

510(k) SUMMARY

K 964853

Submitted by:

Mary Ellen Snyder **MAR 31 1997**
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

November 26, 1996

Proposed Device:

IntraVia™ Empty Plastic Container

Predicate Devices:

Viaflex® Empty Plastic Container

Proposed Device Description:

Baxter is currently marketing a line of empty Viaflex® plastic containers used for the preparation and administration of drug admixtures. We propose to change the materials of the container sheeting, administration and medication ports and medication site and market the container under the tradename IntraVia™ Container, Empty.

The primary reason for the change in container materials is to allow a change in sterilization methods from ETO to gamma sterilization. In addition, use of the IntraVia™ container in place of the Viaflex® container offers several benefits including use of standard thermoplastic methods for recycling and reduction in the amounts of environmental contaminants released during incineration of PVC such as hydrochloric acid and dioxins. The material change in the medication site is being made to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed IntraVia™ container is the same in overall design and intended use as the currently marketed Viaflex® container. The IntraVia™ container differs from the Viaflex® container in material composition and sterilization method.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The biological and chemical reactivity of the new container materials have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the proposed empty IV container and its drug compatibility characteristics have been generated. Functional performance studies included residual volume, fill volume, spike insertion/removal force and burst testing. Performance testing indicate that the proposed container meets or exceeds all functional requirements and support its suitability for use.

Drug compatibility studies were conducted with commonly admixed drugs or those that have a high potential to adsorb to the container under representative storage conditions. Results of drug compatibility evaluations support the suitability of the new container for its intended use.

HFZ-480 (B Bolden)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: February 27, 1997
From: CSO, Program Operations Staff, HFZ-404, Office of Device Evaluation, CDRH
Subject: Request for Consultation (Con97.006) on Premarket Notification K964853 IntraVia Empty Container
To: Liz Ortuzar, HFD-6, CDER

Sponsor: Baxter Healthcare Corporation, Round Lake, IL

The referenced sponsor has submitted a premarket notification for the product above. The firm claims that the device is intended to be used for the preparation and administration of drug admixtures, including Doxorubicin, 5-Fluorouracil and Morphine sulfate.

We are requesting CDER's consultative review on the adequacy of the firm's submissions concerning drug absorption, biocompatibility and the answers they submitted in response to our specific questions (see the first six pages of Volume 2). To facilitate the timeliness of our Inter-Center consults, we would like to set-up a tele-conference call with the reviewing and other responsible ODE personnel. This method of handling InterCenter consults is a direct result of a meeting between Dr. Murray Lumpkin, Dr. Susan Alpert and myself. We would like this tele-conference to be scheduled to take place in approximately 30 days, on or about March 31, 1997. Please advise us of the names of the individuals in CDER who should attend this tele-conference and we will schedule it with them directly. Please provide this list by either sending me an EMail message (my symbol is EMB) or calling me at (59)4-1190 by COB March 7th. Thank you.

Eugene M. Berk

Attachment

cc:

HFZ-404(EMBerk)

HFZ-480(BBolden **Note 1:** As part of the agreement we worked out with CDER to expedite our consultation requests, CDRH (meaning the Division representatives from CDRH) will either prepare a memo of teleconference or consider videotaping (or audio taping) the teleconference as documentation of the consult. If a memo of tele-conference or meeting (if the meeting is a face to face meeting with the CDER people located over here at Corporate Blvd.) is prepared, a draft of that memorandum will be sent to CDER for their concurrence. If no comments are received within a reasonable amount of time (let's say 5 working days from the date of the draft of the memo) that will constitute our written documentation of consult.

Note 2: Work with Rob McGeehan regarding the setting up of the tele-conference equipment. His phone # is 44774 Ext. 185.

Drafted:EMBerk:2/27/97



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1997

Ms. Mary Ellen Synder
Regulatory Affairs Manager
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K964853
Trade Name: IntraVia Empty Plastic Container
Regulatory Class: II
Product Code: KPE
Dated: March 14, 1997
Received: March 17, 1997

Dear Ms. Synder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

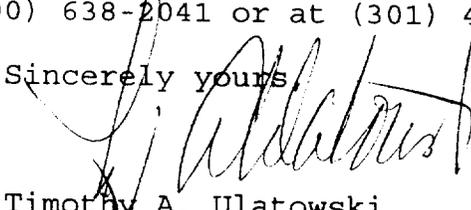
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Snyder

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

510(K) ROUTE SLIP

510(k) NUMBER K964853 PANEL HO DIVISION DDIG BRANCH GHDB

TRADE NAME INTRAVIA CONTAINER, EMPTY

COMMON NAME I,V, CONTAINER

PRODUCT CODE KPE CONTAINER, I.V.

APPLICANT BAXTER HEALTHCARE CORP.

SHORT NAME BAXTHEAL

CONTACT MARY E SNYDER

DIVISION _____

ADDRESS ROUTE 120 AND WILSON ROAD

ROUND LAKE, IL 60073

PHONE NO. (847) 270-4644

FAX NO. (847) 270-4668

MANUFACTURER BAXTER HEALTHCARE CORP. OF PUE
BAXTER HEALTHCARE CORP.

REGISTRATION NO. 2649614
2618677

DATE ON SUBMISSION 26-NOV-96

DATE DUE TO 510(K) STAFF 16-FEB-97

DATE RECEIVED IN ODE 03-DEC-96

DATE DECISION DUE 03-MAR-97

DECISION

DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>S001</u>	<u>14-MAR-97</u>	<u>17-MAR-97</u>	<u>31-MAY-97</u>	<u>15-JUN-97</u>	

CORRESPONDENCE	SENT	DUE BACK	
<u>C001</u>	<u>27-FEB-97</u>	<u>29-MAR-97</u>	<u>HOLD LETTER</u>

26 BYB

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>ADD-TO-FILE</u>	<u>21-FEB-97</u>	<u>24-FEB-97</u>	<u>25-APR-97</u>		

Is this 510(k) identified as a Class III device YES NO
 Is this 510(k) the result of additional information YES NO

h



Memorandum

From: ^{3/24/97} Reviewer(s) - Name(s) Brenda Bolte

Subject: 510(k) Number K964853/S1

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____
- 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 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? YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

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 panel and class: II 80 KPE Additional Product Code(s) with panel (optional):

Review: [Signature] (Branch Chief) [Signature] (Branch Code) 3/25/97 (Date)

Final Review: _____ (Division Director) 3/27/97 (Date)

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K964853 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION 3/24/97

Reviewer: Brenda J. Bolden Division/Branch: DDIGD/GH

Trade Name: IntraVia Empty Container

Common Name: IV Container

Panel: 80 Product Code: KPE Class: II

Product To Which Compared: Baxter Viaflex containers

510(k) Number: K922214, K932477, K945193

- | | YES | NO | |
|--|--------------|--------------|------------------------------------|
| 1. IS PRODUCT A DEVICE? | <u> x </u> | <u> </u> | IF NO STOP |
| 2. DEVICE SUBJECT TO 510(K)? | <u> x </u> | <u> </u> | IF NO STOP |
| 3. SAME INDICATION STATEMENT? | <u> x </u> | <u> </u> | IF YES GO TO 5 |
| 4. DO DIFFERENCES ALTER THE EFFECT
OR RAISE NEW ISSUES OF SAFETY
OR EFFECTIVENESS? | <u> </u> | <u> *</u> | IF YES STOP > NE |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS? | <u> </u> | <u> x </u> | IF YES GO TO 7 |
| 6. COULD THE NEW CHARACTERISTICS
AFFECT SAFETY OR EFFECTIVENESS? | <u> x </u> | <u> *</u> | IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE
ENOUGH? | <u> </u> | <u> </u> | IF YES STOP > SE
IF NO GO TO 10 |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS
QUESTIONS? | <u> </u> | <u> *</u> | IF YES STOP > NSE |
| 9. ACCEPTED SCIENTIFIC METHODS
EXIST? | <u> x </u> | <u> </u> | IF NO STOP > NSE |
| 10. PERFORMANCE DATA AVAILABLE? | <u> x </u> | <u> </u> | IF NO REQUEST DATA |
| 11. DATA DEMONSTRATE EQUIVALENCE? | <u> x </u> | <u> *</u> | > |

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: The empty plastic containers are for the preparation and administration of drug admixtures.
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.

Baxter is planning to manufacture and market their plastic I.V. container with a change in the materials of the container sheeting and port tubes. The reason for the change to the polyolefin is to allow a change in sterilization from EtO to gamma sterilization. Also, use of the IntraVia instead of the Viaflex PVC container allows use of standard thermoplastic methods for recycling. The change from natural gum rubber to synthetic polyisoprene in the medication site is to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

SE Information

A comparison chart is included in attachment 4.0. Baxter is planning to market 50mL, 150mL, 250mL, 500mL, 1L, 1.5L, 2L, and 3L sizes. The current Viaflex device has a vent port for EtO venting. A 1975 catalog page is included with the Viaflex container.

Baxter submitted another document, K922214 for a Viaflex container for drug admixturing in sizes from 50mL-400mL. That 1992 document was for a change in sterilization from EtO to gamma and material changes from PL 146 PVC and R-205 gum rubber to PL 1860 and R-217 gum rubber. Baxter decided to use the pre-Amendments device rather than the 1992 device as the predicate device. (b) (4)

[REDACTED]

Materials

(b) (4)

[REDACTED]

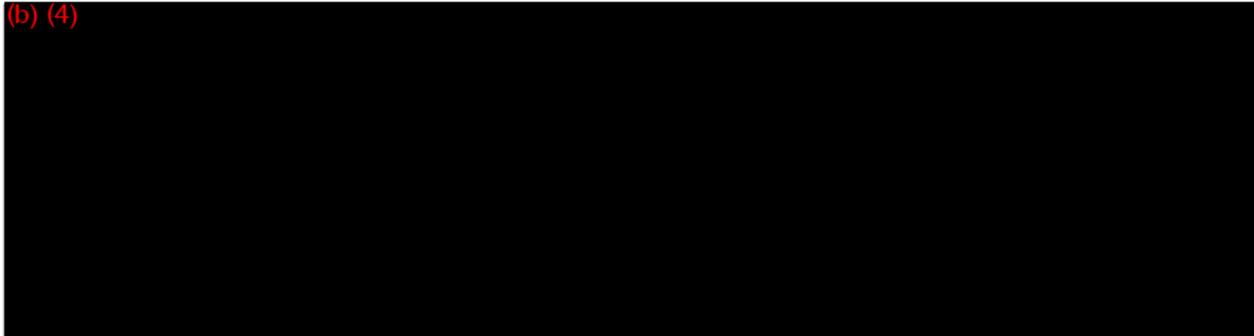
Biocompatibility

Testing for the PL 2408 with v4923 included cytotoxicity, sensitization,

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intracutaneous, hemolysis, and systemic toxicity and USP physico-chemical tests.

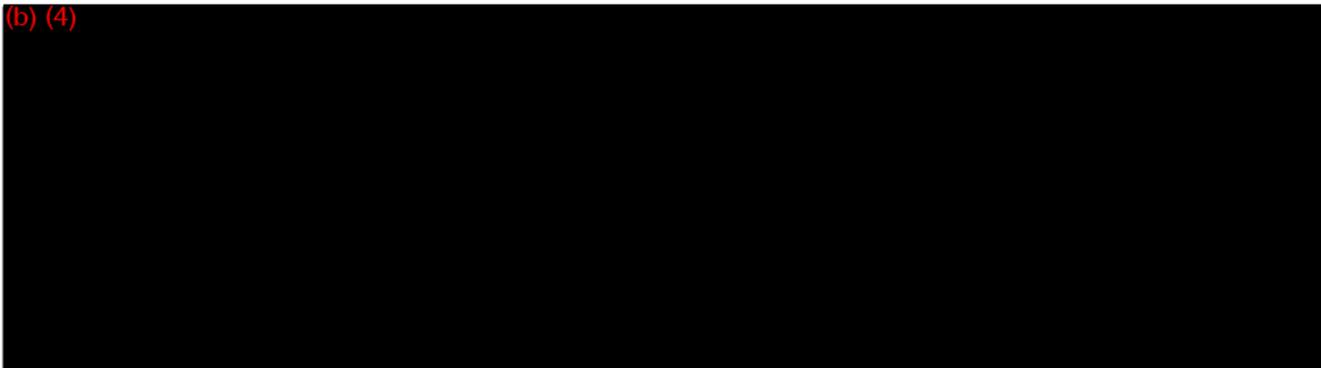
(b) (4)



Performance Data

Data about functional performance of the proposed container and its drug compatibility is in attachment 6. All references to drug information has been deleted by Baxter from the document.

(b) (4)



Labeling

Copies of current and proposed labeling is included. They did include on the device label the statement "adhere to storage requirements of added medications." There is also a statement indicating that some components contain DEHP.

See previous memos about issues related to the drug compatibility concerns.

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**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED
(DELETE QUESTIONS WHICH ARE NOT APPLICABLE)**

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

There were sterilization and material changes.

6. EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

These new characteristics could adversely affect safety or effectiveness if the materials are not biocompatible or improperly sterilized.

8. EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

The questions are not new since these types of devices have been reviewed previously.

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATE THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT:

With passing results of the performance tests (such as pressure/leak testing, residual volume, forces tests, etc.) and results demonstrating that the devices meet specifications, I believe the devices are SE to their predicate devices.


Brenda J. Bolden
3/24/97

K964853/S1

Baxter

March 14, 1997

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

FDA/CDRH/OCE/DMC

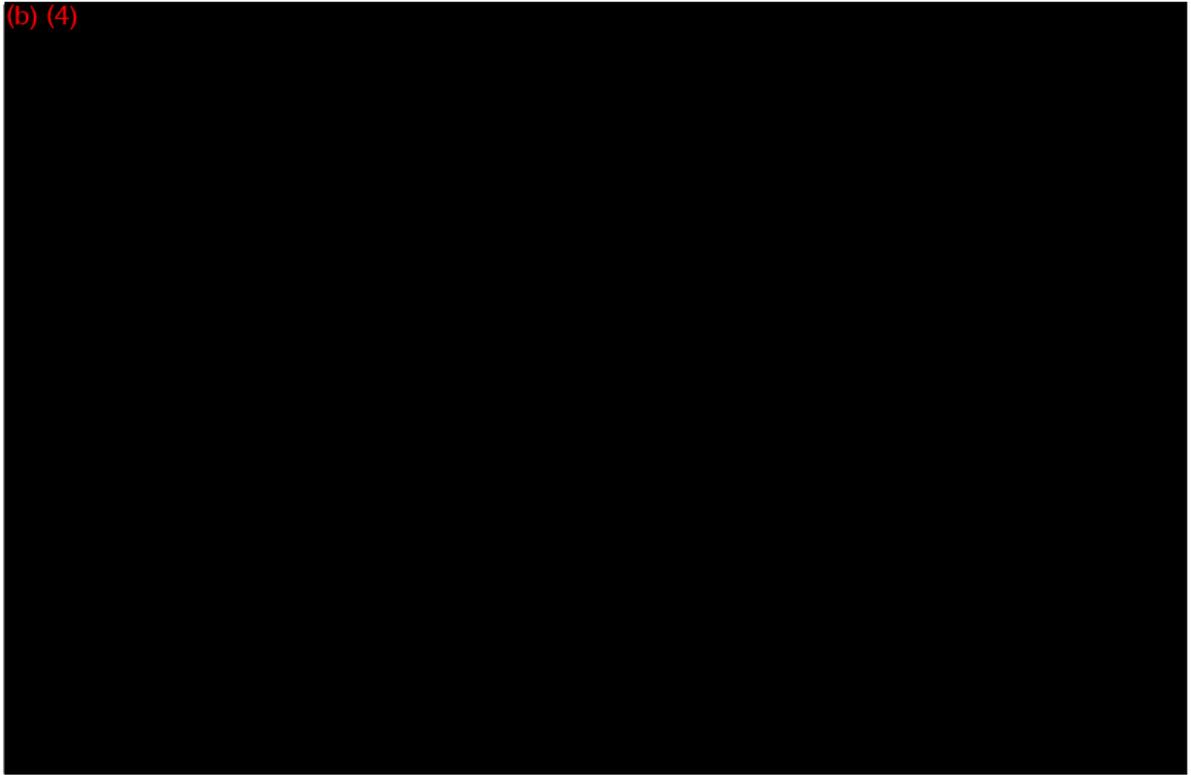
17 MAR 97 10 03

RECEIVED

**RE: K964853 - IntraVia™ Empty Plastic Container
Request for Additional Information**

Dear Colleague:

(b) (4)



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Baxter

Thank you for your assistance in expediting review of this file. If you have any questions or require additional information, please contact me or Marcia Marconi, Vice President, Regulatory Affairs at (847) 270-4637.

Sincerely,



Mary Ellen Snyder
Regulatory Affairs Manager
(847) 270-4644
(847) 270-4668 (FAX)

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March 17, 1997

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

BAXTER HEALTHCARE CORP.
ROUTE 120 AND WILSON ROAD
ROUND LAKE, IL 60073
ATTN: MARY E. SNYDER

510(k) Number: K964853
Product: INTRAVIA
CONTAINER, EMPTY

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance 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

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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

February 28, 1997

BAXTER HEALTHCARE CORP.
ROUTE 120 AND WILSON ROAD
ROUND LAKE, IL 60073
ATTN: MARY E. SNYDER

510(k) Number: K964853
Product: INTRAVIA
CONTAINER, EMPTY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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

Sincerely yours,

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



Memorandum

From: ^{2/26} Reviewer(s) - Name(s) B. Boede

Subject: 510(k) Number K964853

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- 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 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? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 307.95 (doesn't apply for SEs):

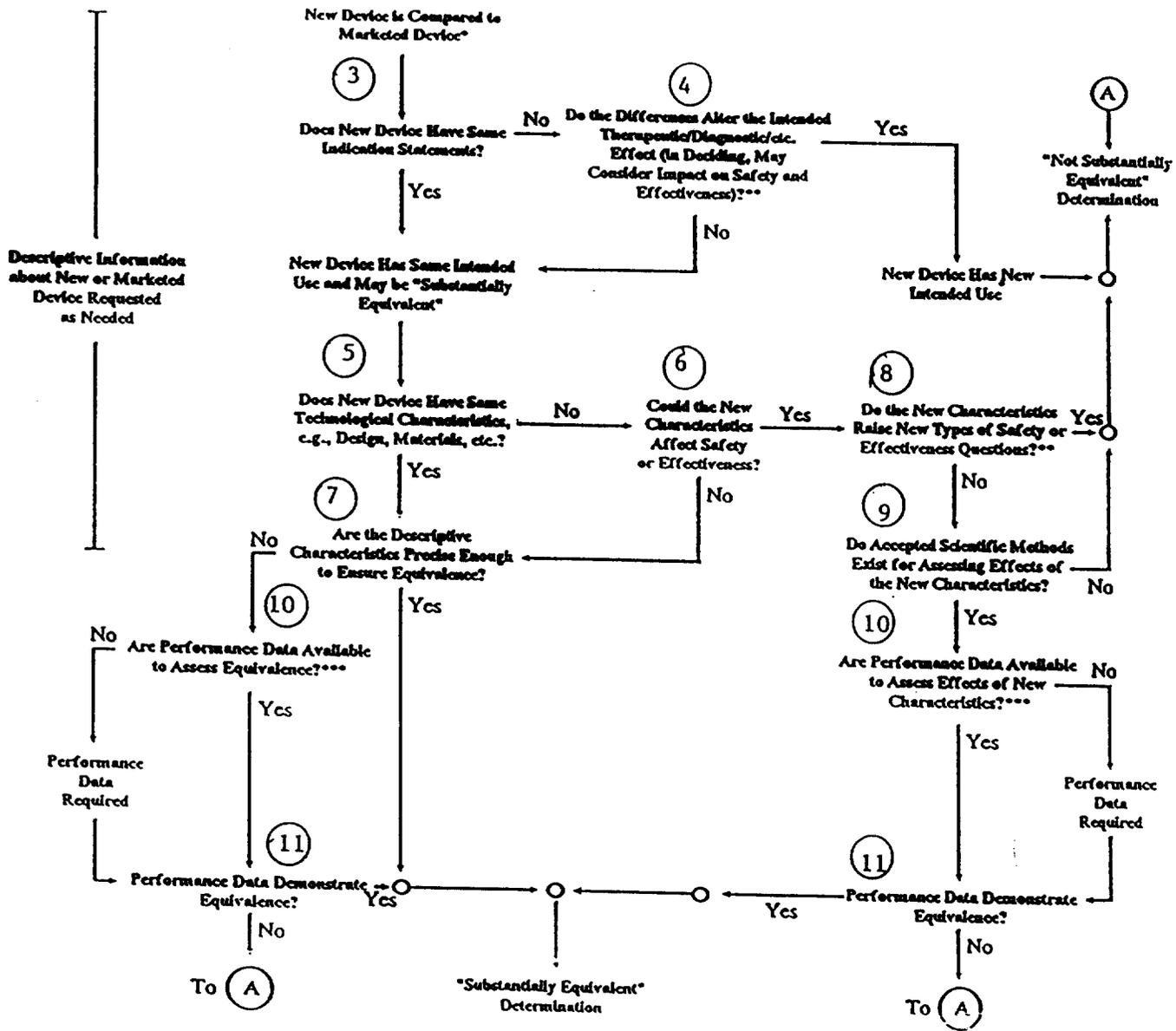
- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: _____ Additional Product Code(s) with panel (optional): _____

Review: Patricia Ciccone 611D B 2-27-97
(Branch Chief) (acting) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

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



- 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.

MEMO RECORD

DATE: 2/24/97

FROM: Brenda Bolden, Biologist

DIVISION: DDIGD/GH

TO: The Record

OFFICE: ODE

SUBJECT: Baxter Intravia Empty Container, K964853

SUMMARY

Baxter is planning to manufacture and market their plastic I.V. container with a change in the materials of the container sheeting and port tubes.

They currently market a line of empty Viaflex containers (pre-Amendments) for the preparation and administration of drug admixtures. Baxter did not mention it but I noted another Viaflex container in K922214 with more PVC components but the same use in preparation of drug admixtures in sizes from 50-

(b) (4)



Section 2.0, p.22 contains drawing and materials for the proposed IntraVia empty container. See above materials.

Section 3.0, p.23 containers drawing and materials for the current Viaflex container.

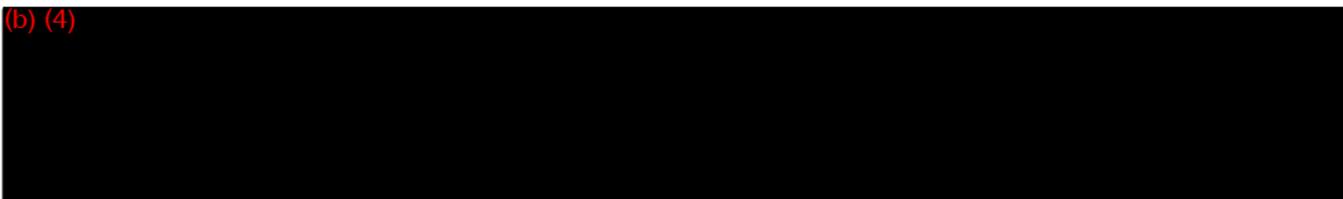
(b) (4)



SE Information

A comparison chart is included in attachment 4.0. Baxter proposed to market 50mL, 150mL, 250mL, 500mL, 1L, 1.5L, 2L, and 3L sizes. The current Viaflex device has a vent port just for EtO venting. A 1975 catalog page is included with the Viaflex container.

(b) (4)



(b) (4)

Some of their other containers include: K922214, K932477, and K945193. Other containers in general include: K940258, K941731, etc.

Materials

(b) (4)

Biocompatibility

Testing for the (b) (4) included cytotoxicity, sensitization, intracutaneous, hemolysis, and systemic toxicity and USP physico-chemical tests.

(b) (4)

Performance Data

Data about functional performance of the proposed container and its drug compatibility is in attachment 6.

(b) (4)

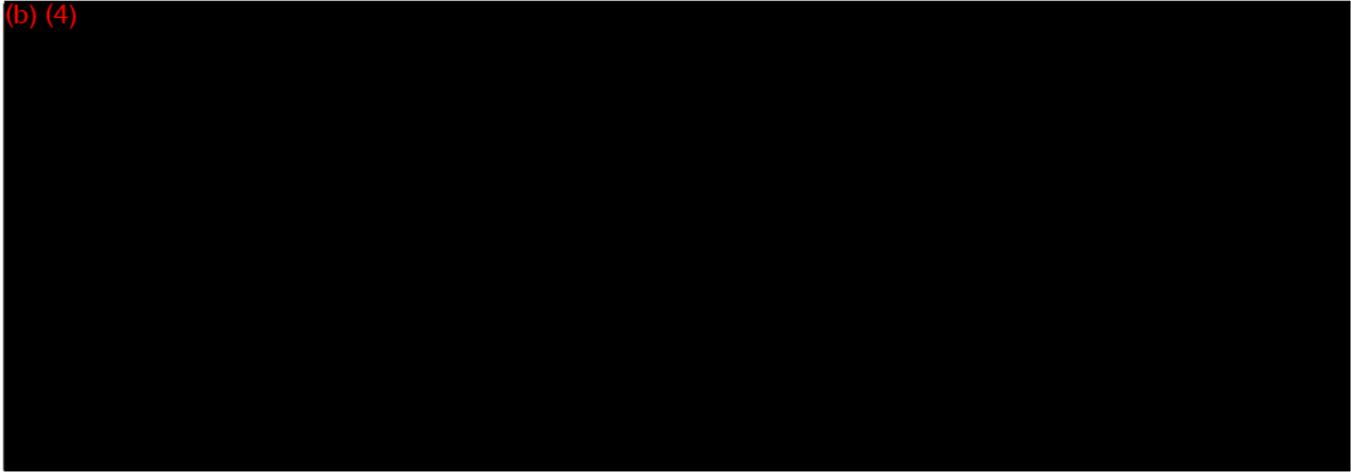
Drug Compatibility

(b) (4)

18

(b) (4)

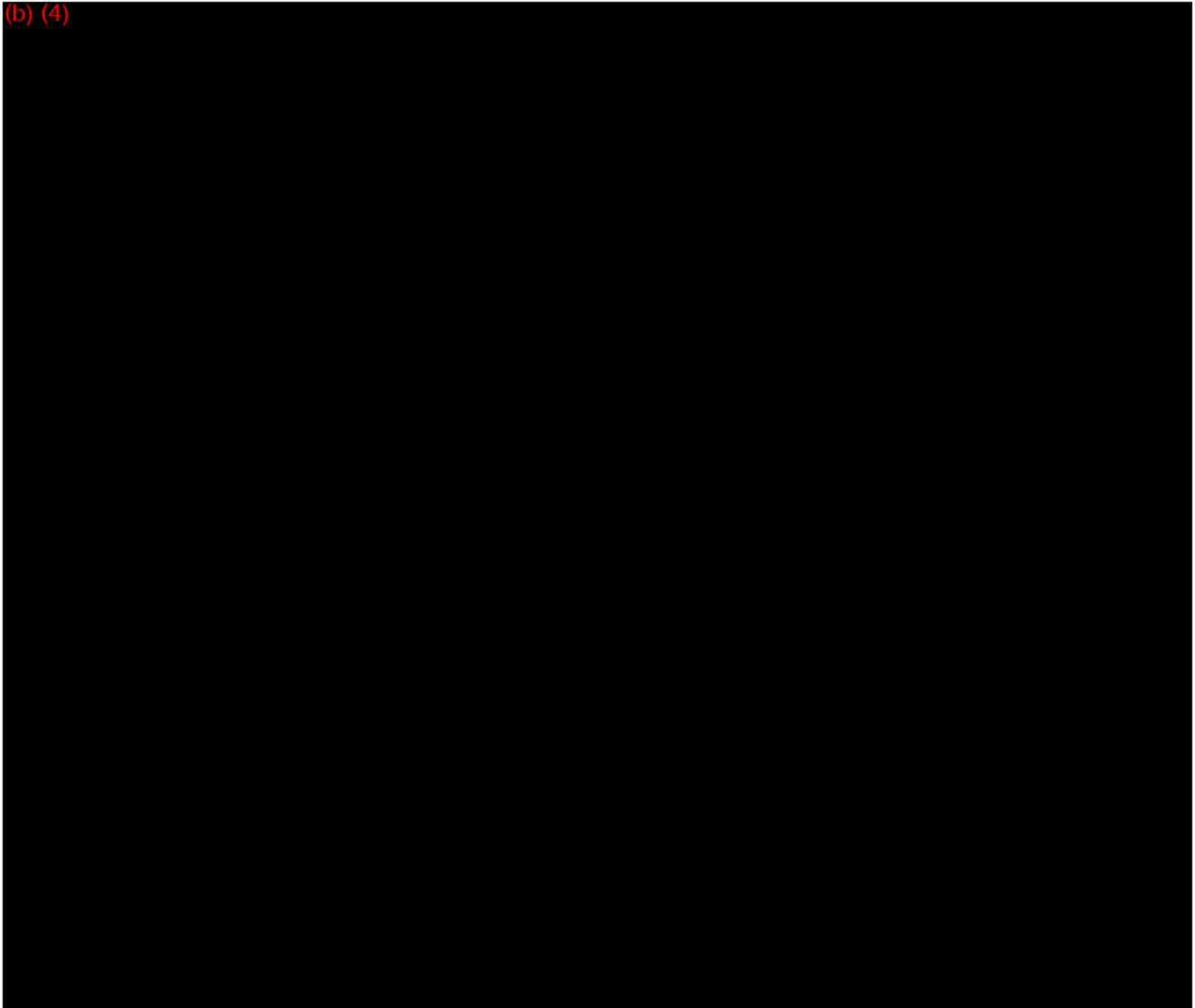
(b) (4)



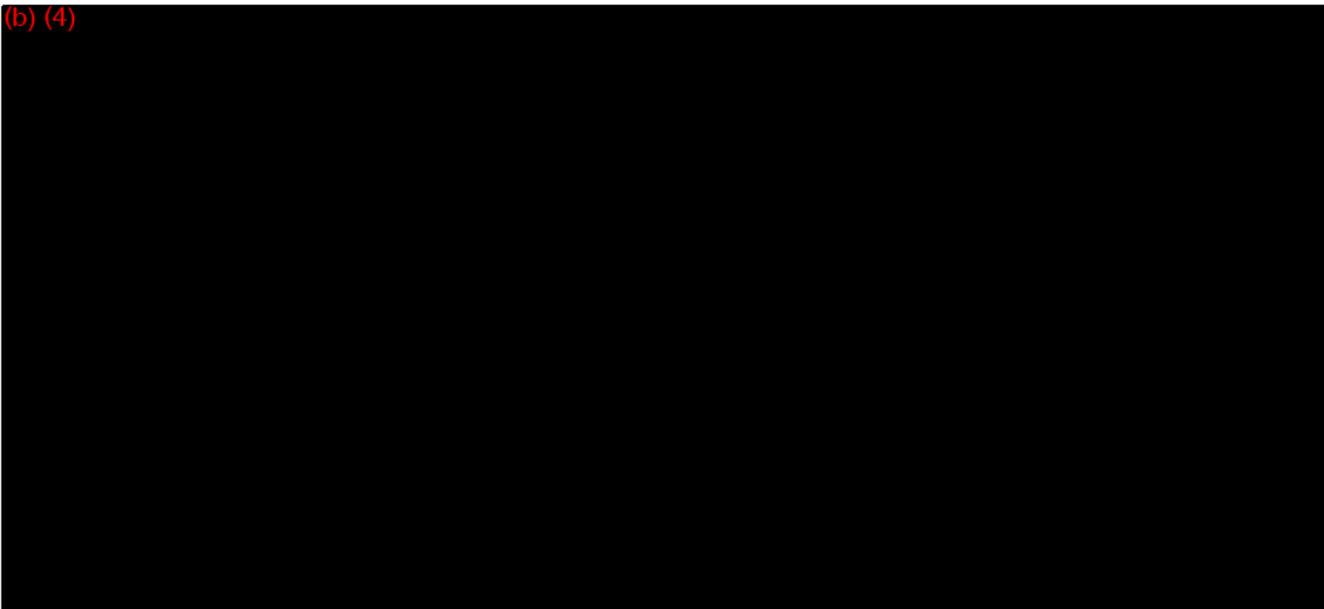
Labeling

Copies of current and proposed labeling is included. They did include on the device label the statement "adhere to storage requirements of added medications." There is also a statement indicating that some components contain DEHP.

