

K101477

**SECTION 5: 510(K) SUMMARY**

SEP 28 2010

**1. SUBMITTER INFORMATION**

Name: GlaxoSmithKline Consumer Healthcare

Address: 1500 Littleton Road  
Parsippany, NJ 07054-3884

Contact Person: Wendy A. McManus

Telephone/Fax: 973-889-4415  
973-889-2501 (fax)

Date Summary Prepared: May 25, 2010

**2. DEVICE NAME**

Device Name: Biotène Dry Mouth Oral Rinse

Trade or Proprietary Name: Biotène Dry Mouth Oral Rinse

Common or Usual Name: Saliva, Artificial

Classification Name (if known): Saliva, Artificial

**3. IDENTIFICATION OF EQUIVALENCE**

Laclede, Inc. *Oral Balance Gel* cleared in K061331  
Laclede, Inc. *Oral Balance Liquid* cleared in K061331

**4. DEVICE DESCRIPTION**

Biotène Dry Mouth Oral Rinse is a specially formulated artificial saliva substitute which contain moisturizers, humectants, a protein, and patented salivary enzymes, that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of Dry Mouth. The liquid products are supplied in PET



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Wendy McManus  
Regulatory Associate  
GlaxoSmithKline Consumer Healthcare (GSKCH)  
1500 Littleton Road  
Parsippany, New Jersey 07054

SEP 28 2010

Re: K101477  
Trade/Device Name: Biotene Dry Mouth Oral Rinse  
Regulation Number:  
Regulatory Class: Unclassified  
Product Code: 76 LFD  
Dated: September 17, 2010  
Received: September 20, 2010

Dear Ms. McManus:

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

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

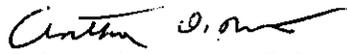
Page 2- Ms. McManus

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

  
Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, general Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510K Notification

Biotène Dry Mouth Oral Rinse  
GlaxoSmithKline Consumer Healthcare, L.P.

K101477

**SECTION 4: INDICATIONS FOR USE STATEMENT**

SEP 28 2010

**510(k) Number (if known):** N/A

**Device Name:** Biotène Dry Mouth Oral Rinse

**Indications for Use:**

Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness.

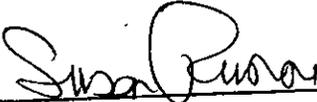
(PLEASE DO NOT WRITE BELOW THIS LINE,-CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Officers of Device Evaluation (ODE)**

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use  \_\_\_\_\_

(Per 21 CFR 801.109)

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

510(k) Number: K101477

K101477

510K Notification

Biotène Dry Mouth Oral Rinse  
GlaxoSmithKline Consumer Healthcare, L.P.

SEP 28 2010

bottles of various sizes, including an 8 oz., 16 oz., and 33.8 oz., and also 15 ml. multi-layer laminated foil pouches.

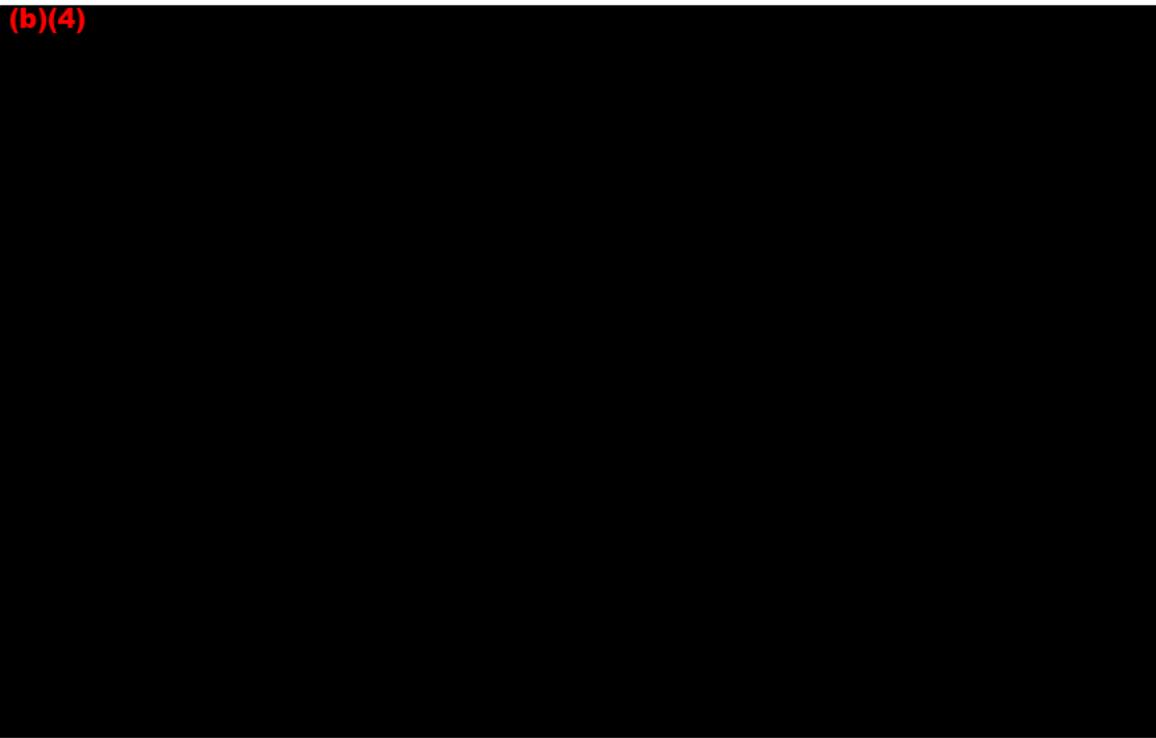
**5. STATEMENT OF INTENDED USE**

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

The *Indication for Use*: Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritations, and lubricates oral dryness.

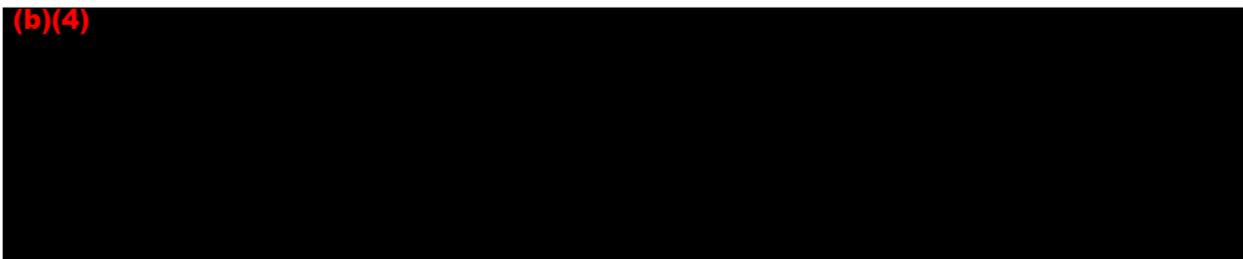
**6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS**

(b)(4)



**7. Discussion and conclusions from the nonclinical and clinical tests**

(b)(4)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Regulatory Associate  
GlaxoSmithKline Consumer Healthcare (GSKCH)  
1500 Littleton Road  
Parsippany, New Jersey 07054

SEP 28 2010

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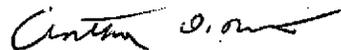
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Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, general Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510K Notification

Biotène Dry Mouth Oral Rinse  
GlaxoSmithKline Consumer Healthcare, L.P.

K101477

**SECTION 4: INDICATIONS FOR USE STATEMENT**

SEP 28 2010

510(k) Number (if known): N/A

Device Name: Biotène Dry Mouth Oral Rinse

**Indications for Use:**

Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness.

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

**Concurrence of CDRH, Officers of Device Evaluation (ODE)**

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use

(Per 21 CFR 801.109)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K101477

K101477

510K Notification

Biotène Dry Mouth Oral Rinse  
GlaxoSmithKline Consumer Healthcare, L.P.

SEP 28 2010

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The *Indication for Use*: Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritations, and lubricates oral dryness.

