CARRASYN®</b> Hydrogel Wound Dressing, approximately 1/4" thick, covering involved area including marginal areas. Apply as often as needed. If gauze is used as a wound dressing, it should be moistened. Either Ultra-Klear™ or Cara-Klear™ is the recommended moistening agent.</p>	<p>Preparing and cleansing the wound site: <b>DuoDERM® CGF®</b> dressings are sterile and should be handled appropriately. Choose a dressing that will extend at least 1/2" beyond the wound margin. Cleanse the wound according to hospital practice, irrigate with saline and dry the surrounding skin to ensure it is free of any greasy substance. Use of the dressings help facilitate the liquefaction and removal of dead tissue however, eschar that is particularly thick or fused to the wound margins should be removed prior to application of the dressing.</p>
INGREDIENTS	INGREDIENTS	INGREDIENTS
<p>Purified water, liquid paraffin, Ethylene glycol (Seacate), Stearic Acid, Propylene glycol, Paraffin wax, Squalene, Avocado oil, Troloxamine/Sodium Alginate, Triethanolamine, Cetyl palmitate, Methylparaben (sodium salt), Sorbic acid (as potassium salt), Propyl paraben (sodium salt), Fragrance</p>	<p>Purified Water, Polyvinylpyrrolidone, Panthenol, Carbomer 940, Triethanolamine, Glutamic Acid, Methylparaben, Sodium Chloride, Imidazolidinyl Urea, Sodium Benzoin, Potassium Sorbate, Sodium EDTA, Acemannan Hydrogel, Citric Acid (may be added for pH adjustment, Sodium Metabisulfite</p>	<p>Ingredients unidentified in 510(k).</p>
CONTRAINDICATIONS	ADVERSE REACTIONS	CONTRAINDICATIONS
<p>On skin rashes related to food or medicine allergies and when an allergy to one of the ingredients is known.</p>	<p>Sensitivity to <b>CARRASYN®</b> Hydrogel Wound Dressing is infrequent. If a reaction is observed, discontinue use and consult a physician. If healing seems to stop, it may be related to a nutritional deficiency, especially vitamins C &amp; E &amp; zinc. Consult a physician for assistance with wounds that do not heal normally.</p>	<p>Use on patients with known sensitivity to <b>DuoDERM® CGF®</b> Dressing.</p>

<sup>1</sup> **BIAFINE®** is substantially equivalent to the **DuoDERM®** hydrogel which impregnates the gauze.

WARNING	WARNING	PRECAUTIONS
<p><b>BIAFINE®</b> does not contain a sun screen and should not be used prior to exposure to the sun. Do not use on bleeding wounds until bleeding has been stopped. For dermal ulcers, including full thickness wounds and pressure sores, consult a physician. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and all similar products out of the reach of children. Follow directions for use. If condition does not improve in 10 to 14 days, consult a physician.</p>	<p>If condition worsens or does not improve within 10 to 14 days consult a physician. Keep this and all similar products out of the reach of children.</p>	<p>When used on Dermal Ulcers:</p> <ol style="list-style-type: none"> <li>1. Initial use of this product should be under the direction of a health professional.</li> <li>2. DuoDERM® CGF® Dressings only provide local management of the wound site. In pressure sore care, other aspects such as repositioning of the patient and nutritional support should not be neglected. In leg ulcer care, lack of adequate rest in patients with vascular (arterial or venous) insufficiency can increase the amount of local edema and hinder potential healing.</li> <li>3. Increased Wound Size: Deeper tissue damage may have already occurred under an apparent superficial dermal ulcer. When using any occlusive dressing in the presence of necrotic material, the wound may increase in size and depth during the initial phase of management as the necrotic debris is cleaned away. Leg ulcers resulting from vasculitis may rapidly deteriorate during exacerbation of the underlying disorder.</li> </ol> <p><b>Odor:</b> Wounds, particularly those that are large or necrotic, are often accompanied by a disagreeable odor; however, this is not necessarily indicative of infection. The odor should disappear when the wound is cleaned (see infection).</p> <p><b>Infection:</b> If signs of clinical infection should develop, such as uncharacteristic odor or change in the color of the exudate, fever or cellulitis (tenderness and erythema in the area of the wound), a bacterial culture of the wound site should be taken. If clinical signs of infection are present, appropriate medical treatment should be initiated. DuoDERM® dressings may be continued during the treatment at the discretion of the clinician.</p> <p><b>Third Degree Burns:</b> The use of DuoDERM® CGF® dressings on full thickness burns has not been evaluated.</p> <p><b>Granulation:</b> Excessive granulation tissue may develop in some wounds when using "occlusive" dressings.</p>

(b)(4)

Rx only.  
NDC XXXX-XXXX-XX

# EPI CERAM™

Skin Barrier Emulsion

Store at 15°C to 30°C (59°F to 86°F).  
Do not freeze.  
For topical dermatological use only.

Epiceram is a skin barrier emulsion to be used to treat xerotic skin conditions reducing transepidermal water loss through the outer layers of the skin and to manage and relieve the burning and itching experienced with various types of dermatoses. Including atopic dermatitis, allergic irritant contact dermatitis, radiation dermatitis and xerosis.

**Directions:** Wash affected area with a suitable cleanser. Apply Epiceram on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist; apply Epiceram in a layer 1mm thick for each square centimeter of skin surface area. In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

**Ingredients:** Calcium Stearate, Capric Acid, Ceramide, Cetyl Alcohol, Cholesterol, Carboxylated Linoleic Acid, Euphorbia Cerifera Wax, Decanoic Acid, Disodium EDTA, Food Starch Modified Corn Syrup Solids, Glycerin, Glyceryl Stearate, Hydroxypropyl Bisphalmitamide MEA, Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxethanol, Phosphoric Acid, Potassium Hydroxide, Squalane, Water.

**Contraindications:** when an allergy to one of the ingredients is known.

**Warnings:** Epiceram does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. In radiation dermatitis and/or in conjunction with ongoing radiation therapy apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary stinging sensation may occur (10 to 15 minutes). Keep this and similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

See package insert for full discussion of Indications, directions, contraindications and warnings.

Distributed by: Ceramide Corp., Denver, CO 80202  
Manufactured by: Topiderm Inc., Amityville, NY 11701

Expiration Date: 2 years from date of manufacture.  
Date of Manufacture:

(b)(4)

(b)(4)

(b)(4)



**INSERT**

**BIAFINE®**

Wound Dressing Emulsion. For Topical Application Only

**PRODUCT DESCRIPTION**

BIAFINE® is a water-based wound dressing emulsion formulated to assist the healing process of dermal wounds. When applied properly to a wound, BIAFINE® provides an optimum moist environment for the healing process and isolates the wound from bacterial and other external contamination

**INDICATIONS FOR USE**

- BIAFINE® is indicated for use in:
  - Minor Abrasions
  - Superficial Wounds
  - Full Thickness Wounds, Pressure Sores, Dermal Ulcers including lower leg ulcers
  - 1st and 2nd Degree Burns, including Sunburns and Radiation Dermatitis
  - Dermal Donor and Graft Site Management

**CONTRAINDICATIONS**

- A known allergy to one of the ingredients in BIAFINE™.