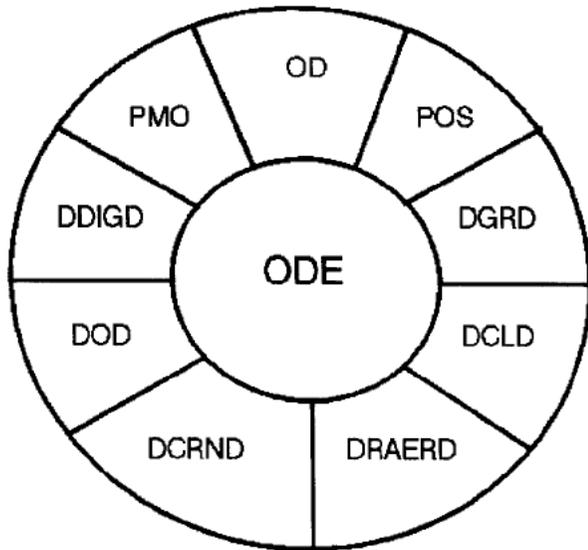
(b) (4)



(b) (4)



**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF DENTAL, INFECTION CONTROL, AND
GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850**



FROM: Brenda Bolden

DATE: 2/25/97

NO. OF PAGES: 2

PHONE NO: (301)594-1287

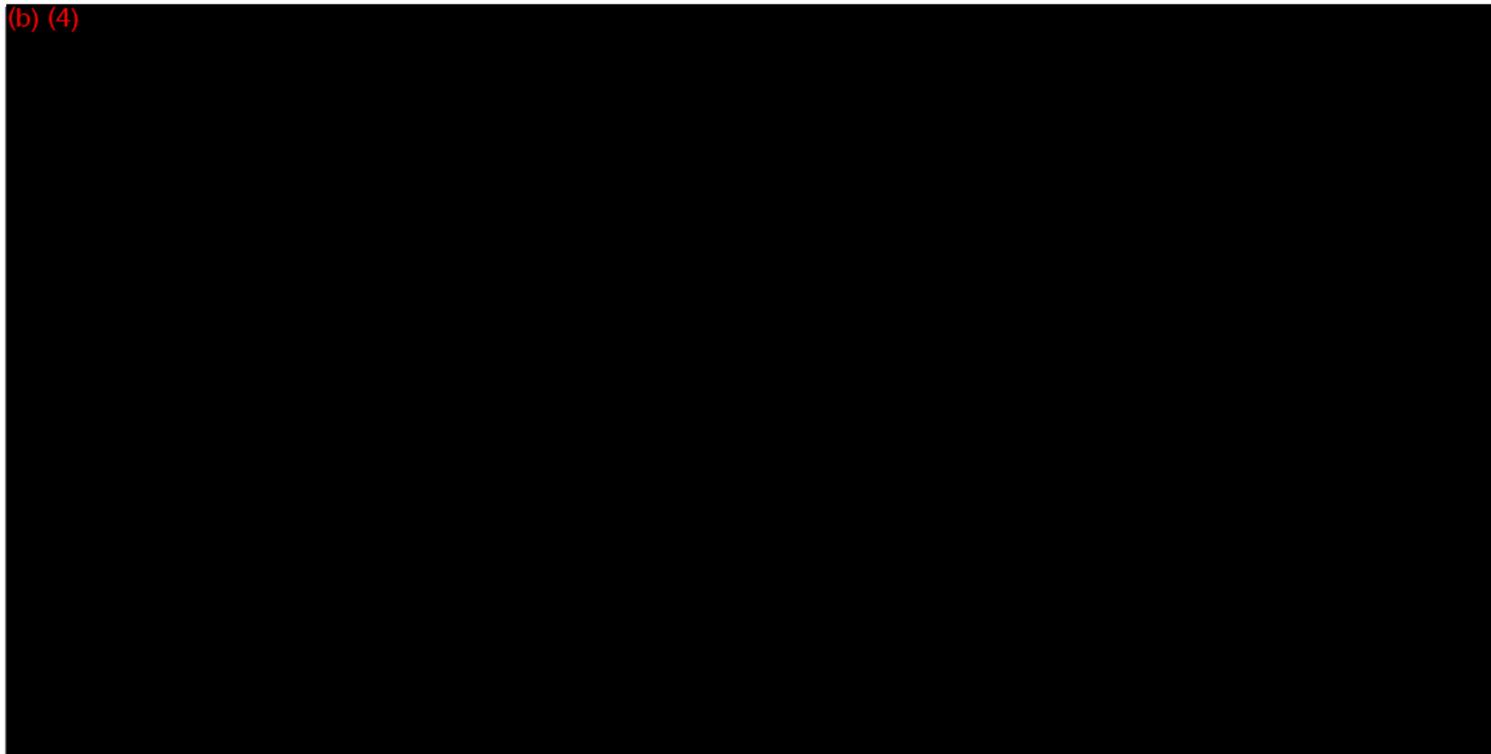
FAX NO: (301)480-3002

TO: Ms. Mary Ellen Snyder

FAX NO: (847)270-4668

SUBJECT: IntraVia Container

(b) (4)



(b) (4)



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○

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K964853/A1

Baxter

February 21, 1997

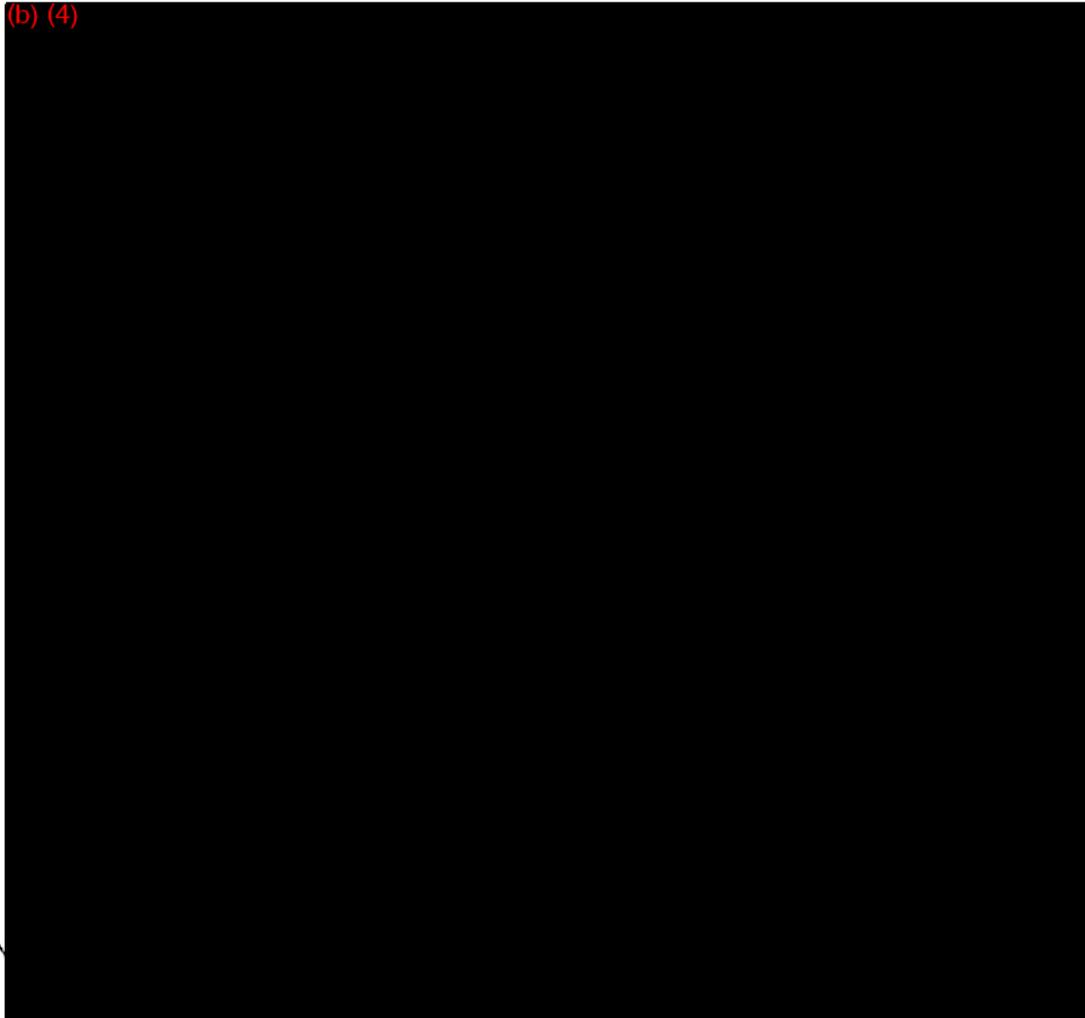
Ms. Brenda Bolden
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation, HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

FEB 24 10 19 AM '97

**RE: K964853 - IntraVia™ Empty Plastic Container
Request for Additional Information**

Dear Ms. Bolden:

(b) (4)



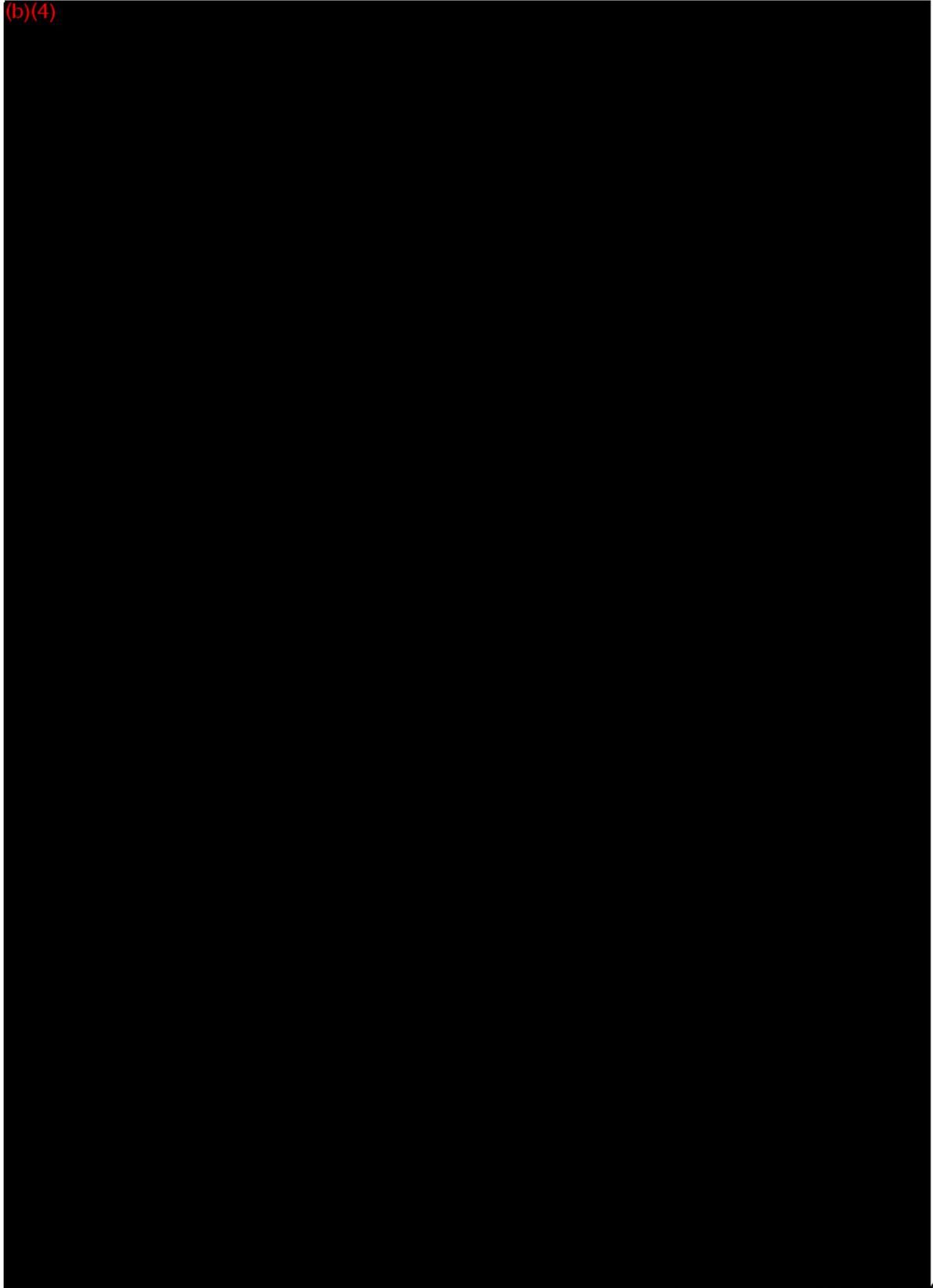
5/13/97

M

Ms. Brenda Bolden
K964853
February 21, 1997

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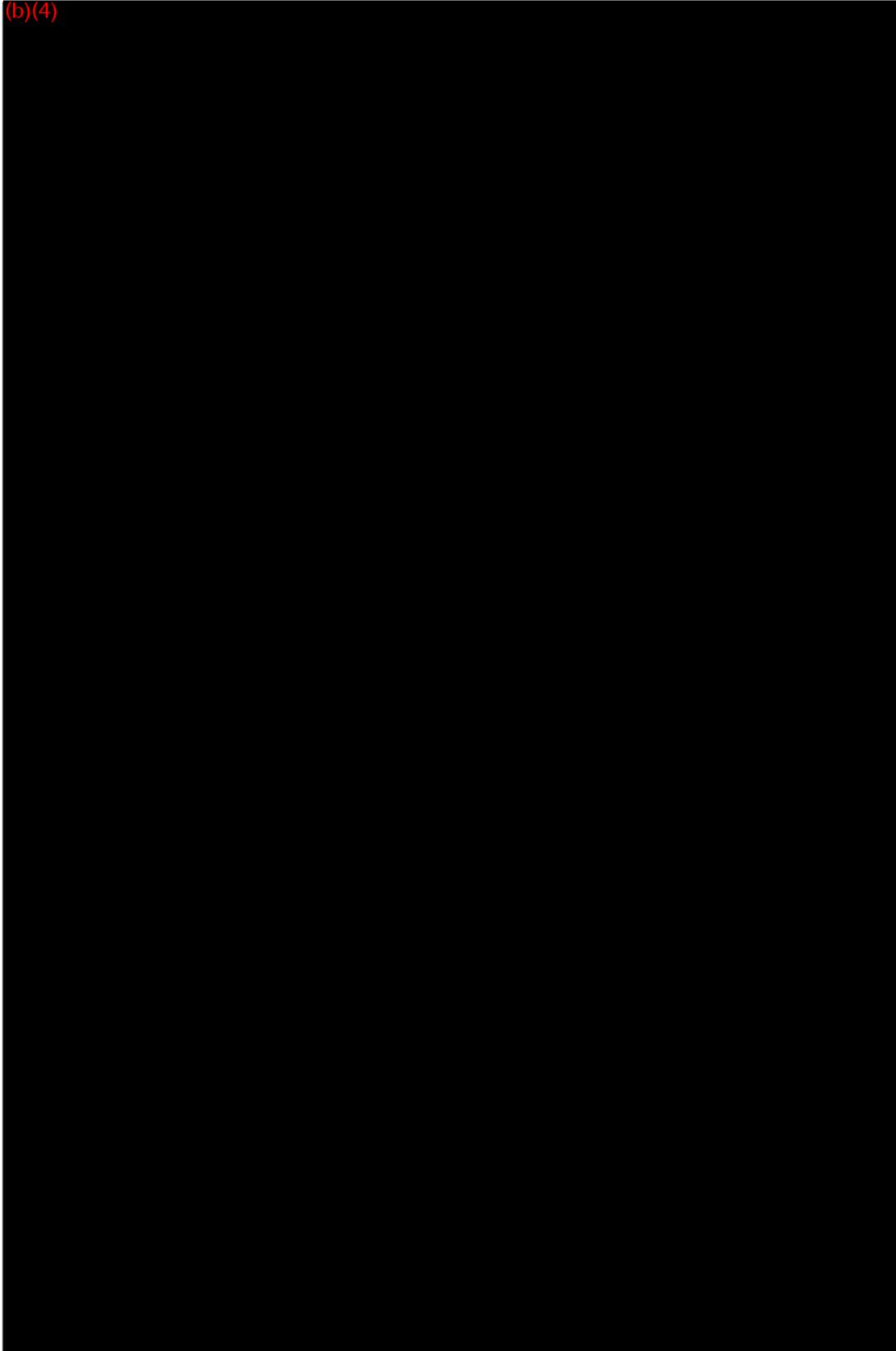
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K964853
February 21, 1997

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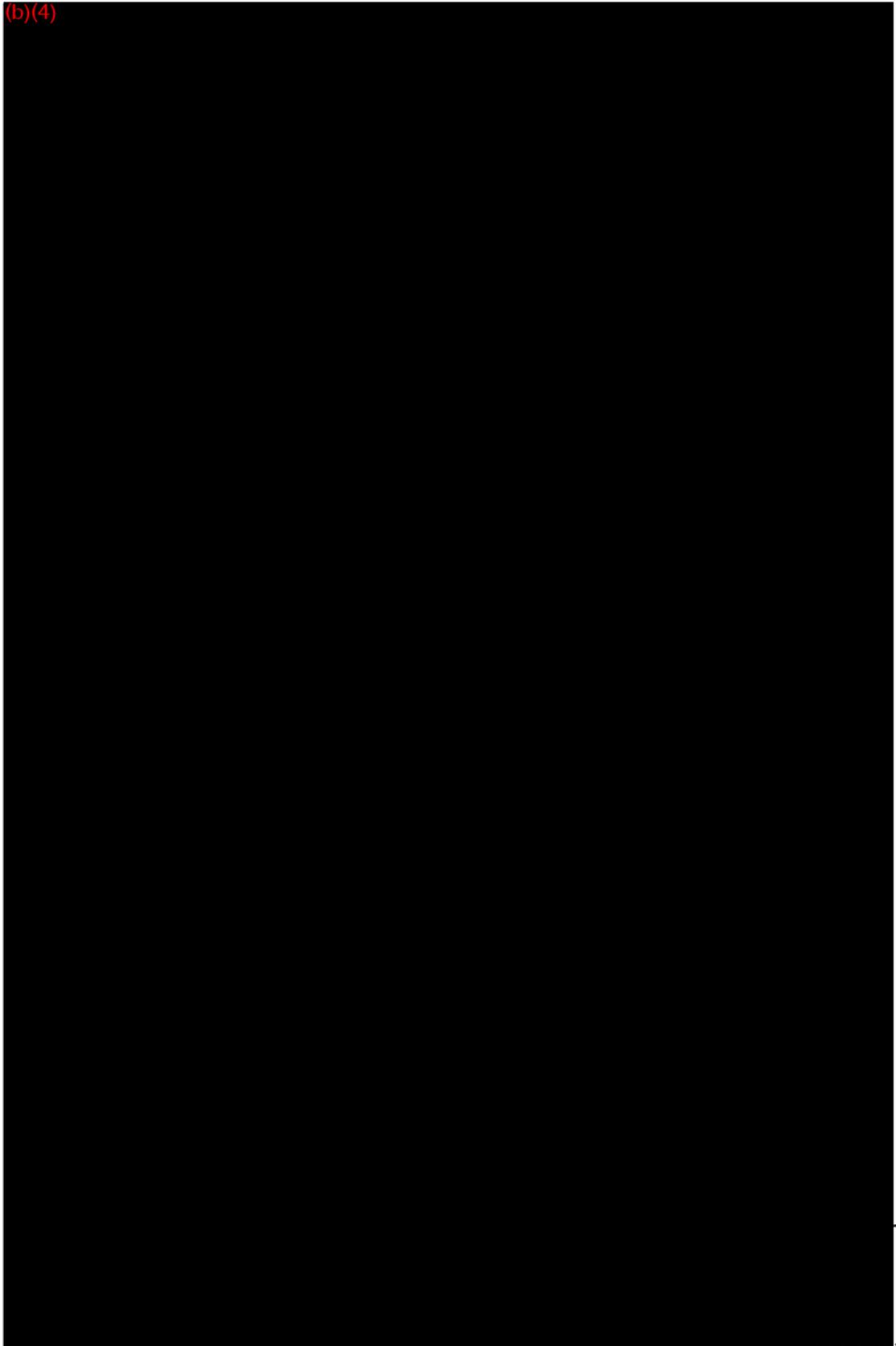


Ms. Brenda Bolden
K964853
February 21, 1997

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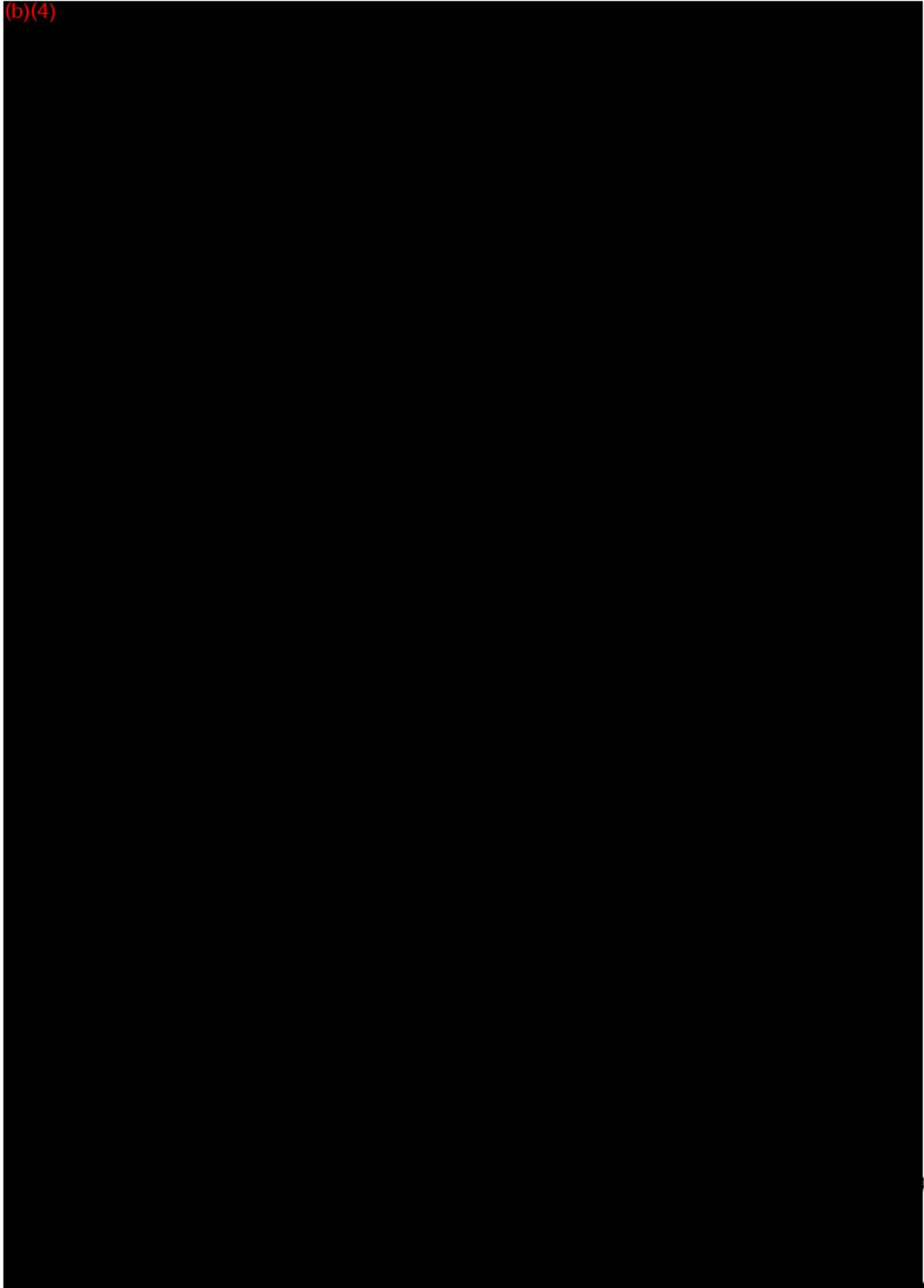


Ms. Brenda Bolden
K964853
February 21, 1997

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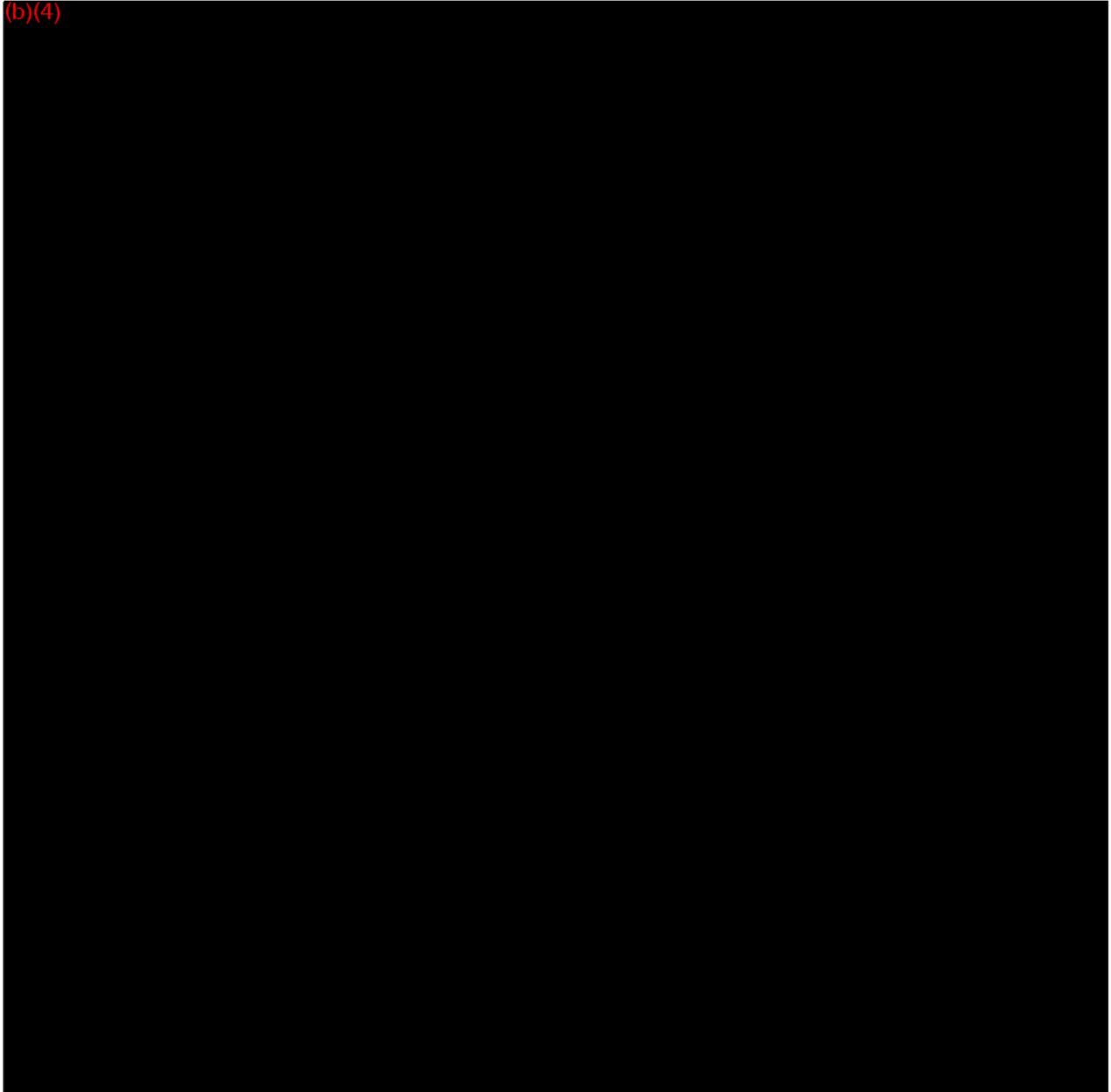