#### 6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

(b)(4)



#### 7. Discussion and conclusions from the nonclinical and clinical tests

Biotène Dry Mouth Oral Rinse has been shown in non-clinical studies to be safe (Toxicology Assessments), and stable (Stability Studies) for its intended use. It has also been shown in clinical studies to be effective (Use Studies). Biocompatibility is addressed in the Statements of Toxicological Evaluation. No other clinical tests were performed other than a Use Study for this submission.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

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

September 20, 2010

GLAXOSMITHKLINE CONSUMER HEALTHCARE (GSKCH)  
 COMSUMER HEALTHCARE  
 1500 LITTLETON ROAD  
 PARSIPPANY, NEW JERSEY 07054  
 UNITED STATES  
 ATTN: WENDY MCMANUS

510k Number: K101477

Product: BIOTENE DRY MOUTH MOUTHWASH,

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

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

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

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

Sincerely,

510(k) Staff



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center 6 WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

August 18, 2010

GLAXOSMITHKLINE CONSUMER HEALTHCARE (GSKCH)  
 COMSUMER HEALTHCARE  
 1500 LITTLETON ROAD  
 PARSIPPANY, NEW JERSEY 07054  
 UNITED STATES  
 ATTN: WENDY MCMANUS

510k Number: K101477

Product: BIOTENE DRY MOUTH MOUTHWASH, B

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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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

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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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

Sincerely yours,



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



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

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

May 28, 2010

GLAXOSMITHKLINE CONSUMER HEALTHCARE (GSKCH)  
 COMSUMER HEALTHCARE  
 1500 LITTLETON ROAD  
 PARSIPPANY, NEW JERSEY 07054  
 UNITED STATES  
 ATTN: WENDY MCMANUS

510k Number: K101477

Received: 5/28/2010

Product: BIOTENE DRY MOUTH MOUTHWASH, B

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely,

510(k) Staff

510K Notification

Biotène Dry Mouth Mouthwash (and variant)  
GlaxoSmithKline Consumer Healthcare, L.P.

K101477



**GlaxoSmithKline**  
1500 Littleton Road  
Parsippany, NJ  
07054-3884

Tel. 973 889 2100  
Fax 973 889 2390  
www.gsk.com

May 25, 2010

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

FDA CDRH DMC

MAY 28 2010

Received

**Re:** 510(k) Notification  
**Trade Name:** Biotène Dry Mouth Mouthwash &  
Biotène PBF Dry Mouth Mouthwash (variant)  
**Common Name:** Saliva, Artificial

Dear Reviewer:

GlaxoSmithKline Consumer Healthcare (“GSKCH”), the submitter, is planning to market an over the counter medical device mouthwash and variant that relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness. This device is substantially equivalent to following marketed devices:

- Bioxtra Moisturizing Gel (K072306) cleared in 2007*
- Oral Neutralizer (K071617) cleared in 2007*
- Mouthkote Oral Moisturizer (K062653) cleared in 2006*

Accordingly, GSKCH intends to introduce this device into interstate commerce for commercial distribution pursuant to section 510(k) of the Federal Food, Drug and Cosmetic Act (“the Act”).

Administrative Information:

<b>Type of 510(k) submission:</b>	Traditional
<b>Device common name:</b>	Saliva, Artificial

510K Notification

Biotène Dry Mouth Mouthwash (and variant)  
GlaxoSmithKline Consumer Healthcare, L.P.

**Trade name:** Biotène Dry Mouth Mouthwash  
Biotène PBF Dry Mouth Mouthwash

**Contact Person:** Wendy A. McManus  
Regulatory Associate  
973-889-4415

**Classification Regulation:** Unclassified

**Device Class:** Class U

**Panel:** Dental

**Product Code:** LFD

**Basis for your submission:** New device

GSKCH requests that FDA hold this submission as confidential commercial information as to its intent to market this device as stated in 21 CFR 807.95(b). GSKCH considers its intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure. Furthermore, GSKCH requests that confidentiality be extended to the maximum limit permitted in 21 CFR 807.95(d) such that the 510(k) summary is released no sooner than 30 days after notification in writing by FDA to GSKCH regarding the substantial equivalence determination.

GSKCH has taken precautions to protect the confidentiality of its intent to market the device. The company understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact the undersigned by telephone at 973-889-4415 or by fax at 973-889-2501 if you have any questions or need additional information.

Sincerely,



Wendy A. McManus  
Regulatory Associate, US Regulatory Affairs  
GlaxoSmithKline Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884  
(973) 889-4415

## **510K Notification**

# **Biotène Dry Mouth Mouthwash & Biotène PBF Dry Mouth Mouthwash (variant)**

**Published on 27 May 2010**

**Document No: 0b00233c8082c0a3**



***Consumer Healthcare, L.P.  
1500 Littleton Road  
Parsippany, NJ 07054-3884***

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## Table of Contents

### 510K Notification

	Page
<b>FDA Form 3674.....</b>	<b>1</b>
<b>Section 1. Medical Device User Fee Cover Sheet .....</b>	<b>3</b>
<b>Section 2. CDRH Premarket Review Submission Cover Sheet .....</b>	<b>5</b>
<b>Section 3. 510(k) Cover Letter .....</b>	<b>11</b>
<b>Section 4. Indications for Use Statement .....</b>	<b>14</b>
<b>Section 5. 510(k) Summary .....</b>	<b>15</b>
<b>Section 6. Truthful and Accuracy Statement .....</b>	<b>17</b>
<b>Section 7. Class III Summary and Certification .....</b>	<b>18</b>
<b>Section 8. Financial Certification or Disclosure Statement.....</b>	<b>19</b>
<b>Section 9. Declarations of Conformity and Summary Reports.....</b>	<b>20</b>
<b>Section 10. Executive Summary .....</b>	<b>21</b>

## **Table of Contents**

510K Notification

<b>Section 11. Device Description .....</b>	<b>25</b>
<b>Section 12. Substantial Equivalence Discussion.....</b>	<b>32</b>
<b>Section 13. Proposed Labeling .....</b>	<b>34</b>
<b>Section 14. Sterilization and Shelf Life .....</b>	<b>38</b>
<b>Section 15. Biocompatibility.....</b>	<b>39</b>
<b>Section 16. Software.....</b>	<b>40</b>
<b>Section 17. Electromagnetic Compatibility and Electrical Safety .....</b>	<b>41</b>
<b>Section 18. Performance Testing - Bench .....</b>	<b>42</b>
<b>Section 19. Performance Testing - Animal .....</b>	<b>43</b>
<b>Section 20. Performance Testing - Clinical .....</b>	<b>44</b>
<b>Section 21. Other .....</b>	<b>45</b>

510K Notification

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



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration  
**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with**  
**Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

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

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER <b>GlaxoSmithKline Consumer Healthcare (GSKCH)</b>	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <b>May 25, 2010</b>
3. ADDRESS (Number, Street, State, Zip Code): <b>1500 Littleton Road Parsippany, NJ 07054-3884</b>	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) <b>(973) 889-2100</b> (Fax) <b>(973) 889-2501</b>

**PRODUCT INFORMATION**

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

**BIOTENE DRY MOUTH MOUTHWASH**

**BIOTENE PBF MOUTH MOUTHWASH**

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES  
 IND     NDA     ANDA     BLA     PMA     HDE     510(k)     PDP     OTHER

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

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

**CERTIFICATION STATEMENT / INFORMATION**

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

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

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

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

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

NCT Number(s): \_\_\_\_\_

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. TYPED NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 <b>Wendy A. McManus</b> <b>Regulatory Affairs Associate</b>
13. ADDRESS (Number, Street, State, Zip Code) (of person identified in Nos. 11 and 12) <b>1500 Littleton Road Parsippany, NJ, 07054-3884</b>	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) <b>(973) 889-4415</b> (Fax) <b>(973) 889-2501</b>
	15. DATE OF CERTIFICATION

Form FDA 3674 (11/08) (Front)

Doc ID 0900233c8082c110

**Instructions for Completion of Form FDA 3674****Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information** - **For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.
 