**WARNINGS**

- In radiation dermatitis and/or in conjunction with ongoing radiation therapy, do not apply BIAFINE® to the radiation treatment area within 4 hours prior to a radiation session. BIAFINE® should be applied immediately following radiation sessions (see Instructions for Use in Radiation Dermatitis).
- Do not apply BIAFINE® to dermal grafts until after the graft has successfully taken.

**PRECAUTIONS AND OBSERVATIONS**

- For the treatment of any dermal wound, consult a physician. Use BIAFINE® only as directed.
- BIAFINE® is non-toxic, however it is for external use only and should not be ingested or taken internally
- BIAFINE® does not contain a sunscreen and should not be used prior to exposure to the sun.
- Do not use on bleeding wounds until the bleeding has been stopped.
- The use of BIAFINE® on skin rashes due to allergies has not been studied sufficiently and is therefore not recommended.

- After application, a temporary tingling sensation may occur (10 to 15 minutes).
- If clinical signs of infection are present, appropriate anti-bacterial treatment should be initiated. Use of BIAFINE® must be continued during the anti-infective therapy.
- If condition does not improve within 10 to 14 days, consult a physician.
- Keep this and all similar products out to the reach of children.

## INSTRUCTIONS FOR USE

### 1st and 2nd Degree Burns, Including Sunburns

- Take precaution in removing any clothing near the affected area.
- Apply BIAFINE® as soon as possible, on and around the affected area, in a thick ¼ to ½ inch layer until the skin no longer absorbs the product. A white, waxy residue will remain. If pain from the burn persists, apply thinner layers of BIAFINE™ until the pain has ceased.
- Continue to apply BIAFINE® until the affected area has healed completely. Application of BIAFINE® to the affected area should continue during any subsequent physical therapy treatments

### Wounds, Abrasions, Full Thickness Wound and Dermal Graft Site Management

- Wash affected area with saline, clean water, a suitable wound cleanser, or a disinfectant.
- Apply BIAFINE® on and around the affected area in thick layers, ¼ to ½ inch thick.
- If a gauze dressing is to be used, the gauze should be moistened.
- Reapply BIAFINE® as described above every 24 to 48 hours or until the wound or lesion has healed fully
- For Donor Sites: Apply BIAFINE® after skin removal and cover with a moist dressing. Leave for 7 days.
- For Dermal Grafts: Apply BIAFINE® to the graft site only after the graft has taken successfully.
- BIAFINE® can be washed away with a saline solution or clean water without causing damage to the newly formed tissues.

### Radiation Dermatitis

- Apply a generous amount of BIAFINE®, three times per day to the treated area, gently massaging the area until BIAFINE® is completely absorbed. A white, waxy residue will remain.
- Do not apply BIAFINE® to the treatment area within 4 hours prior to a radiation session (see Warnings). Apply BIAFINE® following the session and twice more during the day.
- Continue to apply BIAFINE® as described above until the skin has fully recovered. Consult your radiation therapist.

## INGREDIENTS

BIAFINE® contains purified water, liquid paraffin, ethylene glycol (stearate), stearic acid, propylene glycol, paraffin wax, squalene, avocado oil, trolamine/sodium alginate,

triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (as potassium salt), propyl paraben (sodium salt) fragrance.

**HOW SUPPLIED**

BIAFINE® Wound Dressing Emulsion is available in 3.3 oz. (93 g), lined tubes. 48 tubes per case.

Manufactured for:  
Medix Pharmaceuticals Americas, Inc.  
1800 M Street, N.W. Suite 450  
Washington, D.C. 20036

Manufactured by:  
Laboratoire Médix, S.A.  
18. rue Saint-Mathieu  
78550 Houdan, France

# EPICERAM™

Skin Barrier Emulsion

**For Topical Dermatological Use Only**

**Rx only**

## PRODUCT DESCRIPTION

EPICERAM™ is a skin barrier emulsion to be used to treat xerotic skin conditions reducing transepidermal water loss through the outer layers of the skin and to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic irritant contact dermatitis, radiation dermatitis and xerosis.

## INDICATIONS FOR USE

EPICERAM™ is specially formulated to treat xerotic skin conditions by reducing excessive transepidermal water loss and to provide a favorable environment to allow the natural healing process to occur.

## CONTRAINDICATIONS

When an allergy to one of the ingredients is known.

## WARNINGS

Epiceram does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. In radiation dermatitis and/or in conjunction with ongoing radiation therapy apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

## PRECAUTIONS AND OBSERVATIONS

For the treatment of any dermal wound, consult a physician.

- ~ Use EPICERAM™ Skin Barrier Emulsion only as directed.
- ~ EPICERAM™ Skin Barrier Emulsion is non-toxic, however it is for external use only and should not be ingested or taken internally.
- ~ If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of EPICERAM™ Skin Barrier Emulsion may be continued during the anti-infective therapy.
- ~ If condition does not improve within 10 to 14 days, consult a physician.
- ~ EPICERAM™ Skin Barrier Emulsion does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas.
- ~ In radiation dermatitis and/or in conjunction with ongoing radiation therapy, apply following radiation therapy.
- ~ Do not apply within 4 hours prior to radiation therapy.
- ~ Apply twice daily or as indicated by the radiation therapist.
- ~ Following the application of EPICERAM™ Skin Barrier Emulsion a temporary tingling sensation may occur (10 to 15 minutes).
- ~ Keep this and other similar products out of the reach of children.

## INSTRUCTIONS FOR USE

Wash affected area with a suitable cleanser. Apply Epiceram on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist; apply Epiceram in a layer 1mm thick for each square centimeter of skin surface area. In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

## INGREDIENTS

Carbomer, Capric Acid, Ceramide, Cetyl Alcohol, Cholesterol, Conjugated Linoleic Acid, Euphorbia Cerifera Wax, Decanoic Acid, Disodium EDTA, Food Starch Modified Corn Syrup Solids, Glycerin, Glyceril Stearate, Hydroxypropyl Bispalmitamide MEA, Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Phosphoric Acid, Potassium Hydroxide, Squalane, Water.