Ms. Brenda Bolden
K964853
February 21, 1997

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Sincerely,



Mary Ellen Snyder
Regulatory Affairs Manager
(847) 270-4644
(847) 270-4668 (FAX)



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6

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 1.0

Comparison of Functional Testing Results

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 2.0

**Draft Container Labeling
Proposed IntraVia™ Empty Container**

(From p. 81 of 11/26/96 Original Submission)

FEB 21 1997

Attachment 7.0

Representative IntraVia™ Empty Container
Container Labeling

LOT EXP
2B8011

IntraVia™ Container 30
150 mL Capacity

— STERILE NONPYROGENIC FLUID PATH USE 60
ONLY WITH MEDICATIONS THAT ARE
COMPATIBLE WITH EACH OTHER MIX
THOROUGHLY CAUTIONS SQUEEZE AND
INSPECT FILLED BAG DISCARD IF LEAKS ARE
— FOUND MUST NOT BE USED IN SERIES 90
CONNECTIONS FEDERAL (USA) LAW
RESTRICTS THIS DEVICE TO SALE BY OR ON
ORDER OF A PHYSICIAN ~~ADHERE TO STORAGE~~
REQUIREMENTS OF ADDED MEDICATIONS

— **Baxter** 120
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA 
MADE IN USA

NOV 26 1996
81
FEB 21 1997
10 33

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 3.0

**Summary of Observations/Results for ISO 10993-1 Testing
(Table 1. PL2408 and Table 3. R-256
of 11/26/96 Original Submission- pp. 29-30)**

FEB 21 1997

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Attachment 4.0

**Results of ISO-10993-1 Biological Testing
(Test Data Sheets and Study Reports)**

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 4.1

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



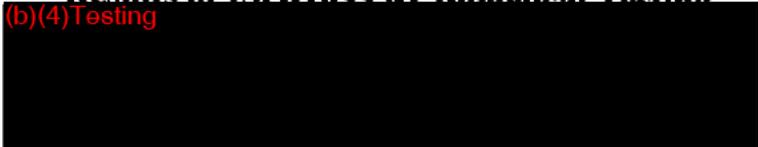
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K964853
February 21, 1997

Attachment 4.1a

Results of ISO-10993-1 Biological Testing
(b)(4) Testing



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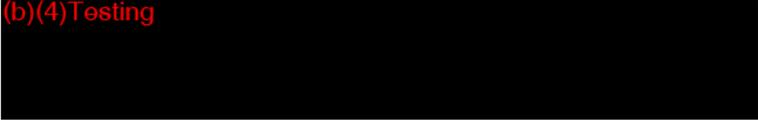
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K964853
February 21, 1997

Attachment 4.1b

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



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K964853
February 21, 1997

Attachment 4.1c

Results of ISO-10993-1 Biological Testing

(b)(4) Testing

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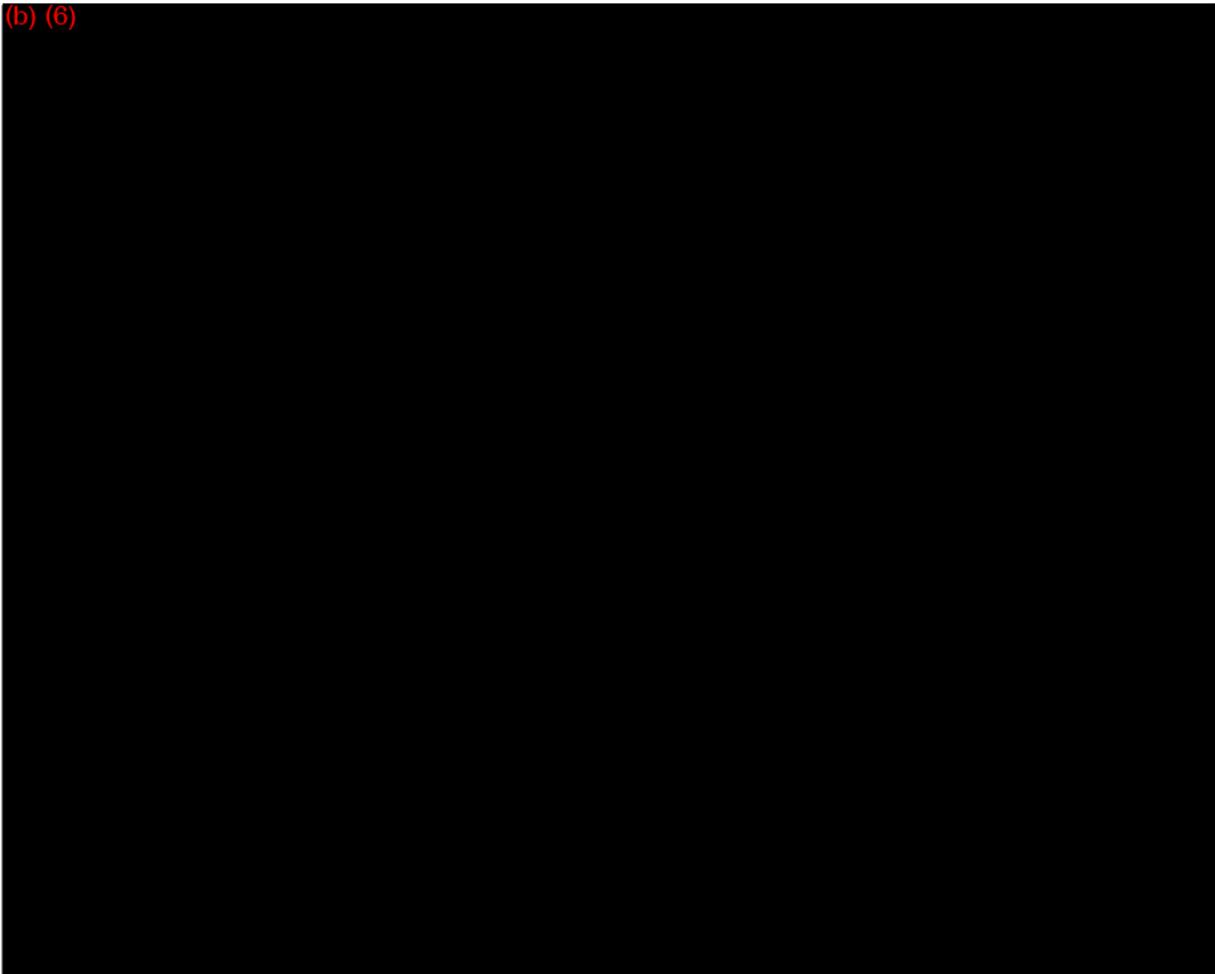
APPENDIX B
LIST OF PROFESSIONAL AND SUPERVISORY PERSONNEL

FEB 21 1997

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APPENDIX B
STUDY PERSONNEL LIST

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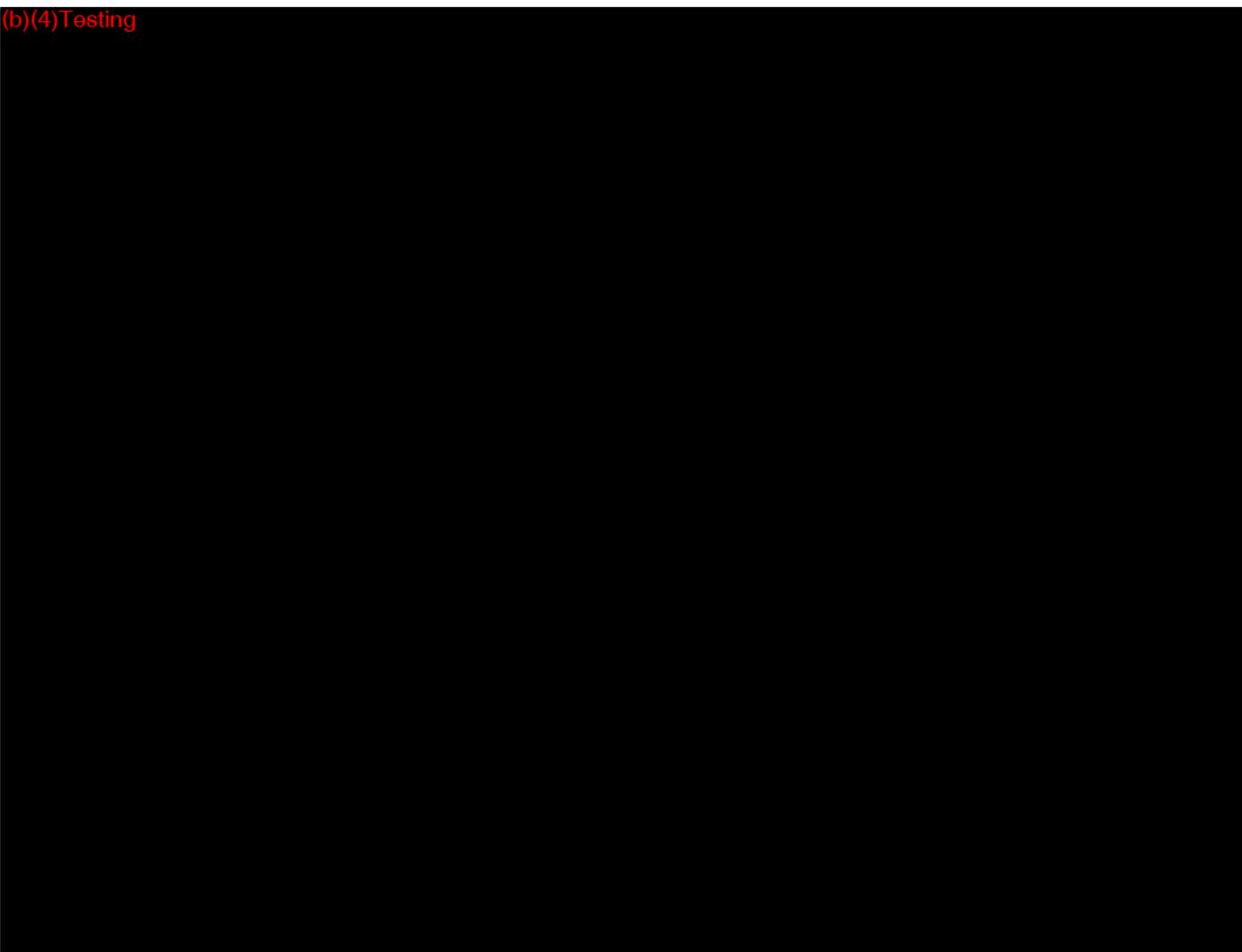
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APPENDIX C
DATA INTEGRITY STATEMENT

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(b)(4) Testing



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APPENDIX D
PROTOCOL

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K964853
February 21, 1997

Attachment 4.1d

Results of ISO-10993-1 Biological Testing

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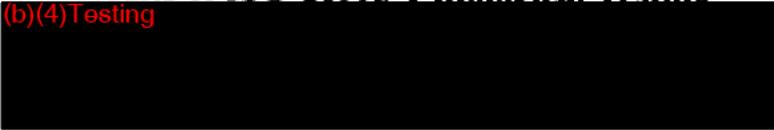
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K964853
February 21, 1997

Attachment 4.1e

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



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February 21, 1997

Attachment 4.2

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



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K964853
February 21, 1997

Attachment 4.2a

Results of ISO-10993-1 Biological Testing

(b)(4)Testing



NOTE: This material is also referred to as PRJ 16441 in the attached data sheet which was a preliminary formulation number.

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K964853
February 21, 1997

Attachment 4.2b

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



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February 21, 1997

Attachment 4.2c

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



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TABLE OF CONTENTS

	Page No.
I. SUMMARY	5
II. STUDY INFORMATION	7
III. MATERIALS AND METHODS	9
IV. RESULTS AND CONCLUSIONS	23
V. DATA TABLES	28

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(b) (4)

SECTION I. SUMMARY

INTRODUCTION AND CONCLUSIONS

(b) (4)

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LOJ

(b)(4) Testing

SECTION II. STUDY INFORMATION

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SECTION III. MATERIALS AND METHODS

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SECTION IV. RESULTS AND CONCLUSIONS

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SECTION V. DATA TABLES

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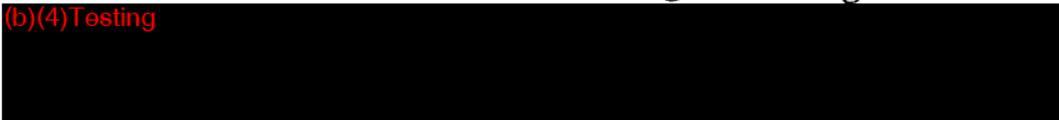
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K964853
February 21, 1997

Attachment 4.2d

Results of ISO-10993-1 Biological Testing

(b)(4) Testing



(b)(4) Testing




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K964853
February 21, 1997

Attachment 4.2e

Results of ISO-10993-1 Biological Testing

(b)(4) Testing

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**510(k) Premarket Notification
Intra Via™ Empty Plastic Container**

	Yes Present Omission Justified	No Inadequate Omitted
<p>G. Is this device subject to issues that have been addressed in specific guidance document(s)?</p> <p>If yes, continue review with checklist from any appropriate guidance documents.</p> <p>If no, is 510(k) sufficiently complete to allow substantive review?</p>		X
<p>H. Other (specify)</p>		

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Please Note: Information in parenthesis indicates where in the document items can be found.

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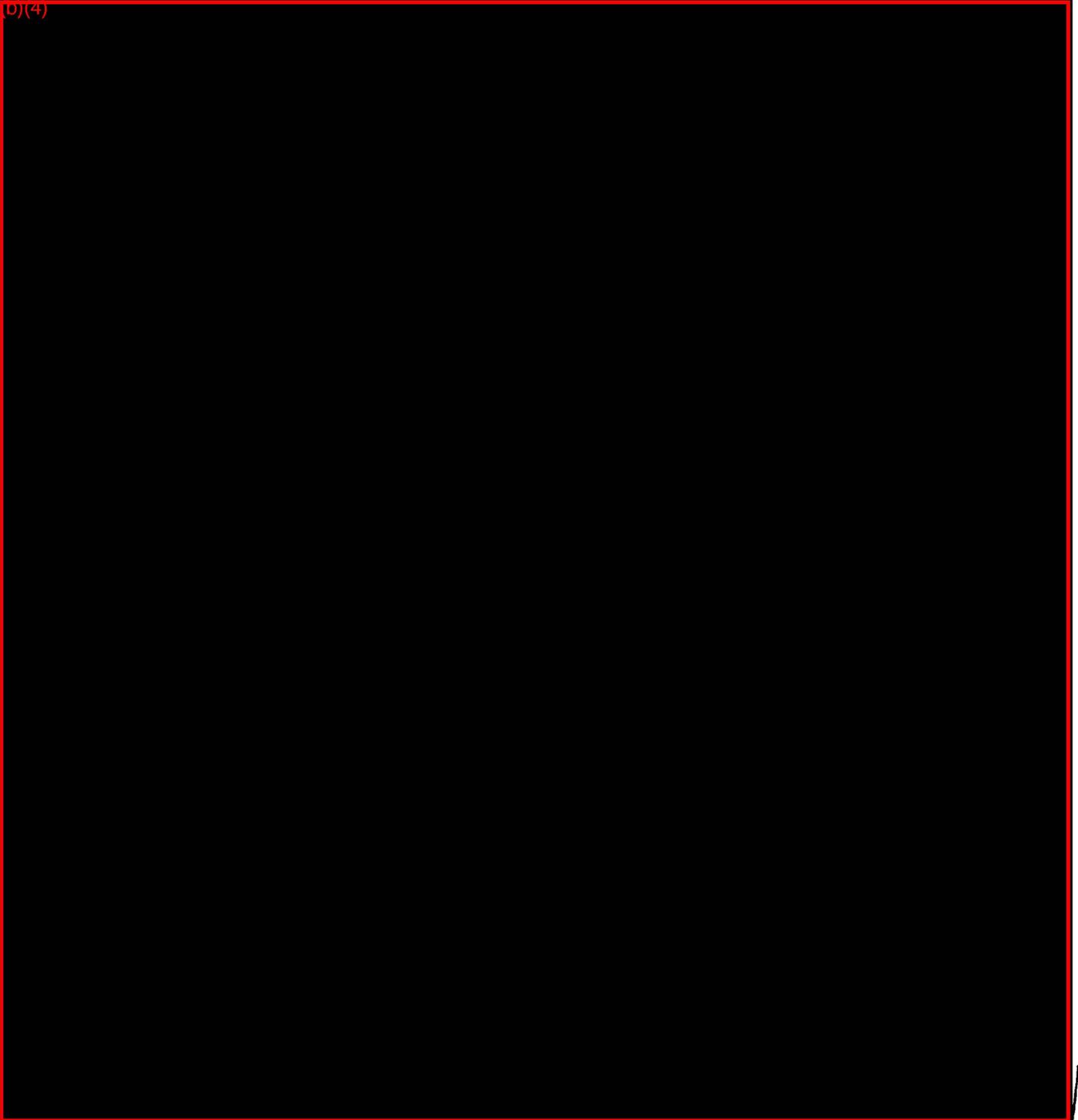


Attachment 2.0

**Diagram of Components and Materials
Proposed IntraVia™ Empty Container**

Attachment 2.0

Diagram of Components and Materials
Proposed IntraVia™ Empty Container



Attachment 3.0

**Diagram of Components and Materials
Current Viaflex® Empty Plastic Container**

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510(k) Premarket Notification
IntraVia™ Empty Plastic Container

Attachment 3.0

Diagram of Components and Materials
Current Viaflex® Empty Plastic Container

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Attachment 4.0

Comparison Chart

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Attachment 4.0

Comparison Chart

Product Feature	Proposed Intra Via™ Empty Container	Marketed Viaflex® Empty Container
(b)(4) 		

Attachment 5.0

Material Evaluation

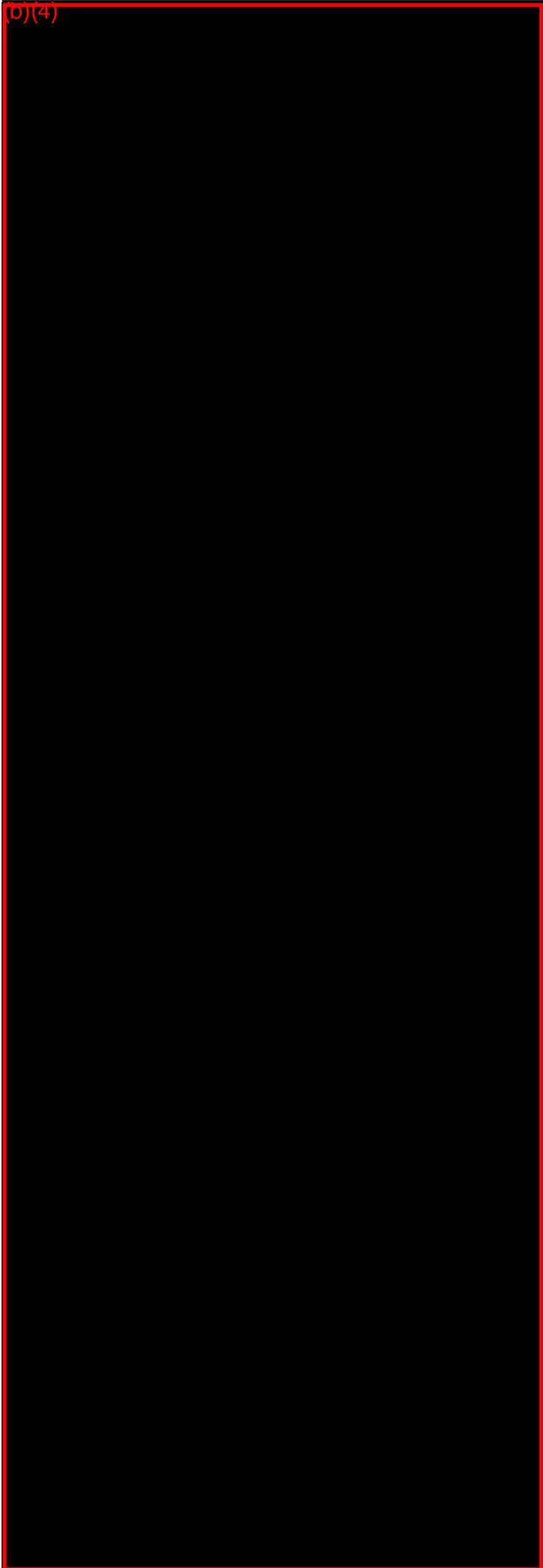
- Attachment 5.1** Prior Material Use
- Attachment 5.2** Summary of USP Physico-Chemical
and ISO-10993-1 Biological Testing

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NON

**ATTACHMENT 5.1
PRIOR MATERIAL USE
PROPOSED INTRAVIA™ EMPTY CONTAINER**



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ATTACHMENT 5.2

SUMMARY OF USP PHYSICO-CHEMICAL AND ISO-10993-1 BIOLOGICAL TESTING



**TABLE 1. PL 2408
BIOLOGICAL TEST SUMMARY**

IN VITRO ASSAYS ^a			IN VIVO ASSAYS ^a						
Direct Contact ^b	Agar Diffusion ^b	Hemolysis	Sensitization	Systemic Toxicity ^c			Intracutaneous Reactivity ^c		
				S	SA	SO	S	SA	SO
P,0	P,0	non-hemolytic	P	P	P	P	P	P	P

a P indicates passed.

b Toxicity scores of 0 follow the toxicity ratings of P (pass). Samples were evaluated on a scale of 0 (no toxicity) to 4+ (severe toxicity).

c Extracts tested; S, saline; SA, saline-alcohol; SO, and sesame oil.

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not

**TABLE 2. PL 2408
USP PHYSICO-CHEMICAL TEST SUMMARY**

Buffering Capacity (mL 0.01N NaOH)	Heavy Metals (ppm)	Nonvolatile Residues
0.05 ^a	<1 ^b	0.2 mg ^c

- a limit is not more than 10 mL of titrant
- b limit is not more than 1 ppm
- c limit is not more than 15 mg



**TABLE 3. R-256
BIOLOGICAL TEST SUMMARY**

IN VITRO ASSAYS ^a				IN VIVO ASSAYS ^a				
Direct Contact ^b	Agar Diffusion ^b	Hemolysis	Mutagenicity	Sensitization	Systemic Toxicity ^c		Intracutaneous Reactivity ^c	
					S	SO	S	SO
P,2+	F,3+	non-hemolytic	P	P	P	P	P	P

- a P indicates passed; F indicates fail.
- b Toxicity scores of 0 follow the toxicity ratings of P (pass). Samples were evaluated on a scale of 0 (no toxicity) to 4+ (severe toxicity).
- c Extracts tested; S, saline; SO, and sesame oil.

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NOT

TABLE 4. R-256
USP PHYSICO-CHEMICAL TESTS FOR ELASTOMERICS TEST SUMMARY

Extractant	Turbidity ^a	Total extractables (mg)	Heavy Metals	Change in pH	UV maxima	Reducing Agents
water	3.58	2.4	pass	-0.58	1.8218 @ 202 nm 0.1167 @ 262 nm 0.1147 @ 268 nm	0.0
IPA ^a	0.589	73.0	N/A ^c	N/A ^c	N/A ^c	N/A ^c

^aIsopropanol

^bmeasured in nephlos turbidity units (NTU)

^cN/A = Not applicable

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Attachment 6.0

Performance Data

Attachment 6.1 - Functional Testing

Attachment 6.2 - Drug Compatibility Testing

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Attachment 6.1

**Summary of Functional Testing
IntraVia™ Empty Plastic Container**

TEST & METHOD	REQUIREMENTS	RESULTS
Static Hanger Hole Testing	(b)(4)	
Residual Volume Testing (b)		
Burst Testing (b)		
Max Fill Volume Test		
Port Closure Removal Test (b)		
Spike Insertion/ Removal Force Test		

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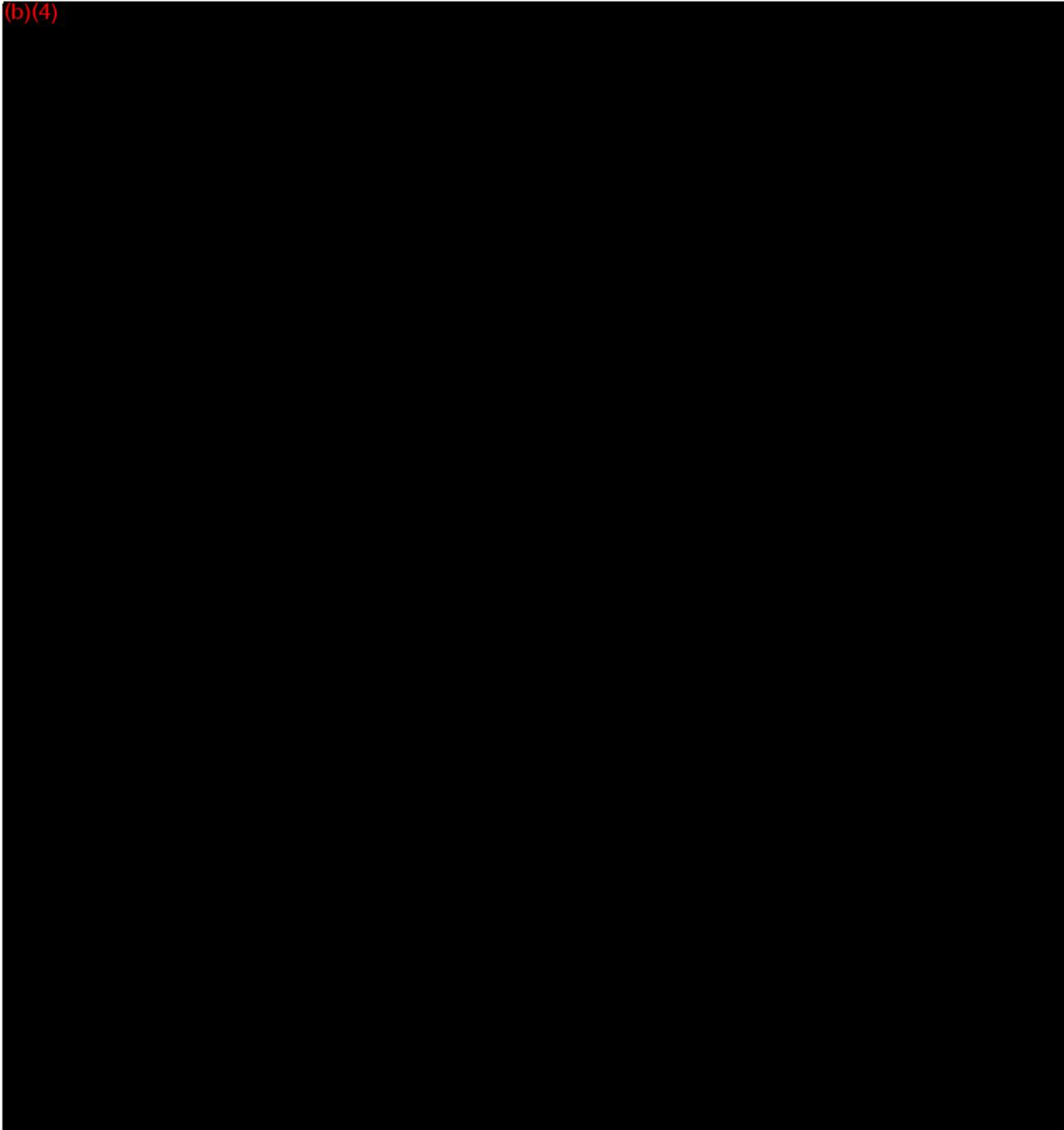
Attachment 6.2
IntraVia™ Empty Container
Drug Compatibility Evaluations

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ATTACHMENT 6.2
INTRAVIA™ EMPTY CONTAINER
DRUG COMPATIBILITY EVALUATIONS

