DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven L. Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Incorporated
8550 Higuera Street
Culver City, California 90232

JAN 10 2007

Re: K062176
Trade/Device Name: Relief ACP Oral Care Gel
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 8, 2007
Received: January 9, 2007

Dear Mr. Ziemba:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

E. Indications for Use Statement

510(k) Number: K062176

Device Name: Relief ACP Oral Care Gel

Intended Use

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR Section 801.109)

Susan Runner

n of Anesthesiology, General Hospital,
ion Control, Dental Devices

K062176

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2007

Mr. Steven L. Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Incorporated
8550 Higuera Street
Culver City, California 90232

Re: K062176
Trade/Device Name: Relief ACP Oral Care Gel
Regulation Number: 21 CFR 872.3260
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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

E. Indications for Use Statement

510(k) Number: K062176

Device Name: Relief ACP Oral Care Gel

Intended Use

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

Per 21 CFR Section 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K062176

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

December 22, 2006

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Product: RELIEF ACP ORAL CARE GEL

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. 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 International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 10, 2006

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Product: RELIEF ACP ORAL CARE GEL

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. 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 International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor 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

August 17, 2006

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Received: 16-AUG-2006
Product: RELIEF ACP ORAL CARE GEL

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(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 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

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Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

August 01, 2006

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Received: 31-JUL-2006
Product: RELIEF ACP ORAL CARE
User Fee ID Number: 6026527

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

K062176

NEW 510K FILING

RELIEF ACP ORAL CARE GEL

DISCUS DENTAL, INC.
CULVER CITY, CA 90232

DE
II

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

DISCUS DENTAL INC
8550 Higuera Street
Culver City CA 90232
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

2. CONTACT NAME
(b) (6)

2.1 E-MAIL ADDRESS
(b) (6)

2.2 TELEPHONE NUMBER (include Area code)
(b) (6)

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
(b) (6)

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

OE II

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

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
$(b) (4)

10-Jul-2006

Form FDA 3601 (08/2003)

Close Window

10 July 2006

IC 18

P7

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Section A

Administrative Information

A. Administrative Information

1.	**Submission From:**	Discus Dental, Inc.
2.	**Contact Regarding Submission:**	Steven L. Ziemba Vice-President, Regulatory Affairs Discus Dental, Inc. 8550 Higuera Street Culver City, CA 90232 (b) (6)
3.	**Establishment Registration Number:**	2032714
4.	**Proprietary Name:**	Relief ACP Oral Care Gel
5.	**Common/Usual Name:**	Tooth Desensitizer
6.	**Classification Name:**	Cavity Varnish (LBH)
7.	**Manufacturer:**	(b) (4)
8.	**Classification:**	Class II (21 CFR 872.3260)
9.	**Performance Standard:**	Not applicable
10.	**Manufacturing, Packaging and Record Retention:**	Discus Dental, Inc.

Section B

510(k) Summary

B. 510(k) Summary - Relief ACP Oral Care Gel

1. Date of Summary:

2. Date of Summary Preparation: July 6, 2006

3. Submitting Firm: Discus Dental, Inc.

4. Contact Person: Steven L. Ziemba, M.S. Vice-President, Regulatory Affairs
Discus Dental, Inc.
8550 Higuera Street
Culver City, CA 90232
310.845.8345
310.845.1537 - fax

5. Name of Medical Device
Proprietary Name: Relief ACP Oral Care Gel

Common/Usual Name: Tooth Desensitizer

Classification Name: Cavity Liner (LBH)

6. Description of Medical Device - Relief ACP Oral Care Gel is a 5% potassium nitrate gel with 0.22% sodium fluoride and amorphous calcium phosphate that desensitizes teeth via the well documented effects of potassium nitrate and the effect of occlusion of dentinal tubules by sodium fluoride and amorphous calcium phosphate. It is intended for application to the teeth in either a dental tray or application via a toothbrush.

7. Intended Use - Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity.

8. Substantial Equivalence Determination - Discus Dental, Inc. has determined that Relief ACP Oral Care Gel is substantially equivalent to the following commercially marketed products:

Predicate Device	Company	510(k) No.
Tooth Desensitizer	Cosmedent, Inc.	K0502263
D/Sense 1-Step	Centrix, Inc.	K021146

END OF 510(k) SUMMARY

Section C

Certification of Truthful and Accurate Submission

C. Certification of Truthful and Accurate Submission (21 C.F.R. § 807.87(j))

I certify that, in my capacity as Vice-President, Regulatory Affairs for Discus Dental, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for Relief ACP Oral Care Gel are truthful and accurate, and that no material fact has been omitted.

(b) (6)

Signature
Steven L. Ziemba, M. Sc.

25 July 2016
Date

Section D

510(k) Statement

D. 510(K) Statement

I certify that, in my capacity as the Vice-President, Regulatory Affairs for Discus Dental, Inc., I will make available all information included in the 510(k) Summary section of this premarket notification for Relief ACP Oral Care Gel within 30 days of the request being received by me from any person if the device described in this premarket notification submission is determined to be substantially equivalent by the FDA.

(b) (6)

Steven L. Ziemba, M. Sc.

25 July 2006

Date

Section E

Indications for Use Statement

E. Indications for Use Statement

510(k) Number: _____

Device Name: Relief ACP Oral Care Gel

Intended Use

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
Per 21 CFR Section 801.109)

Section F

Technical Information

F. Technical Information

1. Description of the Medical Device

Relief ACP Oral Care Gel (Relief) is a clear gel intended for application to the teeth via brushing or a custom dental tray for a maximum of 30 minutes. The gel consists of 5% potassium nitrate in a (b) (4) and also contains 0.22% sodium fluoride, amorphous calcium phosphate ((b) (4)), (b) (4), and peppermint flavor.

Potassium Nitrate	5%
Sodium Fluoride	(b) (4) %

The Relief ACP Oral Care Gel will be sold in 3 cc syringes.

2. Intended Use

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

3. Substantial Equivalence Determination

Discus Dental, Inc. has determined that Relief ACP Oral Care Gel is substantially equivalent to the following commercially marketed products:

Predicate Device	Company	510(k) No.
Tooth Desensitizer	Cosmedent, Inc.	K052263
D/Sense 1-Step	Centrix, Inc.	K021146

Product	510K	Company	KNO3	Fluoride	Coating Compound	Intended Use
Tooth Desensitizer	052263	Cosmedent	(b) (4)			Treat dentin sensitivity
D/Sense 1-step	021146	Centrix				Film forming liner and desensitizer for application to dentin, prior to placement of a restoration.
Relief ACP Gel		Discus	5%	0.22%	Amorphous calcium phosphate	Forms a layer of calcium phosphate and potassium nitrate to treat dentin sensitivity.

The amount of potassium nitrate (5%) and sodium fluoride (0.22%) in this product also are within ranges of those ingredients found in many commercially marketed over-the-counter dentifrices.

4. Testing of the Device

Discus has conducted (b) (4) testing to verify the (b) (4) and (b) (4) content of the Relief gel. Further, the potassium nitrate content (5%) and sodium fluoride content (0.22%) have been verified using methods outlined in USP 28.

The following biocompatibility tests will be been completed on the finished product. It is expected that results of that testing will demonstrate that Relief gel has biocompatibility characteristics that allow it to be considered biocompatible for its intended use according to ISO 10993-1:2003; (Surface device; skin contact; limited duration) once the testing is completed:

Biocompatibility Tests to be Conducted

Cytotoxicity –ISO 10993-5
Sensitization - per ISO 10993-10
Irritation/Intracutaneous Reactivity per ISO 10993-10

The product will not be introduced into commercial distribution until these tests have been successfully completed. Copies of these test reports will be kept on file at Discus Dental, Inc.

5. Stability Testing

Product Packaging and Labeling

Testing of packaged samples of the Relief gel (b) (4) demonstrate that no significant changes in material characteristics occur (b) (4). Due to its similar formula and expected degradation characteristics compared to existing over-the-counter dentifrices marketed by Discus Dental, Inc., the product will be labeled with a (b) (4) month shelf-life, subject to confirmation with stability testing data.

Section G

Manufacturing Information

G. Manufacturing Information

The (b) (4) will be (b) (4)
(b) (4) :
(b) (4)

Note: Each unit carton of Relief gel will be labeled with lot number and expiration date (b) (4) using labeling approved by Discus Dental, Inc.

Distribution and market vigilance will be (b) (4)

Section H

Risk Analysis

H. Risk Analysis

Discus has conducted an analysis to assess all of the known risks associated with use of Relief ACP Oral Care Gel (Relief gel), in comparison with risks associated with other similar and currently marketed products. This Risk Analysis is intended to assess all of the known risks associated with Relief gel in comparison to risks associated with other dental impression materials currently marketed in the United States and E.U.

1.0 Product: Dental desensitizing gel

2.0 Description: Relief gel is a 5% potassium nitrate gel with 0.22% sodium fluoride and amorphous calcium phosphate that desensitizes teeth via the well documented effects of potassium nitrate and the effect of occlusion of dentinal tubules by sodium fluoride and amorphous calcium phosphate in dentifrices.

3.0 Trade Name: Relief ACP Oral Care Gel

4.0 Intended Use: Relief gel is indicated for relief of discomfort from dentin sensitivity..

5.0 Device Classification: Class II medical device in the United States (per 21 CFR 872.3260) and Class I medical device in the European Union per the following rationale from the MDD (93/42/EEC) Annex IX:

Rule	Status	Comment	Classification
1	Not Applicable	Invasive device.	N/A
2	Not Applicable	Invasive device.	N/A
3	Not applicable	Invasive device.	N/A
4	Not Applicable	Invasive Device.	N/A
5	Applies	Invasive device, intended for transient use.	I
6	Not Applicable	Not a surgically invasive device.	N/A
7	Not Applicable	Not a surgically invasive device.	N/A
8	Not Applicable	Not an implantable device.	N/A
9	Not Applicable	Not an active device.	N/A
10	Not Applicable	Not an active device.	N/A
11	Not Applicable	Not an active device.	N/A
12	Not Applicable	Not an active device.	N/A
13	Not Applicable	Does not include a medicinal product.	N/A
14	Not Applicable	Not used for contraception or prevention of STD's.	N/A
15	Not Applicable	Not intended for use with contact lenses. Not intended for cleaning or disinfecting other medical devices.	N/A
16	Not Applicable	Not intended for recording X-ray diagnostic images.	N/A
17	Not Applicable	No animal –derived tissues or material.	N/A

5.1 **Classification Summary (E.U.)**: Although desensitizing gels do penetrate a body orifice (mouth), they are not surgically invasive and are intended only for transient (i.e., less than 60 minutes) use in the mouth. Thus, the device is correctly classified in the European Union under Rule 5 as Class I.

6.0 Required Skill or Training: No special training is required for dental professionals. This device is intended for dispensing by dental professionals and for use in either an in-office setting (via dental trays) or for at-home use (via a toothbrush).

7.0 Can Patient Influence Use of Device: Yes, patient could be non-cooperative.

8.0 Environment Where Used: Dental operatory or home use. Non-sterile environment.

9.0 Special Patient Needs: None applicable for handicapped, elderly or pediatric patients.

10.0 Intended Patient Contact: None.

11.0 Materials/Specifications: Specifications on file at Discus Dental, Inc.

12.0 Energy or Substances Delivered To Patient: None.

13.0 Biological Materials Processed by Device: None

14.0 Device Supplied Sterile? No. Device is not intended to be sterilized by user.

15.0 Does the Device Modify the Patient's Environment?: No

16.0 Measurements Made by Device: None

17.0 Is Device Interpretive?: No

18.0 Does Device Interact with other Devices or Drugs? No

19.0 Use with Other Devices: There are no accessories or ancillary items for use with this device.

20.0 Unwanted Output of Energy or Substances: N/A.

21.0 Susceptibility To Environmental Influence: N/A.

22.0 Essential Consumables or Accessories: Not applicable

23.0 Device Software: Not applicable.

24.0 Routine Maintenance or Calibration: N/A.

25.0 Device Software: None.

26.0 Delayed or Long-Term Effects from Use: None anticipated.

27.0 Lifetime of Device: This device will be labeled with a shelf-life (expiration date) of (b) (4) months from the date of packaging; subject to confirmation with empirical test data.

28.0 Potential Hazards Due to Hidden Failure Modes: Misuse of the product could result in patient swallowing product. No known hazard due to swallowing, but package insert provides warning not to swallow. Improper application could result in lack of desired effect; package insert provides adequate directions for use.

Types of Potential Patient Hazards Associated with Device:

29.0 Environmental: N/A

30.0 Routine Use of Device: None.

31.0 Biological: None.

32.0 Product Failure or Malfunction: Only possible failure mode with this product is degradation of the product due to aging. If this were to occur, the material may not provide desired sensitivity relief and would either be discarded by the practitioner or would require an additional application of the product to achieve desired results. In such cases, the patient is exposed to no risk.

33.0 Misuse of the Device: Improper application could result in lack of desired effect. In such cases, the patient is exposed to no risk, as the material is not known to have deleterious effects on patients.

Estimation of Risk for Each Listed Potential Hazard and Measures Taken to Reduce Risk:

34.0 Routine Use of Device: When used as directed, Relief gel and all similar dental desensitizing products have no known risks. The active ingredients, potassium nitrate and 0.22% sodium fluoride are routinely used in over-the-counter dentifrices, with no known problems. Thus, the risk due to misuse of this product is identical to other dental desensitizing agents and dentifrices with fluoride and/or potassium nitrate currently marketed in the United States and E.U. **Estimated Potential Risk: Zero & equivalent to existing dental desensitizing agents and dentifrices.**

35.0 Product Failure or Malfunction: Only possible failure mode with this product is degradation of the product due to aging. If this were to occur, the material may not provide desired sensitivity relief and would either be discarded by the practitioner or would require an additional application of the product to achieve desired results. In such cases, the patient is exposed to no risk. Thus, the risk due to product failure or malfunction of this product is identical to other dental desensitizing agents or dentifrices currently marketed in the United States and E.U. **Estimated Potential Risk: Zero & equivalent to existing dental desensitizing agents and dentifrices.**

36.0 Misuse of Device: The only potential misuse of this device is swallowing by the patient. Product labeling contains appropriate warnings to the practitioner to warn against swallowing of risks to the patient due to misuse. The labeling provides adequate warnings to allow the practitioner to understand proper use-parameters for the product. The risk due to misuse of this product is identical to or lower than similar dental desensitizing agents and dentifrices impression materials currently marketed in the United States and E.U. **Estimated Potential Risk: Zero & equivalent to existing existing dental desensitizing agents and dentifrices.**

Summary of Other Potential Risks

37.0 **Control of Manufacturing Processes**: Manufacturing, packaging and inspection of Relief gel is controlled (b) (4) using (b) (4) Oversight of (b) (4) (b) (4) an appropriate quality system for controlling and detecting defective units in compliance with 21 CFR 820 and ISO 13485 (2003). Discus Dental operates in compliance with ISO 13485 (2003).