**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services  
Food and Drug Administration  
Office of the Chief Information Officer (HFA-250)  
5600 Fishers Lane  
Rockville, MD 20857

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

Form FDA 3674 (11/08) (BACK)

**SECTION 1: MEDICAL DEVICE USER FEE COVER SHEET**

*Form FDA 3601 – ATTACHED*

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2011

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER Write the Payment Identification number
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  GLAXOSMITH KLINE CONSUMER HEALTHCARE 1500 LITTLETON ROAD PARSIPPANY NJ 079054 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****5710	2. CONTACT NAME Wendy McManus 2.1 E-MAIL ADDRESS wendy.a.mcmanus@gsk.com 2.2 TELEPHONE NUMBER (include Area code) 973-889-2100 4415 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> )  Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input checked="" type="checkbox"/> NO		
PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION		05-May-2010

(b)(4)

**SECTION 2: CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

*FORM FDA 3514 - ATTACHED*

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>CDRH PREMARKET REVIEW SUBMISSION COVER SHEET</b>			Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
Date of Submission May 25, 2010		User Fee Payment ID Number MD 6049285-956733		FDA Submission Document Number (if known)
SECTION A TYPE OF SUBMISSION				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name GlaxoSmithKline Consumer Healthcare (GSKCH)		Establishment Registration Number (if known)		
Division Name (if applicable) Consumer Healthcare		Phone Number (including area code) 973-889-4415		
Street Address 1500 Littleton Road		FAX Number (including area code) 973-889-2501		
City Parsippany	State / Province NJ	ZIP/Postal Code 07054	Country USA	
Contact Name Wendy A. McMauns				
Contact Title Regulatory Associate		Contact E-mail Address wendy.a.mcmanus@gsk.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

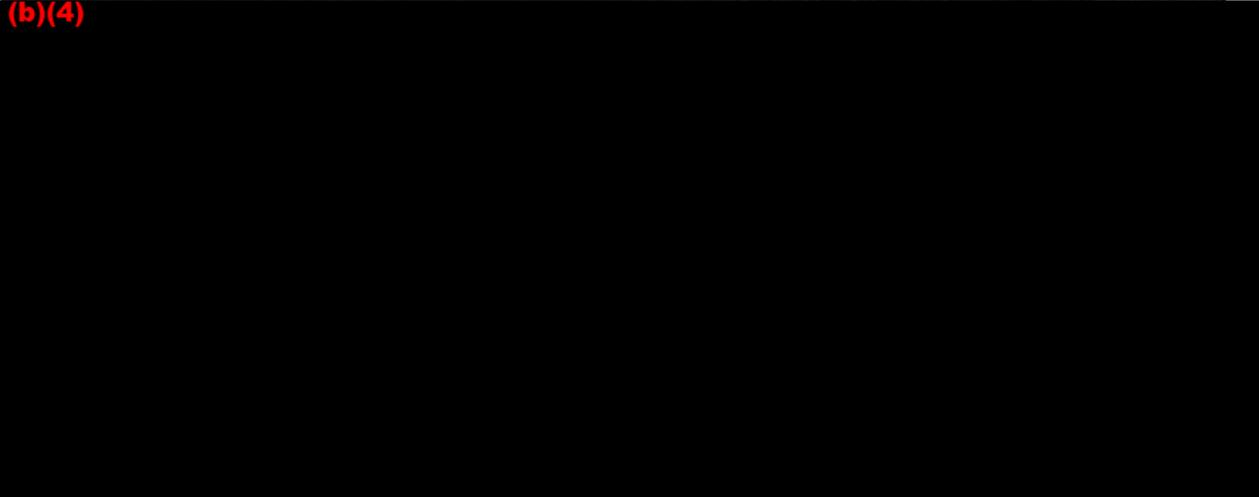
SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

510K Notification

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS											
Product codes of devices to which substantial equivalence is claimed										Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
1	LFD	2		3		4		5			
6		7		8		9		10			
Information on devices to which substantial equivalence is claimed (if known)											
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer						
1	K072306	1	Bioxtra Moisturizing Gel	1	Bio-X Healthcare S.A.						
2	K071617	2	Oral Neutralizer	2	Oral Biotech						
3	K062653	3	MouthKote Oral Moisturizer	3	Parnell Pharmaceuticals, Inc.						
4		4		4							
5		5		5							
6		6		6							
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS											
Common or usual name or classification name: SALIVA, ARTIFICIAL (DENTAL)											
	Trade or Proprietary or Model Name for This Device					Model Number					
1	BIOTENE DRY MOUTH MOUTHWASH					1					
2	BIOTENE PBF DRY MOUTH MOUTHWASH					2					
3						3					
4						4					
5						5					
FDA document numbers of all prior related submissions (regardless of outcome)											
1	2	3	4	5	6	7	8	9	10	11	12
Data Included in Submission <input type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials											
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS											
Product Code LFD		C.F.R. Section (if applicable) N/A				Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Unclassified					
Classification Panel Dental											
Indications (from labeling) BIOTENE DRY MOUTH MOUTHWASH: RELIEVES THE SYMPTOMS OF DRY MOUTH; REFRESHES, MOISTURIZES, CLEANS, SOOTHES ORAL IRRITATION, & LUBRICATES ORAL DRYNESS. BIOTENE DRY MOUTH PBF MOUTHWASH: RELIEVES THE SYMPTOMS OF DRY MOUTH; REFRESHES, MOISTURIZES, CLEANS, SOOTHES ORAL IRRITATION, & LUBRICATES ORAL DRYNESS. WITH REGULAR BRUSHING, IT CAN HELP DISSOLVE, LOOSEN, PREVENT EXCESSIVE PLAQUE BIOFILM (PBF).											

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

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



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

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

SECTION I UTILIZATION OF STANDARDS					
<b>Note:</b> Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
<b>Please include any additional standards to be cited on a separate page.</b>					
<p><b>Public reporting burden for this collection of information</b> is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of the Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, Maryland 20857</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					

**SECTION 3: 510(K) COVER LETTER**

*ATTACHED*



**GlaxoSmithKline**  
1500 Littleton Road  
Parsippany, NJ  
07054-3884

Tel. 973 889 2100  
Fax 973 889 2390  
www.gsk.com

May 25, 2010

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

**Re: 510(k) Notification**  
**Trade Name: Biotène Dry Mouth Mouthwash & Biotène PBF Dry Mouth Mouthwash (variant)**  
**Common Name: Saliva, Artificial**

Dear Reviewer:

GlaxoSmithKline Consumer Healthcare (“GSKCH”), the submitter, is planning to market an over the counter medical device mouthwash and variant that relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness. This device is substantially equivalent to following marketed devices:

- Bioxtra Moisturizing Gel (K072306) cleared in 2007*
- Oral Neutralizer (K071617) cleared in 2007*
- Mouthkote Oral Moisturizer (K062653) cleared in 2006*

Accordingly, GSKCH intends to introduce this device into interstate commerce for commercial distribution pursuant to section 510(k) of the Federal Food, Drug and Cosmetic Act (“the Act”).

Administrative Information:

<b>Type of 510(k) submission:</b>	Traditional
<b>Device common name:</b>	Saliva, Artificial

**Trade name:** Biotène Dry Mouth Mouthwash  
Biotène PBF Dry Mouth Mouthwash

**Contact Person:** Wendy A. McManus  
Regulatory Associate  
973-889-4415

**Classification Regulation:** Unclassified

**Device Class:** Class U

**Panel:** Dental

**Product Code:** LFD

**Basis for your submission:** New device

GSKCH requests that FDA hold this submission as confidential commercial information as to its intent to market this device as stated in 21 CFR 807.95(b). GSKCH considers its intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure. Furthermore, GSKCH requests that confidentiality be extended to the maximum limit permitted in 21 CFR 807.95(d) such that the 510(k) summary is released no sooner than 30 days after notification in writing by FDA to GSKCH regarding the substantial equivalence determination.

GSKCH has taken precautions to protect the confidentiality of its intent to market the device. The company understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please do not hesitate to contact the undersigned by telephone at 973-889-4415 or by fax at 973-889-2501 if you have any questions or need additional information.

Sincerely,



Wendy A. McManus  
Regulatory Associate, US Regulatory Affairs  
GlaxoSmithKline Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884  
(973) 889-4415



**SECTION 5: 510(K) SUMMARY****1. SUBMITTER INFORMATION**

Name: GlaxoSmithKline Consumer Healthcare

Address: 1500 Littleton Road  
Parsippany, NJ 07054-3884

Contact Person: Wendy A. McManus

Telephone/Fax: 973-889-4415  
973-889-2501 (fax)

Date Summary Prepared: May 25, 2010

**2. DEVICE NAME**

Device Name: Biotène Dry Mouth Mouthwash &  
Biotène PBF Dry Mouth Mouthwash

Trade or Proprietary Name:  
(variant) Biotène Dry Mouth Mouthwash  
Biotène PBF Dry Mouth Mouthwash

Common or Usual Name: Saliva, Artificial

Classification Name (if known): Saliva, Artificial

**3. IDENTIFICATION OF EQUIVALENCE**

Bio-X Healthcare S.A. *Bioxtra Moisturizing Gel* cleared in K072306  
Oral Biotech: *Oral Neutralizer* cleared in K071617  
Parnell Pharmaceuticals, Inc.: *Mouthkote Oral Moisturizer* cleared in K062653

**4. DEVICE DESCRIPTION**

Biotène Dry Mouth Mouthwashes are specially formulated artificial saliva substitutes which contain moisturizers, humectants, a protein, and patented salivary enzymes, that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of Dry Mouth. The liquid products are supplied in PET

bottles of various sizes, including an 8 oz., 16 oz., and 33.8 oz., and also 15 ml. multi-layer laminated foil pouches.