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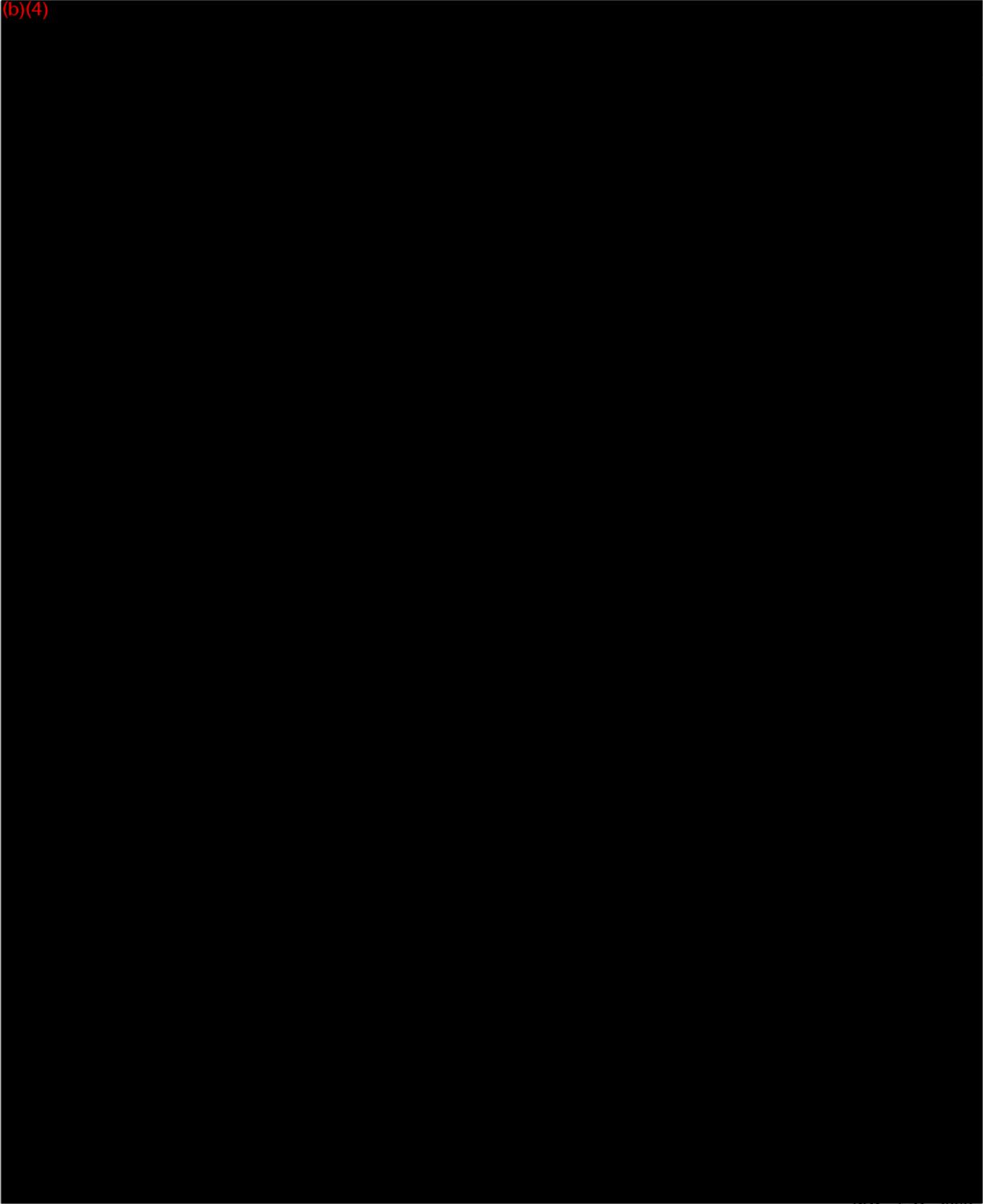
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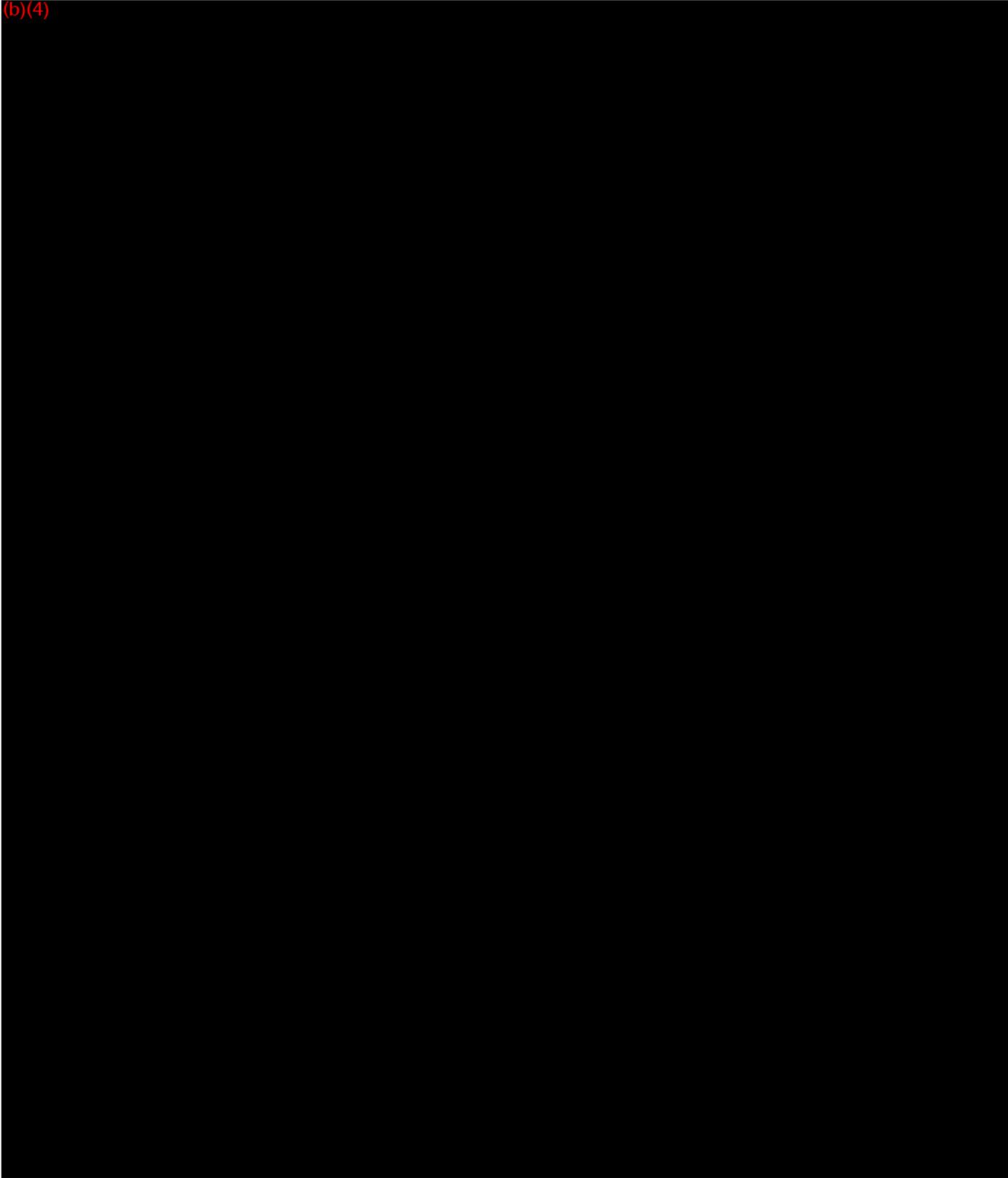
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IntraVia™ Empty Plastic Container

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IntraVia™ Empty Plastic Container

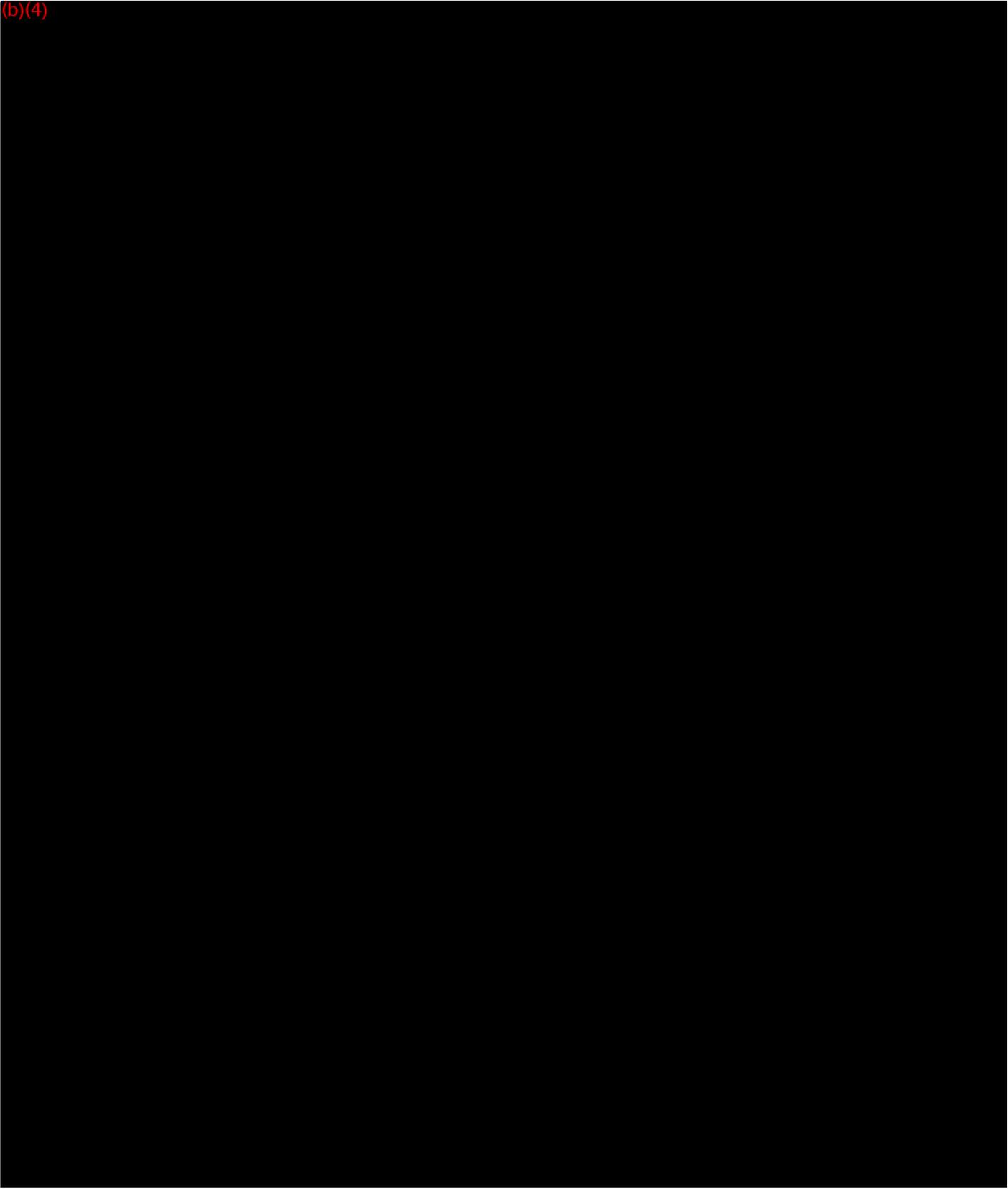
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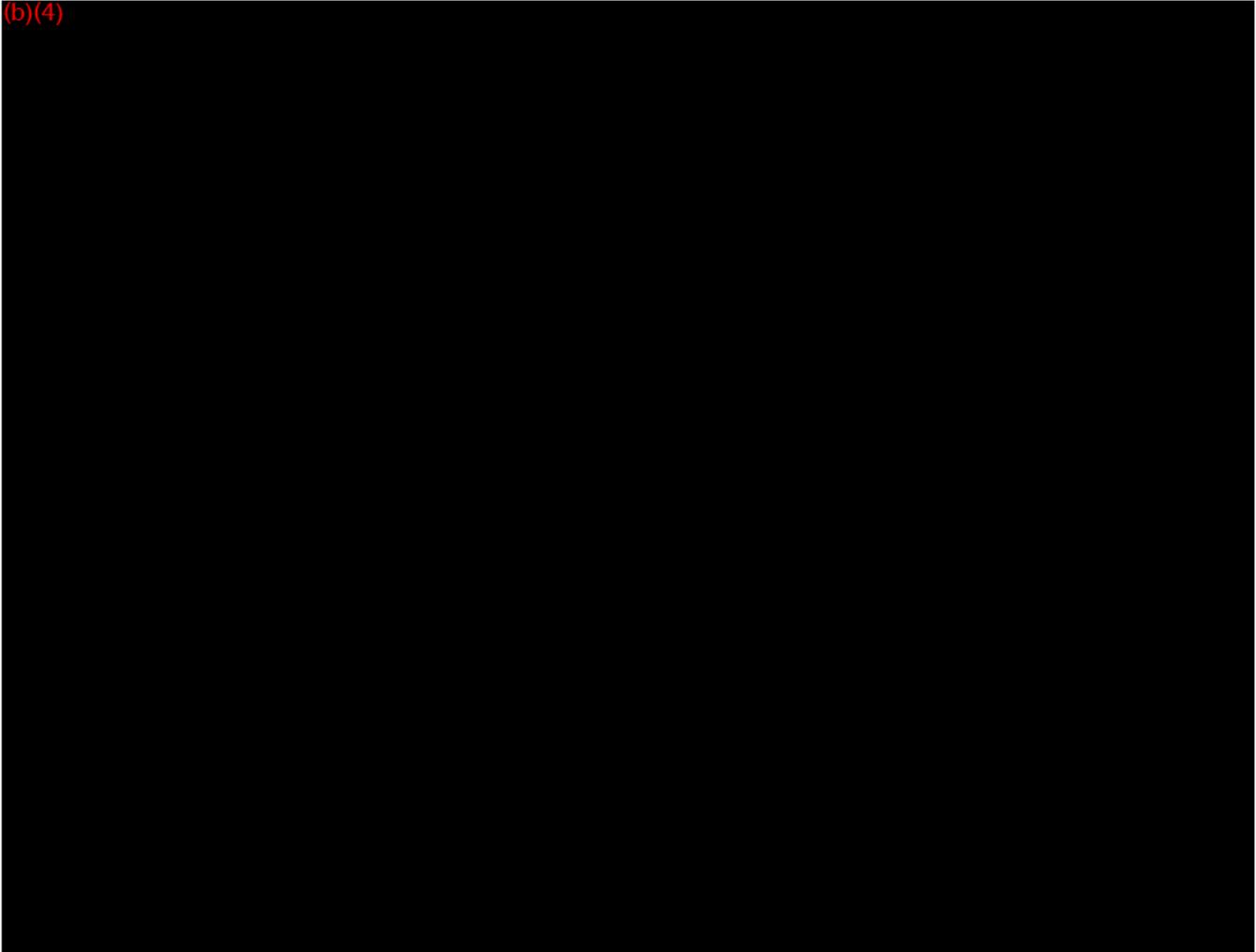
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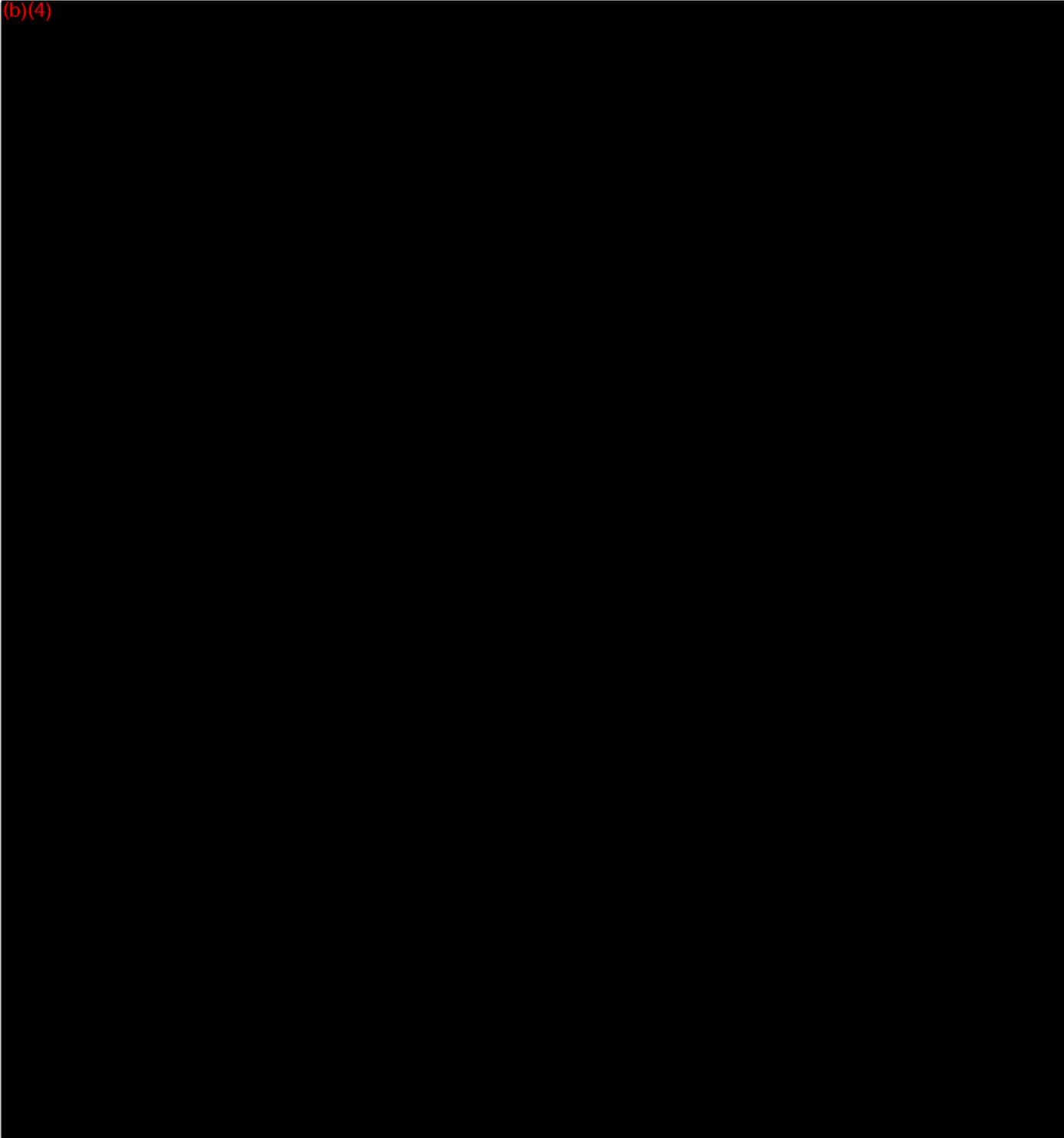
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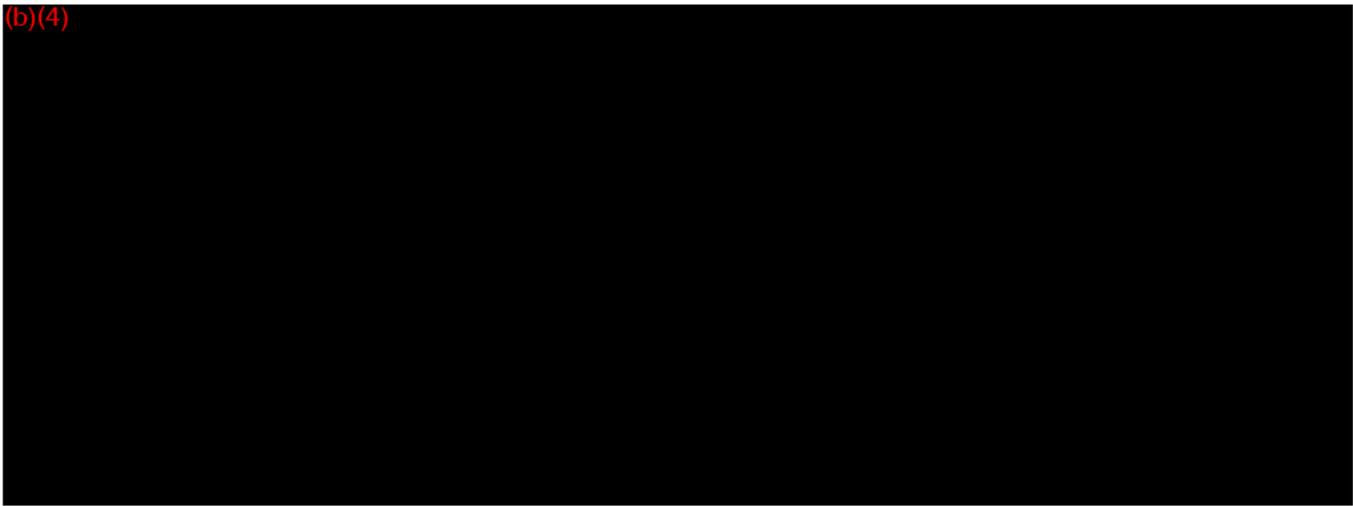
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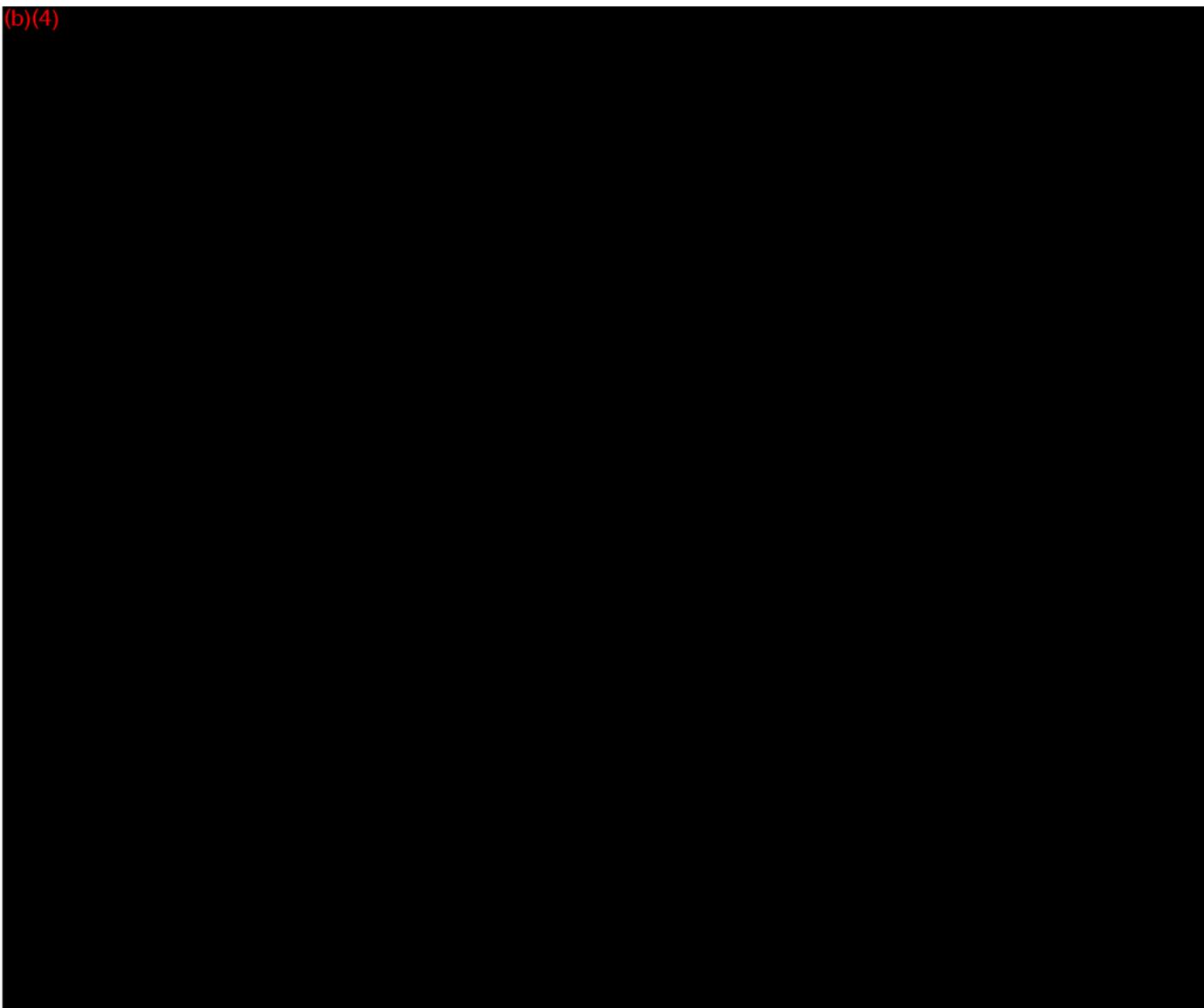
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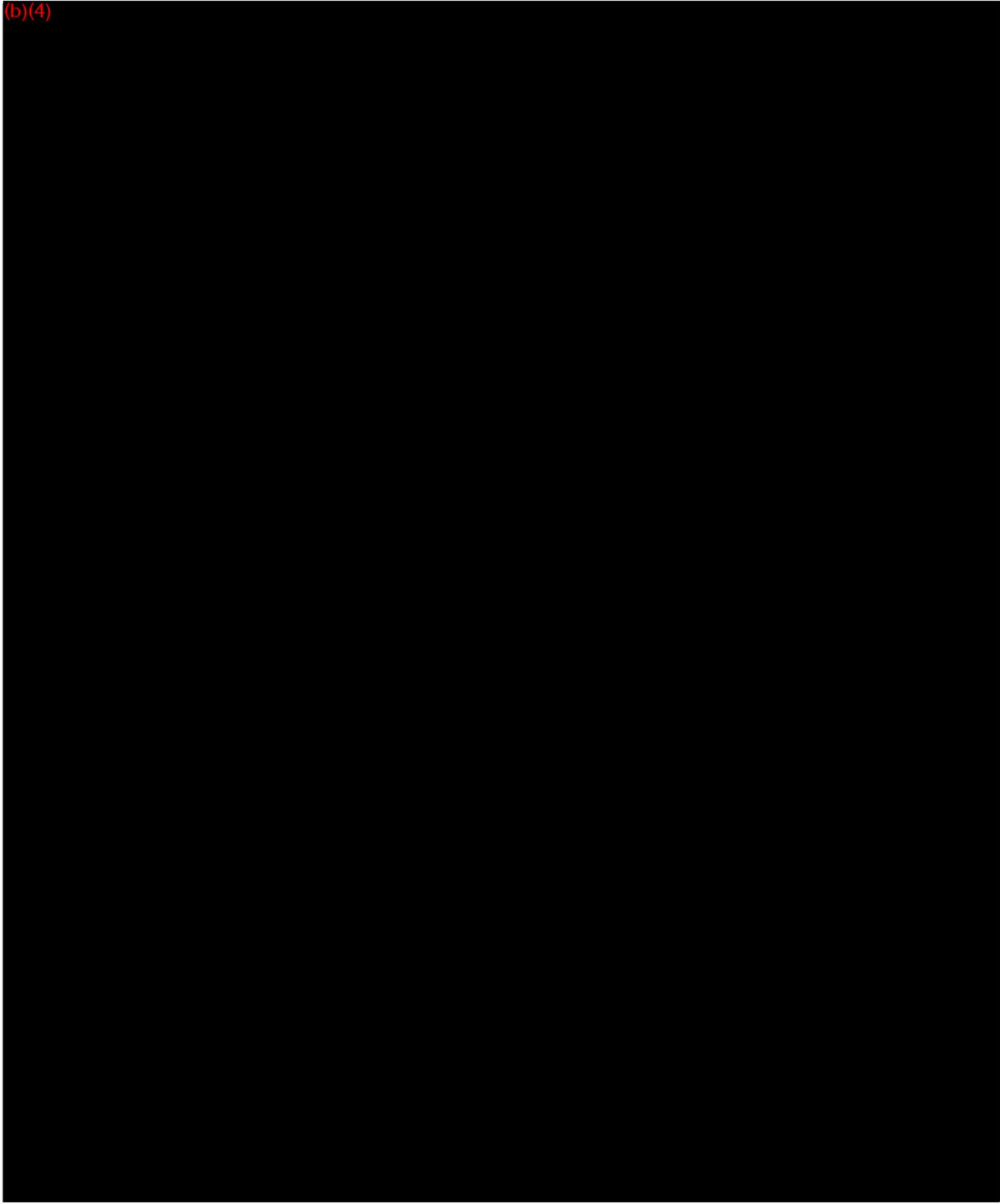
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IntraVia™ Empty Plastic Container

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510(k) Premarket Notification
IntraVia™ Empty Plastic Container