38.0 Summary of Device Processing

(b) (4)

Manufacturing, packaging, inspection, labeling and warehousing:

(b) (4)

Specification Development & Distribution and Market Vigilance
(b) (4)

38.4 All final packaging processes, quality inspection and final release processes are
(b) (4)

Therefore, it can be concluded that the quality systems covering all phases of the manufacturing, inspection, and release of Relief is compliant with 21 CFR 820 and ISO 13485 (2003). **Estimated potential risk due to manufacturing: Zero.**

Review of Other Similar Devices:

39.0 Relief ACP Oral Care Gel is substantially equivalent to other dental desensitizing agents currently marketed in the United States and E.U. Discus believes that Relief ACP Oral Care Gel introduces no new risks not already present in other dental desensitizing agents currently marketed in the United States and E.U. A matrix of the design attributes of Relief gel and other marketed predicate products that are currently marketed in the United States and E.U. follows.

Predicate Device	Company	510(k) No.
Tooth Desensitizer	Cosmedent, Inc.	K0502263
D/Sense 1-Step	Centrix, Inc.	K021146

Product	510K	Company	KNO3	Fluoride	Coating Compound	Intended Use
Tooth Desensitizer	052263	Cosmedent	(b) (4)			Treat dentin sensitivity
D/Sense 1-step	021146	Centrix				Film forming liner and desensitizer for application to dentin, prior to placement of a restoration.
Relief ACP DesensitzingGel		Discus				Forms a layer of calcium phosphate and potassium nitrate to treat dental sensitivity.

40.0 Summary of Steps Taken to Minimize Risk: Discus formulated this product so that no mixing or special handling by the practitioner in the dental office is required. Further, detailed Instructions for Use are provided which give the practitioner instructions on the proper use of the product.

40.1 Discus, (b) (4) purchase the components of this device only from approved vendors as specified in pertinent specifications listed in the company's Device Master Record. Discus requires that vendors maintain compliance with pertinent quality system standards. Discus has developed a Device Master Record which includes all applicable Work Instructions and specifications used to ensure proper and repeatable manufacturing of this device. These include several quality control inspections and tests which ensure that each device is functioning as designed and in compliance with approved specifications in the Device Master Record. Discus therefore believes that all potential risks associated with this type of device have been reduced as much as possible to acceptable levels.

41.0 Summary of Potential Benefits Associated with this Device: This device is indicated for relief of discomfort from dentin sensitivity.

42.0 Summary of Risk to Benefit Analysis: There are no known risks associated with proper use of this device.

The only possible failure mode with this product is degradation of the product due to aging. If this were to occur, the material may not provide desired sensitivity relief and would either be discarded by the practitioner or would require an additional application of the product to achieve desired results. In such cases, the patient is exposed to no risk.

Improper application of the product could result in lack of desired effect. In such cases, the patient is exposed to no risk, as the material is not known to have deleterious effects on patients. Thus, the risk due to product failure or malfunction of this product is identical to other dental desensitizing agents and over-the-counter dentifrices currently marketed in the United States and E.U. Labeling includes specific cautions and warnings to alert users to these potential hazards.

43.0 **CONCLUSION**: Introduction of Relief ACP Oral Care Gel introduces no new risks for use of the product as a dental desensitizing agent but it provides the benefit to the user of having an easy-to-use product for reducing dental sensitivity.

Failure Mode Effects Analysis Table
Relief ACP Gel

(b) (4)

Conclusions: All risks are considered to be negligible (minor, unlikely and adequately reduced to acceptable levels by steps outlined above). All of the foreseeable risks are identical or lower than those with currently marketed dental desensitizing agents or over-the-counter dentifrices..

This risk analysis was completed by Steven L. Ziemba, M.Sc. My signature below indicates that I certify that this Risk Analysis is, to the best of my knowledge, true, accurate and complies with ISO 14971.

(b) (6)

Steven L. Ziemba, M.Sc.

25 July 2006
Date

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Section I

Product Labeling

Section I

1. Labeling for Relief ACP Oral Care Gel

I. Product Labeling

The labeling for Relief ACP Desensitizing Gel is similar to that used for other commercially available dental desensitizing agents. Labeling text for the package insert, syringe and unit cartons for the product are shown on the attached pages followed by similar labels from competitor's products.

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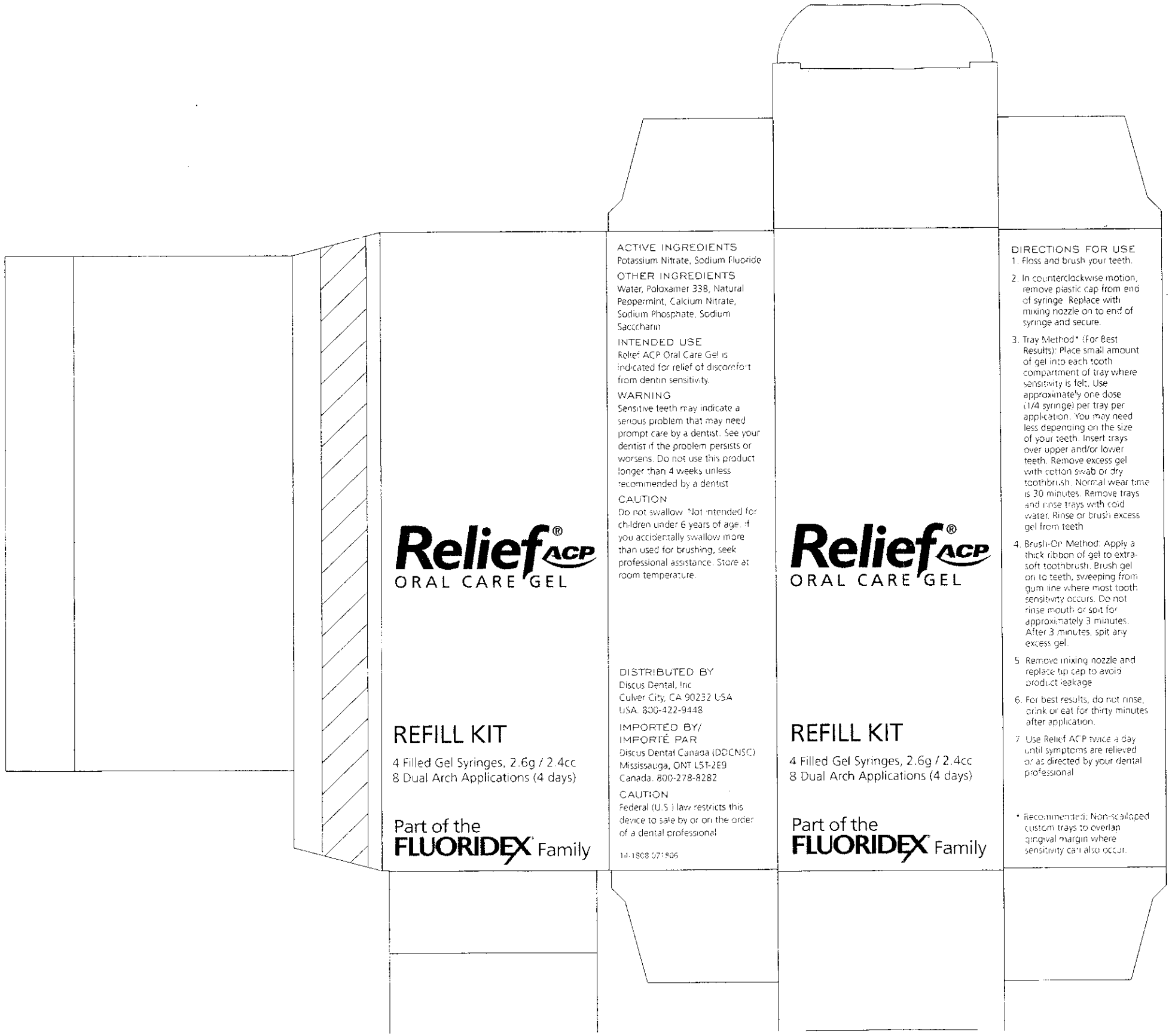

Relief® ACP
ORAL CARE GEL

REFILL KIT

4 Filled Gel Syringes, 2.6g / 2.4cc
8 Dual Arch Applications (4 days)

Part of the FLUORIDEX® Family

ACTIVE INGREDIENTS
Potassium Nitrate, Sodium Fluoride

OTHER INGREDIENTS
Water, Poloxamer 338, Natural Peppermint, Calcium Nitrate, Sodium Phosphate, Sodium Saccharin

INTENDED USE
Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity.

WARNING
Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist

CAUTION
Do not swallow. Not intended for children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance. Store at room temperature.

DISTRIBUTED BY
Discus Dental, Inc
Culver City, CA 90232 USA
USA: 800-422-9448

IMPORTED BY/
IMPORTÉ PAR
Discus Dental Canada (DDCNSC)
Mississauga, ONT L5T-2E9
Canada: 800-278-8282

CAUTION
Federal (U.S.) law restricts this device to sale by or on the order of a dental professional

14-1808-071906

DIRECTIONS FOR USE

1. Floss and brush your teeth.
2. In counterclockwise motion, remove plastic cap from end of syringe. Replace with mixing nozzle on to end of syringe and secure.
3. Tray Method* (For Best Results): Place small amount of gel into each tooth compartment of tray where sensitivity is felt. Use approximately one dose (1/4 syringe) per tray per application. You may need less depending on the size of your teeth. Insert trays over upper and/or lower teeth. Remove excess gel with cotton swab or dry toothbrush. Normal wear time is 30 minutes. Remove trays and rinse trays with cold water. Rinse or brush excess gel from teeth
4. Brush-On Method: Apply a thick ribbon of gel to extra-soft toothbrush. Brush gel on to teeth, sweeping from gum line where most tooth sensitivity occurs. Do not rinse mouth or spit for approximately 3 minutes. After 3 minutes, spit any excess gel.
5. Remove mixing nozzle and replace tip cap to avoid product leakage
6. For best results, do not rinse, drink or eat for thirty minutes after application.
7. Use Relief ACP twice a day until symptoms are relieved or as directed by your dental professional

* Recommended: Non-scalloped custom trays to overlap gingival margin where sensitivity can also occur.

Relief® ACP
ORAL CARE GEL

REFILL KIT

4 Filled Gel Syringes, 2.6g / 2.4cc
8 Dual Arch Applications (4 days)

Part of the FLUORIDEX® Family

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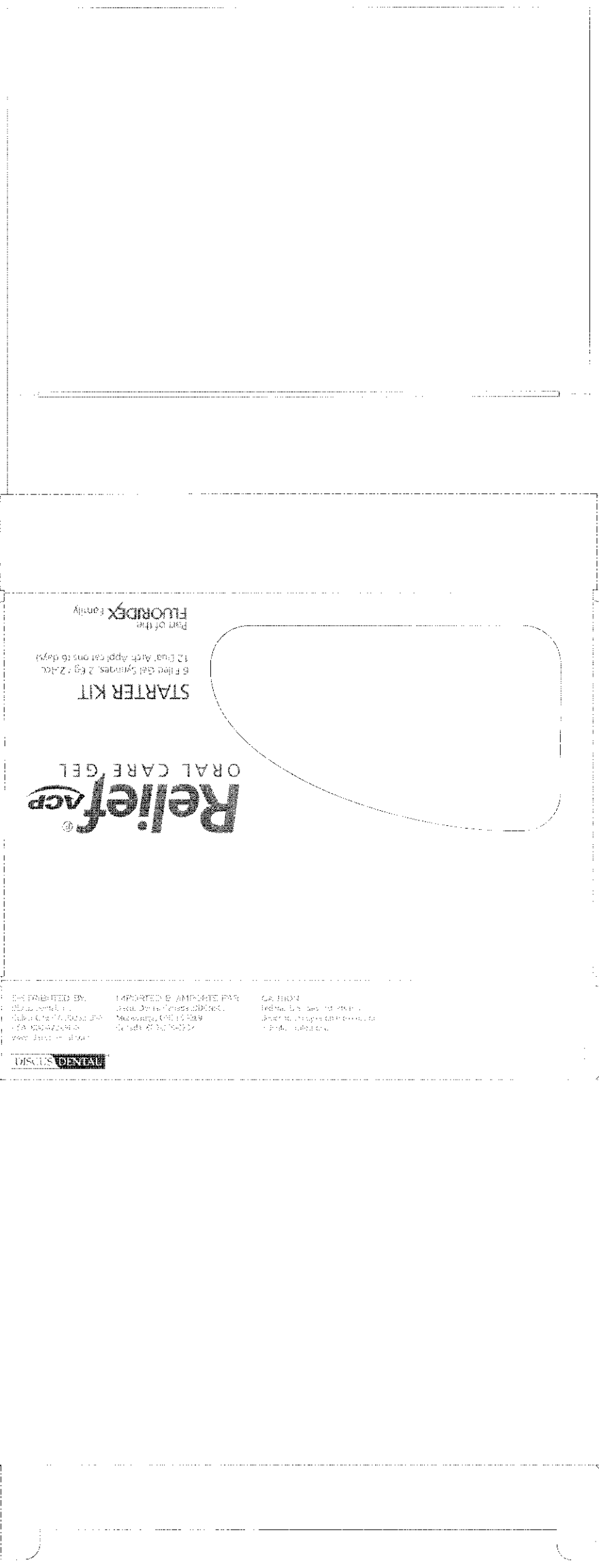

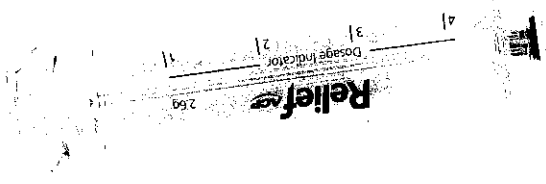

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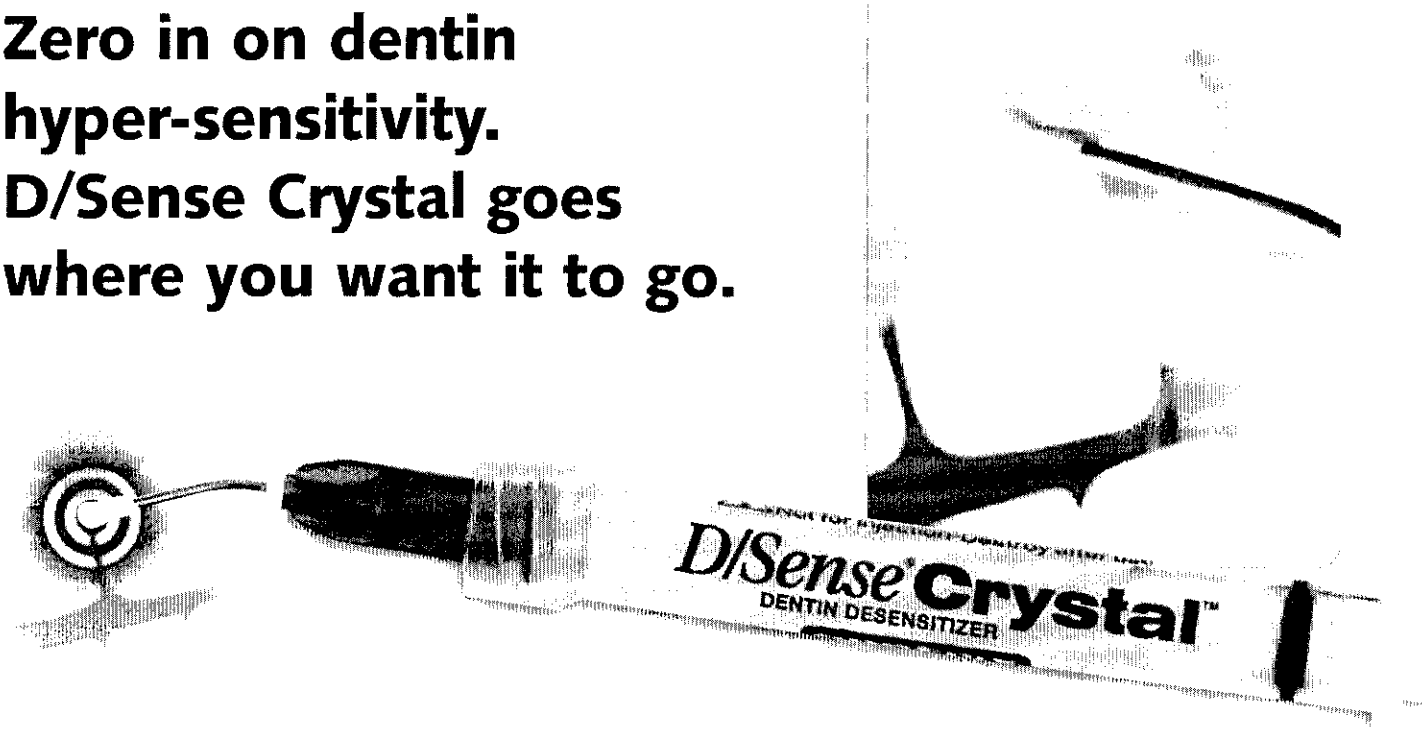
Section I

2. Labeling for Predicate Products

Zero in on dentin hyper-sensitivity. D/Sense Crystal goes where you want it to go.