#### **5. STATEMENT OF INTENDED USE**

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

#### **6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS**

(b)(4)



#### **7. Discussion and conclusions from the nonclinical and clinical tests**

Biotène Dry Mouth Mouthwashes have been shown in non-clinical studies to be safe (Toxicology Assessments) and stable (Stability Studies) for its intended use. They have also been shown in clinical studies to be effective (Use Studies). No other clinical tests were performed other than a Use Study for this submission.

**SECTION 6: TRUTHFUL AND ACCURACY STATEMENT**

I certify that, in my capacity as *Regulatory Associate* of GlaxoSmithKline Consumer Healthcare, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



---

Wendy McManus

## **SECTION 7: CLASS III SUMMARY AND CERTIFICATION**

*This section does not apply as this is not a Class III device.*

**SECTION 8: FINANCIAL CERTIFICATION or DISCLOSURE STATEMENT**

*This section does not apply to this device as no clinical study (other than a Use Study) is included in this submission, therefore Form 3454 or Form 3455 is not attached.*

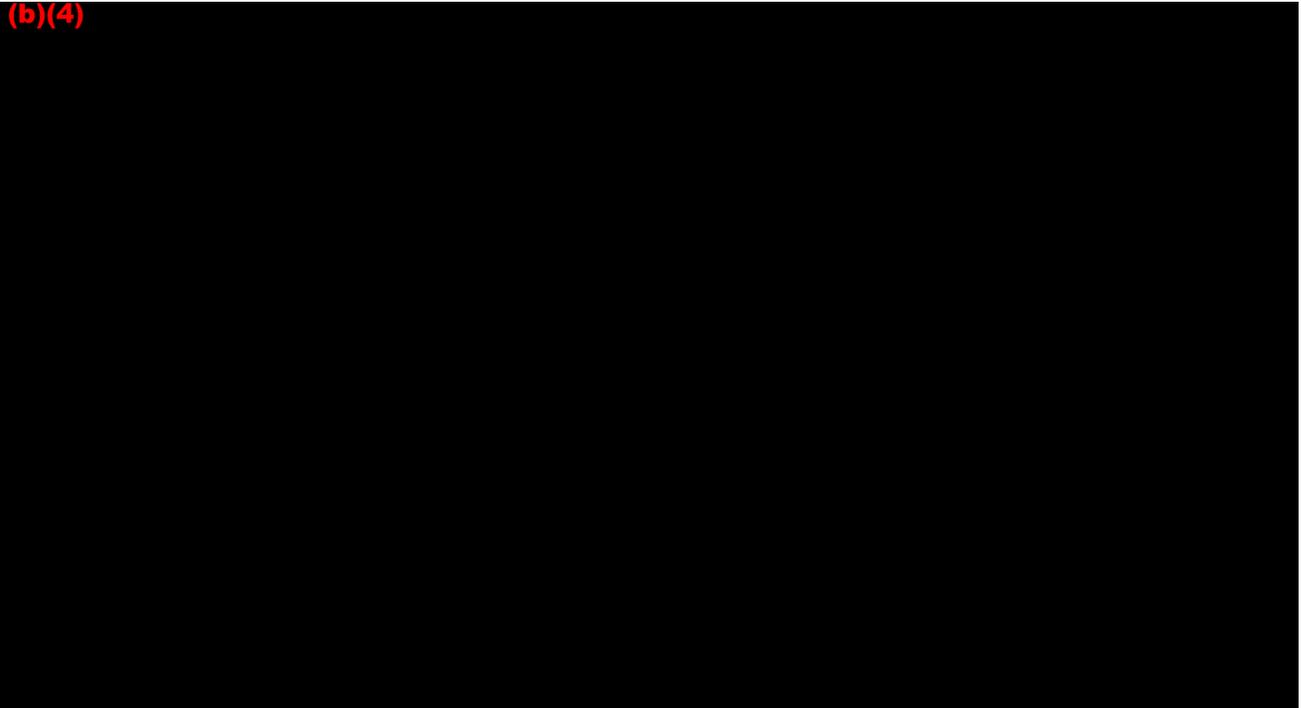
## **SECTION 9: DECLARATIONS of CONFORMITY & SUMMARY REPORTS**

*This section does not apply as the Biotène Dry Mouth Mouthwashes are substantially equivalent to several marketed devices: Bioxtra Moisturizing Gel (K072306) cleared in 2007, Oral Neutralizer (K071617) cleared in 2007, and Mouthkote Oral Moisturizer (K062653) cleared in 2006.*