## HOW SUPPLIED

EPICERAM™ Skin Barrier Emulsion is available in a 50 g tube, NDC XXXX-XXXX-XX

Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

Distributed by: Ceragenix Corp., Denver, CO. 80202      Manufactured by: Topiderm Inc., Amityville, NY. 11701

**Rx ONLY - Prescription Medical Device; Federal law restricts this device to sale by or on the order of a physician.**

**USE BIAFINE<sup>®</sup> FOR THORACIC RADIATION THERAPY INDUCED SKIN REACTIONS PICTURED BELOW**

**CLINICAL STUDY Bibliography/Commentary**

**Pending Clinical Studies**

Study: RT0G Protocol #99-13 "A Phase 3 Comparison of BIAFINE<sup>®</sup> for Radiation Induced Skin Toxicity in Patients Undergoing Radiation Therapy for Advanced Squamous Cell Carcinomas of the Head & Neck".

Commentary: A three arm protocol designed to demonstrate the prophylactic and interventional benefits of BIAFINE<sup>®</sup>, as well as, performance against best standard treatment at each facility tested. 547 patients entered at over 100 radiation centres from 1/1/01 to 4/1/02. Results available Spring 2003.

**Published Clinical Studies**

Study: "A Phase 2 Study Assessing the Effectiveness of Biafine Cream as a Prophylactic Agent for Radiation-Induced Acute Skin Toxicity to the Breast in Women Undergoing Radiotherapy with Concomitant CMF Chemotherapy", Int. J. Radiation Oncology Biol. Phys., Vol. 51, No. 1, pp. 81-86, 2001.

Commentary: 80% of Patients not treated with BIAFINE<sup>®</sup> developed confluent moist desquamation so severe that several required interruption of radiation therapy until the acute radiation dermatitis subsided. Patients treated prophylactically from simulation with BIAFINE<sup>®</sup> required no treatment delays or interruptions and the grade 2 toxicity patients degree of moist desquamation was radically reduced to what is described in the study as "a little blistering".

**For additional product information, case histories and to request clinical studies please visit our website at [www.BIAFINE.com](http://www.BIAFINE.com)**



**YOUR PARTNER IN HEALING**

MEDIX PHARMACEUTICALS AMERICAS, INC.  
12505 Starkey Road, Suite M, Largo, FL 33773  
Phone: (727) 507-9844 FAX: (727) 507-9855  
1-888-BIAFINE (242-3463)

**REDNESS & ERYTHEMA**



Before BIAFINE<sup>®</sup>



After BIAFINE<sup>®</sup>

**DRY DESQUAMATION**



Before BIAFINE<sup>®</sup>



After BIAFINE<sup>®</sup>

**MOIST DESQUAMATION**



Before BIAFINE<sup>®</sup>



After BIAFINE<sup>®</sup>

BIAFINE<sup>®</sup> is an Rx Only medical device available on the order of a physician or properly licensed practitioner.

**BIAFINE<sup>®</sup> RE**  
Radiodermatitis Emulsion

Take Action Against Reactions<sup>®</sup>



**Helps Prevent and Manage Skin Reactions**

**Provides Deep Dermal Hydration**

**Soothing and Cooling on Application**

F-7

# how BIAFINE® works

## PROTECTION AGAINST REACTIONS

### PROVIDES DEEP DERMAL HYDRATION

BIAFINE® is an excellent moisturizer. Within the first hour of application an equilibrium is achieved in which 41% of the hypo-tonic water content of BIAFINE® is drawn deep into the dermal layer of the skin.

### SOFTENS SKIN

The emollient action of BIAFINE® keeps skin supple, elastic and intact minimizing skin breakdowns throughout radiation treatment sessions.

### REPLENISHES NATURAL SKIN BARRIER FUNCTION

Skin barrier/gate keeper function is important for regulating trans-epidermal water loss (TEWL). If the skin's lipid content drops, TEWL increases. BIAFINE® strengthens skin's lipid/fatty acid composition with Stearic Acid and emollients, gate keeper function is increased, leading to increased skin moisture & ultimate homeostasis.

## DOES NOT INTERFERE WITH TREATMENTS

BIAFINE® is quickly absorbed into the skin, it does not induce a bolus effect or interfere with radiation treatments in any way if applied four hours prior to a radiation treatment session.

## MANAGEMENT OF REACTIONS

### ERYTHEMA & REDNESS

BIAFINE® induces a cooling effect, reducing redness and irritation. Refrigerate BIAFINE® to maximize its cooling effect.

### DRY DESQUAMATION

BIAFINE® moisturizes the skin. Reducing chafing and irritation. Apply BIAFINE® generously to maximize its moisturizing effect.

### MOIST DESQUAMATION

BIAFINE® is chemotactic for macrophages when applied to broken skin/dermis, selectively recruiting macrophages 3-10 x the normal amount by actively increasing the IL1/IL6 ratio. Rapid fibroblast proliferation, granulation, epithelialization and wound closure result.

# formulation

## INGREDIENTS

Demineralized Water  
 41% penetrates to the skin's dermal level within 1 hour of application  
 Liquid Paraffin  
 Protective barrier against skin maceration  
 Monoglycol Stearate  
 Emollient properties maintain healthy skin  
 Stearic Acid  
 Replenishes skin's natural barrier function  
 Propylene Glycol  
 Maintains emulsion properties  
 Paraffin Wax  
 Ensures consistency of the emulsion  
 Squalene  
 Healing, moisturizing and stimuli protection  
 Avocado Oil  
 Natural lipid protects and regenerates the skin  
 Triolamine/Sodium Alginate  
 Used to stimulate macrophage proliferation  
 Triethanolamine  
 Maintains the proper pH balance  
 Cetyl Palmitate  
 Surfactant with emollient properties  
 Methylparaben  
 Product base preservative  
 Sorbic Acid  
 Assists in maintaining pH balance  
 Propylparaben  
 Product preservation with anti-fungal properties  
 Yerbatone  
 Masks odors associated with skin breakdowns

# instructions

## APPLICATION INSTRUCTIONS

### Protection Against Reactions

Gently massage BIAFINE® into the irradiated area, three times per day, seven days per week

Begin applications immediately following first radiation session

Do not apply BIAFINE® four hours prior to a radiation session

### Management of Erythema & Dry Desquamation

Gently massage a generous amount of BIAFINE® on and around the irradiated area, three times per day, seven days per week

Do not apply BIAFINE® four hours prior to a radiation session

### Management of Moist Desquamation

Apply a thick layer (1/4" to 1/2" thick) of BIAFINE® to moistened gauze or any other type of occlusive dressing large enough to cover the entire open wound/moist desquamation area.