Pain relief in 30 seconds.
Centrix makes treating dentin hyper-sensitivity easier. Guaranteed.

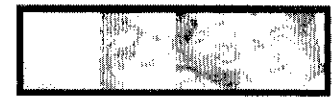
D/Sense® Crystal.™ The only desensitizer that 10 out of 10 dental evaluators recommend you try for yourself*.

D/Sense Crystal is a one-step, dual-action desensitizer and cavity liner. It reacts with dentin to precipitate microcrystals of calcium oxalate and potassium nitrate. These crystals penetrate deeply into the tubules and seal the dentinal surface with a continuous, acid-resistant complex (typically less than 3 microns thick).

- Patented single-component, dual-action formula
- Provides fast desensitizing with deep, long lasting crystal formation
- Occludes dentinal tubules with calcium oxalate and potassium nitrate
- Unique delivery system
  - Time-saving, single step technique, less waste – apply what is needed
- SofNeedle™ Applicator
  - Accurate, direct application – gentle on soft tissue

THE DENTAL ADVISOR ++++

CENTRIX
D/Sense® Crystal™
Dual-Action Crystal Precipitate Desensitizer



centrix®
Making Dentistry Easier.℠

* Independent Lab. Data on file

Ordering is easy. Call 800-235-5862 or contact your preferred dealer.
Visit dsensecrystal.com for more information.

CE 0510

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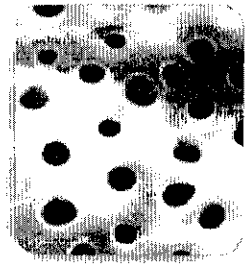
CENTRIX

D/Sense® Crystal™

Dual-Action Crystal Precipitate Desensitizer

INDICATIONS FOR USE

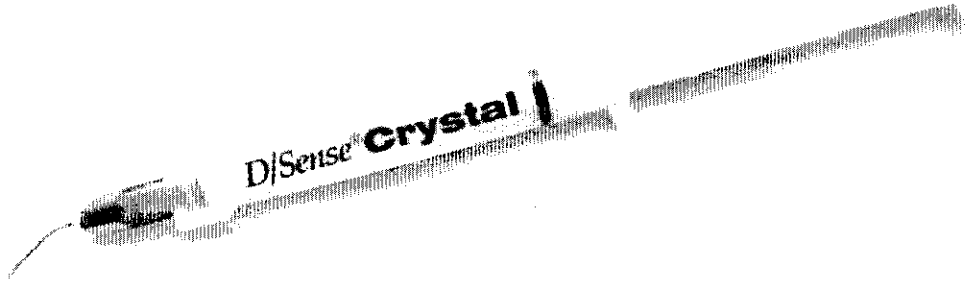
- Cervical erosions
- Under crowns and bridges, when a standard cement is used
- On any exposed dentin surface, such as the margins around temporary crowns
- Before and after tooth bleaching
- Under restorations
- Gingival recession
- Before and after prophy



Dentin before treatment with D/Sense Crystal.

SofNeedle Tip accurately treats dentin without harming soft tissue.

Dentin after treatment with D/Sense Crystal.



- Active ingredient - potassium binoxalate
- ADA CDT CODE 09910

ORDERING INFORMATION:

D/SENSE CRYSTAL
REF 310106 6 x 1.0ml Multi-use syringes + 24 SofNeedle Tips

THE DENTAL ADVISOR ++++

SUGGESTED ACCESSORY:

REF 290038 SofNeedle 22ga tips, 144

Ordering is easy.
Call 1-800-235-5862
or contact your preferred dealer.

centrixdental.com

International Sales & Product Information

FOR EUROPE:
Centrix BV
Bergweg 169, 3707 AC Zeist
The Netherlands
Tel: +31 (0)30 692 70 50
Fax: +31 (0)30 693 14 21
europe@centrixdental.com

FOR ASIA:
Hans Ukens
Tel: +49 4931 959656
Email: ukens@attglobal.net

RISK FREE **Our Guarantee** — If you are not 100% satisfied, simply return the product for a complete refund. It's that easy.

MK0003 REV C

centrix®
Making Dentistry Easier.℠

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DISCUS DENTAL®
INCORPORATED

Labeling for Tooth Desensitizer made by Cosmedent is not available. The website for Cosmedent is www.cosmedent.com

8550 Higuera Street · Culver City, CA 90232 · www.discusdental.com · Tel. 310.845.8200 · Fax 310.845.1500

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Andrew I. Steen

Subject: 510(k) Number K062176/S2

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

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

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	(b) (4)	
Special 510(k)?		
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

- ☐ A 510(k) summary OR ☒ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

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

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: LSH 872.3260 II

Additional Product Code(s) with panel (optional):

Review: Susan Runner (Branch Chief) DE/DB (Branch Code) 1/10/07 (Date)

Final Review: (Division Director) 4/10/07 (Date)

Revised:4/2/03

4

Internal Administrative Form

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

6

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K062176

Reviewer: Andrew I. Steen
Division/Branch: DAGID/DEDB
Device Name: *Relief ACP Oral Care Gel*
Products to Which Compared (510(K) Number If Known):
Multiple Tooth Desensitizer (K052263)
D/Sense 1-Step (K021146)

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

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

1. Method of tubule blockage differs from declared predicates.
2. Method is similar to predicate devices previously cleared but undeclared by applicant.
3. Fluoride release and complete chemical composition required.
4. Data provided as requested.

Relief ACP Oral Care Gel, K062176, Discus Dental, Inc.

1. Intended Use: *Relief ACP Oral Care Gel* is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

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

See attached Review Memorandum.

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication?

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

8

U.S. Department of Health and Human Services
Food and Drug Administration

REVIEW MEMORANDUM

Date: 9 January 2007

From: Andrew I. Steen, Mechanical Engineer, DAGID, HFZ-480

Subject: *Relief ACP Oral Care Gel* (K062176)
Discus Dental, Inc., Culver City, CA

To: The record

Contact: Mr. Steven L. Ziemba. Phone: (b) (6) Fax: (b) (6)
Email: (b) (6)

I. BACKGROUND

Discus Dental Inc., of Culver City, CA, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *Relief ACP Oral Care Gel*, a tooth desensitizer. *Relief ACP Oral Care Gel* is a prescription Class II medical device regulated under 21 CFR 872.3260 as a "Cavity Varnish." The *Relief ACP Oral Care Gel* is listed under product code LBH.

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

II. SUBMISSION CHANGES

On October 4, the reviewer contacted the applicant via phone and requested a complete chemical composition chart including CAS numbers for each chemical, any available biocompatibility data, and release data for the active ingredients. The reviewer also asked the applicant to identify a preference to either the 510(k) summary or 510(k) statement. The applicant stated that the requested data would be provided save the biocompatibility data because (b) (4) The applicant indicated that the 510(k) statement should be used.

On November 17, the applicant responded with the previously requested information.

On December 18, the applicant provided, as per the request of the reviewer, a breakdown of the percent composition of each gel. In addition, the applicant provided several journal articles in support of the device.

On December 20, the reviewer requested additional information from the applicant pertaining to the specific mode of action of this device and the lower percentage of active ingredient when compared to predicate devices.

On January 9, the applicant responded to the previous request with (b) (4) from one of the following groups: (b) (4) (b) (4) (b) (4) contains (b) (4) as active ingredients. The applicant indicated via phone discussion with the reviewer that this product has no 510(k) number and is except under CDER rules, but is for the same intended use of application to sensitive teeth.

III. SUBMISSION SUMMARY

The submission for *Relief ACP Oral Care Gel* consists of a device description, a risk analysis, a predicate device comparison, and draft labeling. Supplement #1 consists of the CAS numbers for the device components, toxicity testing results, and the fluoride ion release data. Supplement #2 consists of a study design and (b) (4) by the device. The primary mode of action for this device is the physical blockage of exposed dentinal tubules by the formation of calcium phosphate precipitate.

The chemical composition of *Relief ACP Oral Care Gel* is as follows:

(b) (4)

The device is packaged in a 3 ml (b) (4) syringe with one gel in each tube. The submission reports that upon mixing calcium phosphate begins to form in the dentinal tubules.

Supplement #1 contains the final report for fluoride ion release testing prepared by (b) (4) (b) (4). The report states that only the (b) (4) portion of the device was tested and therefore the ppm results are divided in half to accurately determine the release of fluoride ions from the entire device. A (b) (4) was performed. The (b) (4) . The fluoride was measure using a (b) (4)

Supplement #1 purports the completion of biocompatibility testing and considers the device biocompatible according to voluntary standard ISO 10993-1:2003 for surface device with skin contact for a limited duration. The following is the reported results. Complete test reports are stated to be on file at the applicant company.

Test:	Results
Cytotoxicity-Direct Contact - ISO 10993-5	Non-cytotoxic
Dermal Irritation - ISO 10993-10	Non-irritating
Murine Local Lymph Node assay – ISO 10993-10	Non-sensitizing

Supplement #2 contains a study design for evaluation of the physical action of this device and the resultant (b) (4) before and after treatment. The (b) (4) images illustrate the dentinal tubules blocked by precipitate after the application of *Relief ACP Oral Care Gel* as compared to (b) (4) negative control dental enamel with no treatment.

The directions for use contained in the submission describe two methods of application of this device. The recommended method utilizes a tray and indicates a 30 min wear time followed by a rinse of the teeth. The alternative method is application of this device to sensitive areas by toothbrush followed by a three minute cure before rinsing excessive product.

Relief ACP Oral Care Gel will be provided as non-sterile. The shelf life is purported to be (b) (4) months based on component similarity to the predicate device; however this date is subject to confirmation by testing.

IV. REVIEWER'S ANALYSIS

No new technological characteristics have been introduced in *Relief ACP Oral Care Gel* that could affect the device's safety or effectiveness. In addition to the predicate devices declared by the applicant, the reviewer utilized *DenShield* (K061359), Quell Desensitizer (K010957), and Butler Nucare Root Conditioner with NovaMin (K033295). The formulation of *Relief ACP Oral Care Gel* is similar to previously cleared predicate devices and raises no biocompatibility concerns. All biocompatibility tests performed by the applicant indicate a biocompatible device. The fluoride released from *Relief ACP Oral Care Gel* is below that which is released by fluoride containing toothpaste and the company is making no claims to the release of fluoride as being significant.

The (b) (4) contained in Supplement #2 demonstrate that this product does block dentinal tubules with a precipitate. This precipitate is theorized but not demonstrated to be Calcium Phosphate. However, the blockage of the tubules is enough to demonstrate that *Relief ACP Oral Care Gel* works in a device-like manner.

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The directions for use contain the proper prescription warning as well as warnings about excessive use and directions to contact a dental professional if problems persist. No unsubstantiated claims are present.

V. RECOMMENDATION

The information submitted by Discus Dental Inc., demonstrates that *Relief ACP Oral Care Gel* (K062176) has the same indications and technological characteristics as a legally marketed device. *Relief ACP Oral Care Gel* is substantially equivalent (SE) to predicate tooth desensitizers.

Primary Reviewer: _____

Andrew I. Steen, B.S.M.E.
Mechanical Engineer

Branch Review: _____

M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Andrew I. Steen

Subject: 510(k) Number K062176/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). Telephone Held
☐ Is substantially equivalent to marketed devices.
☐ NOT substantially equivalent to marketed devices.
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	(b) (4)	
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
☐ A 510(k) summary OR ☒ A 510(k) statement
☐ The required certification and summary for class III devices
☒ The indication for use form

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

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

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

Review: Lein-Ruyee DE/B3 12/20/06
(Branch Chief) (Branch Code) (Date)

Final Review: Susan Runner 12/21/06
(Division Director) (Date)

Revised:4/2/03

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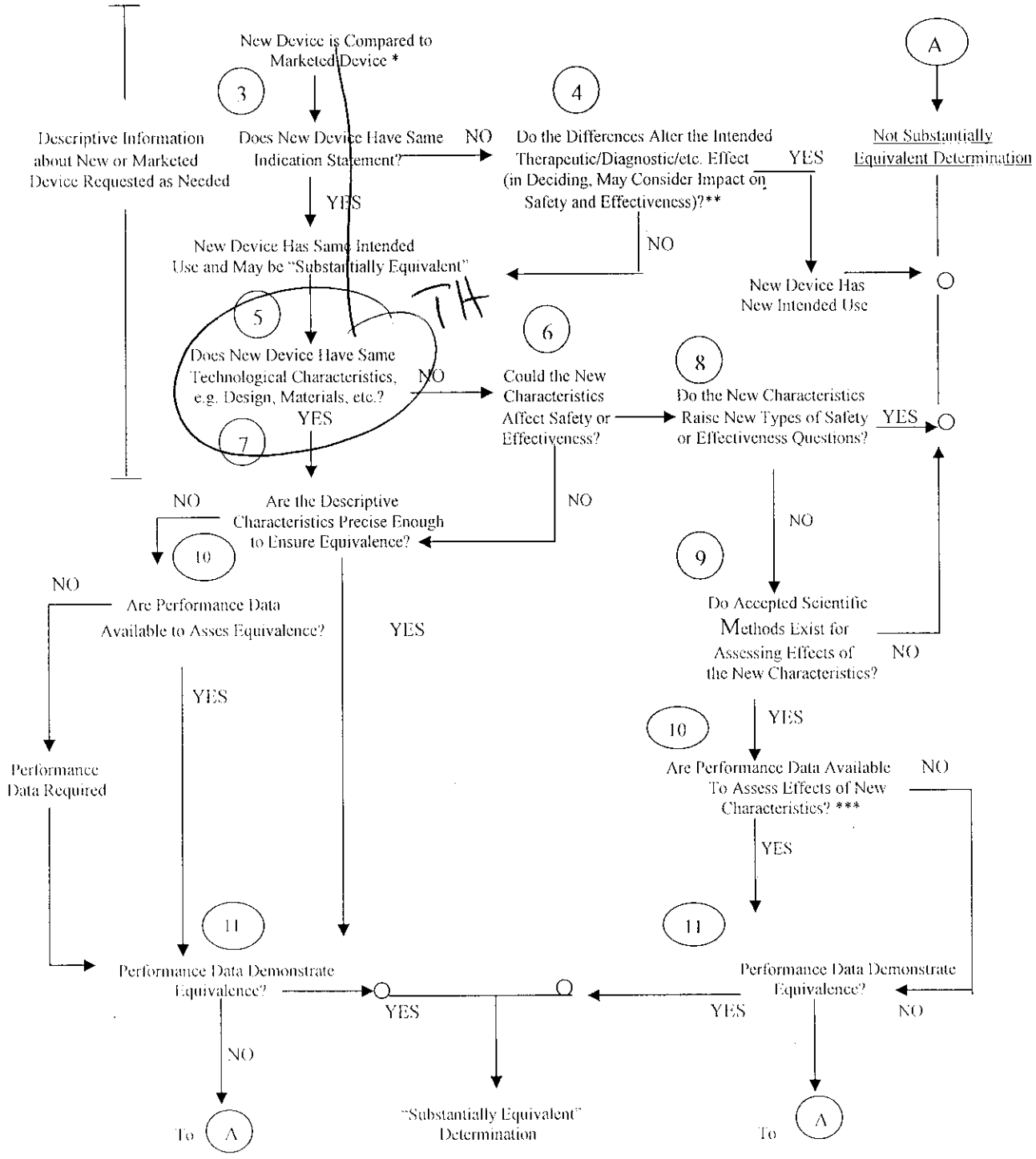
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