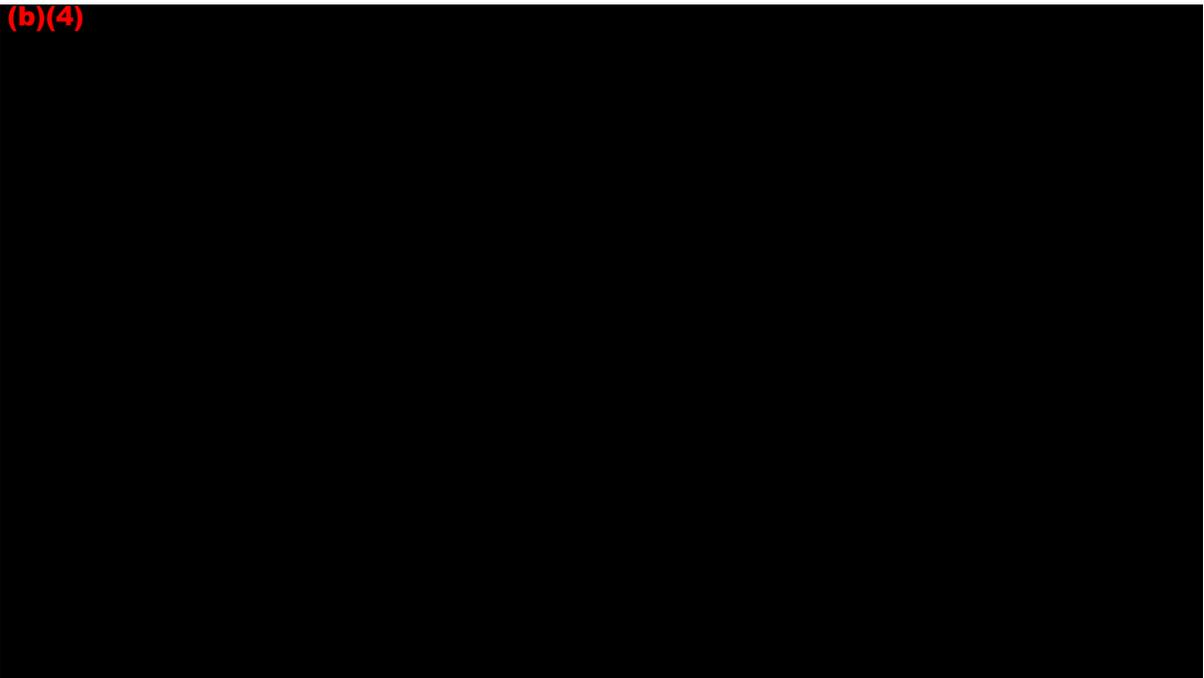
## SECTION 10: EXECUTIVE SUMMARY

### Concise Description of Device, Indications for Use & Technology:

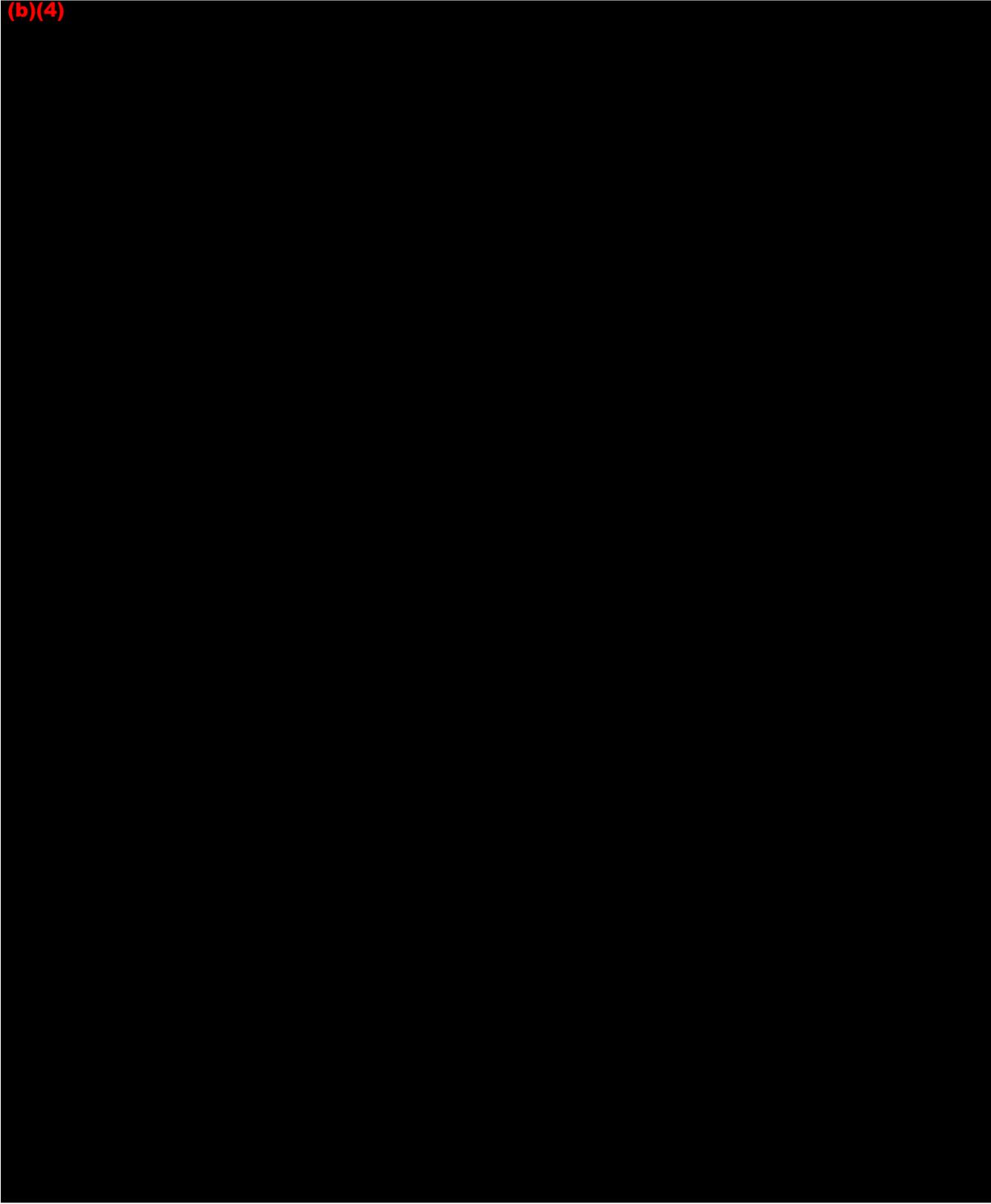
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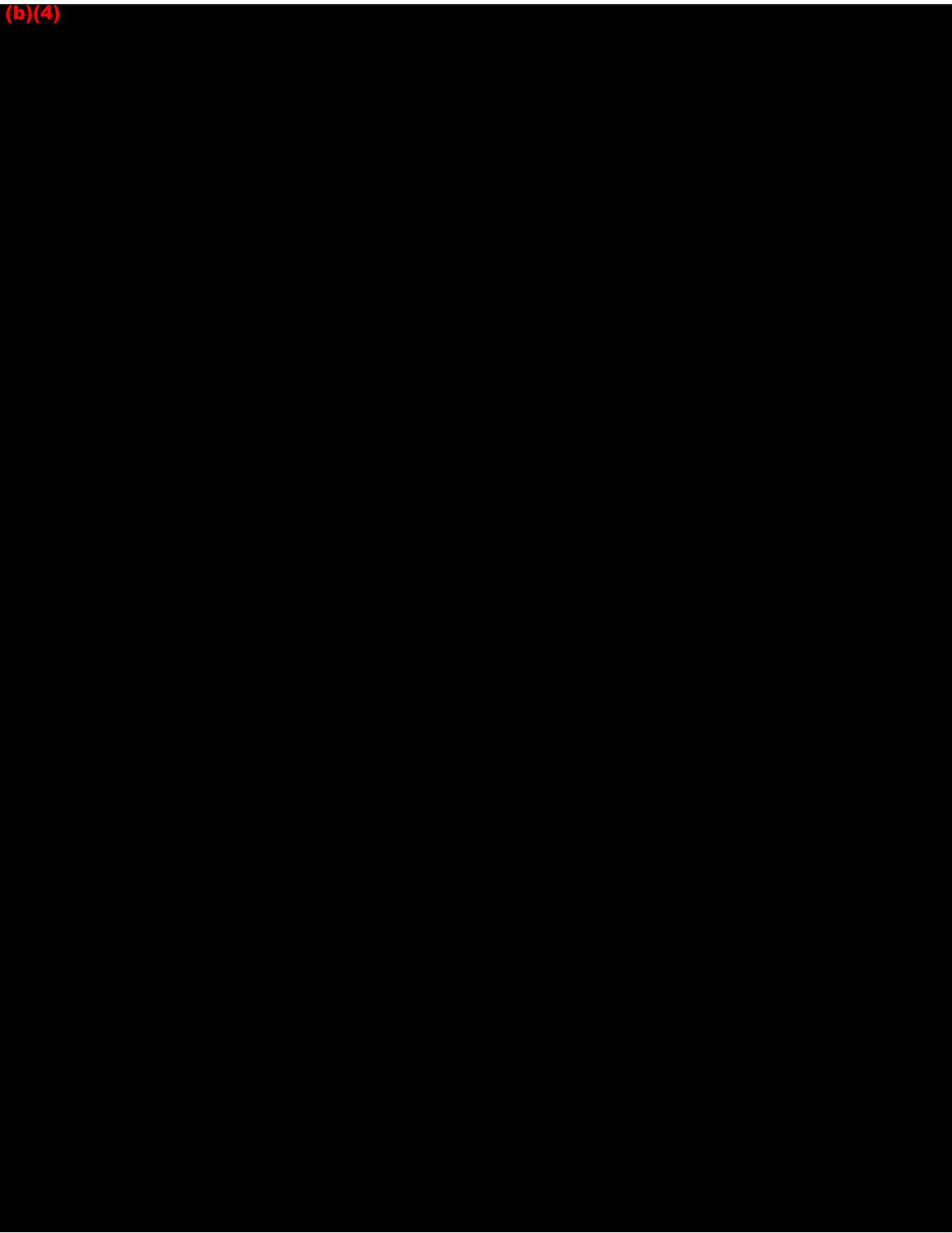
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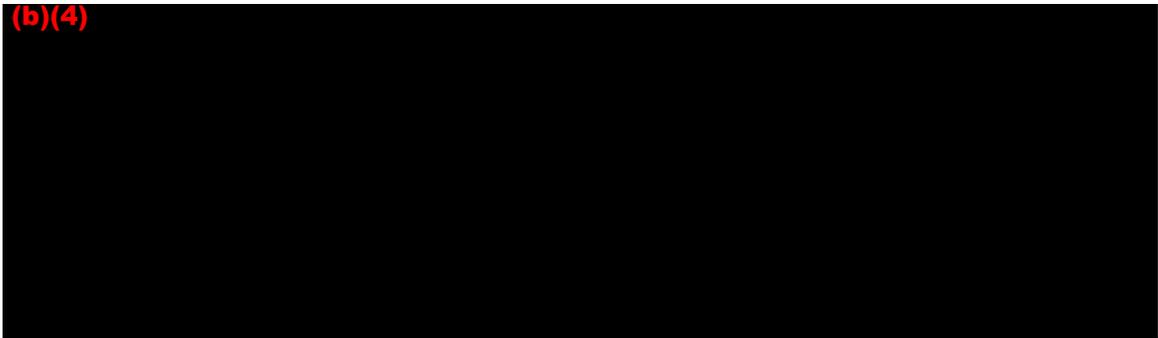


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**Concise Summary of Performance Tests & Results:**

No performance tests were completed as Substantial Equivalence between the proposed devices and the predicates is demonstrated through technical similarity and Intended Use.

Other testing was performed to establish the proposed devices are stable. Safety and efficacy testing summaries are also provided. See *Section 21 Other* for test results.