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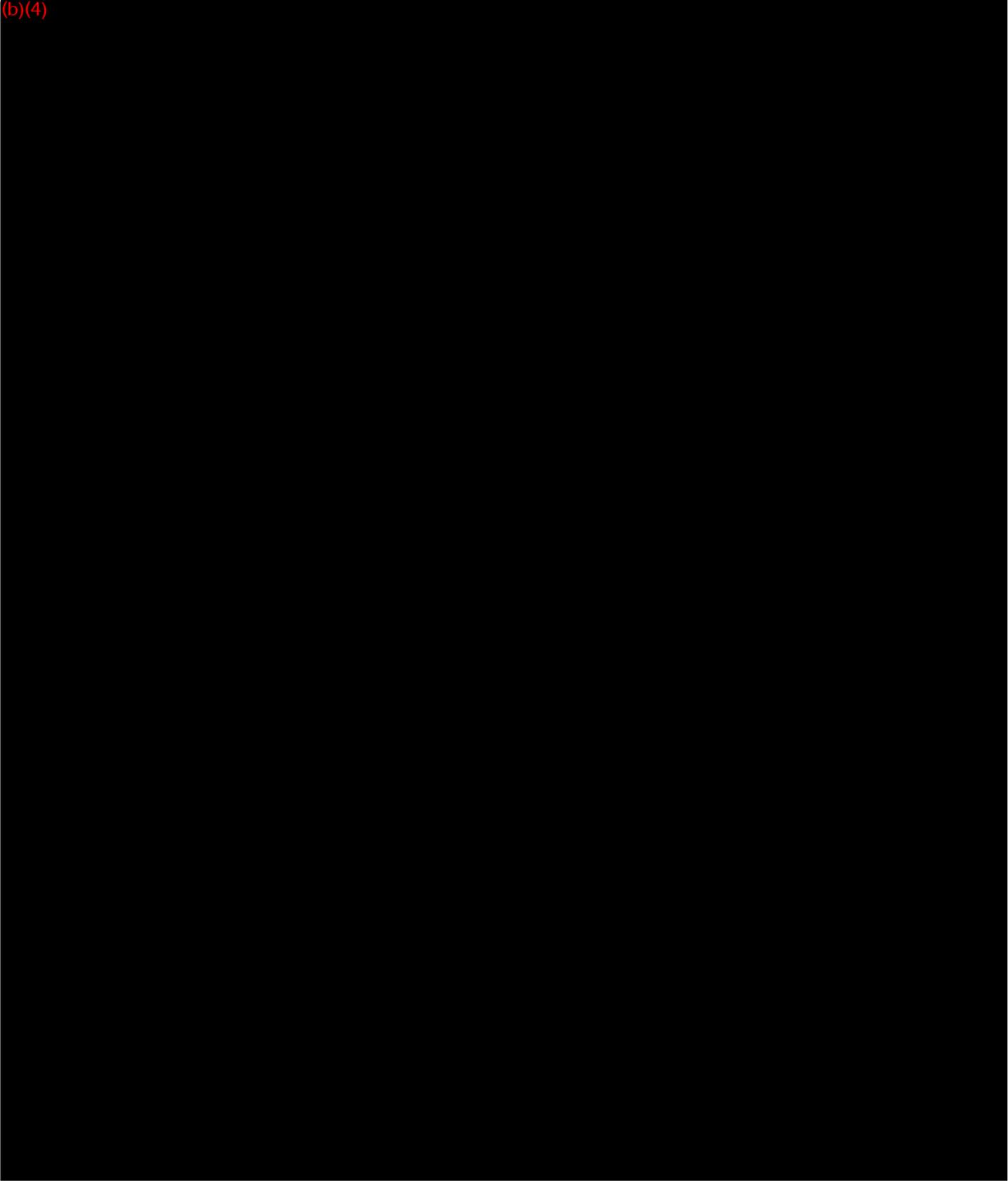
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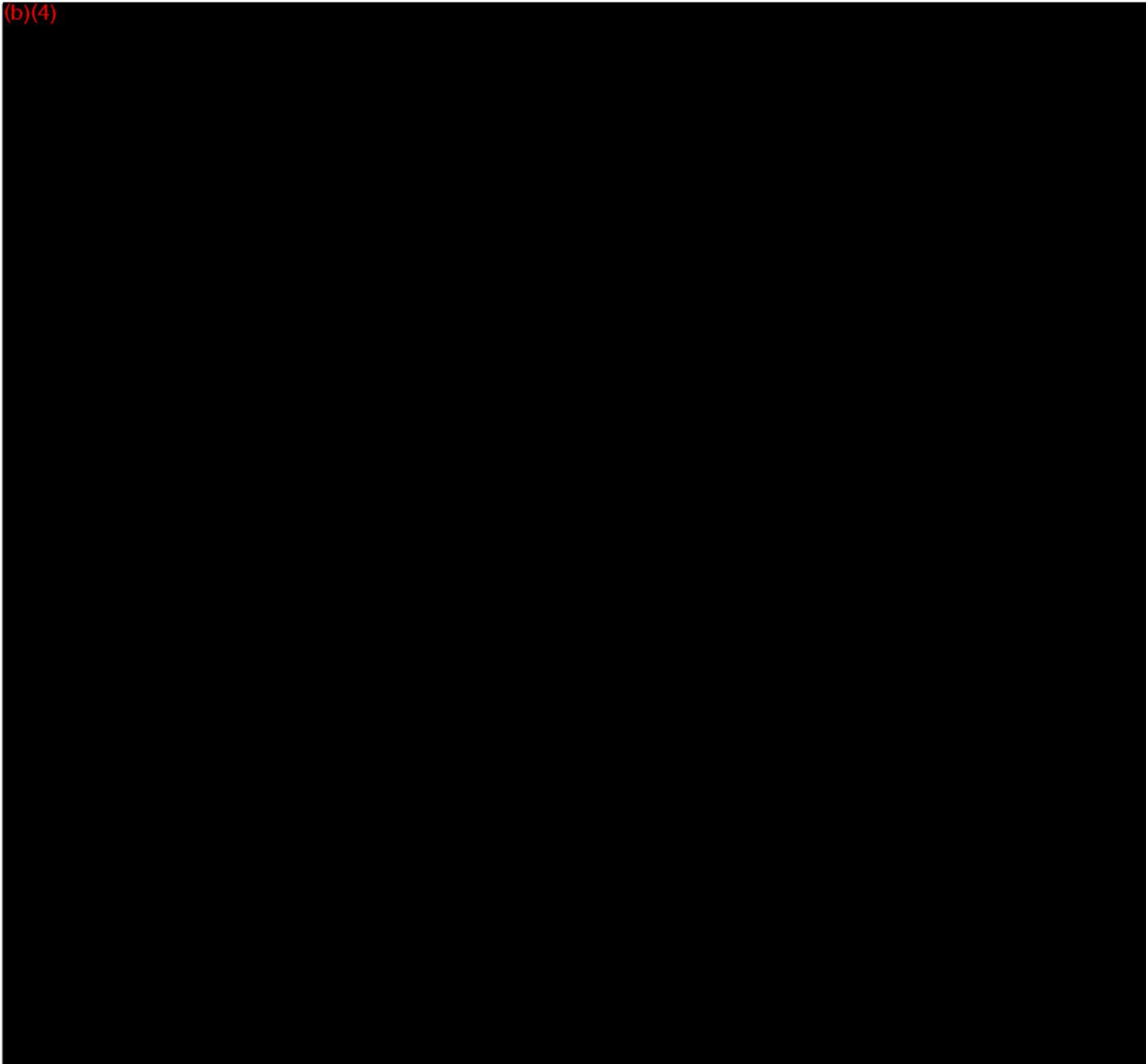
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IntraVia™ Empty Plastic Container

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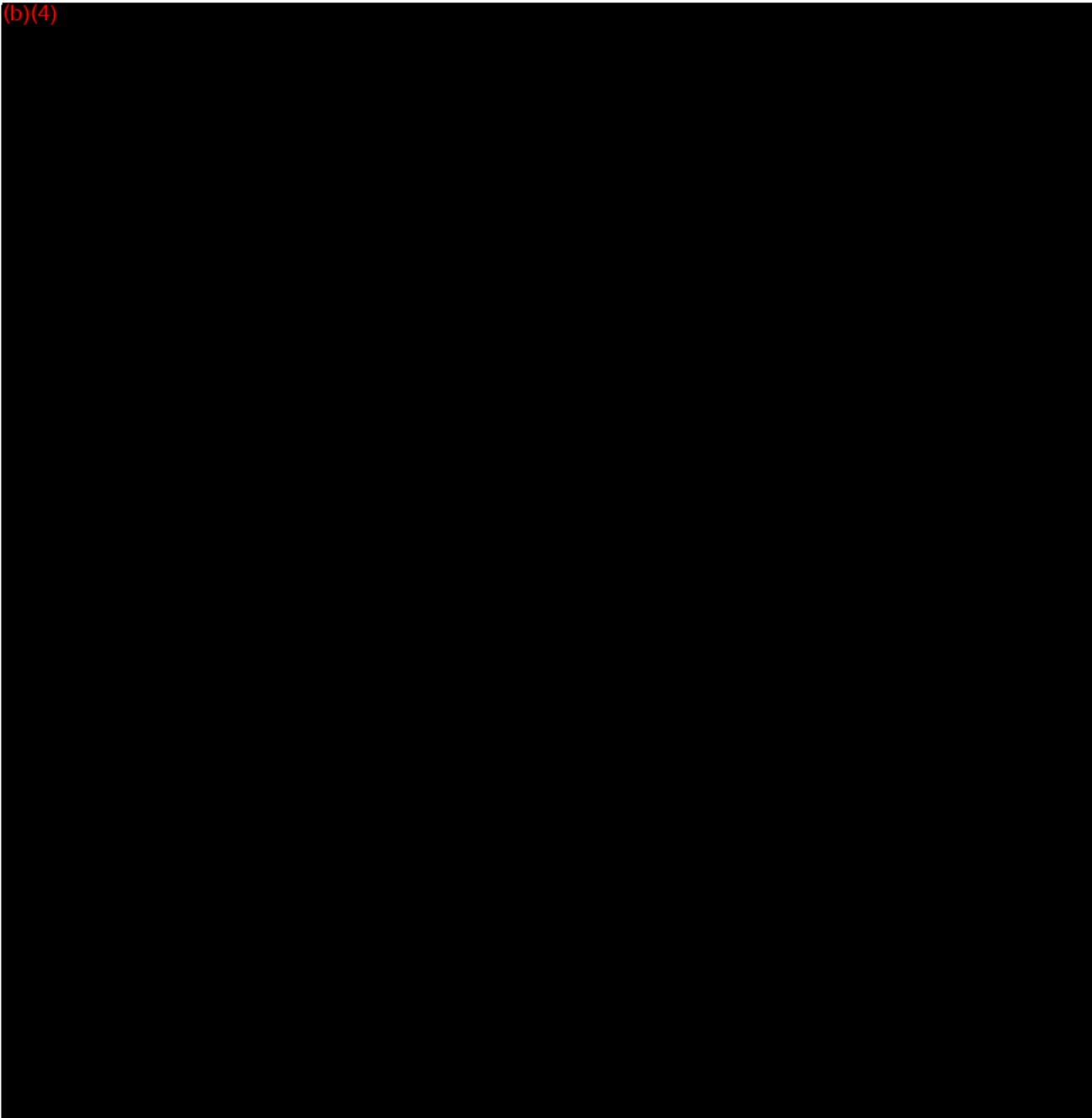
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IntraVia™ Empty Plastic Container

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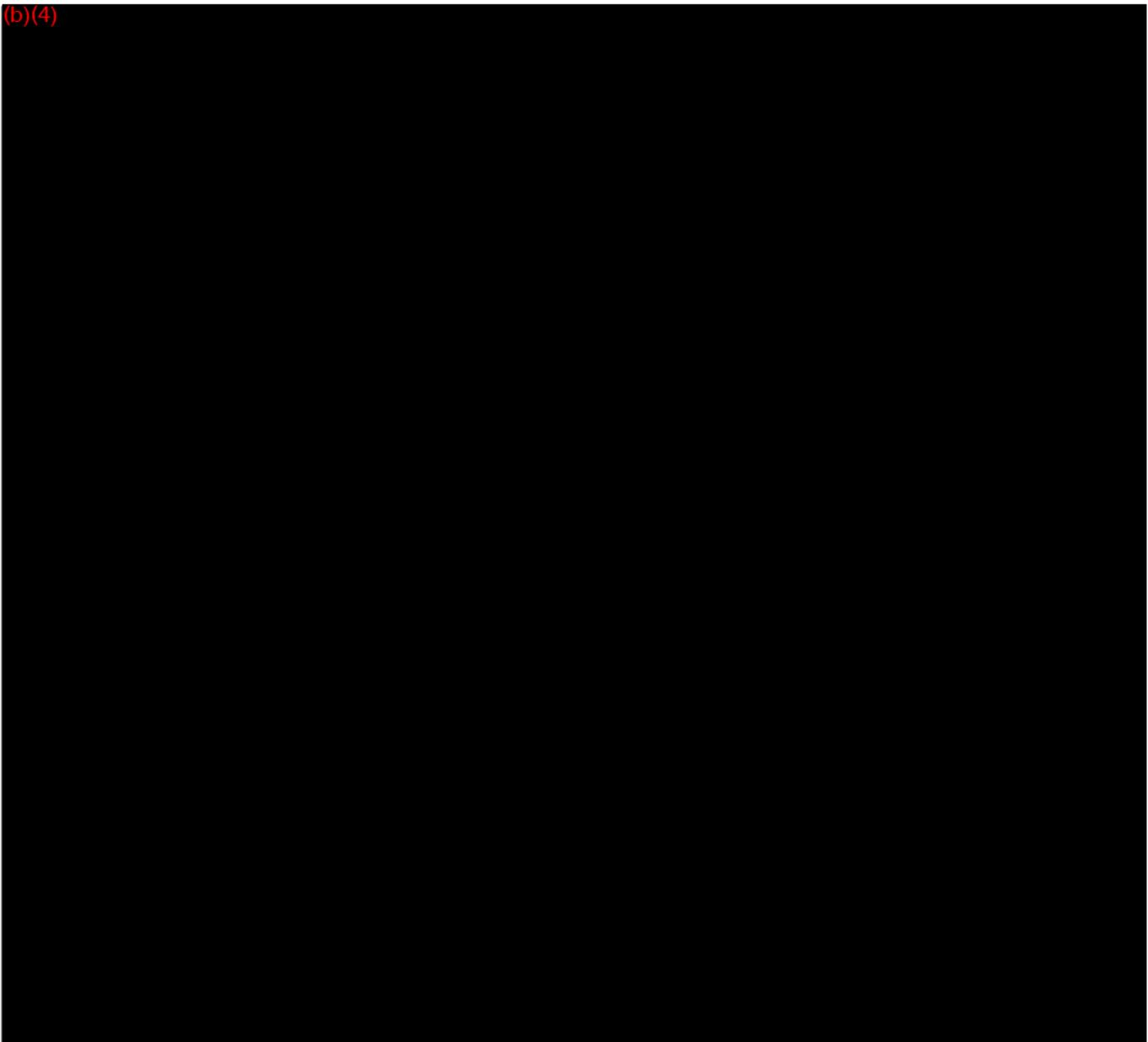
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IntraVia™ Empty Plastic Container

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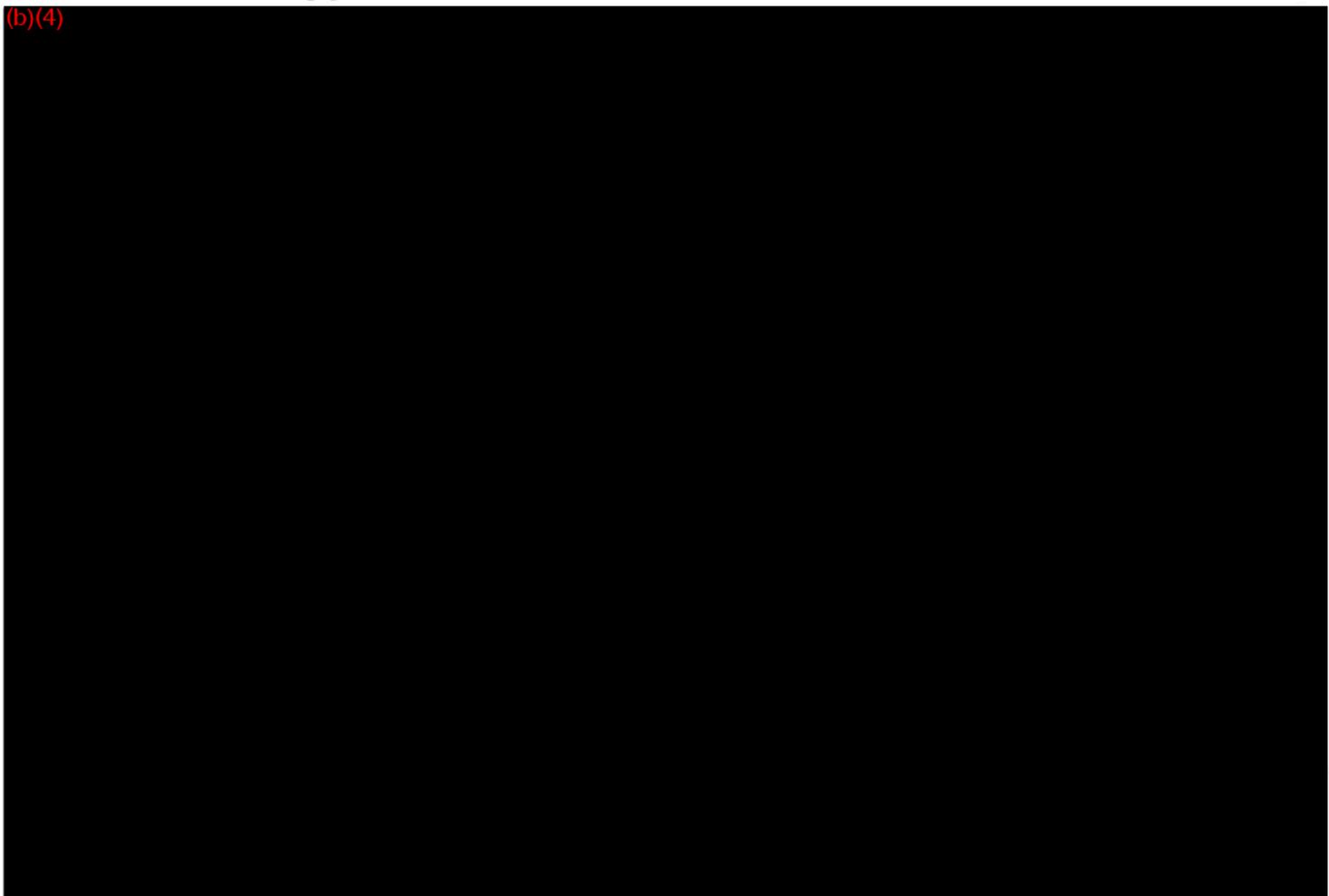
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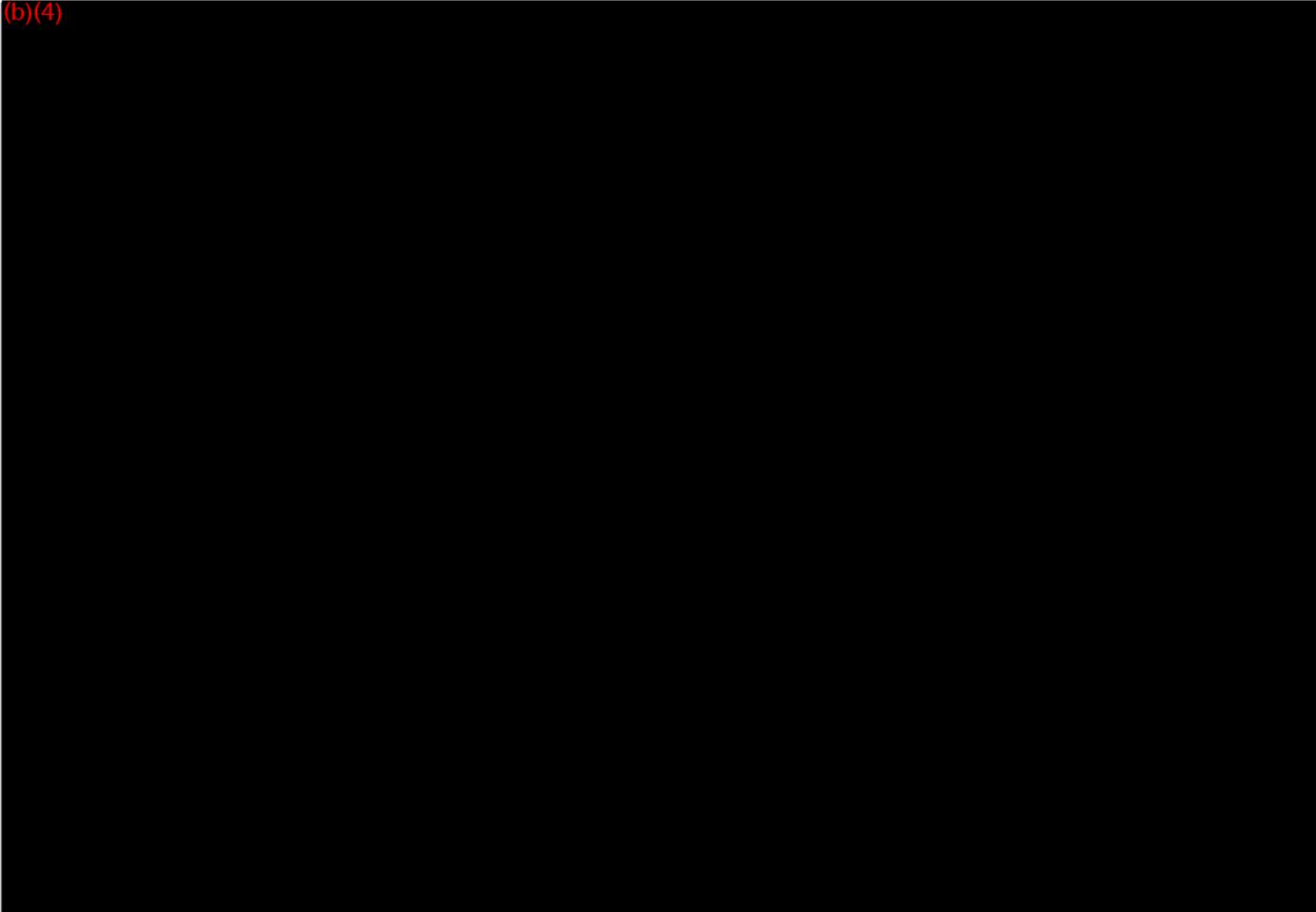
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IntraVia™ Empty Plastic Container

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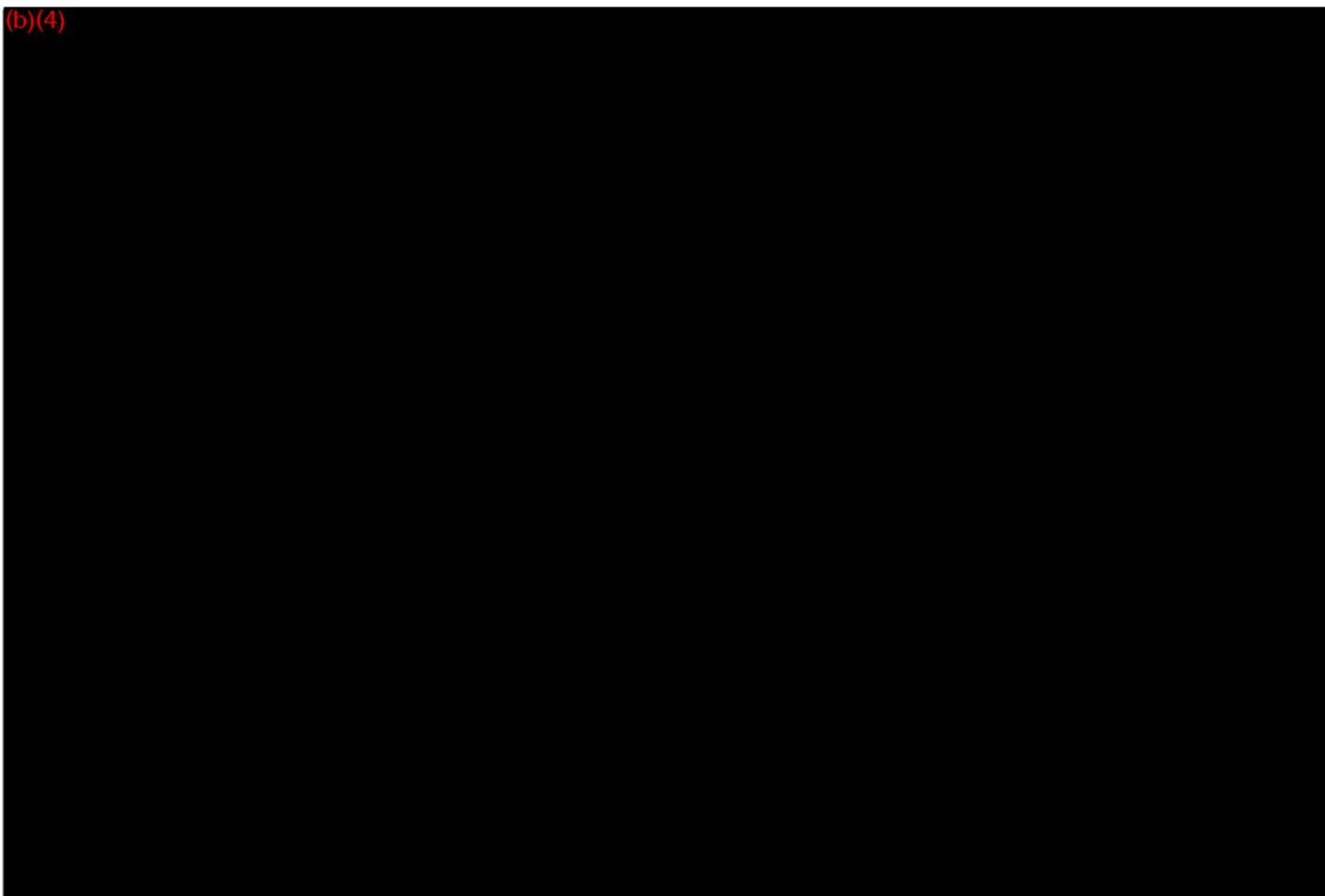
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IntraVia™ Empty Plastic Container

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Attachment 6.2
Drug Compatibility Evaluations
Literature References

NOV 26 1996

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Attachment 7.0

Draft Labeling

Attachment 7.0

Representative IntraVia™ Empty Container
Container Labeling

LOT EXP
 2B8011

— **IntraVia™ Container** **30**
— **150 mL Capacity**

— STERILE NONPYROGENIC FLUID PATH USE **60**
— ONLY WITH MEDICATIONS THAT ARE **90**
— COMPATIBLE WITH EACH OTHER MIX **120**
— THOROUGHLY CAUTIONS SQUEEZE AND **120**
— INSPECT FILLED BAG DISCARD IF LEAKS ARE **120**
— FOUND MUST NOT BE USED IN SERIES **120**
— CONNECTIONS FEDERAL (USA) LAW **120**
— RESTRICTS THIS DEVICE TO SALE BY OR ON **120**
— ORDER OF A PHYSICIAN ADHERE TO STORAGE **120**
— REQUIREMENTS OF ADDED MEDICATIONS

— **Baxter** **120**
— **BAXTER HEALTHCARE CORPORATION**
— **DEERFIELD IL 60015 USA** 
— **MADE IN USA**

81
WS8

Attachment 7.0

Representative IntraVia™ Empty Container
Pouch Labeling

2B8011
Qty. 6

IntraVia™ Container, Empty 150 mL Capacity

Sterile, nonpyrogenic fluid path

Single use only. Do not resterilize.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
Use only with medications that are compatible with each other.

Directions

Use aseptic technique

1. Prepare medication injection site. Insert needle (19 to 22 gauge) from medication container or syringe through medication site. Use smallest gauge needle first.
2. Mix solution thoroughly. For highly concentrated medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
3. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired. Affix transfer label to the bag.
4. Hang container. Remove plastic protector from outlet port. Attach administration set. Refer to set directions.
5. For supplementary medication, inject compatible medication through the medication site on container. Mix solution and medication thoroughly.

Warning

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Use solution within 24 hours after preparation or according to storage requirements in drug package insert, whichever is shorter.

Note

Some product components contain DEHP-plasticized PVC.

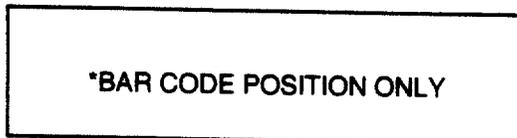
For Product Information
1-800-933-0303

Baxter

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA

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Attachment 8.0

Current Labeling

NOV 26 1996

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Attachment 8.0

Representative Viaflex® Empty Plastic Container
Current Container Labeling

LOT

288011

30 ***Baxter*** **30**

60 **Viaflex® Container** **60**

90 **150 mL Capacity** **90**

120 **STERILE NONPYROGENIC FLUID PATH** **120**

90 **USE ONLY WITH MEDICATIONS THAT ARE** **90**

90 **COMPATIBLE WITH EACH OTHER** **90**

90 **MIX THOROUGHLY** **90**

90 **CAUTIONS SQUEEZE AND INSPECT FILLED** **90**

90 **BAG DISCARD IF LEAKS ARE FOUND** **90**

120 **MUST NOT BE USED IN SERIES CONNECTIONS** **120**

120 **FEDERAL (USA) LAW RESTRICTS THIS** **120**

120 **DEVICE TO SALE BY OR ON ORDER OF A** **120**

120 **PHYSICIAN** **120**

120 **ADHERE TO STORAGE REQUIREMENTS OF** **120**

120 **ADDED MEDICATIONS** **120**

120 **BAXTER HEALTHCARE CORPORATION** **120**

120 **DEERFIELD IL 60015 USA** **120**

120 **MADE IN USA** **120**

Attachment 8.0

Representative Viaflex® Empty Plastic Container
Current Pouch Labeling

2B8011
Qty. 6

Viaflex® Container, Empty

150 mL Capacity

Sterile, nonpyrogenic fluid path

Single use only. Do not re-sterilize.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
Use only with medications that are compatible with each other.

Directions

Use aseptic technique

1. Prepare medication injection site. Insert needle (19 to 22 gauge) from medication container or syringe through medication site. Use smallest gauge needle first.
2. Mix solution thoroughly. For highly concentrated medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
3. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired. Affix transfer label to the bag.
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Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Use solution within 24 hours after preparation or according to storage requirements in drug package insert, whichever is shorter.

Note

This product contains DEHP-plasticized PVC.

For Product Information
1-800-933-0303

Baxter

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA

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All rights reserved.

7-7-2-76A
96/9



THIS ARTWORK REQUIRES THAT THE SUPPLIER INSERT AN HIBC BAR CODE MASTER IN THE POSITION INDICATED. HIBC BAR CODE MUST MATCH HUMAN READABLE ON ART AND ON SPEC. DO NOT ALTER HUMAN READABLE INFORMATION ON ART. BAR CODE MUST CONFORM TO ALL APPLICABLE BAXTER SPECS.