Internal Administrative Form

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

U.S. Department of Health and Human Services
Food and Drug Administration

TELEPHONE HOLD MEMORANDUM

Date: 20 December 2006

From: Andrew I. Steen, Mechanical Engineer, DAGID, HFZ-480

Subject: *Relief ACP Oral Care Gel* (K062176)
Discus Dental, Inc., Culver City, CA

To: The record

Contact: Mr. Steven L. Ziemba, Phone: (b) (6) Fax: (b) (6)
Email: (b) (6)

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Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

II. TELEPHONE HOLD

On December 20, the reviewer contacted the applicant via phone and email in order to discuss the mode of action for the product. Two components of this device, Potassium Nitrate and Sodium Fluoride, are considered drugs by CDRH. The product contains these components in greater amounts than that of the declared method of action, formation of ACP. Predicate devices such as Quell Desensitizer (K010957) and Butler Nucare Root Conditioner with NovaMin utilize Calcium Phosphate forming components in greater amounts. The reviewer informed the applicant that the submission would be placed on hold pending the submission of sufficient data.

Primary Reviewer: _____
Andrew I. Steen, B.S.M.E.
Mechanical Engineer

Branch Review: _____
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

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Steen, Andrew I*

From: Steen, Andrew I*
Sent: Wednesday, December 20, 2006 3:27 PM
To: 'Steven Ziemba'
Subject: Telephone hold Relief ACP K062176

Mr. Ziemba,

This submission notes that the mode of action for this product is the physical blockage of dentinal tubules by calcium phosphate. It has come to my attention that the amount of the calcium phosphate forming materials in your product is much less than that contained in predicate devices. Justification must be shown that the amounts of calcium nitrate and sodium phosphate are significant enough to block the dentinal tubules as described. Another option would be to consider modifying the product to be similar to predicate devices. You may develop other routes of justification and we will certainly consider all information you present.

As this information is necessary to determine substantial equivalence and the information may not be readily available, I am placing this document on telephone hold pending the submission of the requested data.

Please contact me with any questions or concerns.

Andrew I. Steen
Mechanical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
ODE phone: 240-276-3773
OSEL phone: 301-796-0287
fax: 240-276-3789
mail: HFZ-480

Protecting and Promoting Public Health

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Steen, Andrew I*

From: Steven Ziemba [(b) (6)]
Sent: Monday, December 18, 2006 4:30 PM
To: Steen, Andrew I*
Subject: K062176
Attachments: Tung ACP Article.pdf; Zapanta Remin article.pdf; Torrado Toothpaste ACP article.pdf; Relief ACP Gel specs.pdf

Andrew - I found a few articles that talk about ACP - see attached. It was less trouble than I thought to find these. The Tung article is the seminal information on topically applied ACP formulae.

Also, the attached Discus specs list the amounts for each ingredients with their CAS numbers. The gel is (b) (4) (b) (4) as it will begin to form calcium phosphate as soon as it is mixed.

Steven Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Inc. - Quality Counts!
(b) (6) - tel.
- fax

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DISCUS DENTAL
INCORPORATED

FORMULA/COMPOUND SPECIFICATION

(b) (4)

8550 Higuera Street • Culver City, CA 90232 • www.discusdental.com • Tel. 310.845.8200 • Fax 310.845.1537

DISCUS DENTAL
INCORPORATED

FORMULA/COMPOUND SPECIFICATION

(b) (4)

8550 Higuera Street · Culver City, CA 90232 · www.discusdental.com · Tel. 310.845.8200 · Fax 310.845.1537

Amorphous Calcium Phosphates for Tooth Mineralization

CE 2

Ming S Tung, PhD
Senior Project Leader

Frederick C Eichmiller, DDS, BSME
Dental Examiner/Compliance Specialist

American Dental Association Foundation
National Institute of Standards and Technology
Gaithersburg, Maryland

Abstract: *The destruction of tooth structure through caries and erosive processes is due to two types of acidic challenges that affect the tooth in different ways. Acidic attack by cariogenic bacteria initially produces subsurface lesions that weaken the enamel and, if left unchecked, can progress through the enamel and dentin and eventually into the pulpal cavity. Erosive attack by acidic foods and beverages removes mineral from the surface of enamel and initially causes dulling and loss of tooth luster; if left unchecked, it can progress to a more severe loss of enamel thickness and contour. This article focuses on the potential means of improving the cosmetic appearance of teeth by depositing mineral into surface defects. Several approaches use the unique properties of amorphous calcium phosphate (ACP) compounds, which have the highest rates of formation and dissolution among all the calcium phosphates. ACP has been shown to rapidly hydrolyze to form apatite, similar to carbonated apatite, the tooth mineral. Products containing ACP or ingredients that form ACP can include toothpastes, mouth rinses, artificial saliva, chewing gums, topically applied coatings, and other vehicles for topical use. When applied, they readily precipitate ACPs on and into tooth-surface defects. These products hopefully will provide users with new tools to restore and enhance the smoothness and luster of their teeth.*

Learning Objectives

After reading this article, the reader should be able to:

- discuss two kinds of acidic challenges on the integrity of the tooth.
- discuss how and why products containing calcium and phosphate may help enhance tooth mineralization.
- describe two methods for delivery of amorphous calcium phosphate to the oral cavity.
- explain the chemistry of amorphous calcium phosphate as related to tooth remineralization.
- describe possible roles of carbonate in remineralization.

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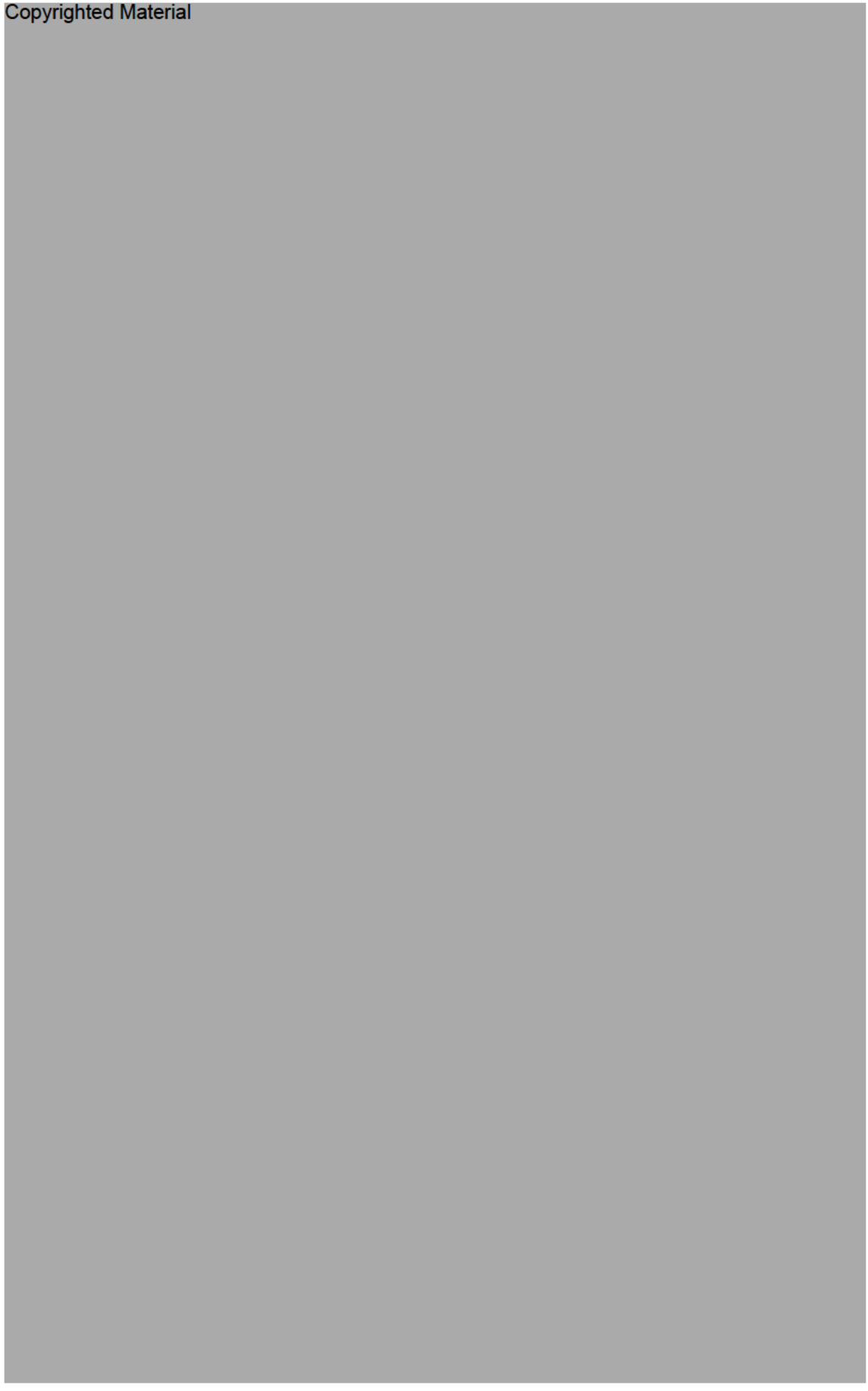
CE 2



CE 2

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CE 2

CE 2

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Calcium Phosphates in Demineralization/Remineralization Processes

Racquel Zapanta LeGeros, PhD

New York University College of Dentistry
New York, New York

Abstract

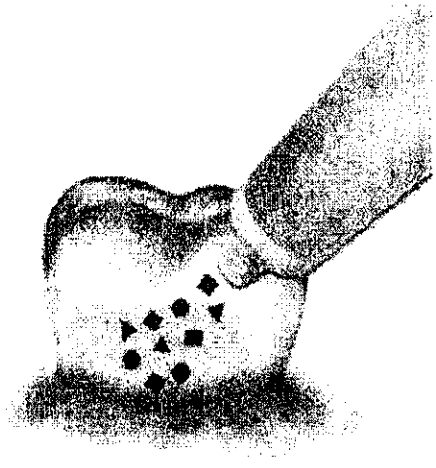
Enamel and dentin caries occur as a result of a shift in the equilibrium between demineralization and remineralization processes, with the demineralization process predominating. Caries lesions can be arrested by timely remineralization strategies. This paper reviews the calcium phosphates and other calcium compounds (*e.g.*, calcium fluoride, CaF_2) associated with the demineralization/remineralization processes. The caries process is initiated by the dissolution of the tooth mineral (calcium carbonatehydroxyapatite) by organic acids (lactic and acetic acid) produced by plaque bacteria acting on dietary carbohydrates or by lowered pH from ingested food and drink. The dissolution increases the concentration of calcium, phosphate/acid phosphate, magnesium, carbonate/bicarbonate ions in the microenvironment of the caries lesion, leading to the formation and transformation of different types of calcium phosphates. In the presence of low levels of fluoride (F^-) ions, (F,OH)-apatite—FHA—forms directly or indirectly by transformation of the other calcium phosphates; at higher concentrations, CaF_2-like materials form which can dissolve to form FHA and provide a supply of F^- in solution. The progress of the caries lesion is decelerated and remineralization accelerated in F-containing enamel. The demineralization/remineralization processes consist of the dissolution of F-poor, Mg- and CO_3-rich dental apatites and the precipitation of F-rich, Mg- and CO_3- poor dental apatites which are more resistant to subsequent acid challenges. The simultaneous presence of calcium (Ca), phosphate (P) and fluoride (F^-) ions in solution compared to the combined presence of (Ca+P), (Ca+F) or (P+F) or F alone, is most effective in inhibiting the dissolution of synthetic or enamel apatite. (**J Clin Dent 10:65–73, 1999.**)

Introduction

the Journal of CONTEMPORARY DENTAL PRACTICE
at www.thejcdp.com
Volume 5 Number 1 February 15, 2004 Winter issue

Remineralization Potential of a New Toothpaste Formulation: An *In-Vitro* Study

Anna Torrado, PhD; Manuel Valiente, PhD; Wu Zhang, MD; Yiming Li, DDS, MSD, PhD; Carlos A. Muñoz, DDS, MSD