## SECTION 11: DEVICE DESCRIPTION

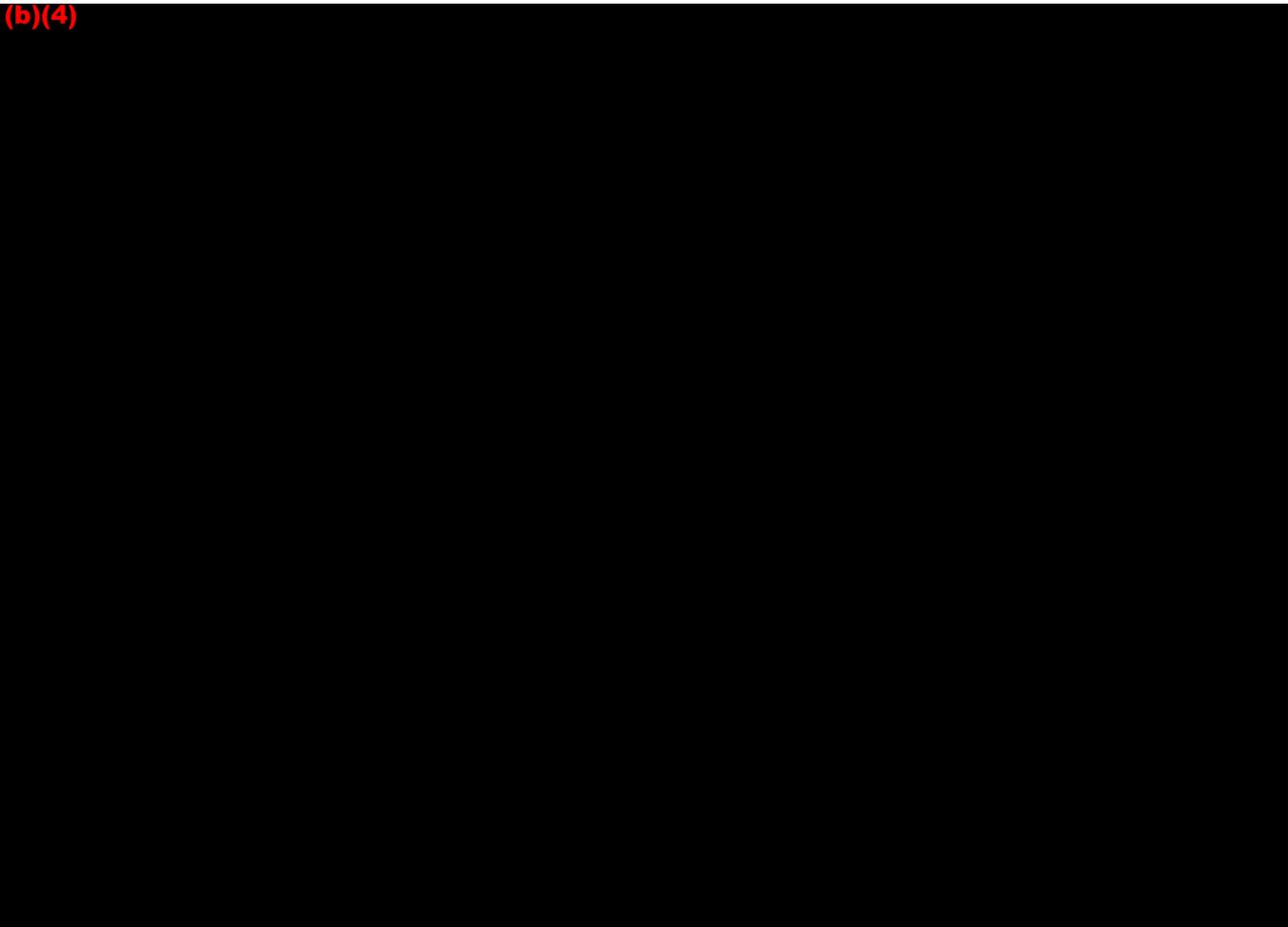
### Describe Performance Specifications:

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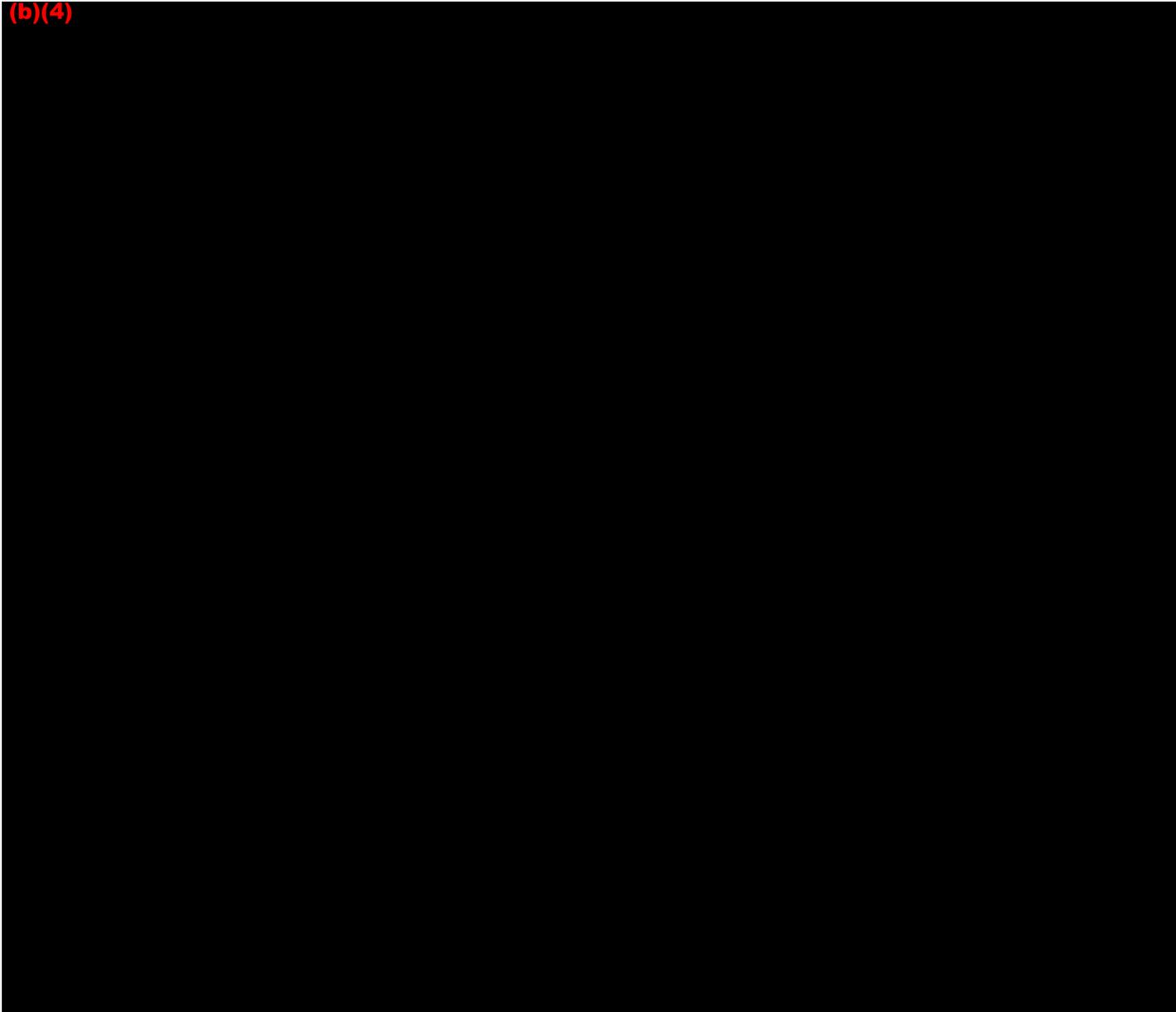
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### Brief Description of the Device Design Requirements:

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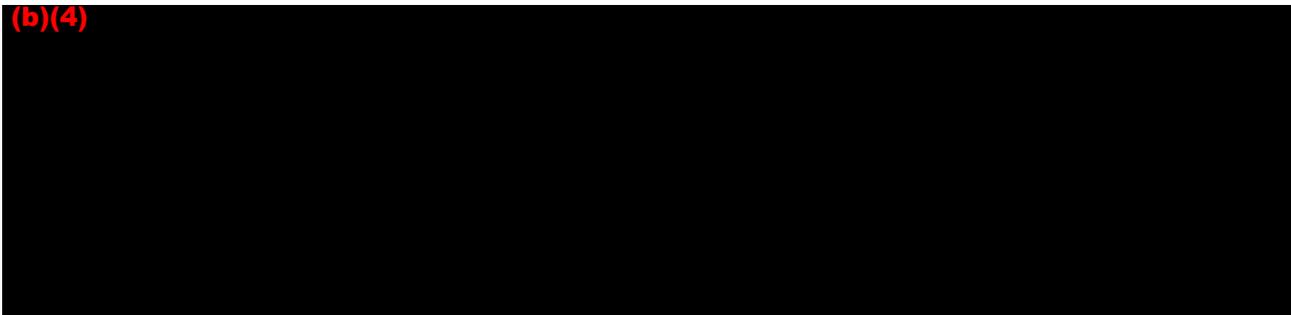