*BAR CODE POSITION ONLY

* + H 1 6 0 2 B 8 0 1 1 1 3 *

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W6

Attachment 9.0
Preenactment Catalogue

Price and Ordering Information

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EFFECTIVE FEBRUARY, 1975



TRAVENOL LABORATORIES, INC.
Deerfield, Illinois 60015

M6h



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SOLUTIONS IN VIAFLEX® PLASTIC CONTAINERS

	Description	Size/ml	Each	per Case	per Case	Num
2B0061	0338-0017-01	5% Dextrose Injection	150	1.90	12	22.80
2B0062	0338-0017-02		250	1.92	12	23.04
2B0063	0338-0017-03		500	1.94	12	23.28
2B0064	0338-0017-04		1000	2.32	12	27.84
2B0163	0338-0023-03	10% Dextrose Injection	500	2.23	12	26.76
2B0164	0338-0023-04		1000	2.60	12	31.20
2B1023	0338-0073-03	2.5% Dextrose and 0.45% Sodium Chloride Injection	500	1.97	12	23.64
2B1024	0338-0073-04		1000	2.36	12	28.32
2B1062	0338-0089-02	5% Dextrose and 0.9% Sodium Chloride Injection	250	2.01	12	24.12
2B1063	0338-0089-03		500	2.09	12	25.08
2B1064	0338-0089-04		1000	2.49	12	29.88
2B1073	0338-0085-03	5% Dextrose and 0.45% Sodium Chloride Injection	500	2.09	12	25.08
2B1074	0338-0085-04		1000	2.49	12	29.88
2B1083	0338-0081-03	5% Dextrose and 0.33% Sodium Chloride Injection	500	2.09	12	25.08
2B1084	0338-0081-04		1000	2.49	12	29.88
2B1092	0338-0077-02	5% Dextrose and 0.2% Sodium Chloride Injection	250	2.01	12	24.12
2B1093	0338-0077-03		500	2.09	12	25.08
2B1094	0338-0077-04		1000	2.49	12	29.88
2B1163	0338-0095-03	10% Dextrose and 0.9% Sodium Chloride Injection	500	2.39	12	28.68
2B1164	0338-0095-04		1000	2.82	12	33.84
2B1321	0338-0049-01	0.9% Sodium Chloride Injection	150	1.90	12	22.80
2B1322	0338-0049-02		250	1.92	12	23.04
2B1323	0338-0049-03		500	1.89	12	22.68
2B1324	0338-0049-04		1000	2.11	12	25.32
2B1803	0338-0129-03	Sodium Lactate Injection	500	3.00	12	36.00
2B1804	0338-0129-04		1000	3.70	12	44.40
2B2063	0338-0111-03	5% Dextrose in Ringer's Injection	500	2.55	12	30.60
2B2064	0338-0111-04		1000	2.98	12	35.76
2B2073	0338-0125-03	Lactated Ringer's (Hartmann's Solution) with 5% Dextrose	500	2.33	12	27.96
2B2074	0338-0125-04		1000	2.87	12	34.44
2B2303	0338-0105-03	Ringer's Injection	500	2.09	12	25.08
2B2304	0338-0105-04		1000	2.47	12	29.64
2B2322	0338-0117-02	Lactated Ringer's Injection	250	2.10	12	25.20
2B2323	0338-0117-03		500	2.29	12	27.48
2B2324	0338-0117-04		1000	2.57	12	30.84
2B5013	0338-0265-03	6% GENTRAN® 75 Injection in 0.9% Sodium Chloride	500	9.62	12	115.44

UNDERFILL VIAFLEX PLASTIC CONTAINERS

2B0081	0338-0017-11	5% Dextrose Injection	50 ml			
2B0082	0338-0017-18		in 150 ml	1.75	48	84.00
			100 ml			
			in 150 ml	1.75	48	84.00
2B1301	0338-0049-11	0.9% Sodium Chloride Injection	50 ml			
2B1302	0338-0049-18		in 150 ml	1.75	48	84.00
			100 ml			
			in 150 ml	1.75	48	84.00

*These products are subject to separate purchasing agreements and are not covered by standard VIAFLEX cc agreements.

EMPTY VIAFLEX® CONTAINERS

2B8004	Empty VIAFLEX Container with Y-Transfer Set	1000	3.85	24	92.40	E1
2B8011	Empty VIAFLEX Container	150	1.75	48	84.00	E1

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product
category
price list

Catalog Number	NDC Number	Description	Size/ml	Price Each	Units per Case	Price per Case	Section Page Number
2B8012		Empty VIAFLEX Container	250	1.75	48	84.00	E1
2B8013			500	1.80	48	86.40	E1
2B8014			1000	1.90	48	91.20	E1

VIAFLEX® ACCESSORIES

2B8031*		Shelf Tray		.12	50	6.00	E8
2B8032*		Expanding Shelf Tray		.27	50	13.50	E8
2B8041*		VIAVAC® Vacuum Unit			1	90.00	E7
2B8061*		Additive Needle		.12	48	5.76	E6
2B8065*		Additive Bands		.015	1000	15.00	E7
2M8009*		Vacuum Pump			1	90.00	E7

*With the exception of payment terms, this item is not covered by terms of any purchasing agreement.

SPECIALTY SOLUTIONS IN PLASTIC CONTAINERS

2B7634	0338-0189-44	TIS-U-SOL® Physiologic Irrigation Solution	1,000	2.08	12	24.96	A2
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Less than 50 Case Order
Price Each Price per Case Units per Case
50 Case Order or more
Price Each Price per Case Units per Case

SOLUTIONS IN UROMATIC™ PLASTIC CONTAINERS

2B7114	0338-0003-44	Sterile Water for Irrigation	1000	1.69	20.28	12	1.38	16
2B7117	0338-0003-47		3000	3.69	14.76	4	3.16	12
2B7124	0338-0047-44	0.9% Sodium Chloride Irrigating Solution	1000	1.69	20.28	12	1.38	16
2B7127	0338-0047-47		3000	3.69	14.76	4	3.16	12
2B7317	0338-0289-47	1.5% Glycine Urologic Irrigating Solution	3000	4.41	17.64	4	3.85	15
2B7357	0338-0295-47	3% Sorbitol Urologic Irrigating Solution	3000	4.41	17.64	4	3.85	15
2B7606	0338-0003-46	Sterile Water for Irrigation	2000	2.52	10.08	4	2.20	8
2B7616	0338-0047-46		0.9% Sodium Chloride Irrigating Solution	2000	2.52	10.08	4	2.20
2B7626	0338-0041-46	0.45% Sodium Chloride Irrigating Solution	2000	2.52	10.08	4	2.20	8

*Any combination of UROMATIC™ plastic, VIAFLEX® plastic and glass containers (solutions or pour bottles) may be applied to 50-case or more price.

Catalog Number	NDC Number	Description	Price Each	Units per Case	Price per Case	Section Page Number
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TRAVENOL SETS AND DIANEAL® EQUIPMENT

2C0001		Standard Administration Set	.83	48	39.84	C1
2C0002		Mini-Drip Administration Set	1.06	48	50.88	C2
2C0005		Extra-Long Administration Set with "Y"-Medication Site	1.15	48	55.20	C1
2C0006		Extra-Long Administration Set	1.07	48	51.36	C1
2C0011		Administration Set with Two "Y"-Medication Sites	1.35	48	64.80	C1
2C0012		Administration Set with Needle	1.07	48	51.36	C1
2C0017		Administration Set with Airway Connector	1.09	48	52.32	C2

NOV 26 199

Attachment 10.0

Substantial Equivalence Decision Tree

W67

510(k) "Substantial Equivalence" Decision Making Process

Baxter Healthcare Corporation is currently marketing a line of empty Viaflex® plastic containers used for the preparation and administration of drug admixtures. They propose to modify these containers in material composition and sterilization method and market them under the trade name IntraVia™ Container, Empty.

Using the logic flow chart entitled "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)¹," we explain how we attained a "Substantial Equivalence" conclusion. A copy of the flow chart, with the decision path highlighted, appears at the end of this attachment.

New Device is Compared to Marketed Devices

The proposed IntraVia™ empty container is the same in overall design and intended use to the currently marketed Viaflex® empty container. The IntraVia™ container differs from the Viaflex container in material composition and sterilization method. The materials of the container sheeting will change from polyvinyl chloride (PVC) to polyolefin. The administration and medication ports on the container will also change from PVC to a multilayer material consisting of polyolefin, SEBS and PVC. In addition, the medication site on the port will change from natural gum rubber to synthetic polyisoprene.

The primary reason for the change to polyolefin materials in the IntraVia™ container is to allow a change in sterilization methods from ETO to gamma sterilization. The change from natural gum rubber to synthetic polyisoprene in the medication site is being made to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

Does New Device Have Same Indication Statements?

Baxter's proposed IntraVia™ container will have the same intended use as the currently marketed Viaflex® empty container. It is intended for use in the preparation and administration of drug admixtures.

New Device has Same Intended Use and May be "Substantially Equivalent"

Does New Device Have Same Technological Characteristics, e.g., Design, Materials?

No. There are three materials in the proposed container which are new materials to Baxter devices. These include the PL 2408 polyolefin material, used for the container sheeting, the v4923 polyolefin material, used as a component of the ports and a constituent of the PL 2408 polyolefin and the R-256 polyisoprene material used for the medication site. Baxter states that the other solution-contacting materials to be used in the proposed IntraVia™ container have been previously used in marketed Baxter products for similar IV solution administration applications.

Could the New Characteristics Affect Safety and Effectiveness?

Yes. The container sheeting and ports come in contact with the infusion solution and therefore could potentially affect the quality or quantity of solution delivered to the patient.

Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?

No. The types of safety and effectiveness questions raised by the new device are the same as those raised by the marketed device, that is the quality and quantity of the solution delivered to the patient.

Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

Yes. The new materials have been evaluated through biological and chemical testing and found to be safe and suitable for their intended use. Summaries of the USP Physico-Chemical testing and ISO-10993 Biological Testing performed on the new materials are provided in Attachment 5.0 - Material Evaluation.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. The ability of the proposed device to meet performance specifications should be assessed.

Are Performance Data Available to Assess Effects of New Characteristics?

Yes. Functional testing has been performed and data is provided in Attachment 6.0 of the submission.

Performance Data Demonstrate Equivalence?

Yes. Performance data indicate that the proposed product meets or exceeds all functional requirements and supports suitability for use.

Substantially Equivalent Determination

Attachment 11.0

Summary of Safety and Effectiveness

W71

NOV 26 1996

94

510(k) SUMMARY

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

November 26, 1996

Proposed Device:

IntraVia™ Empty Plastic Container

Predicate Devices:

Viaflex® Empty Plastic Container

Proposed Device Description:

Baxter is currently marketing a line of empty Viaflex® plastic containers used for the preparation and administration of drug admixtures. We propose to change the materials of the container sheeting, administration and medication ports and medication site and market the container under the tradename IntraVia™ Container, Empty.

The primary reason for the change in container materials is to allow a change in sterilization methods from ETO to gamma sterilization. In addition, use of the IntraVia™ container in place of the Viaflex® container offers several benefits including use of standard thermoplastic methods for recycling and reduction in the amounts of environmental contaminants released during incineration of PVC such as hydrochloric acid and dioxins. The material change in the medication site is being made to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed IntraVia™ container is the same in overall design and intended use as the currently marketed Viaflex® container. The IntraVia™ container differs from the Viaflex® container in material composition and sterilization method.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The biological and chemical reactivity of the new container materials have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the proposed empty IV container and its drug compatibility characteristics have been generated. Functional performance studies included residual volume, fill volume, spike insertion/removal force and burst testing. Performance testing indicate that the proposed container meets or exceeds all functional requirements and support its suitability for use.

Drug compatibility studies were conducted with commonly admixed drugs or those that have a high potential to adsorb to the container under representative storage conditions. Results of drug compatibility evaluations support the suitability of the new container for its intended use.

Attachment 12.0

Truthful and Accurate Statement

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))**

I certify that, in my capacity as Manager, Regulatory Affairs of Baxter Healthcare Corporation, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.



Mary Ellen Snyder

Manager, Regulatory Affairs, I.V. Systems Division

11/25/96

Date

I certify that, in my capacity as Director, Technical Center of Baxter Healthcare Corporation, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.



Terry Kochersperger

Director, Technical Center, I.V. Systems Division

11/25/96

Date

Attachment 13.0

Indication for Use

510(k) Premarket Notification
IntraVia™ Empty Plastic Container

510(k) Number: Not Available

Device Name: IntraVia™ Empty Plastic Container

Indication for Use:

The IntraVia™ Empty Plastic Container is intended for use in the preparation and administration of drug admixtures.

NOV 26 1996
100

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 4.2f

Results of ISO-10993-1 Biological Testing

(b)(4) Testing

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(b)(4) Testing

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FEB 21 1997

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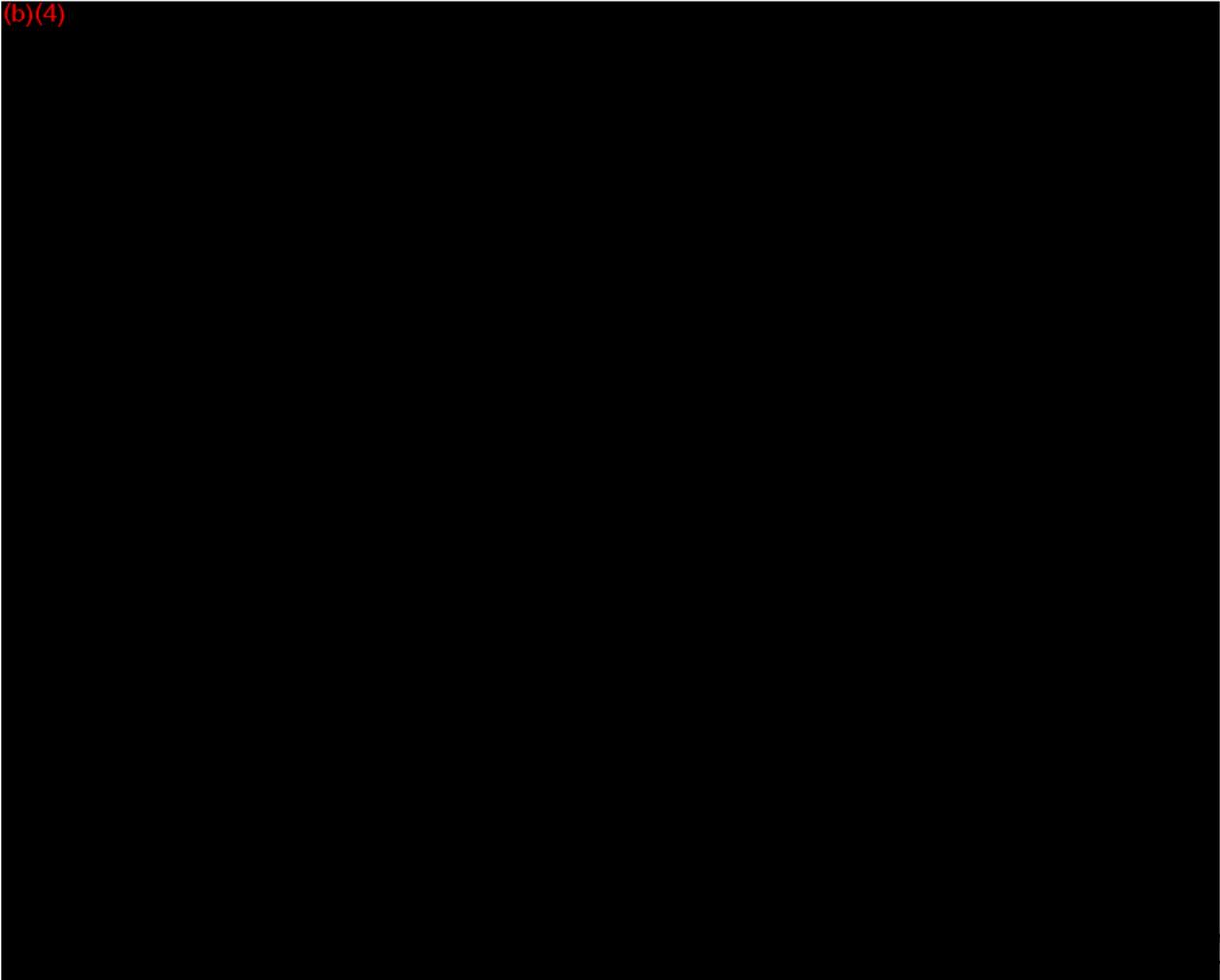
February 21, 1997

Ms. Brenda Bolden
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation, HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

**RE: K964853 - IntraVia™ Empty Plastic Container
Request for Additional Information**

Dear Ms. Bolden:

(b)(4)

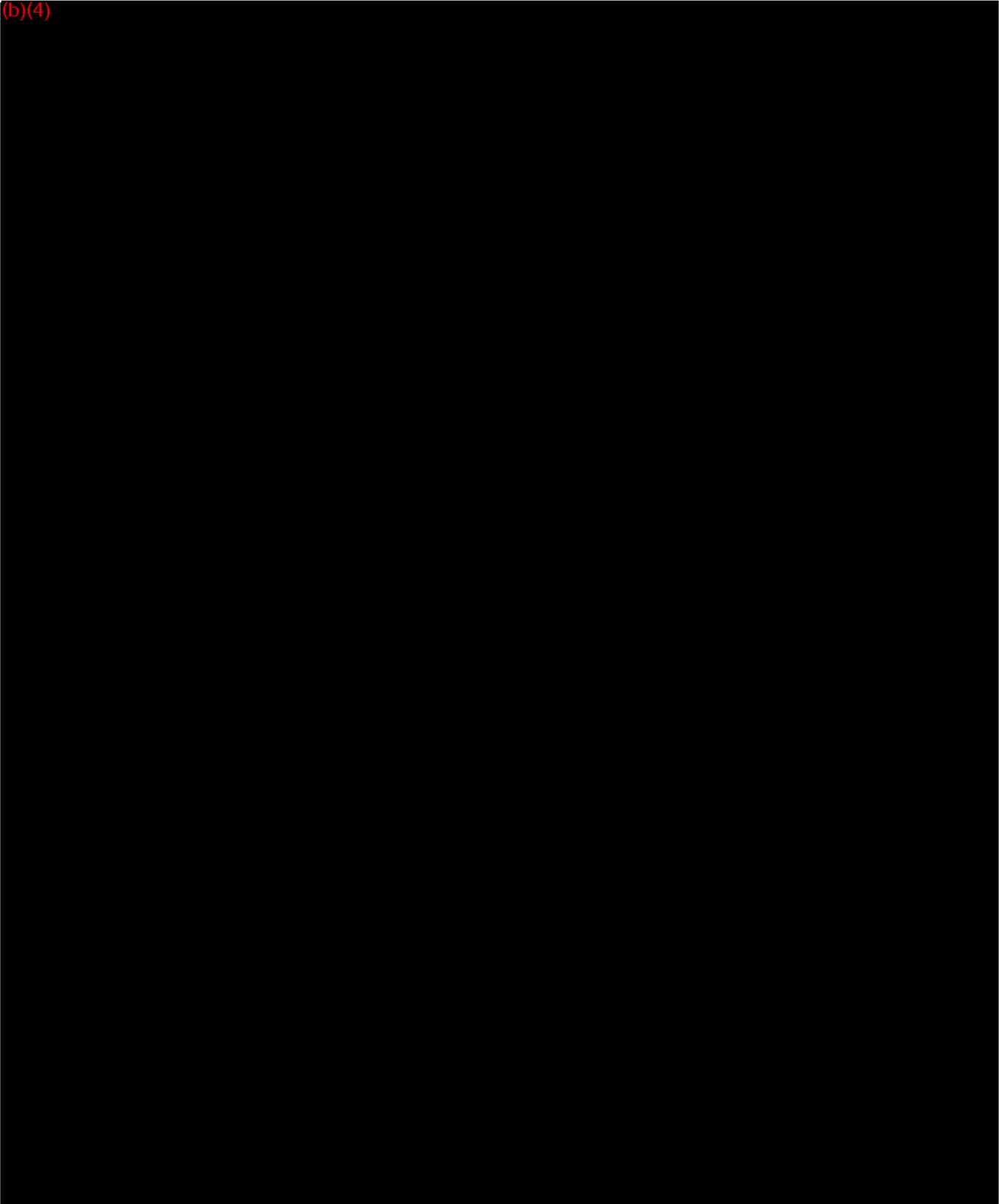


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Ms. Brenda Bolden
K964853
February 21, 1997

Page 2

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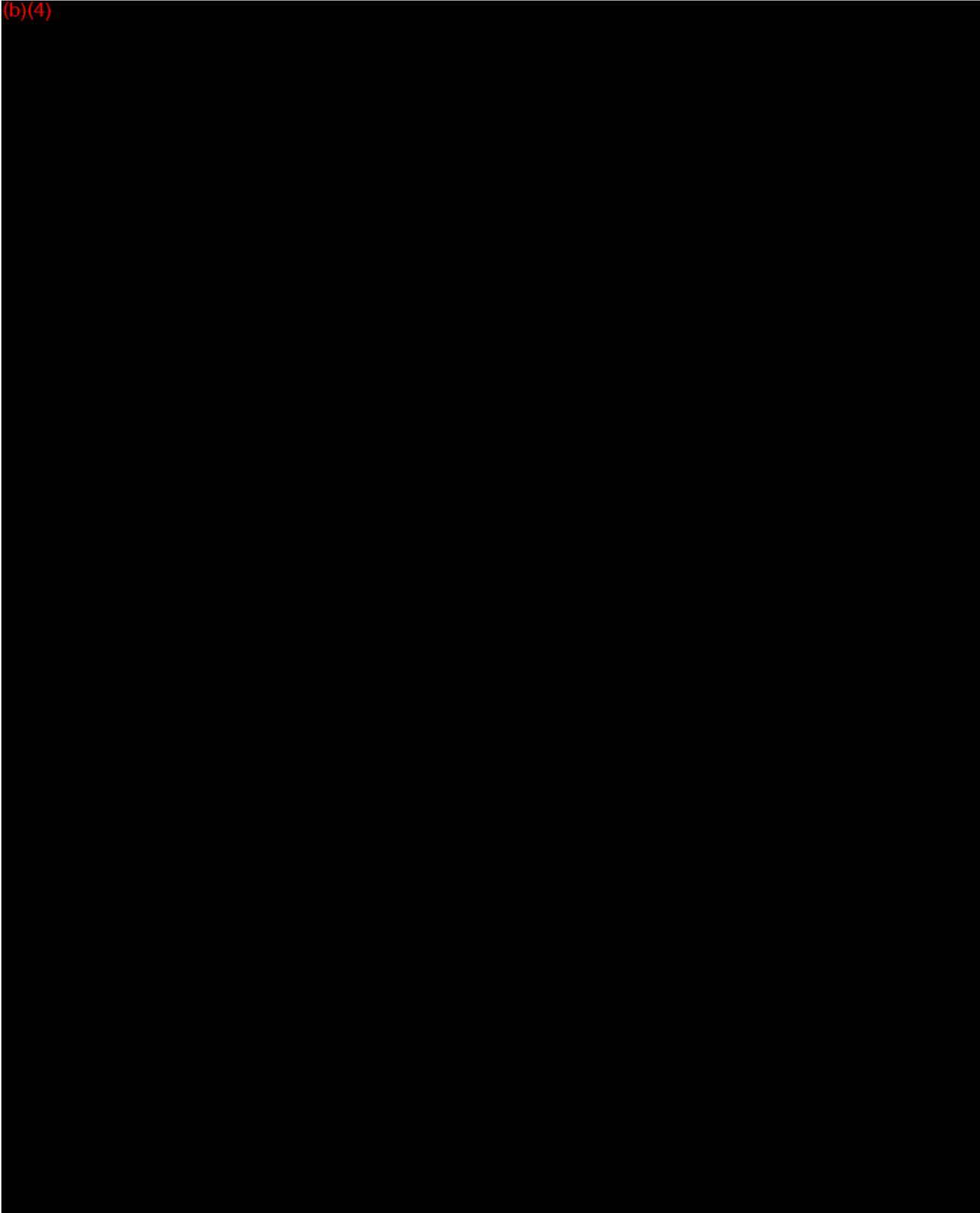


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Ms. Brenda Bolden
K964853
February 21, 1997

Page 3

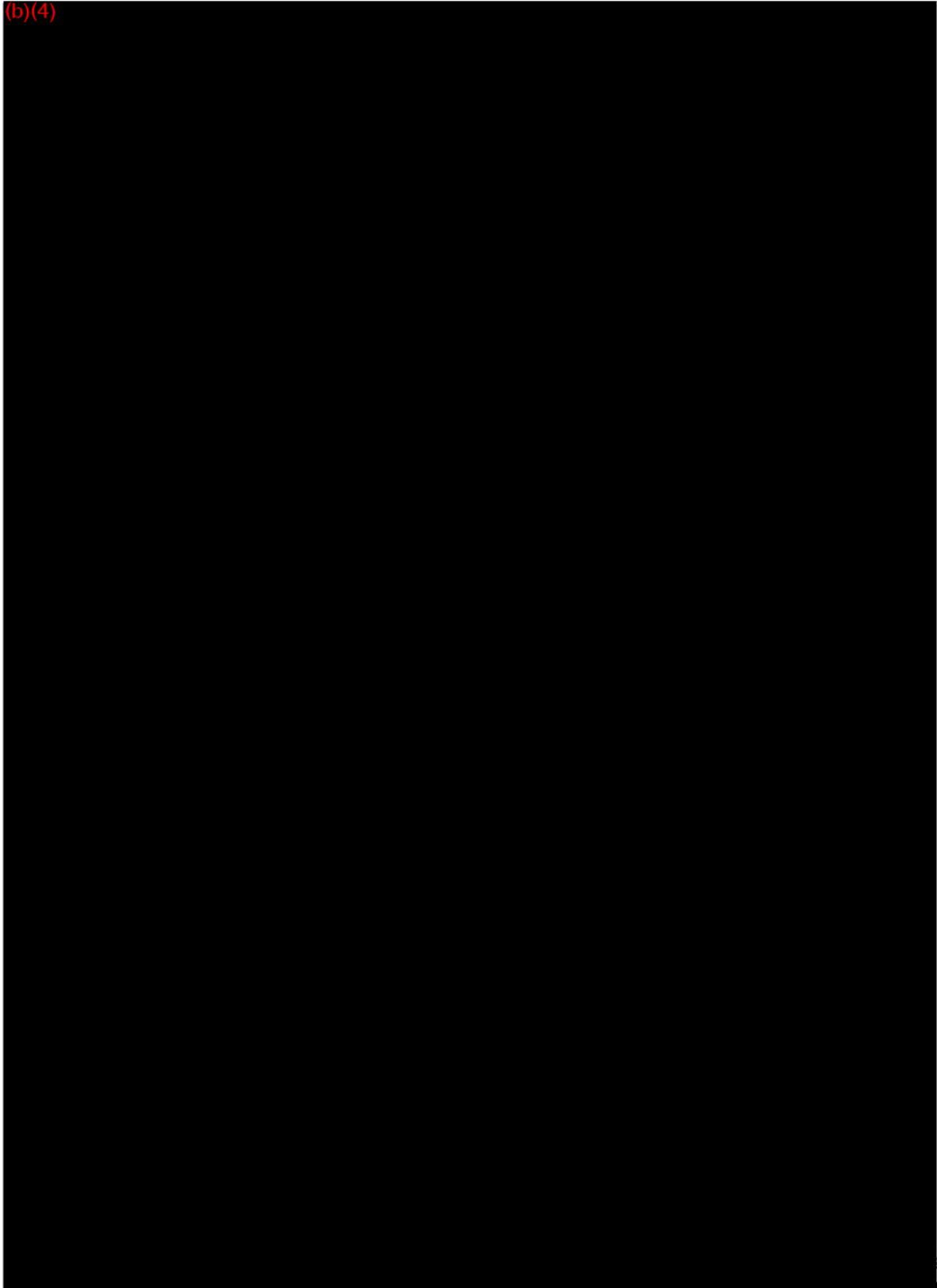
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Ms. Brenda Bolden
K964853
February 21, 1997

Page 4

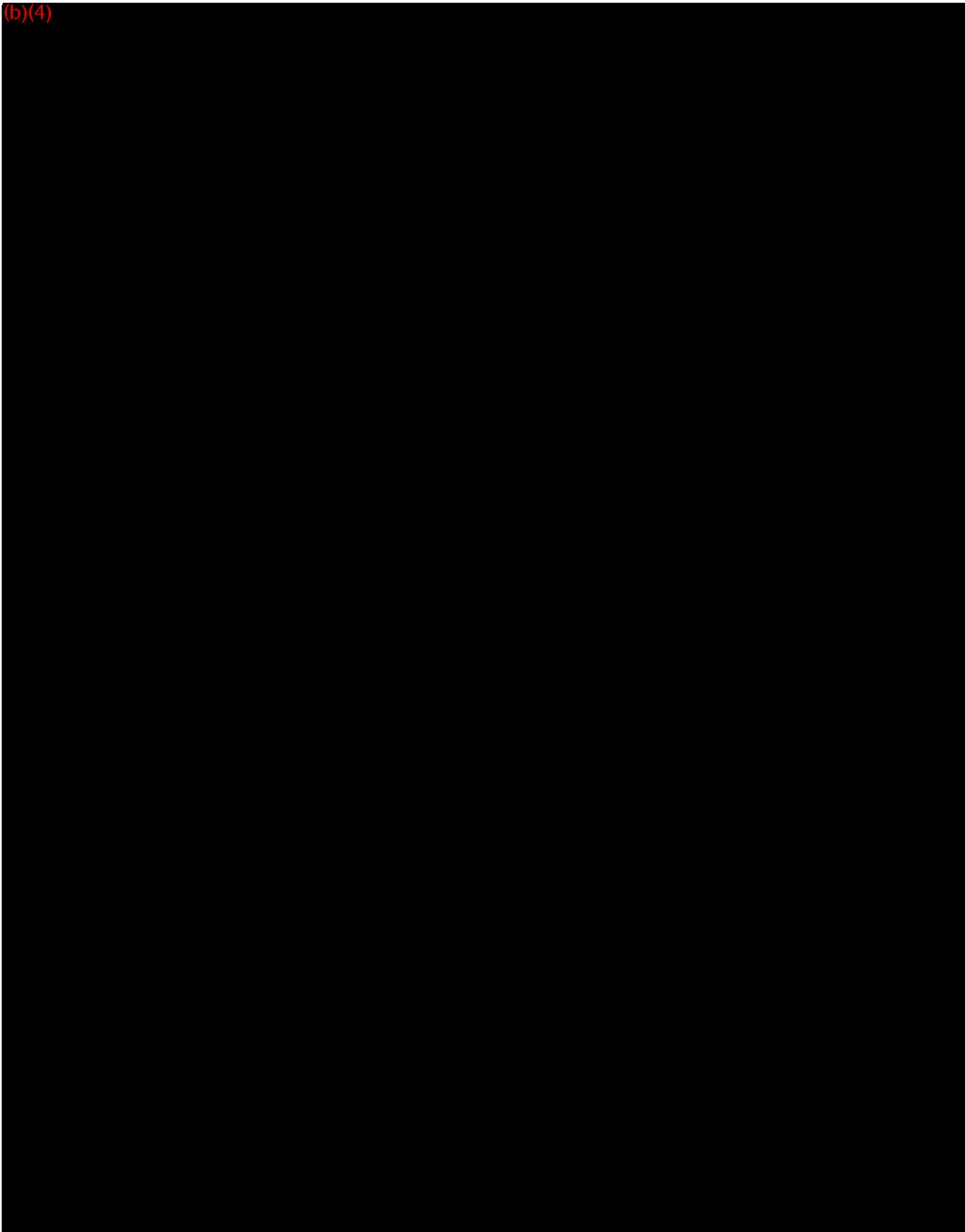
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Ms. Brenda Bolden
K964853
February 21, 1997