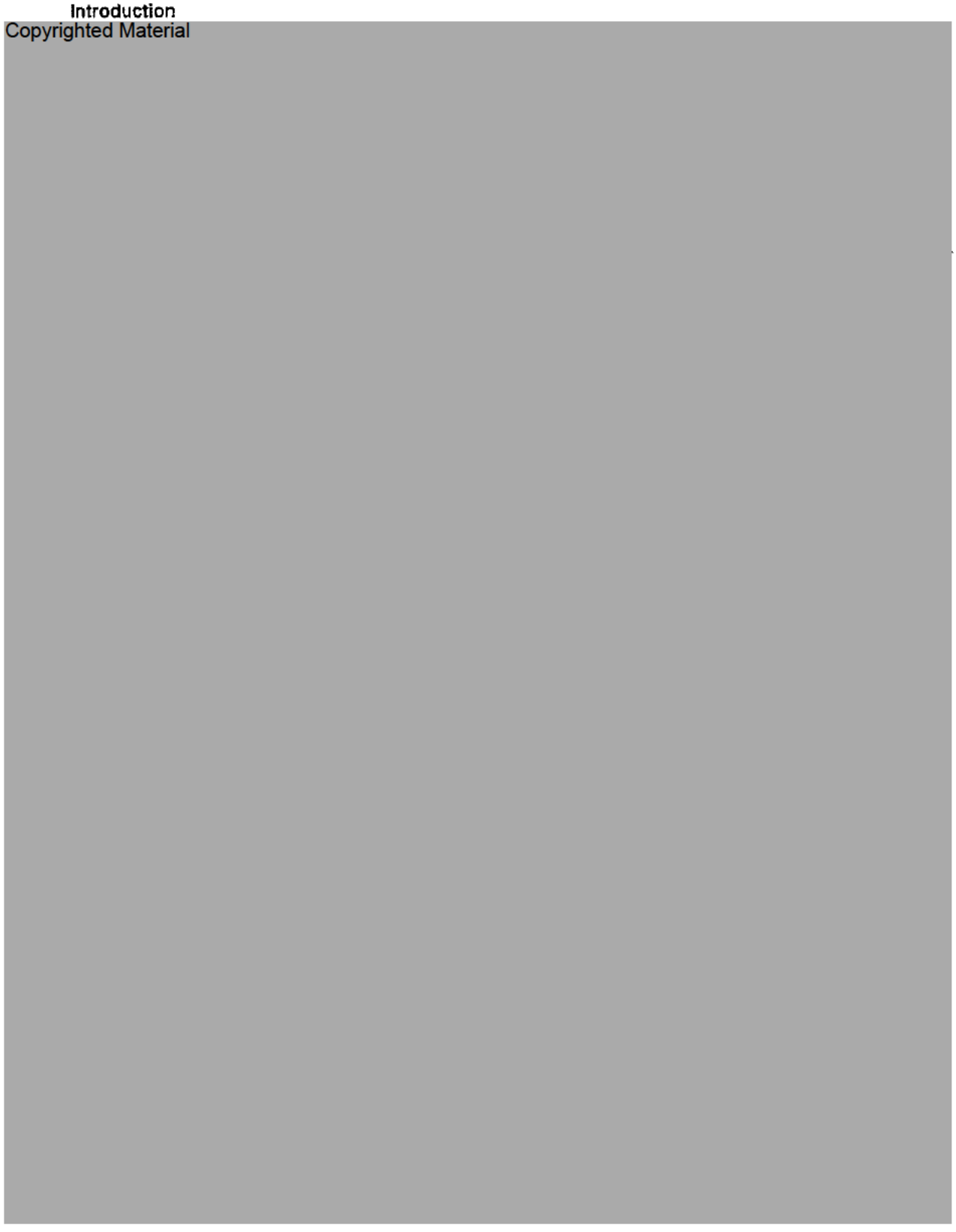


Abstract

The aim of the present study was to determine the ability of a dentifrice containing a mixture of ion-exchange resins (named NMTD), which supplies calcium, fluoride, phosphate, and zinc ions, to promote remineralization and/or inhibit demineralization of dental human enamel in a pH cycling model *in vitro*. A fluoride toothpaste was used as the control. The enamel specimens were tested for microhardness before and after 10 days and 16 days of the demineralizing and remineralizing treatments. The results of this study showed both dentifrices were effective in limiting *in vitro* enamel demineralization although the effects were not significantly different from each other. Inclusion of calcium and phosphate ion-exchange resins in the dentifrice containing a fluoride ion-exchange resin maintained a similar net outcome of the conventional dentifrice in the demineralization/ remineralization process under the experimental conditions employed.

Keywords: Remineralization, toothpaste, ion-exchange, fluoride

Citation: Torrado A, Valiente M, Zhang W, et. al. Remineralization Potential of a New Toothpaste Formulation: An *In-Vitro* Study. J Contemp Dent Pract 2004 February;(5)1:018-030.



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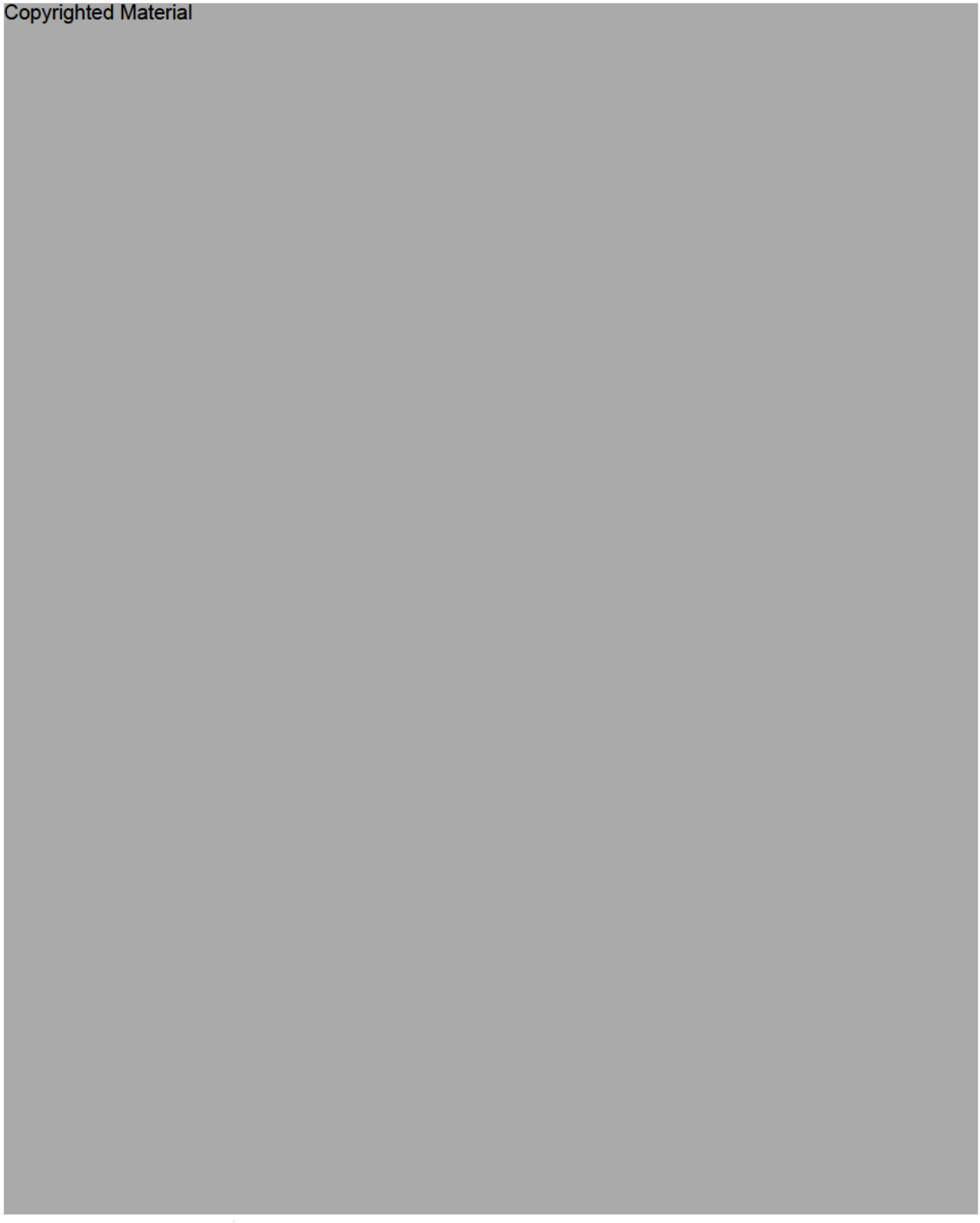

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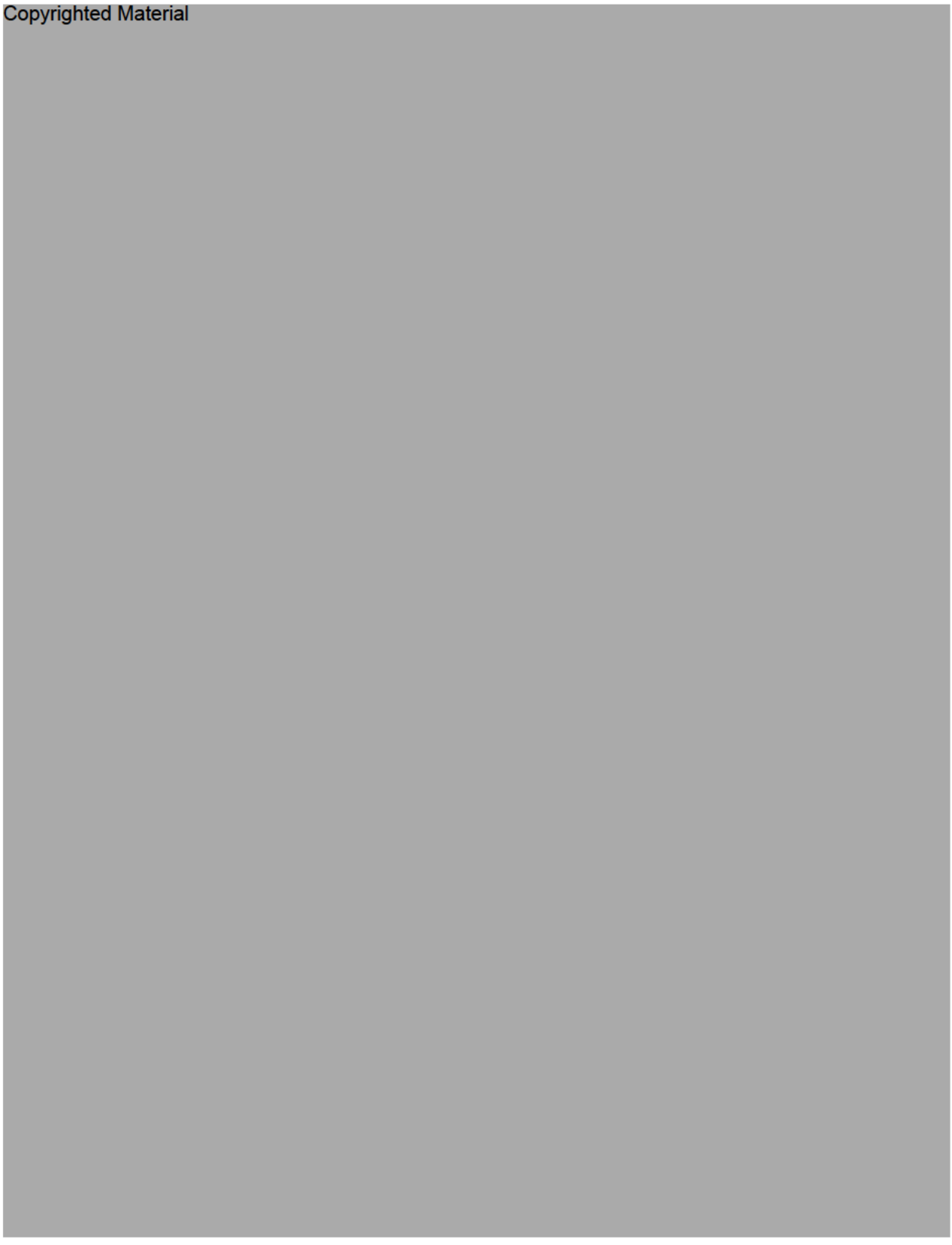

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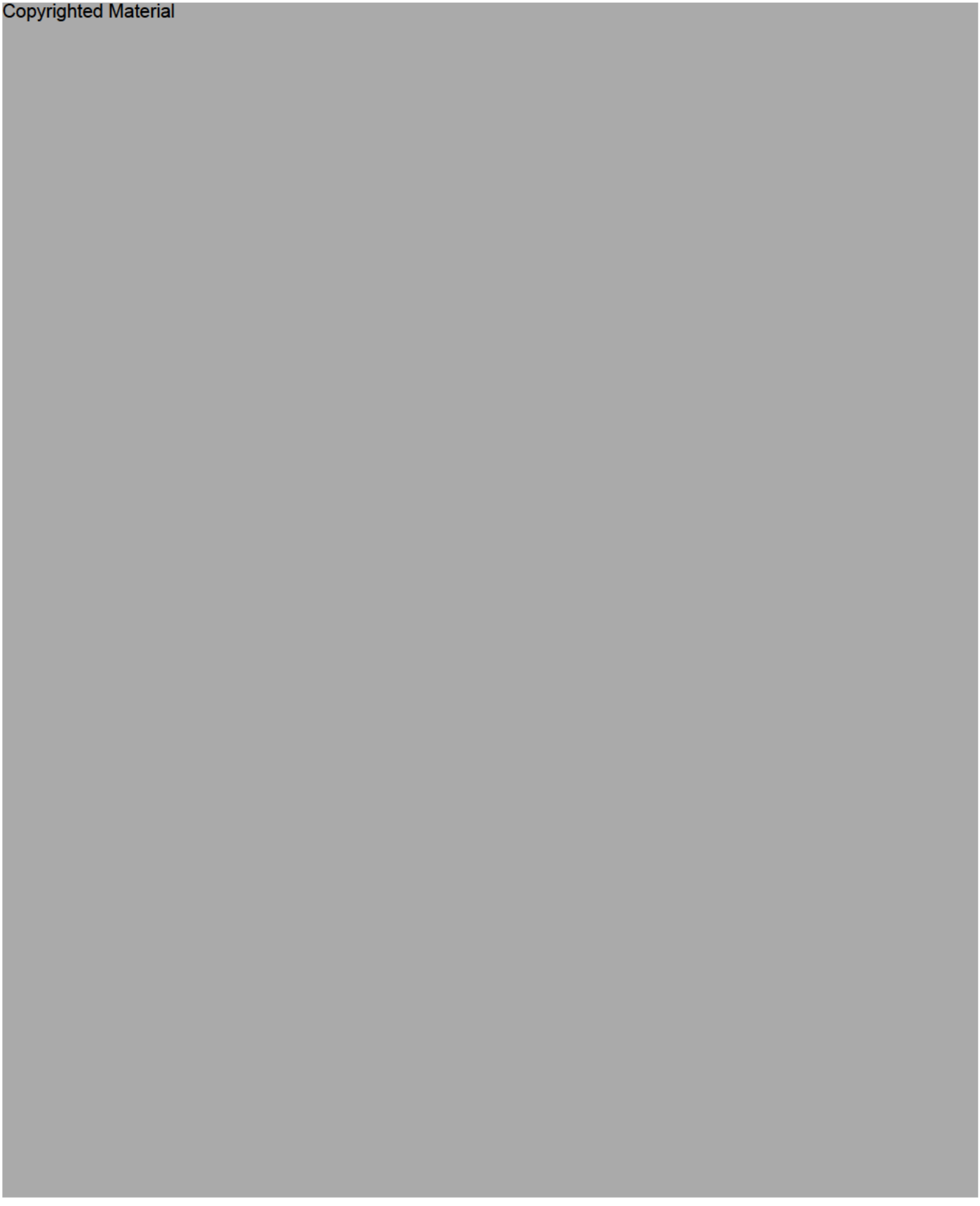