Apply the dressing you covered with BIAFINE® as instructed above, BIAFINE® side to the moist desquamation

Renew dressing every 24 hours (after radiation session)

Do not apply BIAFINE® four hours prior to a radiation session

Please visit our website [www.BIAFINE.com](http://www.BIAFINE.com) or call 1-888-BIAFINE

BIAFINE® is available to local pharmacies on special order from their wholesaler within 24-36 hrs

Wholesaler	BIAFINE® 1.65 oz	BIAFINE® 3.3 oz
Amerisource / Bergen	4021762 / 341594	4466959 / 297002
Cardinal Health	2999977	3022498
Mckesson Drug	1458983	2491140
Morris & Dickson	320556	379966
MPA Code #'s	12418-0401-30	12418-0900-20



F-2

**EXHIBIT G****TABLE OF SUBSTANTIAL EQUIVALENCE**

	<b>EPICERAM™ Skin Barrier Emulsion</b>	<b>SINCLAIR Wound and Skin Emulsion</b>	<b>BIAFINE® Wound Dressing Emulsion</b>
<b>Intended Use</b>	EPICERAM™ is a skin barrier emulsion to be used to treat xerotic skin conditions reducing transepidermal water loss through the outer layers of the skin and to manage and relieve the burning, itching and pain experienced various types of dermatoses, including atopic dermatitis, allergic irritant contact dermatitis, radiation dermatitis and xerosis.	SINCLAIR WOUND AND SKIN EMULSION™ is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis. Sinclair Wound and Skin Emulsion may be used to relieve the pain of first and second degree burns. Sinclair Wound and Skin Emulsion helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	BIAFINE® is intended to be used as wound dressing for the following indications: <ul style="list-style-type: none"> <li>• Superficial wounds</li> <li>• Minor abrasions</li> <li>• Leg ulcers</li> <li>• Donor sites</li> <li>• 1<sup>st</sup> and 2<sup>nd</sup> degree burns, including sunburns</li> <li>• for dermal ulcers, including full thickness wounds and pressure sores, consult a physician</li> <li>• radiation dermatitis</li> </ul>
<b>Directions</b>	Wash affected area with a suitable wound cleanser or disinfectant. Apply EPICERAM™ on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist; apply EPICERAM™ in a layer 1 mm thick for each square centimeter of skin surface area. In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.	Apply Sinclair Wound and Skin Emulsion to the affected skin areas 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover Sinclair Wound and Skin Emulsion with a dressing of choice.	Wash affected area with a suitable wound cleanser or disinfectant. Apply BIAFINE® on and around the affected area and reapply as often as needed. If a gauze dressing is used, the gauze should be moist; apply BIAFINE in thick layers (1/4 to 1/2 inch thick). BIAFINE® can be washed away with a mild solution without causing damage to the newly formed tissues. BIAFINE® helps to isolate the affected area

	EPICERAM™ Skin Barrier Emulsion	SINCLAIR Wound and Skin Emulsion	BIAFINE® Wound Dressing Emulsion
<b>Ingredients</b>	<b>(b)(4)</b>	None listed in 510(k) Summary. Product is believed to contain various lipids as well as licorice extract.	Purified water, Liquid paraffin, Ethylene glycol (stearate), Stearic Acid, Propylene glycol, Parrafin wax, Squalane, Avocado Oil, Trolamine/Sodium Alginate, Triethanolamine, Cetylal palmitate, Methylparaben (sodium salt), Sorbic Acid (as potassium salt), Propyl paraben (sodium salt), Fragrances.
<b>Contra-indications</b>		Not available from 510(k) Summary.	On skin rashes to food or medicine allergies and when an allergy to one of the ingredients is known.

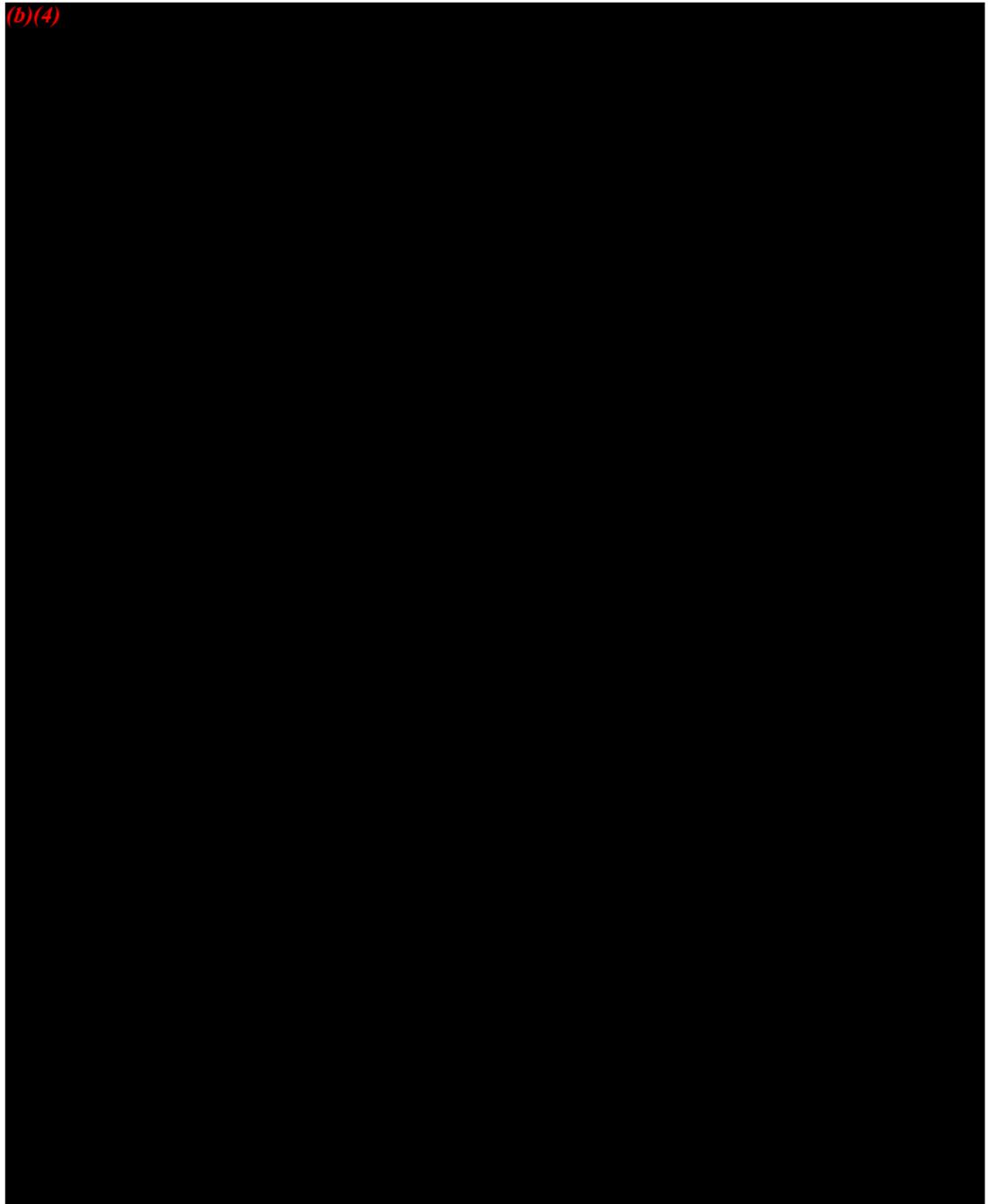
<p><b>Warnings</b></p>	<p><b>EPICERAM™ Skin Barrier Emulsion</b></p> <p>(b)(4)</p>	<p><b>SINCLAIR Wound and Skin Emulsion</b></p> <p>Not available from 510(k) Summary.</p>	<p><b>BIAFINE® Wound Dressing Emulsion</b></p> <p>BIAFINE® does not contain a sun screen and should not be used prior to exposure to the sun. Do not use on bleeding wounds until bleeding has been stopped. For dermal ulcers, including full thickness wounds and pressure sores, consult a physician. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and all similar products out of the reach of children. Follow directions for use. If condition does not improve in 10 to 14 days, consult a physician.</p>
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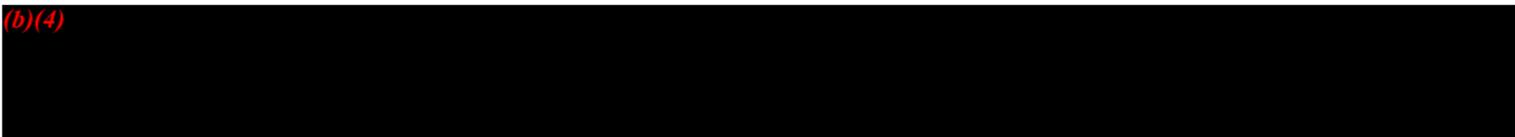
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6.0 Methodology:

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six 4 cm by 4 cm (16 cm<sup>2</sup>) test sites were delineated using a gentian violet surgical skin marker and standard template.

- A) control – untreated intact skin (biological control monitor)
- B) control – untreated site abraded via tape stripping (compromised biological control)
- C) control – intact skin treated with the test material
- D) control – treated site abraded via tape stripping technique (compromised biological control)
- E) eczematous skin – untreated (disease monitor)
- F) eczematous skin – treated with the test product (efficacy evaluation)

The test article was assigned according to a randomized complete block design wherein three sites served as untreated controls while the remaining three sites received treatment of the test material. The test material was applied to the surface of each panelist's forearms and to the eczematous site by a trained technician at a concentration of 1.0 mg/cm<sup>2</sup> and remained in place for a period of six hours.

Biophysical measurements were conducted on the skin surface at time 0 (pre-treatment), and again at three (3) and six (6) hours following a single application of the test material.

#### **Transepidermal Moisture Loss (TEML) – Evaporimeter**

Transepidermal Moisture Loss (TEML) readings of the low level of water that constantly transpires through the skin were instrumentally obtained with a Computerized DermaLab Evaporimeter System, (cyberDERM, Inc., Cortex Technology, Media, Pennsylvania). The DermaLab System has a built-in A/D converter that sends a string of data to the host computer at a rate of 4 lines per second via a direct RS232 connection through a serial interface.

Readings were obtained by placing the probe lightly but uniformly in contact with the skin. A reduction in TEML generally indicates proportionately high film forming characteristics (barrier integrity) of the product.

The environment of the evaluation room was maintained at 22±3°C and 20%-50% relative humidity. Temperature was recorded using an appropriate temperature/humidity recorder. The subjects were allowed to equilibrate in this environment for 15 minutes prior to application.

Table 1

ECZEMA EVALUATION - TEML READINGS -- BASELINE

(b)(4)

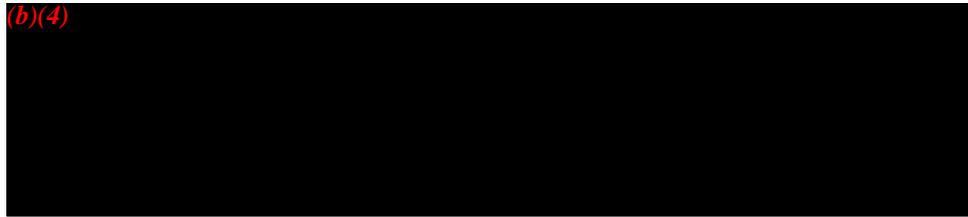
EpiCeram, Lab #

TEML READINGS - BASELINE
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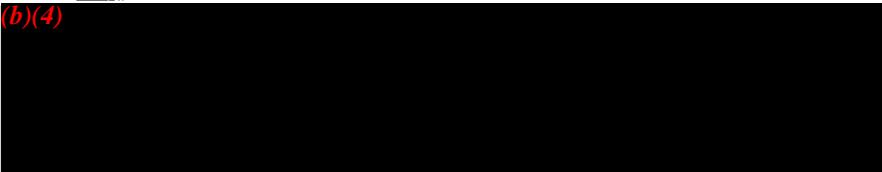
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USE STUDY TO DETERMINE THE ABILITY OF A TOPICALLY APPLIED  
TEST MATERIAL TO PROVIDE RELIEF OF SYMPTOMS  
IN PATIENTS DIAGNOSED WITH ECZEMA

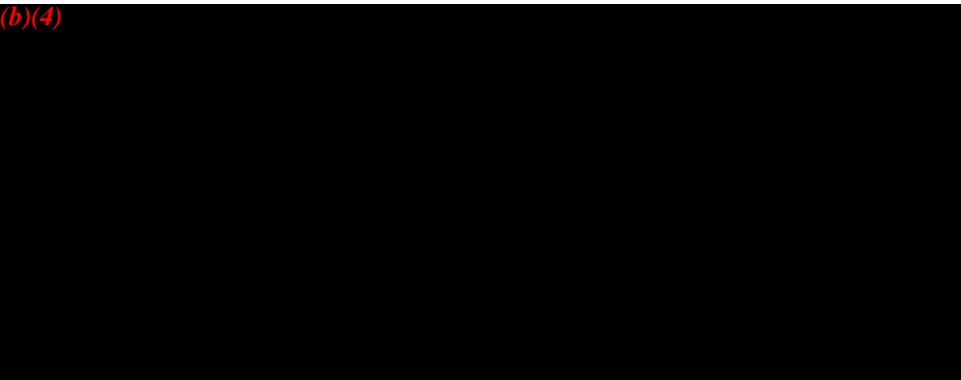
AMA Ref. No.: (b)(4)

Date: (b)(4)