Page 5

(b)(4)

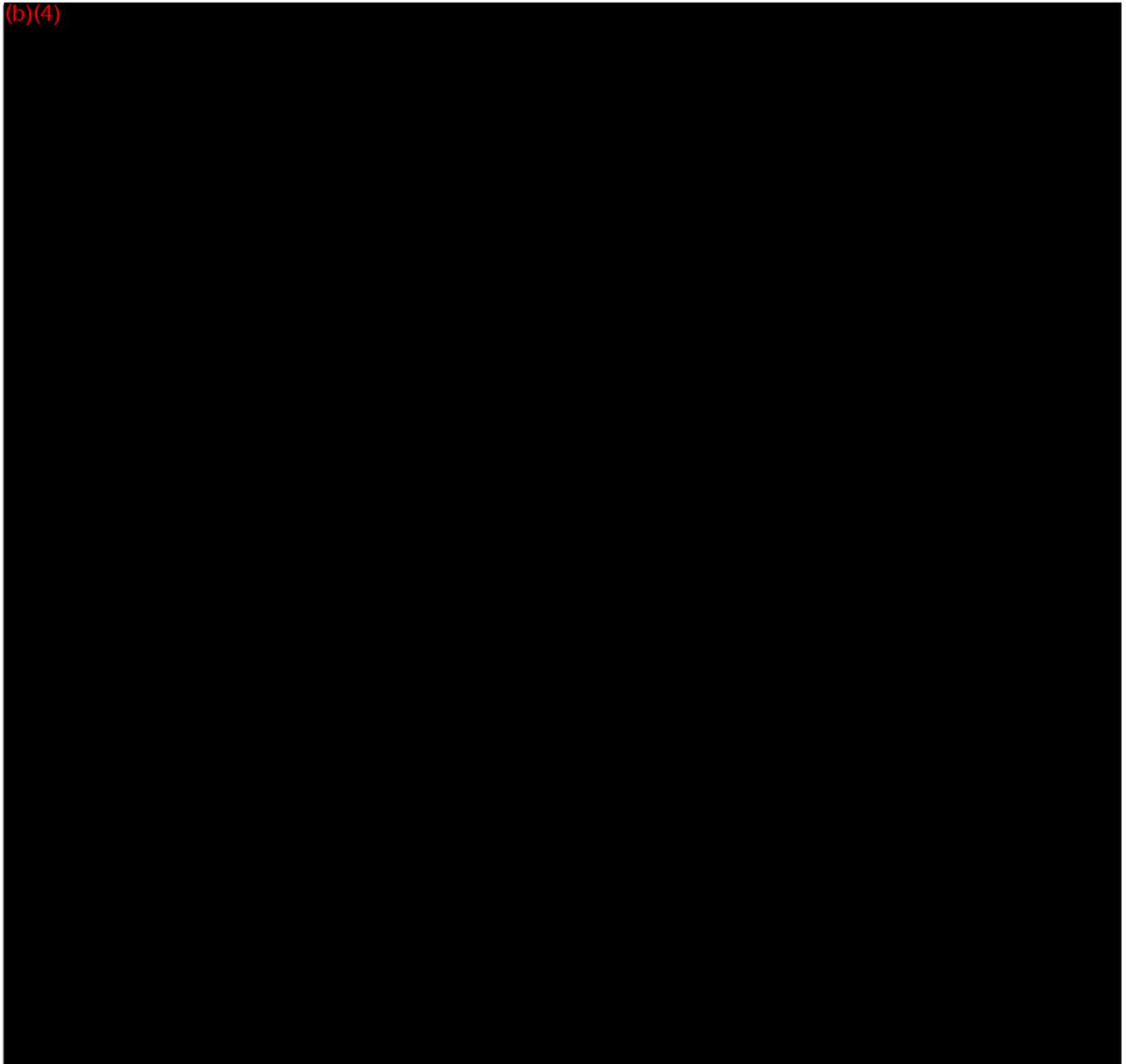


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Ms. Brenda Bolden
K964853
February 21, 1997

Page 6

(b)(4)



Sincerely,

Mary Ellen Snyder
Regulatory Affairs Manager
(847) 270-4644
(847) 270-4668 (FAX)

s:\510\964853r1

FEB 21 1997

3576

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 1.0

Comparison of Functional Testing Results

358 7

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 2.0

**Draft Container Labeling
Proposed IntraVia™ Empty Container**

(From p. 81 of 11/26/96 Original Submission)

FEB 21 1997

360 9

510(k) Premarket Notification
IntraVia™ Empty Plastic Container

Attachment 7.0

Representative IntraVia™ Empty Container
Container Labeling

LOT EXP
2B8011

— **IntraVia™ Container** 30
150 mL Capacity

— STERILE NONPYROGENIC FLUID PATH USE ONLY WITH MEDICATIONS THAT ARE COMPATIBLE WITH EACH OTHER MIX THOROUGHLY CAUTIONS SQUEEZE AND INSPECT FILLED BAG DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN ADHERE TO STORAGE REQUIREMENTS OF ADDED MEDICATIONS 60

— **Baxter** 90
 BAXTER HEALTHCARE CORPORATION
 DEERFIELD IL 60015 USA 
 MADE IN USA 120

NOV 26 1996

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FEB 21 1997

2610

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 3.0

Summary of Observations/Results for ISO 10993-1 Testing

(b)(4)



FEB 21 1997

Handwritten signature and initials

Ms. Brenda Bolden
K964853
February 21, 1997

Attachment 4.0

**Results of ISO-10993-1 Biological Testing
(Test Data Sheets and Study Reports)**

*Please Note: Attachment 4.0 will be supplied in the hard copy
being sent by Federal Express*

FEB 21 1997

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MEMO RECORD

DATE: 1/24/97

FROM: Brenda Bolden, Biologist

DIVISION: DDIGD/GH

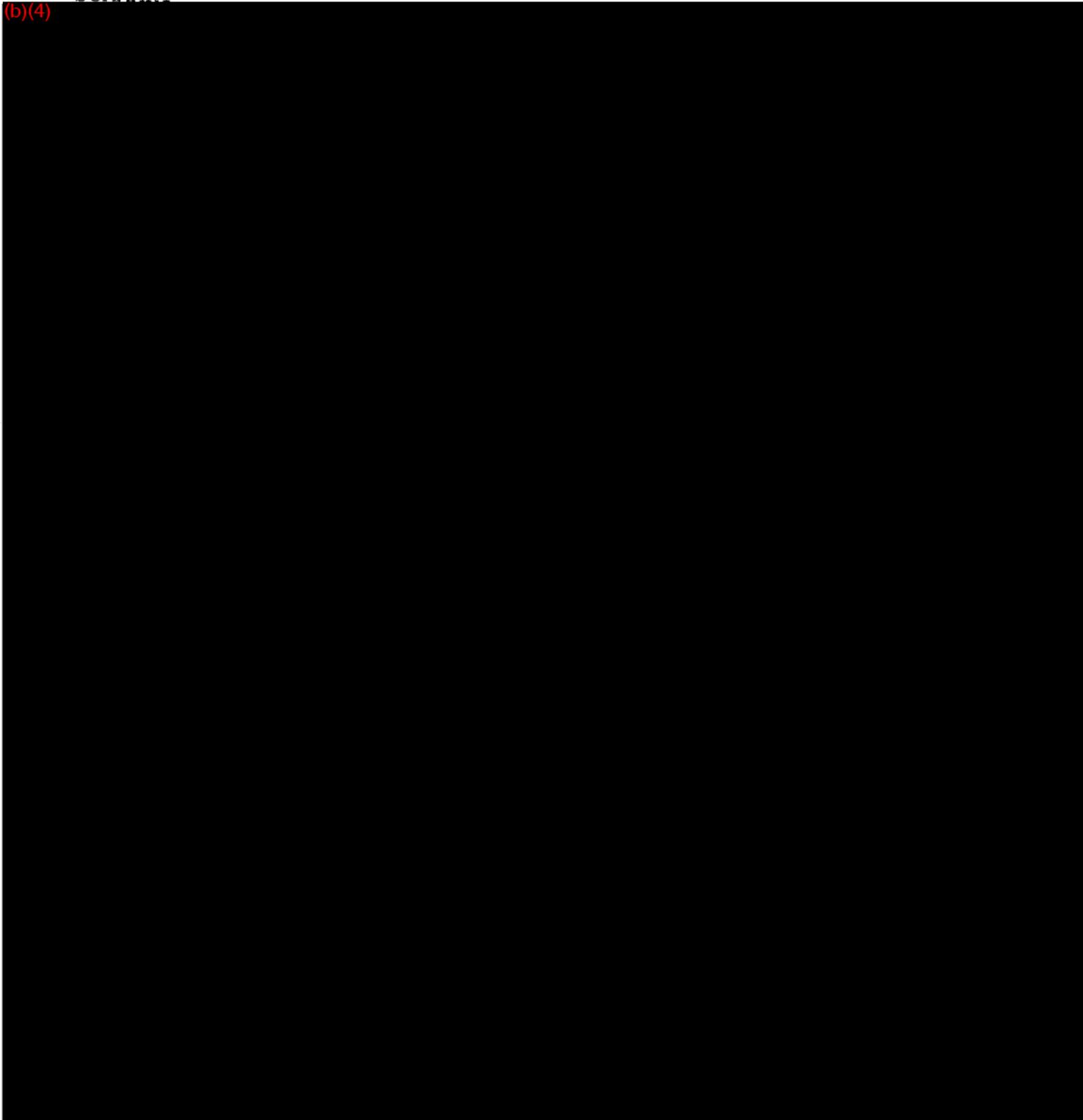
TO: The Record

OFFICE: ODE

SUBJECT: Baxter Intravia Empty Container, K964853

SUMMARY

(b)(4)



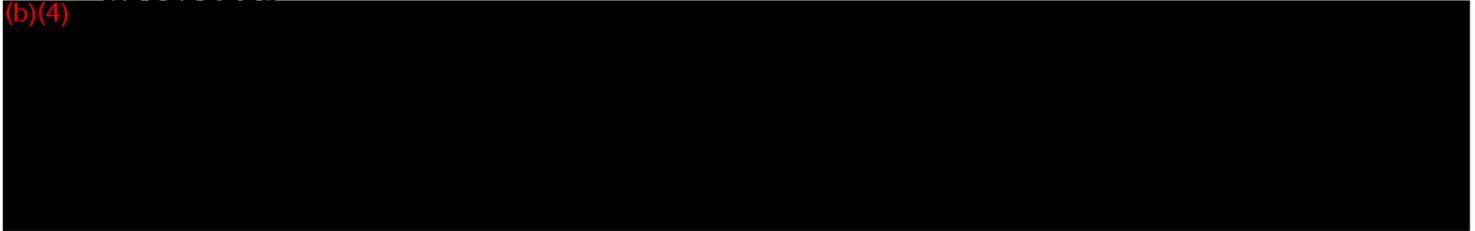
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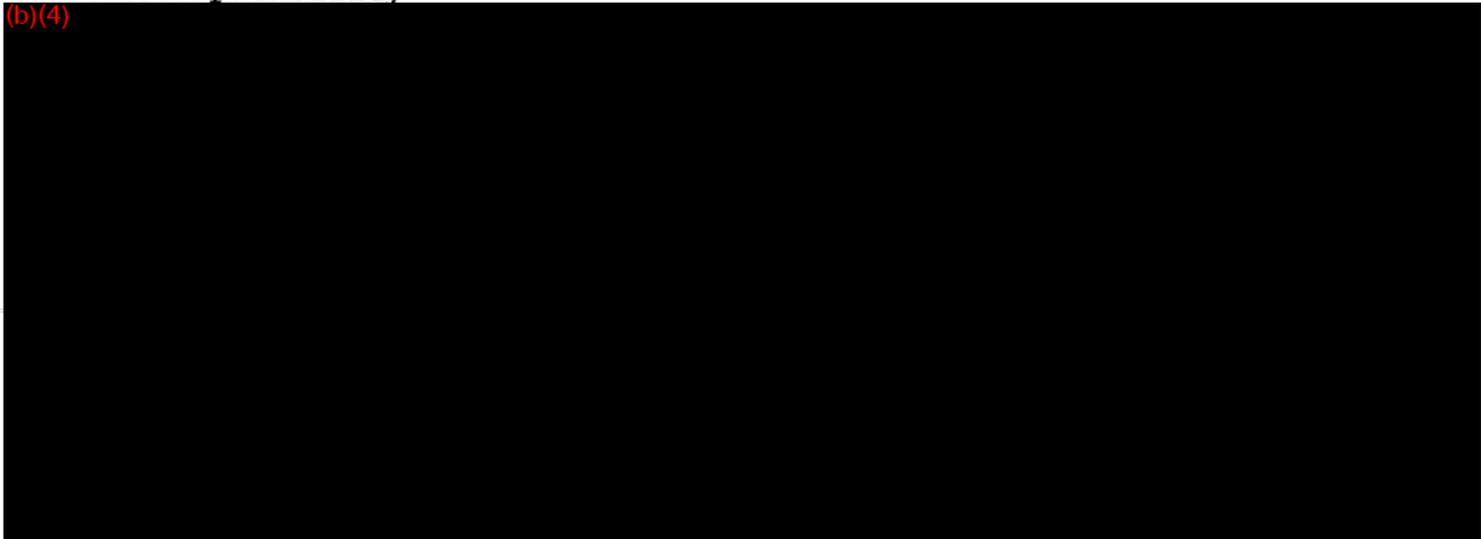
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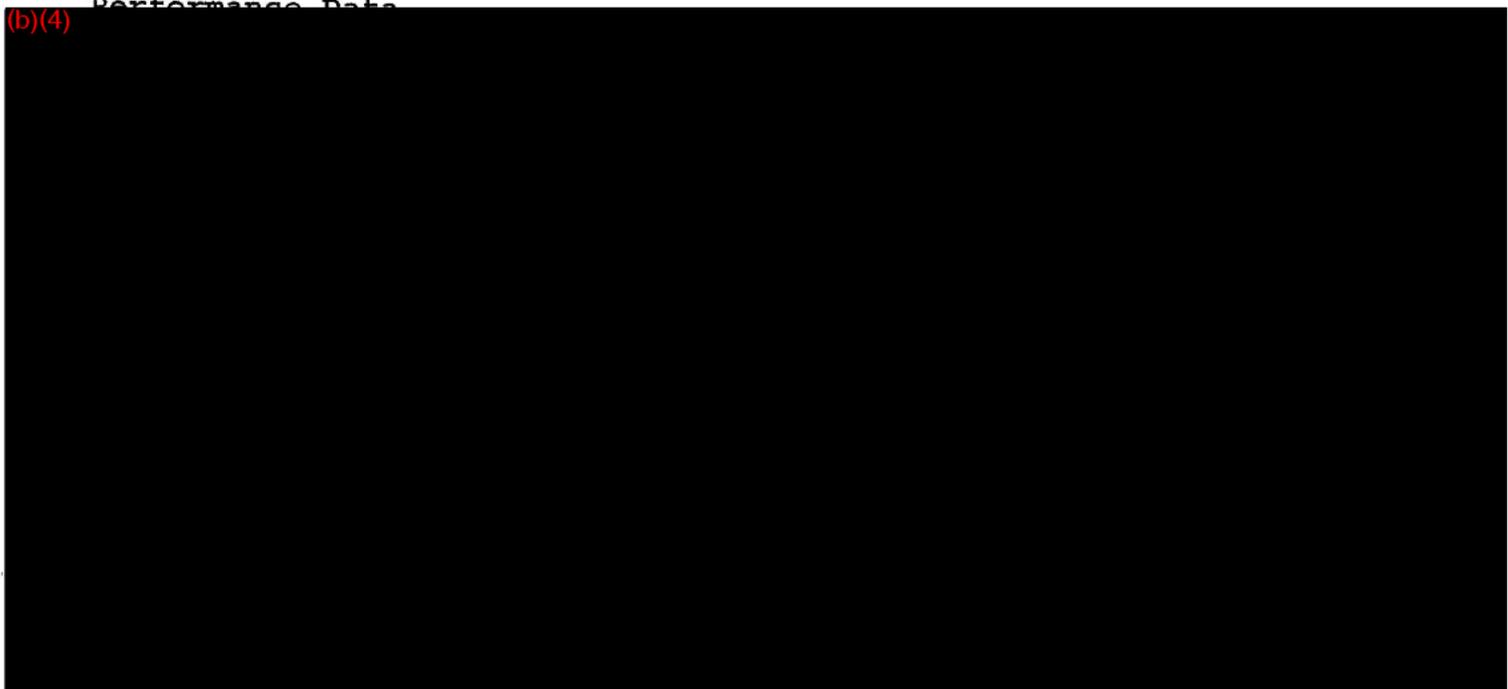
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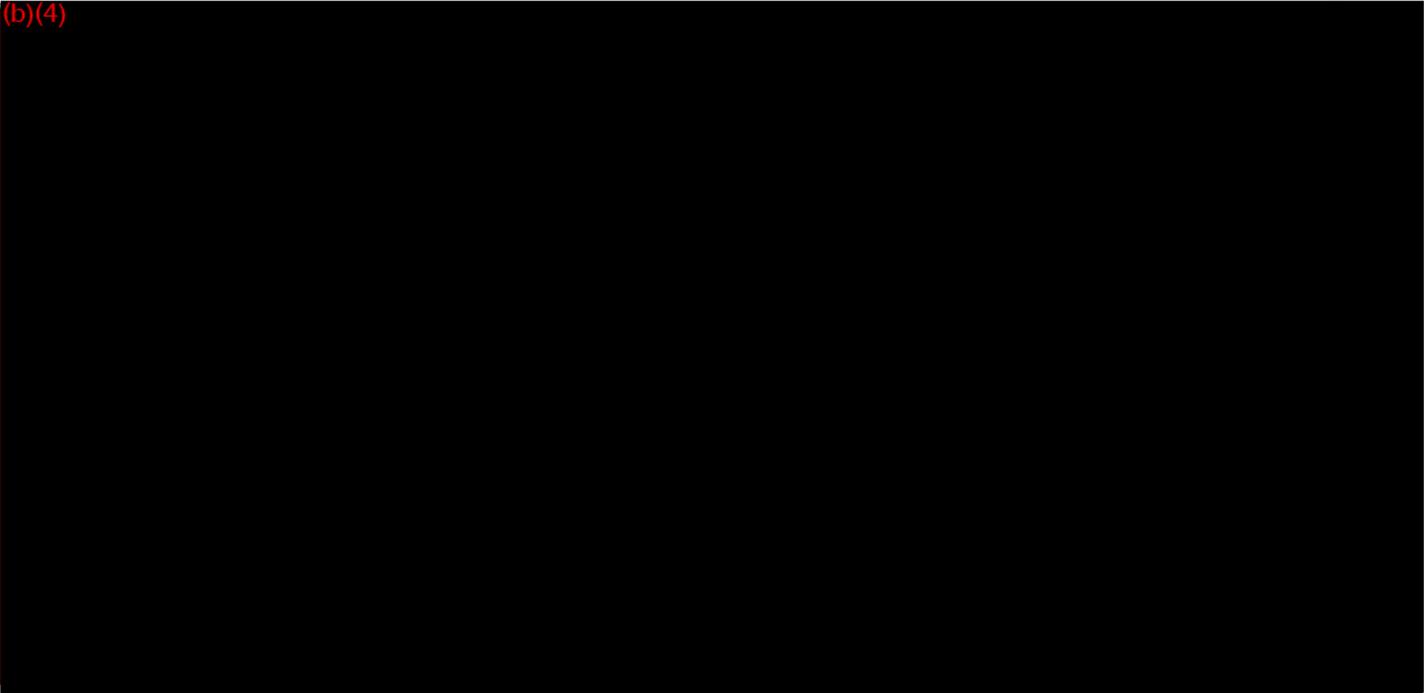
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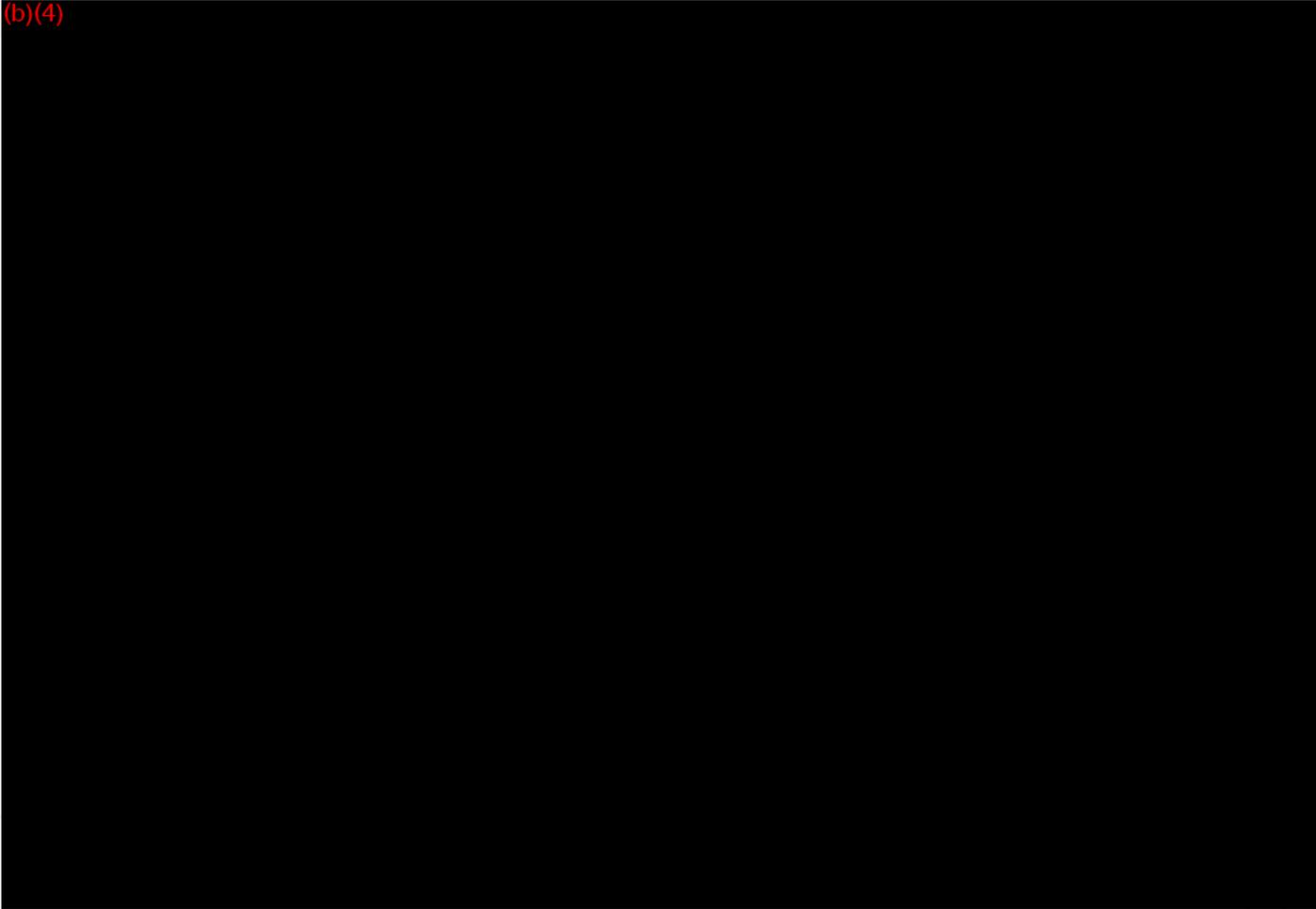
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Labeling

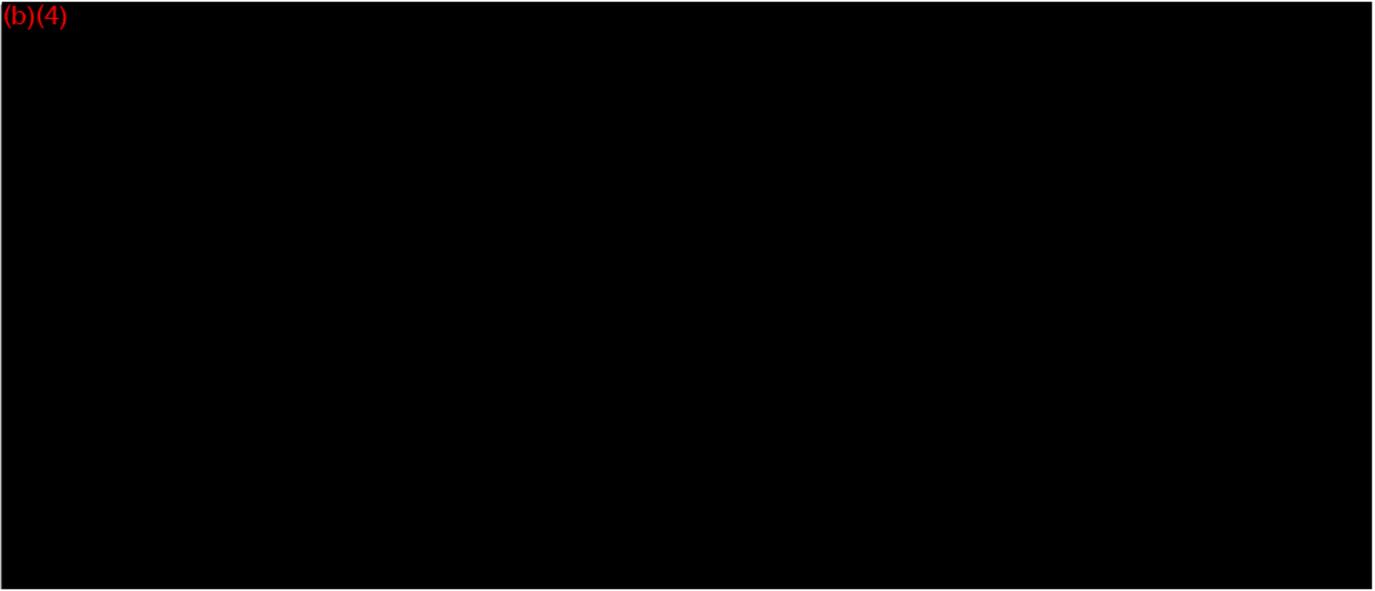
Copies of current and proposed labeling is included.
They did not include on the device label the statement "adhere to storage requirements of added medications."