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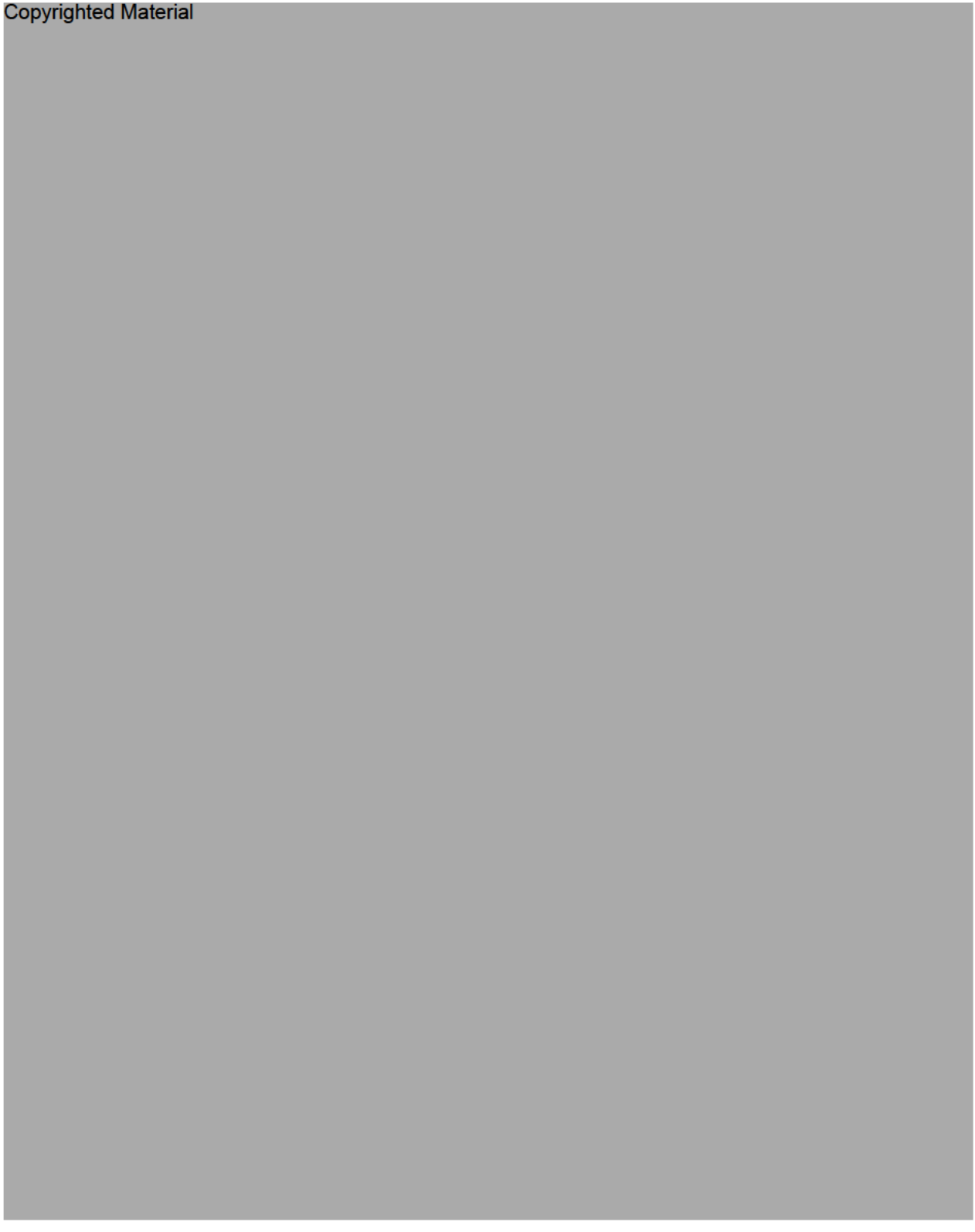

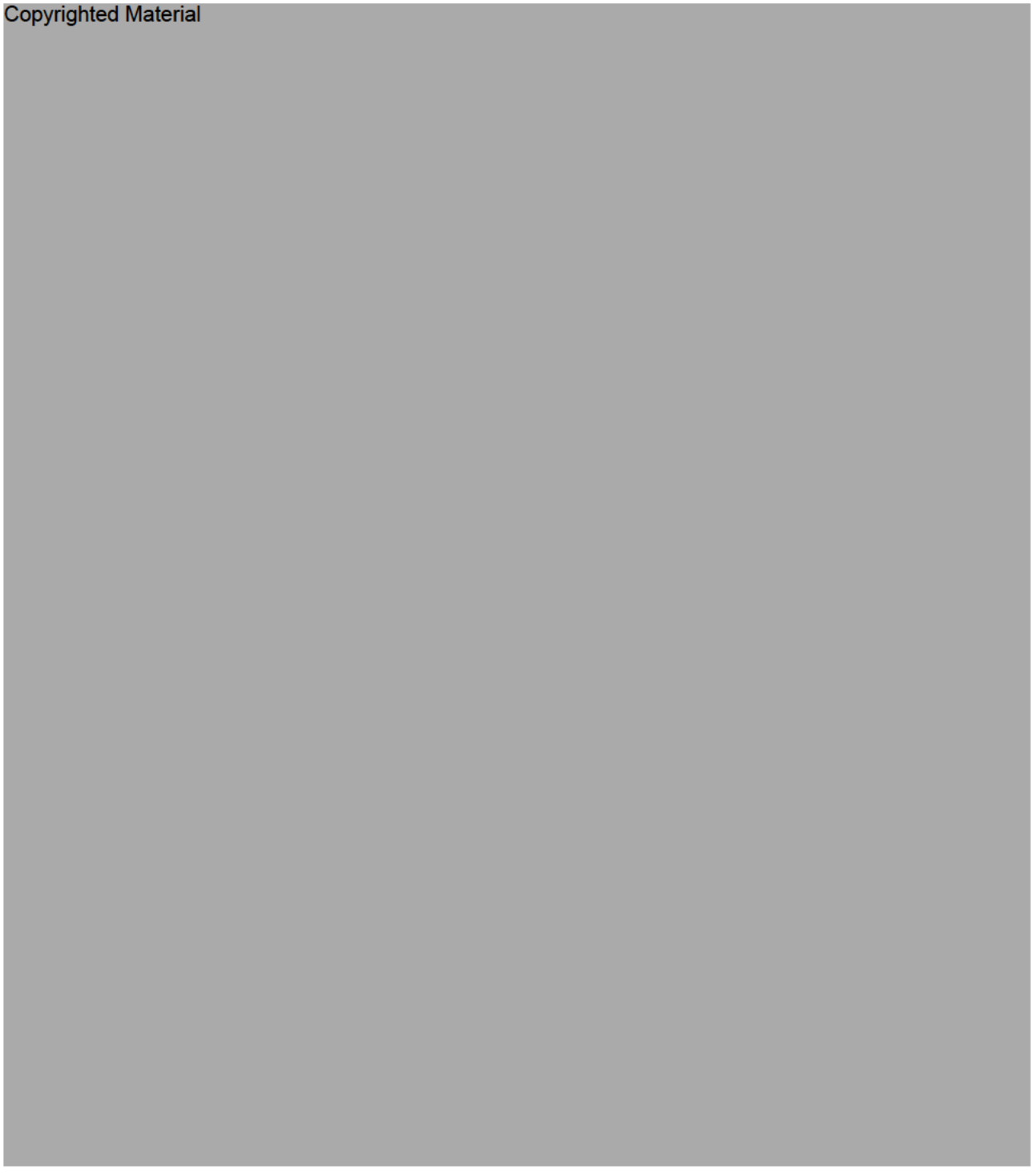

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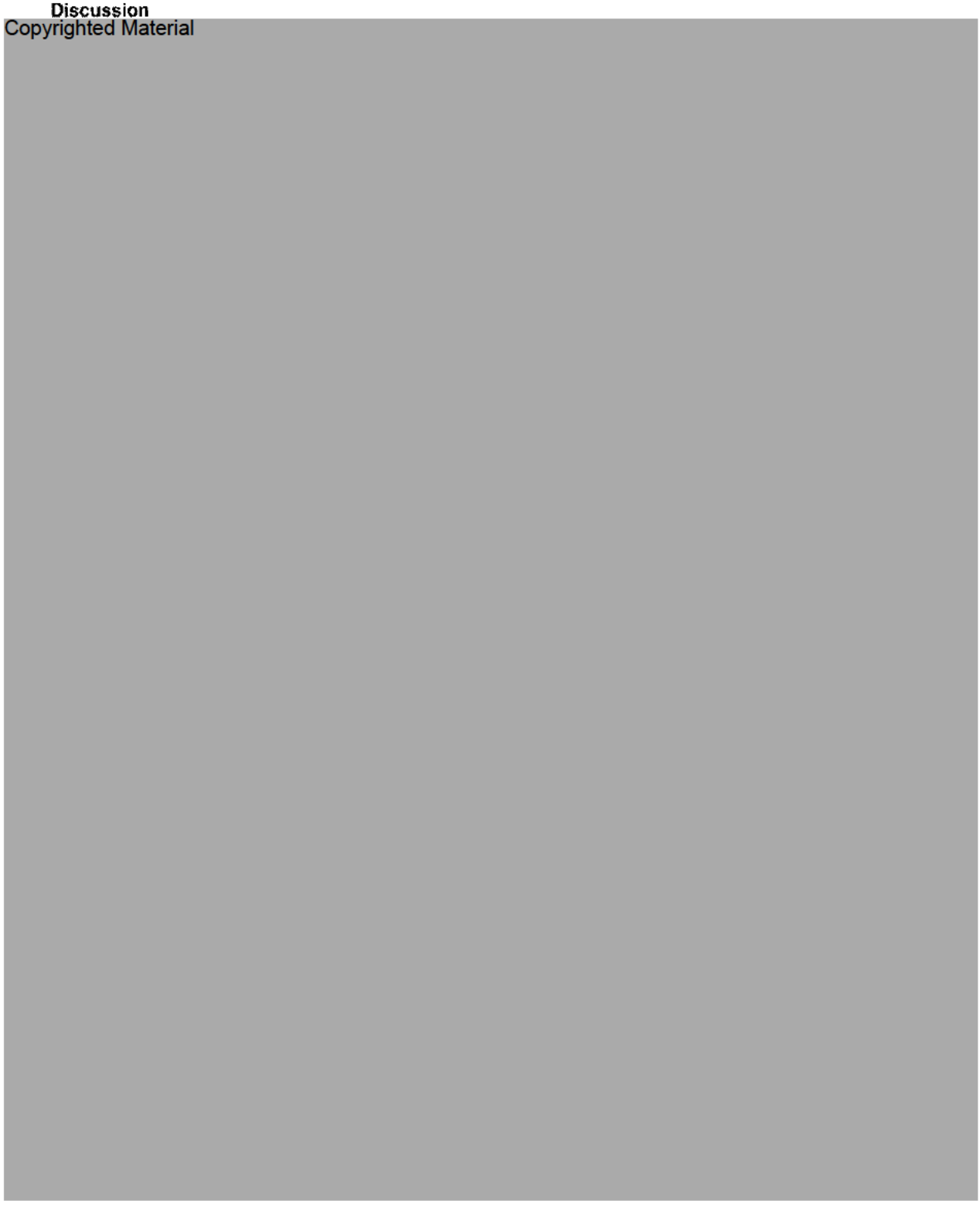
Discussion



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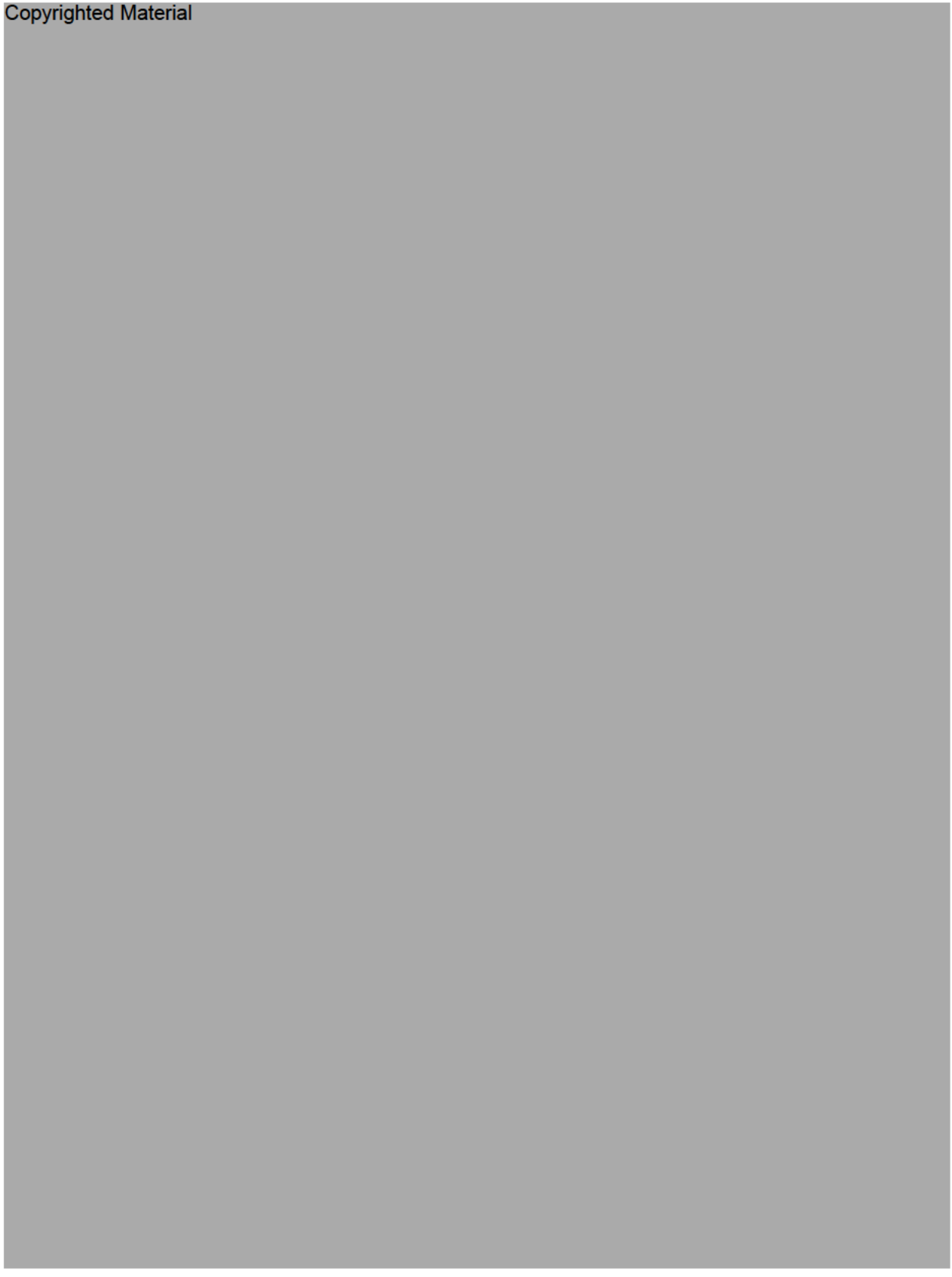

About the Authors

Anna Torrado, PhD

Anna Torrado is a Researcher and Technological Support Specialist at the Center for Separation Sciences (*Centre Grup de Tècniques de Separació en Química, GTS*) at the Analytical Chemistry Division of the Universitat Autonoma de Barcelona, Bellaterra, Spain.

e-mail: Anna.Torrado@uab.es

Manuel Valiente, PhD

Dr. Valiente is the Director of the Center for Separation Sciences (*Centre Grup de Tècniques de Separació en Química, GTS*) and Professor of Analytical Chemistry at the Department of Chemistry of the Universitat Autonoma de Barcelona, Bellaterra, Spain.