**Identify All Models/Variants and Components:**

(b)(4)



(b)(4)



**List of All Patient Contacting Components and Their Respective Materials:**

(b)(4)



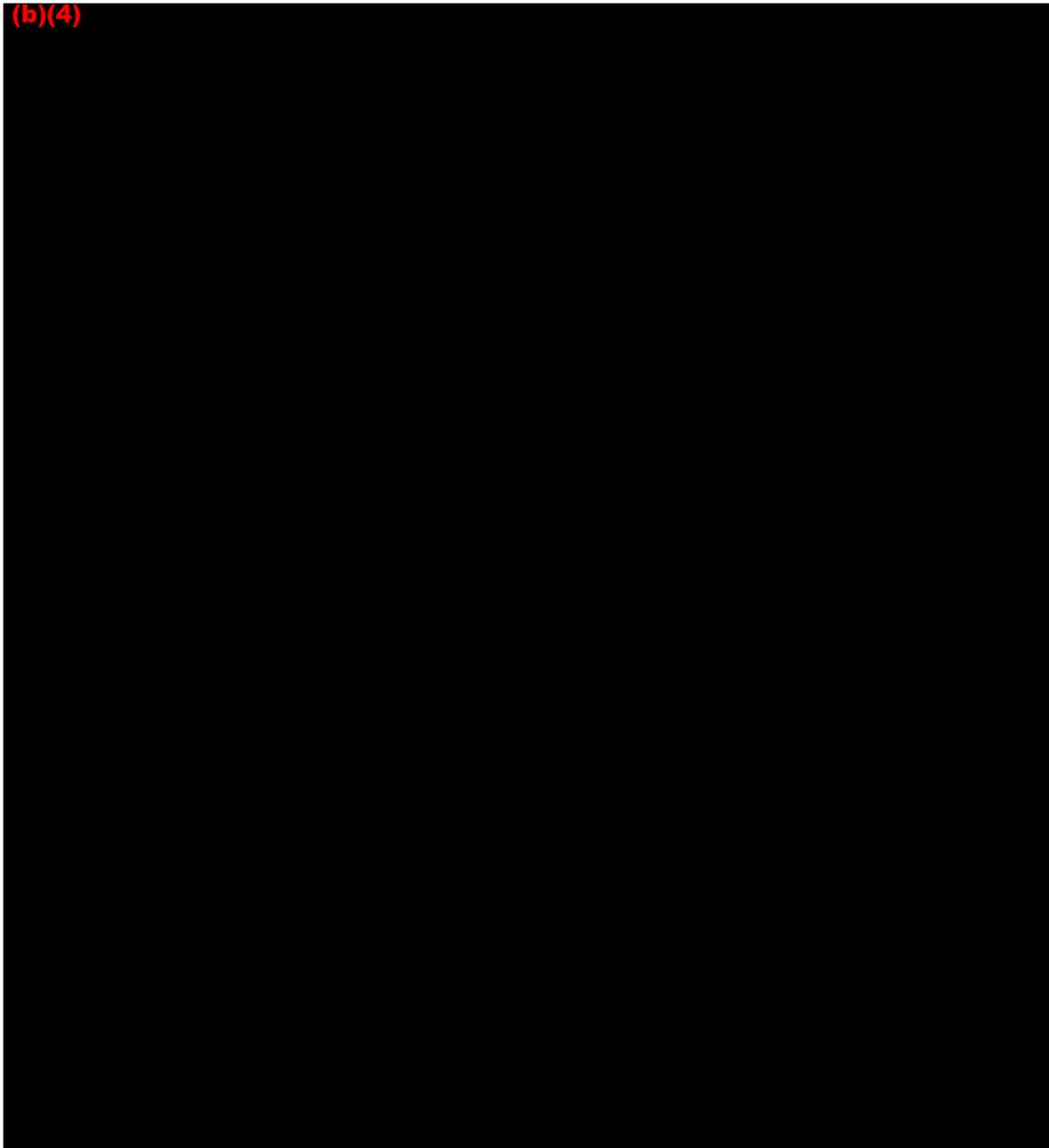
**TABLE 11-1 BIOTENE MOUTHWASH SPECIFICATIONS**