(b)(4)



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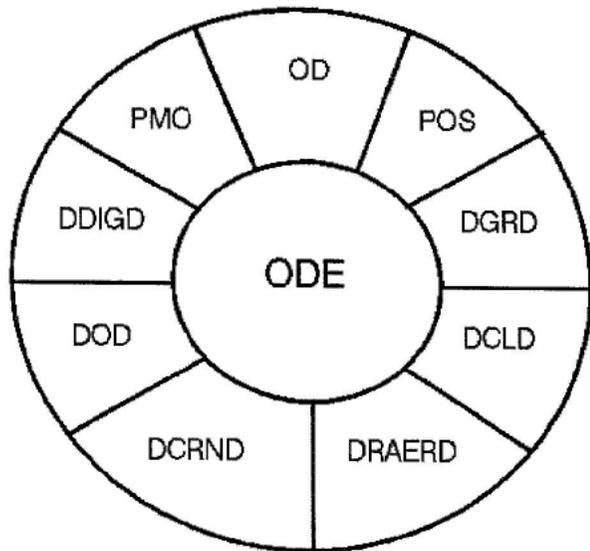
(b)(4)



Brenda Bolden

369

**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF DENTAL, INFECTION CONTROL, AND
GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850**



FROM: Brenda Bolden

DATE: 2/11/97

NO. OF PAGES: 2

PHONE NO: (301)594-1287

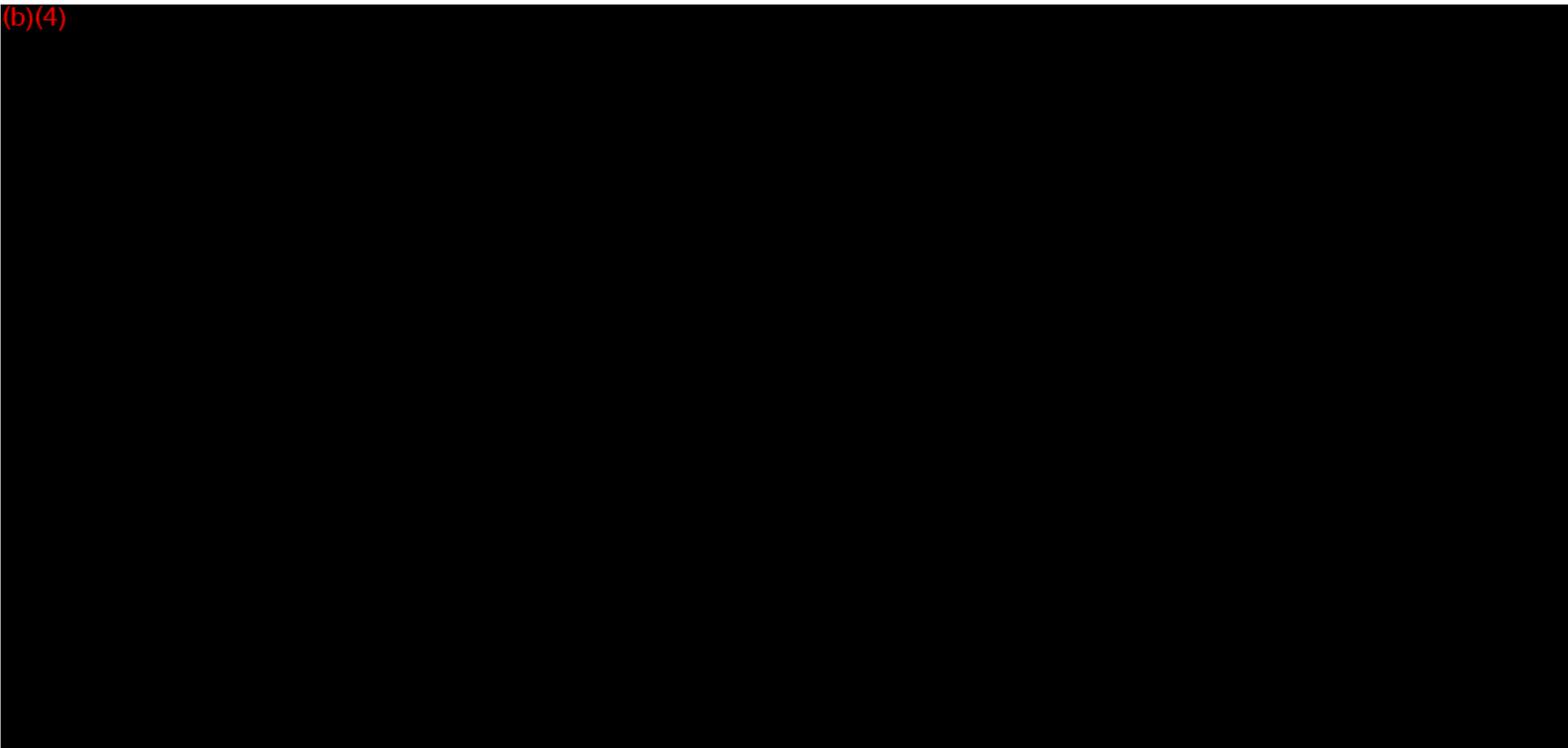
FAX NO: (301)480-3002

TO: Ms. Mary Ellen Snyder

FAX NO: (847)270-4668

SUBJECT: IntraVia Empty Plastic Container

(b)(4)



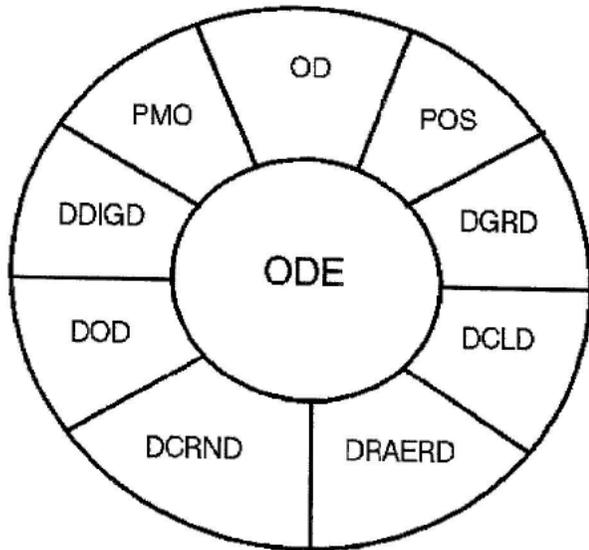
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**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF DENTAL, INFECTION CONTROL, AND
GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850**



FROM: Brenda Bolden

DATE: 2/12/97

NO. OF PAGES: 2

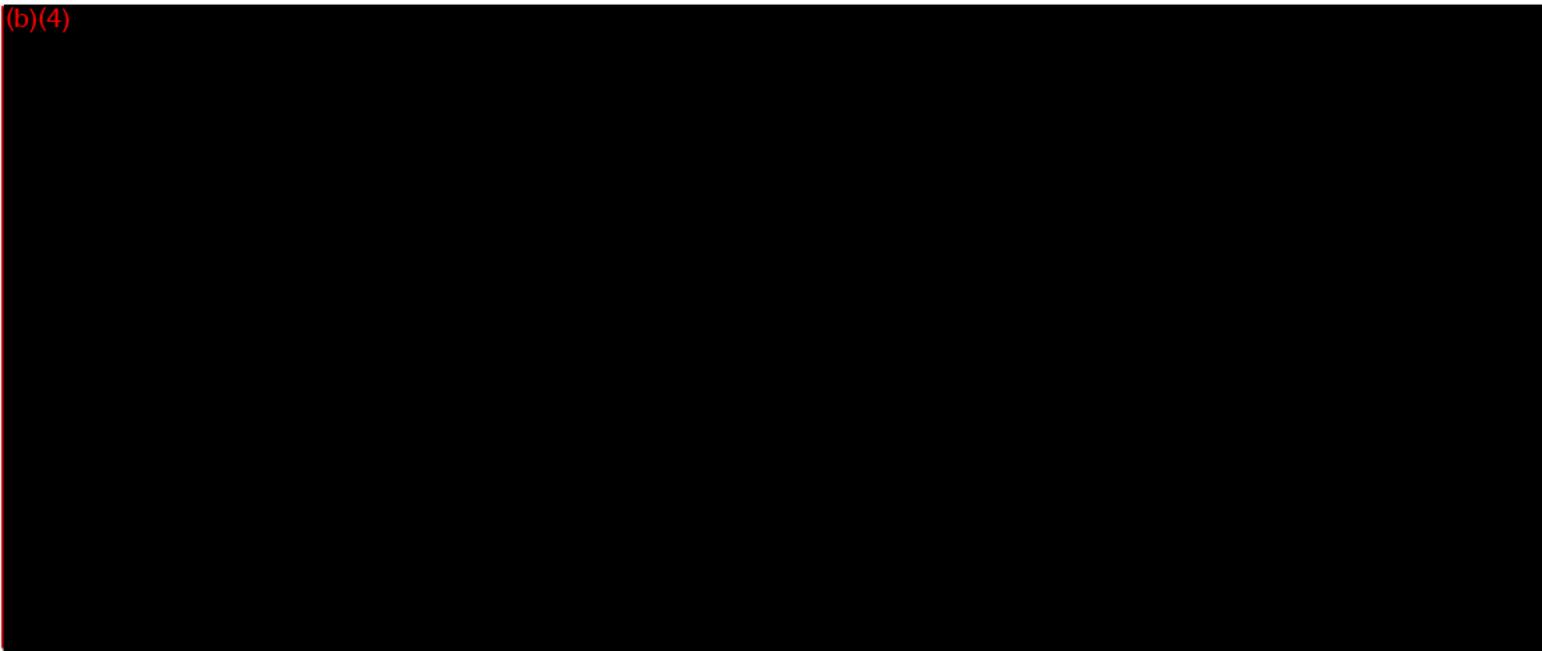
PHONE NO: (301)594-1287

FAX NO: (301)480-3002

TO: Ms. Mary Ellen Snyder

FAX NO: (847)270-4668

SUBJECT: IntraVia Empty Plastic Container



THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

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Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
 Checklist for Premarket Notifications [510(k)s]

Device Trade Name: <u>Intrana Container, Empty</u>		K#: <u>964853</u>	
Submitter Name: <u>Bowter Healthcare Corp.</u>			
Date Received: <u>12/3/96</u>			
90 Day Due Date: <u>3/3/97</u>			
Review Tier (circle one): 1 <u>(2)</u> 3			
Question		Yes	No
A.	Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B.	Is the device exempt from 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C.	Expedited Review Status: Requested by sponsor, or identified by PILOT Division	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Granted by Pilot Division?	<input type="checkbox"/>	<input type="checkbox"/>
D.	Has this device been the subject of a previous NSE decision?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?	<input type="checkbox"/>	<input type="checkbox"/>
E.	Has the sponsor been the subject of an integrity investigation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	If yes, has the ODE Integrity Officer given permission to proceed with the review?	<input type="checkbox"/>	<input type="checkbox"/>

Decision: ACCEPT REFUSE TO ACCEPT

Administrative Reviewer Signature: L. Han Date: DEC -9 1996

Supervisory Signature: B. Bolder Date: 12/10/96

37h

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
 Screening Checklist for Premarket Notifications [510(k)s]
 ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name:

Intravia Container, Empty K964853

Submitter Name:

Baxter Healthcare Corp.

General Content of a 510(k)

MISSING INFORMATION

1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address.

COMMENT:

2.* Safe Medical Device Act of 1990 Requirements:
 a) 510(k) summary or statement (ALL devices)
 b) Truthful and Accurate Statement (see attached)
 c) Class III Certification & Summary (only for Class III devices).
 d) Indication for use statement

COMMENT:

3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device.

COMMENT:

4.* Description of Device (or modification): diagrams, engineering drawings, or photographs.

COMMENT:

5.* Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast:
 a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness.

COMMENT:

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<p>6. <u>Biocompatibility Data</u>: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use.</p> <p>COMMENT:</p>	
<p>7. <u>Sterilization Information</u>: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method.</p> <p>COMMENT:</p>	
<p>8. <u>Software Validation & Verification</u>: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification.</p> <p>COMMENT:</p>	
<p>9. <u>Information Recommended in FDA Guidance</u>: There is an FDA guidance document for this device that recommends additional data.</p> <p>COMMENT:</p>	
<p>10. <u>Kit Information</u>: see attachment if this device is a kit.</p> <p>COMMENT:</p>	

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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

December 04, 1996

BAXTER HEALTHCARE CORP.
ROUTE 120 AND WILSON ROAD
ROUND LAKE, IL 60073
ATTN: MARY E. SNYDER

510(k) Number: K964853
Received: 03-DEC-96
Product: INTRAVIA CONTAINER,
EMPTY

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), 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 January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address DSMO@FDADR.CDRH.FDA.GOV or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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K964853

**510(k) PREMARKET NOTIFICATION
INTRAVIA™ EMPTY PLASTIC CONTAINER**

BAXTER HEALTHCARE CORPORATION

November 26, 1996

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: November 26, 1996

FDA Document Number: **K964853**

Section A **Type of Submission**

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | |

Section B1 **Reason for Submission ----510(k)s Only**

- | | | |
|--|---|---|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Additional or expanded indications | <input checked="" type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other Reason (specify): | | |

Section B2 **Reason for Submission ----PMAs Only**

- | | | |
|---|---|--|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process Change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade Name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Change in correspondent | | |
| <input type="checkbox"/> Other Reason (specify): | | |

Section B3 **Reason for Submission ----IDEs Only**

- | | | |
|--|---|--|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion/extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient semi-annual report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to respond to FDA |
| | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request Meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report Submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Semi-annual progress | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Request for protocol waiver |
| | <input type="checkbox"/> Annual progress | |
| <input type="checkbox"/> Other Reason (specify): | <input type="checkbox"/> Unanticipated adverse effect | |
| | <input type="checkbox"/> Waiver/site limit | |

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Section C		Product Classification			
Product code: 80KPE		C.F.R. Section: 21 CFR § 880.5440		Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: General Hospital					
Section D		Information on 510(k) Submissions			
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1	80KPE	2		3	
4		5		6	
				<input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name			Manufacturer	
1	Pre-enactment 1 Viaflex [®] Empty Container			1 Baxter Healthcare Corporation.	
2	2			2	
3	3			3.	
4	4			4	
5	5			5	
6	6			6	
7	7			7	
Section E		Product Information --- Applicable to All Applications			
Common or usual name or classification name: I.V. Container					
Trade or proprietary or model name				Model number	
1	Intra Via[™] Container, Empty			1 N/A	
2				2	
3				3	
4				4	
5				5	
6				6	
FDA document numbers of all prior related submissions (regardless of outcome):					
1	N/A	2		3	
4		5		6	
7		8		9	
10		11		12	
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human trials					
Indications: The proposed Intra Via [™] Empty Plastic Container is indicated for use in the preparation and administration of drug admixtures.					

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Section F Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2649614	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name: Baxter Healthcare Corporation			
Division name (if applicable): I.V. Systems Division		Phone number (include area code): (787) 735-8021	
Street address: Road 721, K.M. 0.3		FAX number (include area code): (787) 735-6343	
City: Aibonito	State/Province: Puerto Rico	Country:	ZIP / Postal Code: 00705
Contact name: Vincent Roig			
Contact title: Quality Assurance Manager			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2618677	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name: Baxter Healthcare Corporation			
Division name (if applicable): I.V. Systems Division		Phone number (include area code): (787) 828-3700	
Street address: Road 144 KM 20.6		FAX number (include area code): (787) 828-2506	
City: Jayuya	State / Province: Puerto Rico	Country:	ZIP / Postal Code: 00664
Contact name: Jose Rodriguez			
Contact title: Quality Assurance Manager			
<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:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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Section G Applicant or Sponsor			
Company / Institution name: Baxter Healthcare Corporation		FDA establishment registration number: 1417572	
Division name (if applicable): I.V. Systems Division		Phone number (include area code): (847) 270- 4644	
Street address: Route 120 and Wilson Road		FAX number (include area code): (847) 270-4668	
City: Round Lake	State / Province: IL	Country: USA	ZIP / Postal Code: 60073
Signature: <i>Mary Ellen Snyder</i>			
Name: Mary Ellen Snyder			
Title: Manager, Regulatory Affairs			
Section H Submission correspondent (if different from above)			
Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

K964853
847.546.6311
Fax: 847.271.4618



November 26, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20855

DEC 3 1 46 PM '96

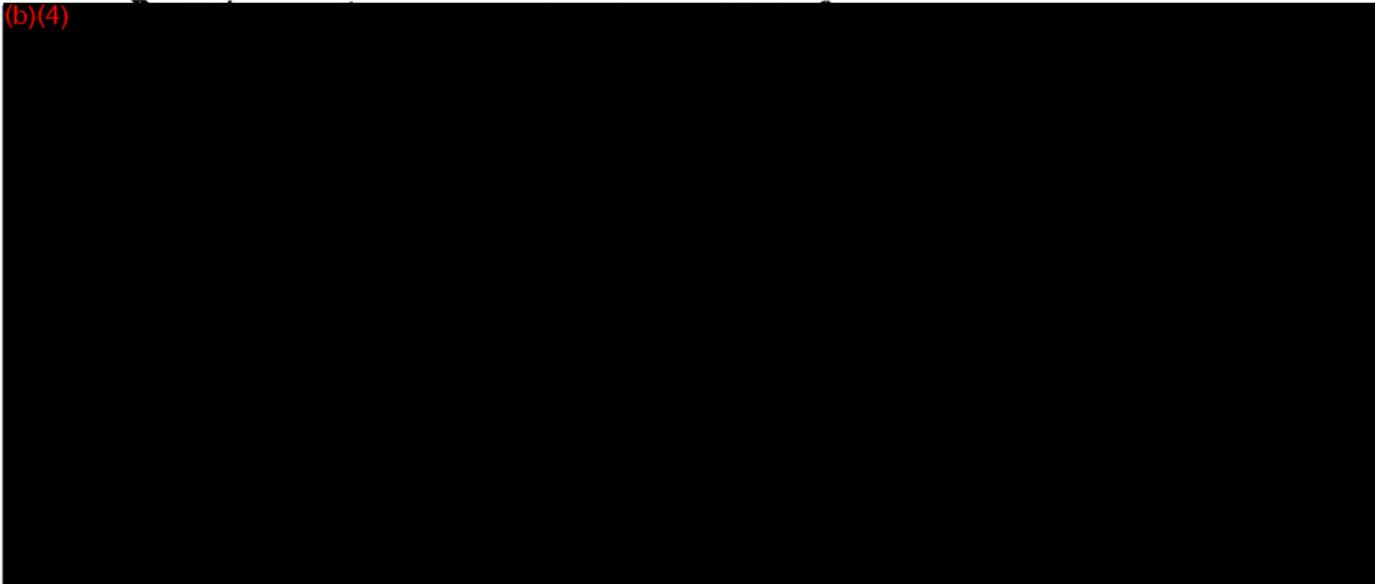
**RE: 510(k) Premarket Notification
IntraVia™ Empty Plastic Container**

Dear Colleague:

This is to notify you of Baxter Healthcare Corporation's intention to manufacture and market our empty plastic I.V. container with a change in the materials of the container sheeting and port tubes.

To assist in your review of this 510(k) notification, we have completed a copy of FDA's "Premarket Notification 510(k) Checklist for Acceptance Decision"¹, and attached it to this submission (see Attachment 1.0 - 510(k) Checklist tab).

Product Change Description:

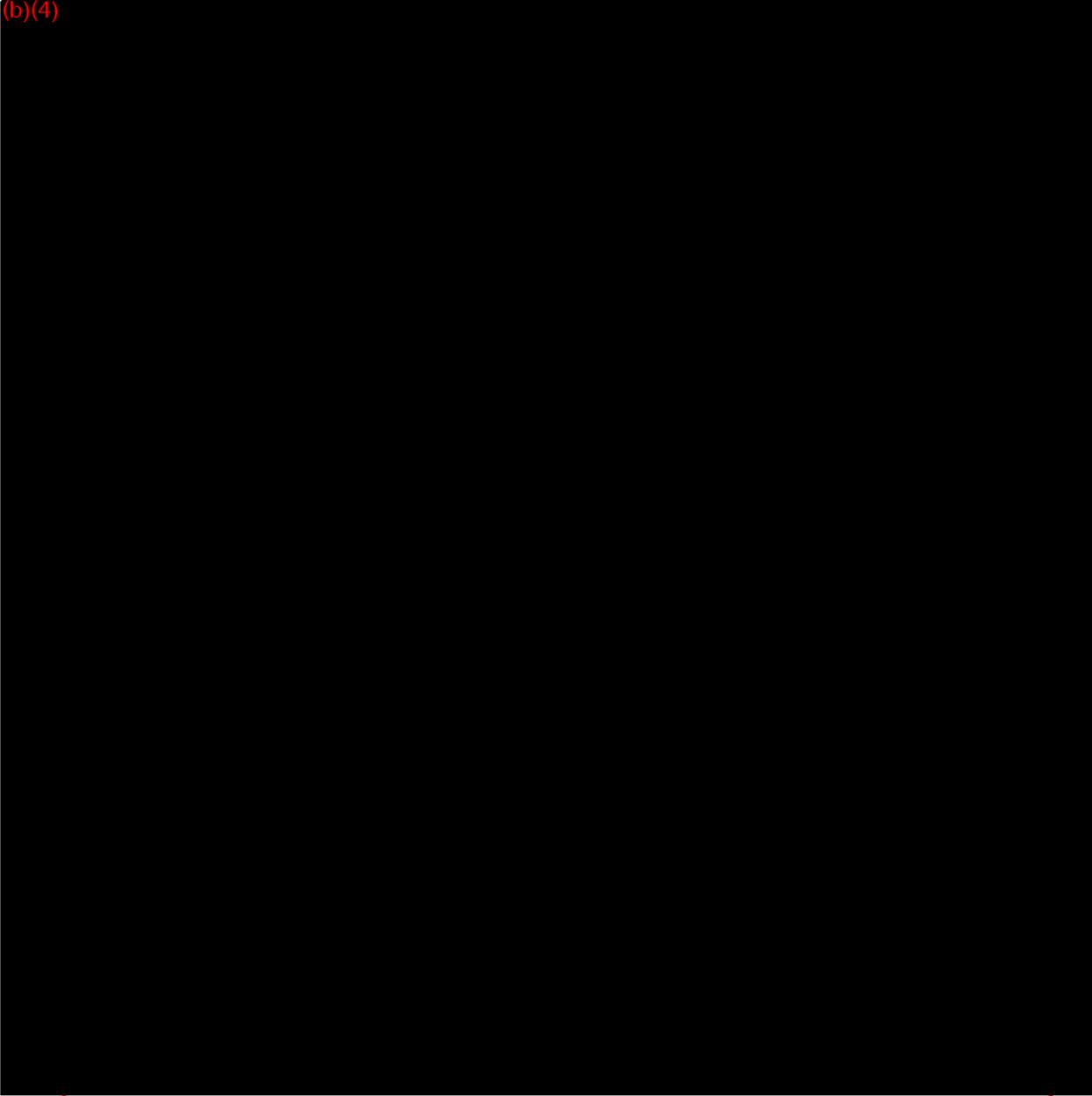


¹ Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy, June 30, 1993.

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Baxter

(b)(4)



Manufacturing Location and Establishment Registration Number:

Baxter Healthcare Corporation
P.O. Box 518
Road 144, KM 20.6
Jayuya, PR 00664
Registration Number: 2618677

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Baxter

Sterilization Location and Establishment Registration Number:

Baxter Healthcare Corporation
P.O. Box 1389
Road 721, KM 0.3
Aibonito, PR 00705
Registration Number: 2649614

Owner/Operator Number: 1417572

Classification:

Class: Class II in 21CFR §880.5025
Panel: General Hospital
Classification Number: 80KPE

Performance Standard: None established under Section 514

Intended Use:

The new gamma irradiated polyolefin-based container has the same intended use as the currently marketed ETO sterilized polyvinyl chloride container. The containers are intended for use in the preparation and administration of drug admixtures.

Performance Data:

Data regarding the functional performance of the proposed container and its drug compatibility characteristics have been generated and are included as Attachment 6.0 - Performance Data. A description of the functional testing along with test results and specifications is provided in Attachment 6.1 - Functional Testing. The data indicate that the container meets or exceeds all functional requirements.

Information regarding the drug compatibility of the proposed container is provided in Attachment 6.2 - Drug Compatibility. (b)(4)

(b)(4)

Labeling/Promotional Material:

Draft labeling for a representative IntraVia™ Empty Container (150 mL size) is provided in Attachment 7.0 - Draft Labeling. Current labeling for a representative Viaflex® Empty Container is provided in Attachment 8.0 - Current Labeling.

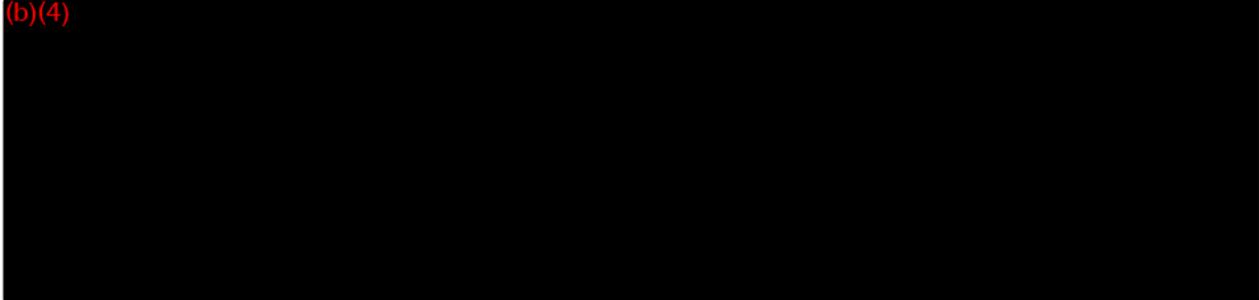
RECEIVED
3 DEC 30 11 22
FDA/CDRH/ODE/DIC

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Baxter

Packaging/Sterilization:

(b)(4)



Substantial Equivalence:

The new gamma irradiated IntraVia™ Empty Container is substantially equivalent, for purposes of the Federal Food, Drug and Cosmetic Act only, to the currently marketed ETO sterilized Viaflex® Empty Container which is a preenactment device first marketed in 1974. This is supported by a copy of Baxter's product catalogue from February, 1975, showing the listings for Empty Viaflex® Containers. The catalogue is provided in Attachment 9.0 - Preenactment Catalogue.

For your convenience, we have explained in Attachment 10.0 - SE Decision Tree, how we reached a substantial equivalence conclusion, using FDA's logic flow chart entitled "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)²".

The term substantial equivalence as outlined in this pre-market notification and the supporting information pertaining to equivalence are intended only to demonstrate equivalence to predicate products for purposes of obtaining clearance of the device pursuant to the Federal Food, Drug and Cosmetic Act. Reference to equivalence as outlined in this submission is in no way related to the term "equivalent" or similar terminology as outlined under the patent laws.

Summary of Safety and Effectiveness:

A summary of safety and effectiveness of the proposed device, as required by the Safe Medical Devices Act of 1990, is provided in Attachment 11.0 - Summary.

Truthful and Accurate Statement:

A certification statement as required by 21 CFR § 807.87(j) is provided in Attachment 12.0 - Certification.

² FDA's Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30, 1993.

Baxter

Indication for Use:

In accordance with FDA requirements effective January 1, 1996, a separate page clearly marked Indication For Use is included as Attachment 13.0 - Indication For Use.

If you have any questions regarding this submission, please do not hesitate to contact me. You may also contact Marcia Marconi, Vice President, Regulatory Affairs, at (847) 270-4637.

Sincerely,



Mary Ellen Snyder
Manager, Regulatory Affairs
(847) 270-4644
(847) 270-4668 FAX

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510(k) Premarket Notification
IntraVia™ Empty Plastic Container

Attachment 1.0

Premarket Notification 510(k) Checklist for Acceptance Decision

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**510(k) Premarket Notification
IntraVia™ Empty Plastic Container**

Premarket Notification (510(k) Checklist for Acceptance Decision

K: _____ **Date DMC Received:** _____

Device Trade Name: IntraVia™ Container, Empty
Reason for 510(k): Material and Sterilization Change - Empty I. V. Container
Division/Branch: DDIGD/General Hospital Devices Branch
Administrative Reviewer Signature: _____ **Date:** _____
Supervisory Signature: _____ **Date:** _____

	Yes Present Omission Justified	No Inadequate Omitted

I. Critical Elements		
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Is device subject to review by CDRH?	X	

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Please Note: Information in parenthesis indicates where in the document items can be found.

**510(k) Premarket Notification
IntraVia™ Empty Plastic Container**

**Attachment 1.0
Page 2**

	Yes Present Omission Justified	No Inadequate Omitted
<p>D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?</p>		X
<p>E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer (ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N-0332, September 10, 1991.)</p>		X
<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>	X	
* Device trade or proprietary name	X (cover letter)	
* Device common or usual name or classification name	X (cover letter)	

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NOV 26 1996
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Please Note: Information in parenthesis indicates where in the document items can be found.

**510(k) Premarket Notification
Intra Via™ Empty Plastic Container**

	Yes Present Omission Justified	No Inadequate Omitted
--	-----------------------------------	--------------------------

* Establishment registration number (only applies if establishment is registered)	X (cover letter)	
* Class into which the device is classified under (21 CFR Parts 862 to 892)	X (cover letter)	
* Classification Panel	X (cover letter)	
* Action taken to comply with Section 514 of the Act	X (cover letter)	
* Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	X (Attachment 7.0)	
* A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	X (Summary of Safety and Effectiveness Attachment 11.0)	
* For class III devices only, a class III certification and a class III summary	N/A	

NOV 26 1996
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Please Note: Information in parenthesis indicates where in the document items can be found.

**510(k) Premarket Notification
Intra Via™ Empty Plastic Container**

**Attachment 1.0
Page 4**

	Yes Present Omission Justified	No Inadequate Omitted
* Photographs of the device (Drawings of the Device are provided)	X (Attachment 2.0)	
* Engineering drawings for the device with dimensions and tolerances (Drawings of the new design in Attachment 2.0 contain key dimensions and tolerances)	X (Attachments 2.0)	
* The marketed device(s) to which equivalence is claimed including labeling and description of the device	X (Cover Letter; Labeling for equivalent device in Attachment 8.0)	
* Statement of similarities and/or differences with marketed device(s)	X (Cover Letter)	
* Data to show consequences and effects of a modified device	X (Attachment 6.0)	

NOV 26 1996


Please Note: Information in parenthesis indicates where in the document items can be found.

**510(k) Premarket Notification
IntraVia™ Empty Plastic Container**

**Attachment 1.0
Page 5**

	Yes Present Omission Justified	No Inadequate Omitted
--	--------------------------------------	-----------------------------

II. Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	X (cover letter)	
B. Contact person, telephone number and fax number	X (cover letter)	
C. Representative/Consultant if applicable	N/A	
D. Table of Contents with pagination	X	
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	X (cover letter)	

III. Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	X (See Attachment 4.0)	

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Please Note: Information in parenthesis indicates where in the document items can be found.

**510(k) Premarket Notification
Intra Via™ Empty Plastic Container**

**Attachment 1.0
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	Yes Present Omission Justified	No Inadequate Omitted
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B. Action taken to comply with voluntary standards	N/A	
C. Performance data		
marketed device		
bench testing	N/A	
animal testing	N/A	
clinical data	N/A	
New device		
bench testing	Attachment 6.0	
animal testing	N/A	
clinical data	N/A	
D. Sterilization information	X (Cover Letter)	
E. Software information	N/A.	
F. Hardware information	N/A	


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Please Note: Information in parenthesis indicates where in the document items can be found.