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Wu Zhang, MD

Dr. Wu Zhang is an Assistant Professor at Loma Linda University School of Dentistry. She serves as the director of Sterilization Assurance Service. Her research interests include pharmacological and biological effects of fluoride; biocompatibility and toxicological evaluation of dental materials; and dental unit waterline disinfection.

e-mail: wzhang@sd.llu.edu

Yiming Li, DDS, MSD, PhD

Dr. Yiming Li is a Professor of Restorative Dentistry and the Director of Biocompatibility and Toxicology Research Laboratory at Loma Linda University School of Dentistry. He is also a Professor in the Department of Microbiology and Molecular Genetics, Loma Linda University School of Medicine. Dr. Li is also a member of a number of committees at the school, university, national and international levels and is a consultant to the American Dental Association. Since 1999, he has been the Chairman for the Specification 41 for Biological Evaluation of Dental Materials. He has more than 170 publications in scientific journals, received a number of awards, and lectured in numerous countries.

e-mail: yli@sd.llu.edu

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Carlos A. Muñoz, DDS, MSD

Dr. Muñoz -Viveros is a graduate of the Universidad Nacional Pedro Henriquez Ureña in the Dominican Republic, where he received his DDS degree in 1978. In 1980, he received his Masters in Prosthodontics from Indiana University. Dr. Muñoz is a member of the American College of Prosthodontics, International Association of Dental Research, Hispanic Dental Association, Academy of Dental Materials and a Fellow of the American College of Dentists. He has presented lectures in Central and South America, the U. S., Asia and Europe. He has authored over 50 scientific articles, contributed to clinical dental texts, serves as journal reviewer. Currently, he is Professor and Director of the Center for Dental Research and Director of the Biomaterials Research Laboratory at Loma Linda University School of Dentistry

e-mail: cmunoz@sd.llu.edu

Acknowledgement

This work was supported by a FI Research Grant from the Autonomous University of Barcelona. The authors wish to thank Neil Jessop for his technical assistance and Professor Josep Mª Suñé from the Industrial Pharmaceutical Technology Department of the University of Barcelona for his collaboration in the new experimental toothpaste development.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Andrew I. Steen

Subject: 510(k) Number K062176

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

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

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
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Is this a prescription device?	(b) (4)	
Was this 510(k) reviewed by a Third Party?		
Special 510(k)?		
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

- ☐ A 510(k) summary OR ☒ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

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

Review: [signature] OEDB 10/6/06
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 10/6/06
for (Division Director) (Date)

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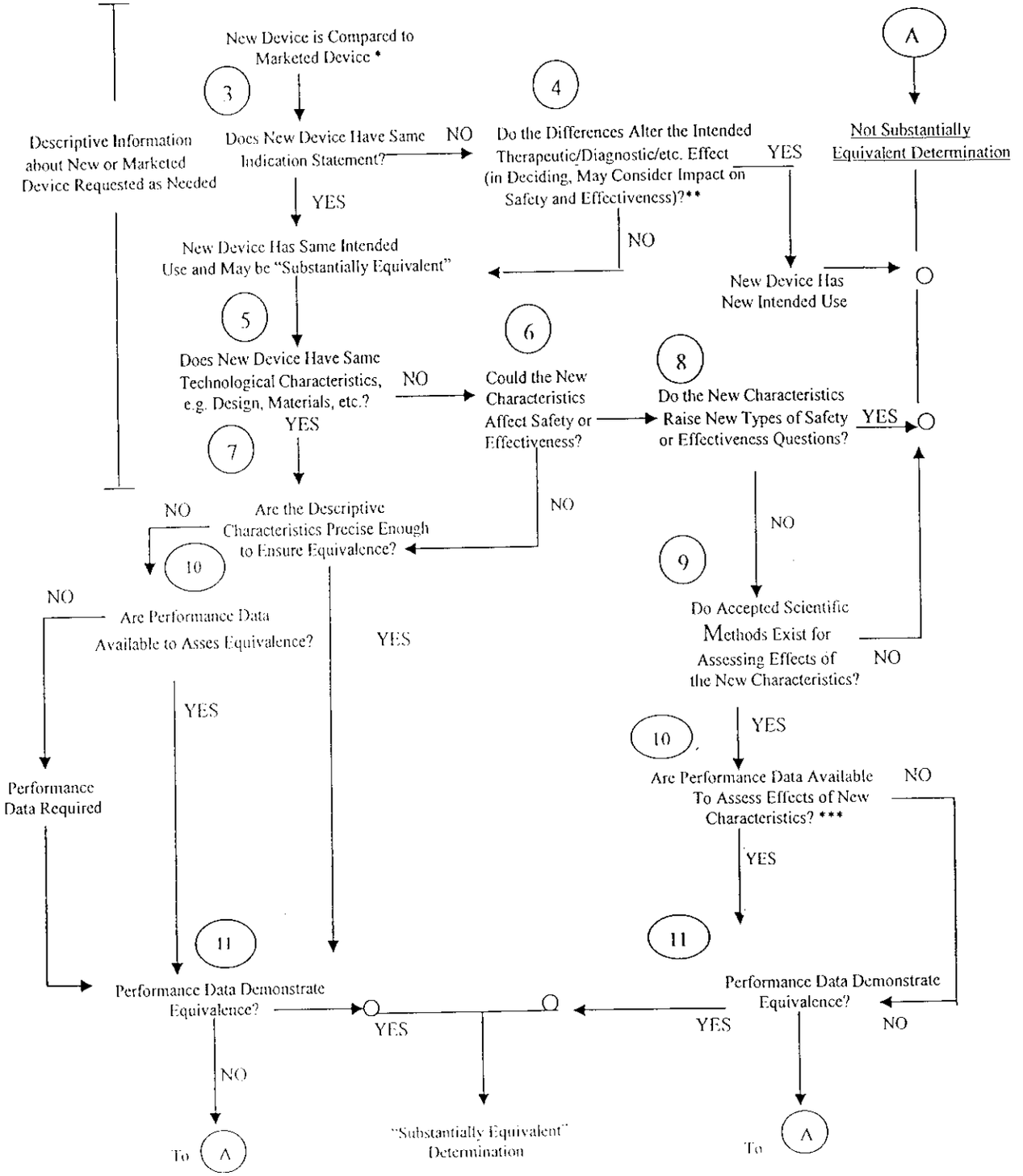
Revised:4/2/03

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



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

Internal Administrative Form

	YES	NO
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8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓ ✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓ ✓

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

510(k) Number: K062176

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

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

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

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

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

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

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

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

Passed Screening ✓ **Yes** ____ **No**

Reviewer:_____

Concurrence by Review Branch:_____

Date: AUG 17 2006

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

U.S. Department of Health and Human Services
FDA Food and Drug Administration

TELEPHONE HOLD MEMORANDUM

Date: 6 October 2006

From: Andrew I. Steen, Mechanical Engineer, DAGID, HFZ-480

Subject: *Relief ACP Oral Care Gel* (K062176)
Discus Dental, Inc., Culver City, CA

To: The record

Contact: Mr. Steven L. Ziemba, Phone: (b) (6) Fax: (b) (6)
Email: (b) (6)

I. BACKGROUND

Discus Dental Inc., of Culver City, CA, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *Relief ACP Oral Care Gel*, a tooth desensitizer. *Relief ACP Oral Care Gel* is a prescription Class II medical device regulated under 21 CFR 872.3260 as a "Cavity Varnish." The *Relief ACP Oral Care Gel* is listed under product code LBH.

Relief ACP Oral Care Gel is indicated for relief of discomfort from dentin sensitivity. The product works by forming a layer of calcium phosphate and potassium nitrate on teeth.

II. TELEPHONE HOLD

On October 4, the reviewer contacted the applicant via phone and requested a complete chemical composition chart including CAS numbers for each chemical, any available biocompatibility data, and release data for the active ingredients. The applicant stated that the (b) (4) and would take approximately (b) (4) (b) (4). The reviewer informed the applicant that the submission would be placed on hold during that time.

Primary Reviewer: _____
Andrew I. Steen, B.S.M.E.
Mechanical Engineer

Branch Review: _____
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

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Steen, Andrew I*

From: Steven Ziemba [(b) (6)]
Sent: Thursday, October 05, 2006 2:44 PM
To: Steen, Andrew I*
Subject: RE: (b) (4)

(b) (4) I think we'll need about a month before I can send you the report.

Steven Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Inc. - Quality Counts!
(b) (6) - tel.
- fax

>>> "Steen, Andrew I*" <andrew.steen@fda.hhs.gov> 10/5/2006 10:44 AM >>>

Mr. Ziemba,

The (b) (4) you have provided seems reasonable and relevant to the device at hand. Please feel free to proceed. Do you have an estimated time for completion (b) (4) ?

Please contact me with any other questions or concerns.

Andrew I. Steen
Mechanical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
ODE phone: 301-827-5283 x126
OSEL phone: 301-796-0287
fax: 301-480-3002
mail: HFZ-480

From: Steven Ziemba [mailto:(b) (6)]
Sent: Thursday, October 05, 2006 11:59 AM
To: Steen, Andrew I*
Subject: (b) (4)

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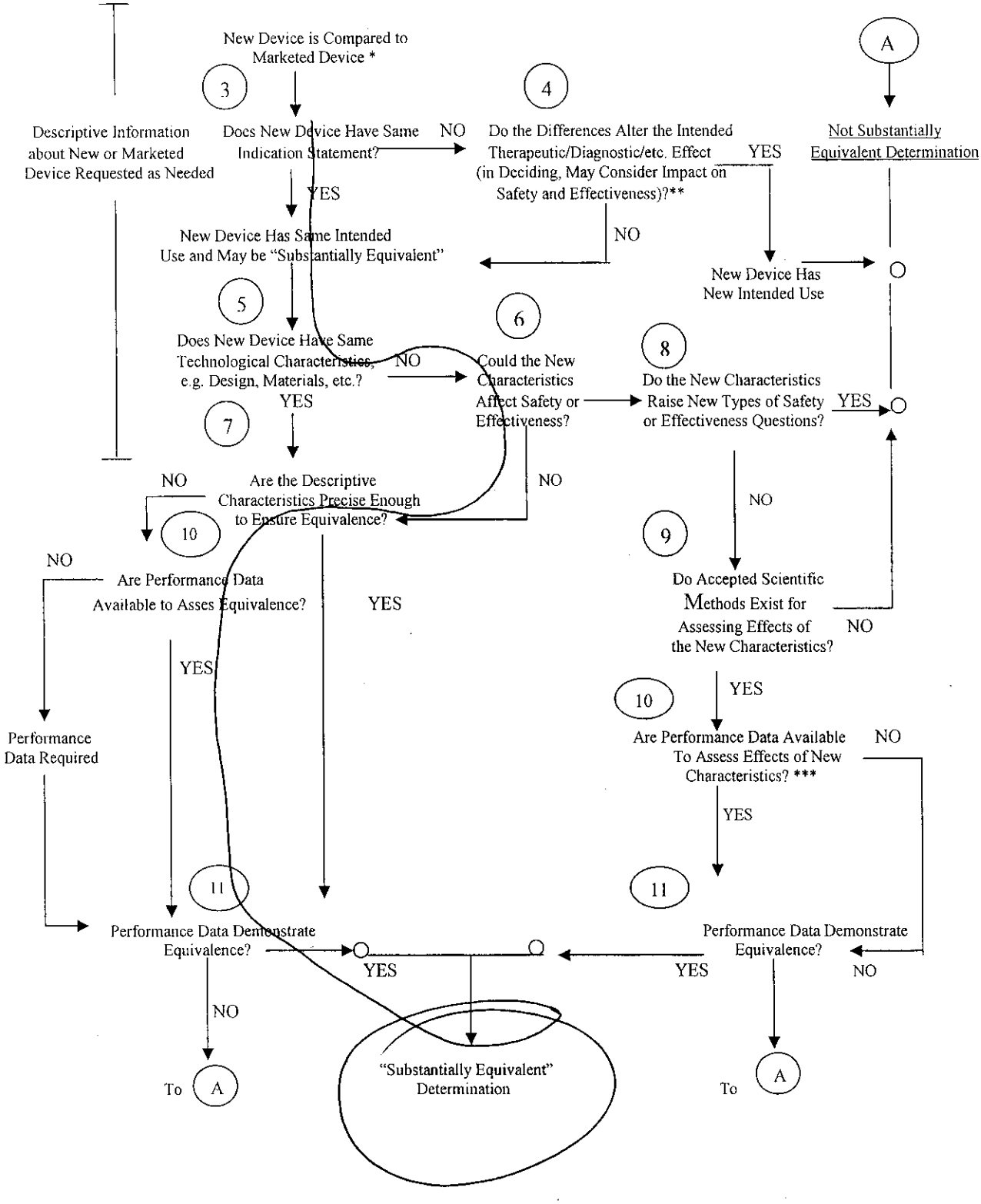
Mr. Steen - Attached is the (b) (4) [redacted] e. Note that it requires (b) (4) [redacted] g. Since the Relief ACP gel is intended to be brushed on or worn in a tray for a maximum of 30 mins., we believe that (b) (4) [redacted] ; (b) (4) [redacted] e, this (b) (4) [redacted] should be applicable. Please let me know your thoughts on this.

Steven Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Inc. - Quality Counts!
(b) (6) [redacted] - tel.
- fax

8 1

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



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

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

November 17, 2006

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Product: RELIEF ACP ORAL CARE GEL

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

DISCUS DENTAL®
INCORPORATED

K062176/S1

Steven L. Ziémba, M Sc.
Vice-President Regulatory Affairs

13 November 2006

Food and Drug Administration
Center for Devices & Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-460)
9200 Corporate Blvd.
Rockville, MD 20850

RE: 510(k) file K062176, Relief® ACP Oral Care Gel; Amendment to add (b) (4)
(b) (4)

Dear Sir or Madam:

We are submitting the attached documentation as an amendment to the subject 510(k) filing regarding the (b) (4) in Relief® ACP Oral Care gel product. We would also like to point out that the following tests that we indicated would be completed before commercial marketing of this product have now been completed with acceptable results (results are on file at Discus):

Test	Result
Cytotoxicity –Direct Contact	Non-cytotoxic
Dermal Irritation	Non-irritating
Murine Local Lymph Node assay (skin sensitization)	Non-sensitizing

Finally, Mr. Andrew Steen requested CAS numbers for the ingredients presented below.

Ingredient	CAS Number
(b) (4)	

We believe this addresses all outstanding issues on this file. Please direct any further questions on this submission to my attention at (b) (6).

Sincerely,
(b) (6)

Steven L. Ziémba, M. Sc.
Vice-President, Regulatory Affairs

K35

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8550 Higuera Street • Culver City, CA 90232 • www.discusdental.com • Tel. 310.845-8345 • Fax 310-845-8647

DISCUS DENTAL®
INCORPORATED

Additional notes from Discus Dental pertaining to (b) (4)

The analyses in this report refer to the fluoride content in the single component of the final gel product that contains fluoride. That is, the Relief ACP gel is packaged in a dual-barrel syringe so that the calcium and phosphate ingredients do not mix and degrade until the product is dispensed. Similarly, only one side of the syringe contains fluoride so that it will not bind with the calcium until the product is dispensed. The samples (b) (4) , (b) (4) for this testing were (b) (4) .