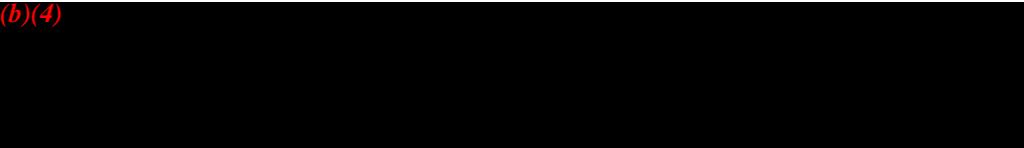


Sponsor: Ceragenix Pharmaceuticals, Inc.  
1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

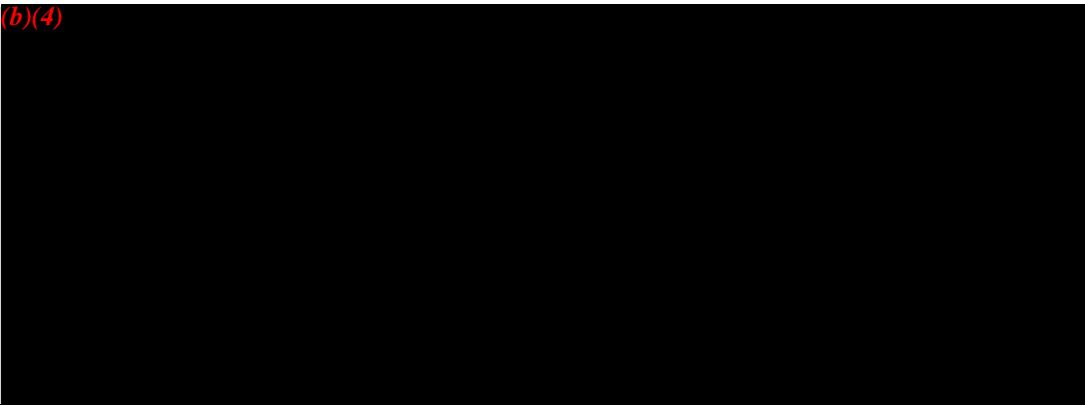
1.0 Objective: (b)(4)



2.0 Sample Description: (b)(4)



3.0 Test Material Handling: (b)(4)



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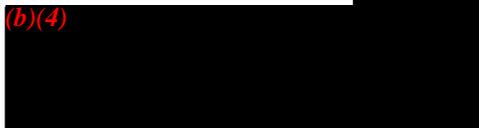


Table 2

(b)(4)

ECZEMA EVALUATION - TEML READINGS -

(b)(4)

EpiCeram, Lab

TEML READINGS - 3 HOURS

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(b)(4)

(b)(4)

Table 3

ECZEMA EVALUATION - TEML READINGS

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(b)(4)

EpiCeram, Lab

TEML READINGS - 6 HOUR EVALUATION

(b)(4)	
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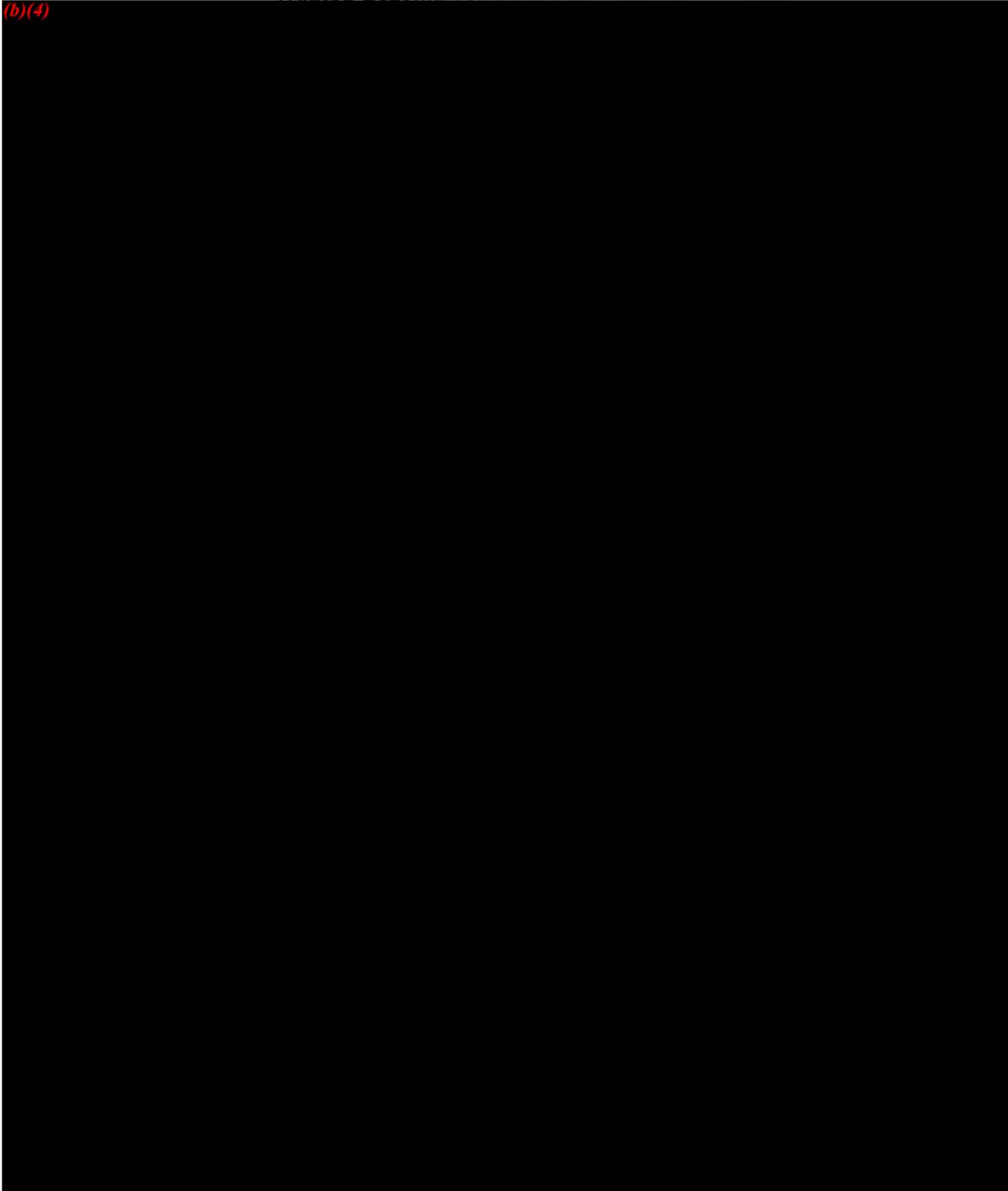
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(b)(4)

Chart 2

TEML % REDUCTION  
Treated Eczema vs. Untreated Eczema

(b)(4)



## 510(k) Summary

### 1. Submission Applicant & Correspondent

Name: Ceragenix Corporation  
Address: 1444 Wazee Street  
Suite 210  
Denver, Colorado 80202

Phone No. (303) 478-8965

Contact Person: Carl Genberg, J.D.