Therefore, the results of this testing must divided in half to get the (b) (4) for the as-dispensed gel. Results for (b) (4) of the gel-component containing fluoride as tested (b) (4) , so the total available ionic fluoride in finished (as dispensed) product would be half of that, (b) (4) . For comparison, the OTC Monograph for Anticaries Drug products (21 CFR 355) allows as much as 1,500 ppm of total fluorine.

(b) (6)

Steven L. Ziemba
Discus Dental, Inc.

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8550 Higuera Street • Culver City, CA 90232 • www.discusdental.com • Tel. 310.845-8345 • Fax 310-845-8647

(b) (4)

October 27, 2006

(b) (6)

Discus Dental
8550 Higuera Street
Culver City, CA 90232

Re: Final Report for (b) (4)

(b) (6),

Enclosed you will find (b) (4)
for you, recently. If you have any questions, please feel free to contact me.

Please arrange (b) (4) with a check payable to (b) (4) and forwarded as outlined in the invoice.

Sincerely,

(b) (6)

(b) (6)

Director, Laboratory Research Facility

(b) (4)

(b) (6)

(b) (4)

60

Final Report: Study (b) (4) s

Total (b) (4) t in a Phosphate ACP Gel Dentifrice

Study Sponsor

Discus Dental
8550 Higuera Street
Culver City, CA 90232

Attn: (b) (6)

Conducting Agency

(b) (4), (b) (6)

Purpose

The purpose of this study was to determine the (b) (4) : of a fresh phosphate ACP gel dentifrice using FDA methods #1 and 29.

Test Product

- (b) (4)

Determination of Total Fluorine. FDA Test #1

Total fluoride was determined using the procedure described for test Number 1 in the FDA Monograph using updated procedures.

(b) (4)

Determination of Soluble Fluorine. FDA Test # 29

Available fluoride was determined using the procedure described for test Number 29 in the FDA Monograph using updated procedures.

(b) (4)

Results

Product	Total Ionic Fluoride	Soluble Ionic Fluoride	Soluble Ionic Fluoride	Soluble Ionic Fluoride
(b) (4)	(b) (4)			

* Mean ± Standard Error of the Mean

All units are parts per million

Soluble = (b) (4)

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(b) (4)

Records Maintained

(b) (4)

This final report was read and approved by the Principal Investigator.

(b) (6) (b) (6)'s Signature _____ Date 10-24-06

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(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

January 09, 2007

DISCUS DENTAL INC.
8550 HIGUERA ST.
CULVER CITY, CA 90232
ATTN: STEVEN L. ZIEMBA

510(k) Number: K062176
Product: RELIEF ACP ORAL CARE GEL

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

K062176/S2

DISCUS DENTAL®
INCORPORATED

08 January 2007

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

RE: 510(k): K062176; Relief® ACP Oral Care Gel; submission of information in response to letter from Agency dated December 22, 2006

Dear Sir or Madam:

Discus Dental, Inc. is submitting information requested via telephone by Andrew Steen regarding the subject 510(k). This information was submitted electronically to Mr. Steen on December 27, 2006. This is a hard-copy submission of the same material which is included on the following pages.

Discus Dental, Inc. considers all the information in this submission to be confidential, proprietary and not publicly disclosable and would appreciate it if the Agency considered it as such. Please direct all questions regarding this submission to my attention at (b) (6), or e-mail at (b) (6)

Sincerely,

(b) (6)

Steven L. Ziémba, M. Sc.

8550 Higuera Street • Culver City, CA 90232 • www.discusdental.com • Tel. 310.845.8200 • Fax 310.845.1500

Steven Ziemba - Re: Telephone hold Relief ACP K062176

From: Steven Ziemba
To: Andrew I* Steen
Date: 12/27/2006 10:02 AM
Subject: Re: Telephone hold Relief ACP K062176
Attachments:

Mr. Steen

Thank-you for your response pertaining to the subject 510(k) filing. Discus Dental, Inc. herewith submits via electronic mail the following information.

It has been postulated (West, NX, Dentine Hypersensitivity; Monogr Oral Sci. 2006;20:173-89) that dentinal sensitivity can be managed via occlusion of dentinal tubules, The intended effect of Relief ACP is to produce a layer of calcium phosphate mineral on tooth surfaces that occludes dentinal tubules and mitigates pain.
The attached report from Dr. Yiming Li, DDS, MSD, PhD at the Loma Linda University School of Dentistry shows that the ingredients in Relief ACP are sufficient to cause immediate precipitation of a layer of hydroxyapatite (calcium phosphate) minerals on the surface of treated teeth samples. That layer has been shown to fully block the dentinal tubules, an effect not seen in control (no treatment) samples or samples treated with another Discus product (Satin Finish). The Satin Finish product is similar to Relief ACP (contains potassium nitrate and sodium fluoride) but it does not contain ACP. Therefore, we believe, as does Dr. Li, that the occlusal effect seen in samples treated with Relief ACP is solely due to the amorphous calcium phosphate in the product.

We cannot address the differences in the amount of calcium phosphate in Relief ACP compared to predicate devices, since the two predicates we listed in the filing do not contain calcium phosphate (to the best of our knowledge). Notwithstanding, we are aware of other products on the market that contain calcium phosphate in various forms (e.g., Novamin). However, the nature of the amorphous calcium phosphate in Relief ACP is such that very little is needed to mix with saliva and immediately precipitate a hydroxyapatite (calcium phosphate) layer on teeth. This effect is demonstrated quite well in Dr. Li's report. That is also the reason why the calcium and phosphate ingredients in Relief ACP are packaged in separate chambers of the dual-barreled syringe in which the final product is supplied. That package configuration ensure that they will not mix and form mineral deposits prior to application to the teeth. Presumably, the ingredients in other products use different forms of mineral precipitation to achieve a similar effect of tubule occlusion and because they are less reactive, they do not always need similar packaging.

We trust this information is sufficient to address your immediate concerns. Discus Dental considers all of the information in this filing to confidential, proprietary and not publicly disclosable and would appreciate it if the Agency would consider it as such. Please direct all question on this filing to my attention at (b) (6) [redacted].

The information in this submission is being submitted only via this electronic message. If the Agency would like printed copies of this to be submitted through Document Mail Center, please notify S. Ziemba.

Steven Ziemba
Vice-President, Regulatory Affairs
Discus Dental, Inc. - Quality Counts!
(b) (6) [redacted] - tel.
- fax

>>> "Steen, Andrew I*" <andrew.steen@fda.hhs.gov> 12/20/2006 12:26 PM >>>

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Mr. Ziemba,

This submission notes that the mode of action for this product is the physical blockage of dentinal tubules by calcium phosphate. It has come to my attention that the amount of the calcium phosphate forming materials in your product is much less than that contained in predicate devices. Justification must be shown that the amounts of calcium nitrate and sodium phosphate are significant enough to block the dentinal tubules as described. Another option would be to consider modifying the product to be similar to predicate devices. You may develop other routes of justification and we will certainly consider all information you present.

As this information is necessary to determine substantial equivalence and the information may not be readily available, I am placing this document on telephone hold pending the submission of the requested data.

Please contact me with any questions or concerns.

Andrew I. Steen
Mechanical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
ODE phone: 240-276-3773
OSEL phone: 301-796-0287
fax: 240-276-3789
mail: HFZ-480

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FINAL REPORT

(b) (4)

Evaluation of Effect of Relief ACP and (b) (4) on (b) (4)

(b) (4)

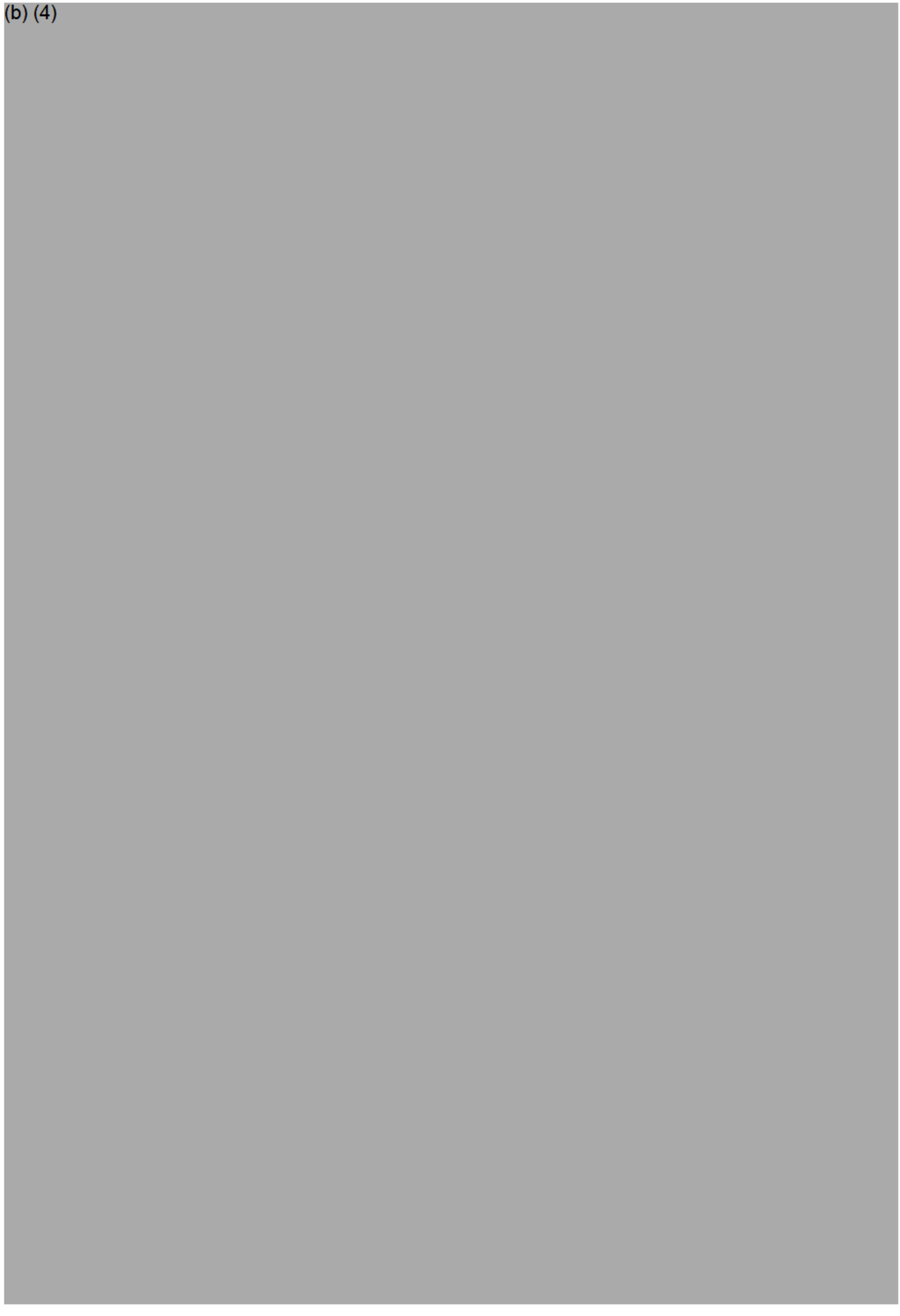
June 5, 2006

FINAL REPORT

(b) (4)

(b) (4)

(b) (4)



(b) (4)

(b) (6)

June 5, 2006
Date

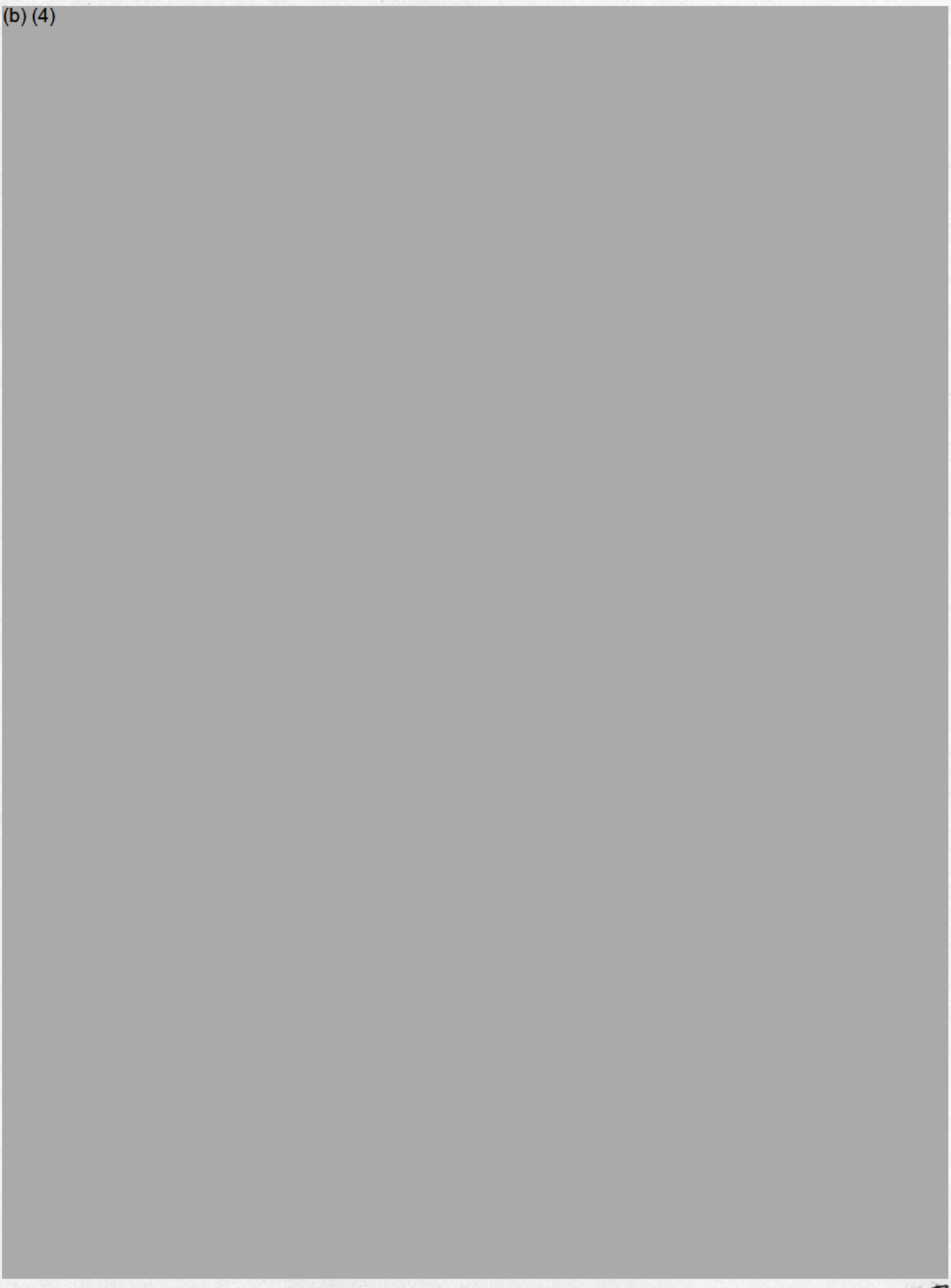
(b) (4)

Table 1

(b) (4)

(b) (4)

(b) (4)



[redacted]