**2. Name of Device:** EPICERAM™ Wound and Skin Barrier Emulsion

Trade/Proprietary/Model Name: EPICERAM™

Common or Usual Name: Wound and Skin Barrier Emulsion

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

### 3. Devices to Which New Device is Substantially Equivalent:

- Sinclair Wound and Skin Emulsion™ - Sinclair Pharmaceuticals, Ltd (K024367, July 28, 2003);
- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) - Medix Pharmaceuticals Americas, Inc. (K964240, Jan. 22, 1997); and
- Carrasyn® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing - Carrington Laboratories, Inc. (K961758, July 11, 1996).

### 4. Device Description:

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use which helps to form a mechanical barrier in the outer layers of the skin to reduce excessive transepidermal water loss.

### 5. Intended Use of the Device:

The device is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve xerotic skin conditions by reducing excessive transepidermal water loss through the outer layers of the skin to relieve and to manage the burning, itching and pain associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

**6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

**7. Tests and Conclusions:**

Functional and performance testing has been conducted to assess the safety and effectiveness of EPICERAM™ Skin Barrier Emulsion and the results are satisfactory.

**ECZEMA CONDITION EVALUATION - ITCH REDUCTION**

EpiCeram, Lab (b)(4)

Table 4  
**VISUAL ANALOG SCALE**

(b)(4)

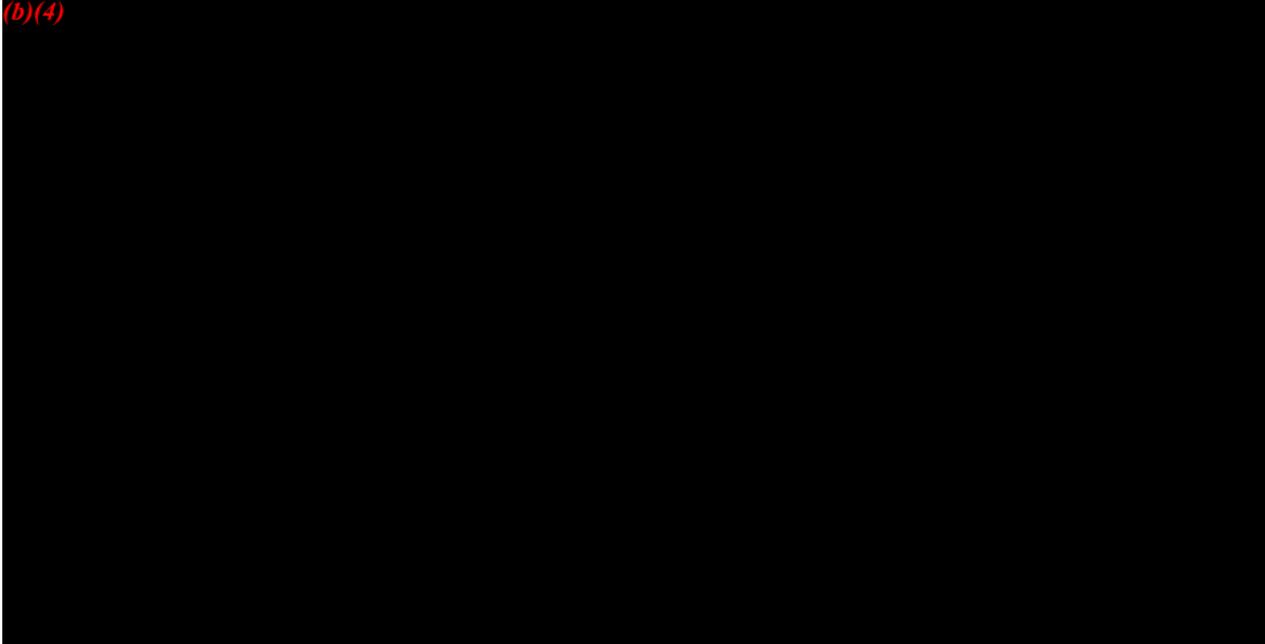
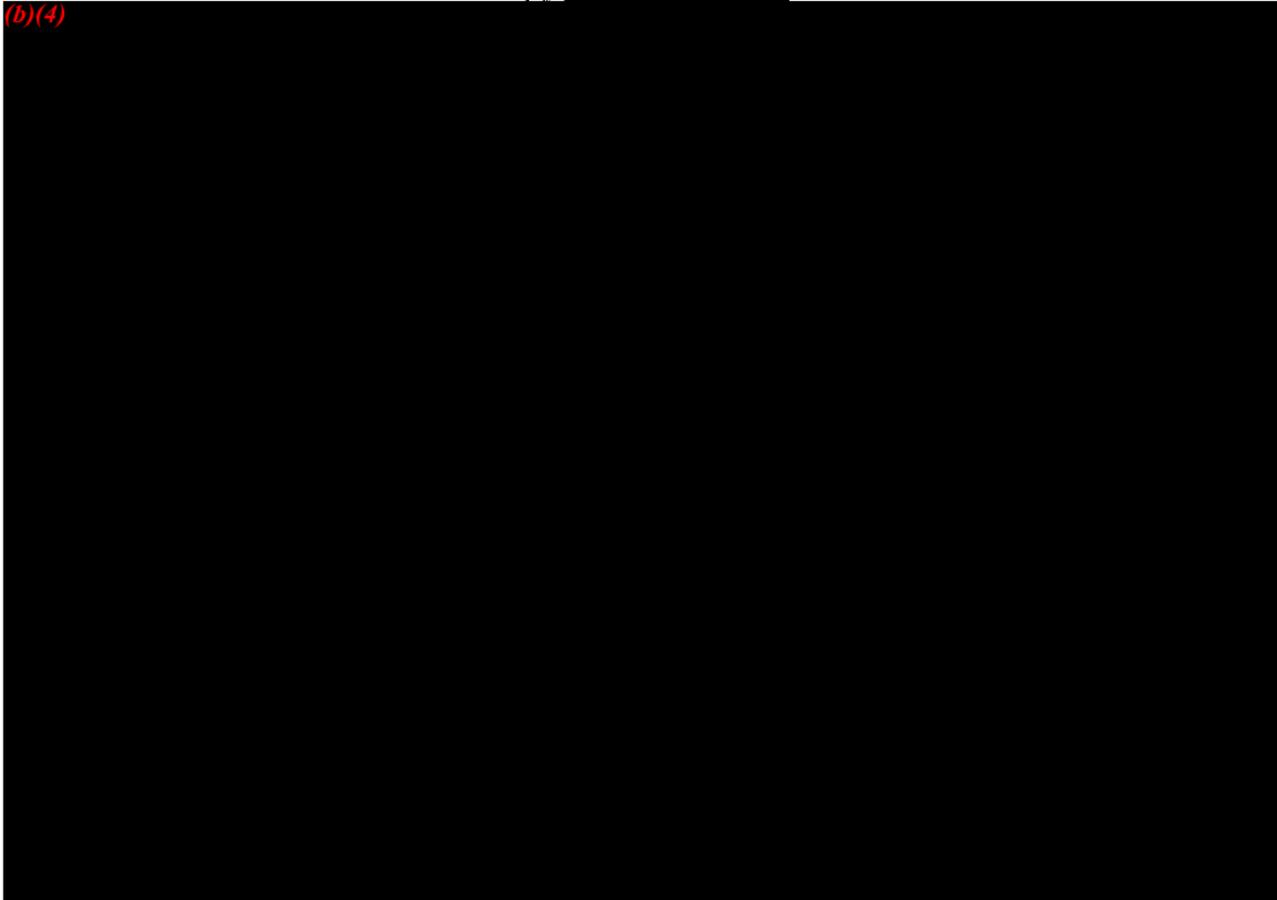


Table 5  
**WONG BAKER SCALE**

(b)(4)



(b)(4)



CERAGENIX PHARMACEUTICALS

Epiceram

(b)(4)



Cytotoxicity Evaluation  
Agar Overlay/L929 Mouse Fibroblast (ISO)

August 5, 2005

(b)(4)



JN05G0751

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TOTAL PAGES IN REPORT: 19

(b)(4)

CERAGENIX PHARMACEUTICALS

Epiceram

(b)(4)

Primary Skin Irritation (USP)  
(GLP)

August 10, 2005

(b)(4)

(b)(4)

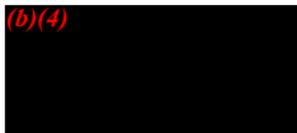


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TOTAL PAGES IN REPORT: 19

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CERAGENIX PHARMACEUTICALS

Epiceram

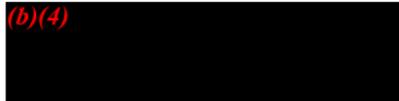
(b)(4)



Primary Skin Irritation (USP) Modified  
(GLP)

August 24, 2005

(b)(4)



(b)(4)

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TOTAL PAGES IN REPORT: 20

(b)(4)



CERAGENIX PHARMACEUTICALS

Epiceram, Lab (b)(4)

Closed Patch Sensitization (ISO 10993)  
(GLP)

September 16, 2005

(b)(4)

(b)(4)

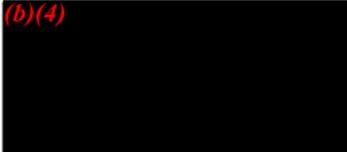


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TOTAL PAGES IN REPORT: 25

**EXHIBIT S**

BOX AND TUBE

(Principal Display Panel)

**EPICERAM™**

*A Ceragenix™ Product®*

Skin Barrier Emulsion for Topical Applications

Prescription Use Only

Manufactured in the United States of America

(box side panel 1)

Distributed by Ceragenix Corporation  
1444 Wazee Street, Suite 210  
Denver, CO 80202  
(720) 946-6440

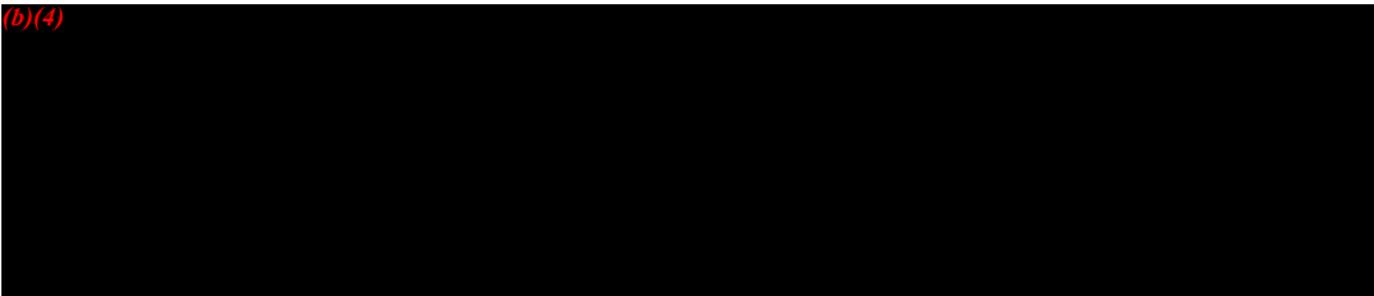
EPICERAM™ is a skin barrier emulsion to be used to treat xerotic skin conditions by reducing excessive transepidermal water loss through the outer layers of the skin and to manage and relieve the burning, itching and pain associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and xerosis.

**DIRECTIONS:** Wash affected area with a suitable wound cleanser or disinfectant. Apply EPICERAM™ on and around the affected area and apply twice daily or as often as needed. If a gauze dressing is used, the gauze should be moist, apply EPICERAM™ in a thin layer (1mg/cm<sup>2</sup>). In the case of radiation dermatitis, apply following radiation therapy (do not apply within 4 hours prior to therapy) and at least twice daily or as indicated by the radiation therapist.

**CONTRAINDICATIONS:** EPICERAM™ is contraindicated when an allergy to one of the ingredients is known.

(box side panel 2)

(b)(4)



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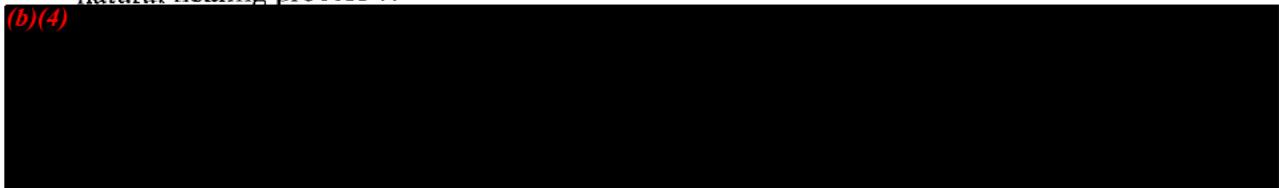
S-1

WARNINGS: EPICERAM™ does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. Do not use on bleeding wounds until the bleeding has stopped. In radiation dermatitis and/or in conjunction with ongoing radiation therapy, apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and all similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

(Back Panel)

EPICERAM™ is specially formulated to treat xerotic skin conditions by reducing excessive transepidermal water loss and to provide a favorable environment to allow the natural healing process to occur.

(b)(4)



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