**Finished Product Specification**

**(b)(4)**



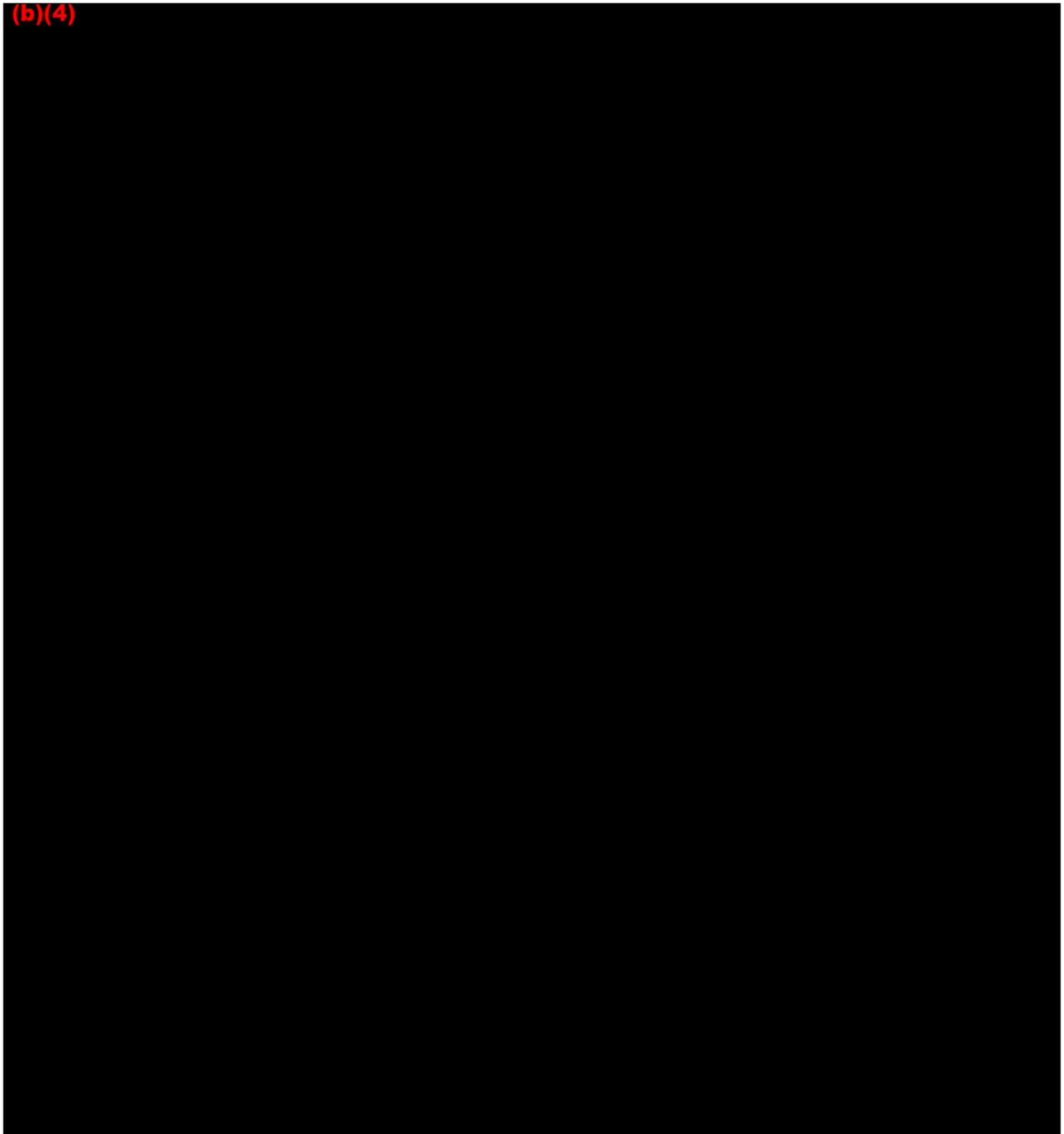
### Finished Product Specification



**TABLE 11-2 BIOTENE PBF MOUTHWASH SPECIFICATIONS**

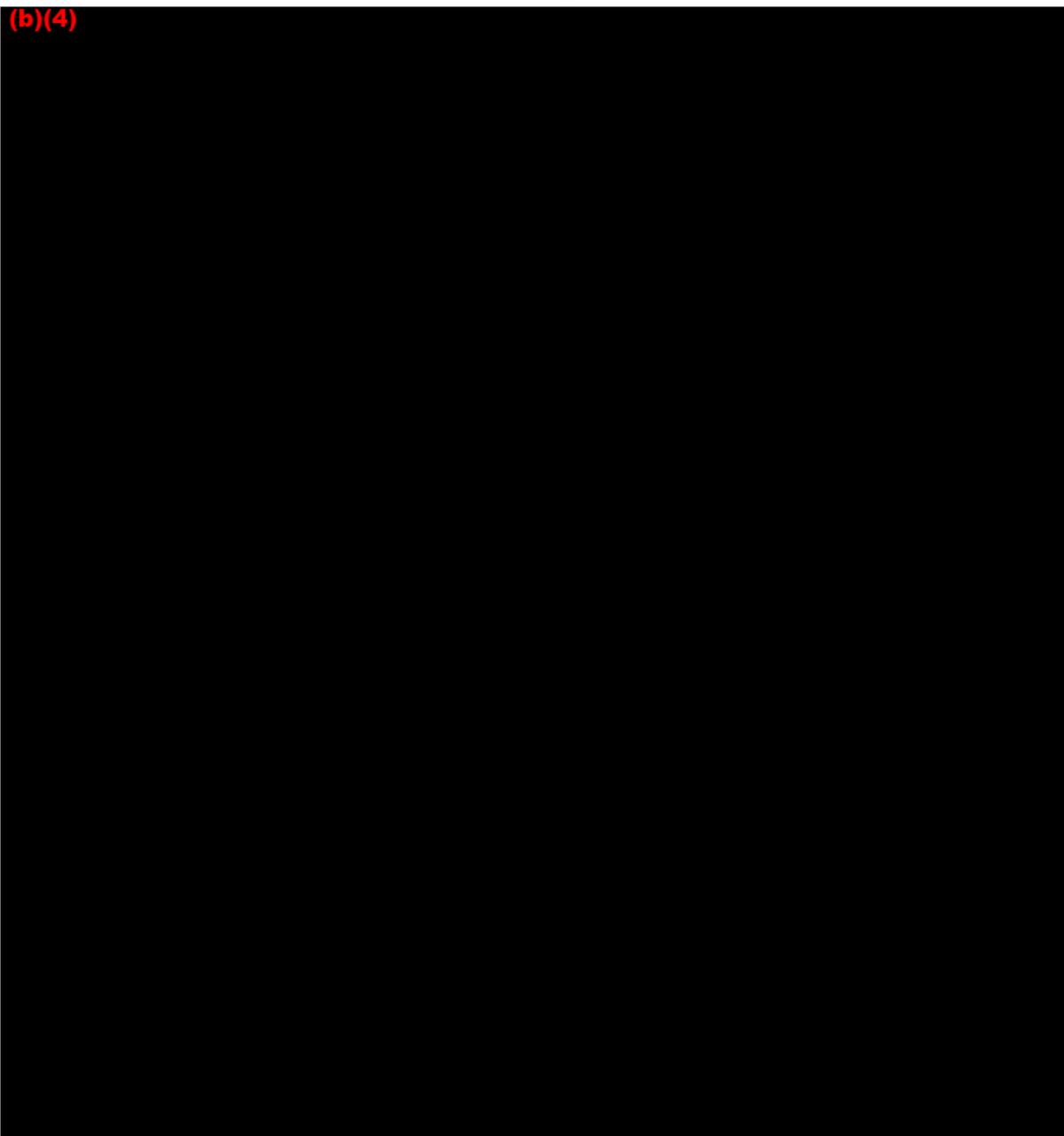
**Finished Product Specification**

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### Finished Product Specification

**(b)(4)**



**SECTION 12: SUBSTANTIAL EQUIVALENCE DISCUSSION****Identity of the Predicate Devices:**

<b>Predicate Trade Name</b>	<b>Submitter/Holder</b>	<b>510(k) #</b>
BioXtra Moisturizing Gel	Bio-x Healthcare S.A.	K072306
Oral Neutralizer	Oral Biotech	K071617
Mouthkote Oral Moisturizer, model 50930	Parnell Pharmaceuticals, Inc.	K062653

**Demonstrate Substantial Equivalence via Indications for Use:**

*Biotène Mouthwash and Biotène PBF Mouthwash* Indications for Use – Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness. Intended Use - Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

Comparative Predicates:

*BioXtra Moisturizing Gel* – Indicated for the symptomatic relief from the effects of a chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors, and other oral symptoms associated with dry mouth.

*Oral Neutralizer* – A refreshing gel, liquid, or spray that diminishes oral discomfort, neutralizes mouth odors, neutralizes and moisturizes oral biofilm, and other symptoms of a chronic or temporary dry mouth/xerostomia as a result of disease such as Sjogren’s Syndrome, oral inflammation, medication, chemo or radiotherapy, stress, or aging.

*MouthKote Oral Moisturizer* – Relieves dry mouth conditions. Intended Use: A pleasant tasting solution that diminishes dry mouth discomfort, mouth odors, and other symptoms of dry mouth.

As demonstrated above, the Biotene Mouthwashes have substantially equivalent *Indications for Use* when compared to the predicates.

**Demonstrate Substantial Equivalence via Technology:**

Both the Biotène Mouthwashes and the Predicates use similar formulation concepts and ingredients specifically incorporated to relieve dry mouth symptoms. These compositions are comprised of: water, humectants/ moisturizers to moisturize, a sweetener to refresh, thickeners/ film formers/ binders to form a film, a preservative

to protect the product's integrity, flavor to refresh, pH adjuster/buffers to maintain adequate pH levels, enzymes, substrates, and a protein (to supplement the loss due to decreased saliva), and an ingredient to clean the oral cavity. In addition to the above ingredients, the Biotène PBF Mouthwash variant and one of the predicates also include ingredients to loosen plaque biofilm.

### ***Bioxtra Moisturizing Gel* Technology versus Biotène Mouthwashes**

Biotène Mouthwashes incorporates the same system as *Bioxtra Moisturizing Gel* - a solvent, humectants/ moisturizers, a sweetener, thickener/film former/binders, pH adjuster/ buffers, a protein, an enzyme system and an ingredient to loosen plaque.

### ***Oral Neutralizer* Technology versus Biotène Mouthwashes**

Biotène Mouthwashes compares to the predicate *Oral Neutralizer* by also using a parallel system to treat dry mouth symptoms including a solvent, a humectant/ moisturizer, a sweetener, a preservative, a flavor, and a pH adjuster/buffer.

### ***Mouthkote Oral Moisturizer* Technology versus Biotène Mouthwashes**

Biotène Mouthwashes and the predicate *Mouthkote Oral Moisturizer* have similar systems including: a solvent, humectants/ moisturizers, sweeteners, a preservative, a flavor, a pH adjuster and an ingredient to offset or mimic protein reduction from reduced saliva.

### **Demonstrate Substantial Equivalence via Performance Specifications & Testing:**

Not applicable, as substantial equivalence was demonstrated between the proposed devices and the predicates through comparable ingredients, formulation functionality, and Indications for Use comparisons.

### **Substantial Equivalence Conclusions:**

Biotène Mouthwashes are very similar to the predicates in terms of intended use and formula composition and do not lead to a new standard of care. These proposed devices do not demonstrate a drastic advance with new or medically significant benefits as compared to the predicates.

### **SECTION 13: PROPOSED LABELING**

LABEL 13-1 Biotène Dry Mouth Mouthwash\* - *attached*

LABEL 13-2 Biotène PBF Dry Mouth Mouthwash\* - *attached*

\* *approved final labels still in process*

**LABEL 13-1 Biotène Dry Mouth Mouthwash**

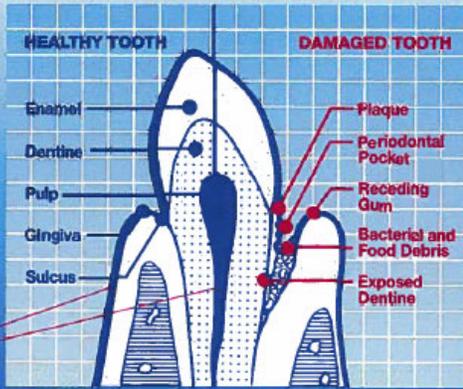
# biotène®

## DRY MOUTH MOUTHWASH

- Bio-Active Enzyme System
- Alcohol-Free
- Refreshes Without Burning



### POTENTIAL IMPACT OF DRY MOUTH



**DIRECTIONS:** Use approximately one tablespoon whenever desired. Swish or gargle thoroughly for 30 seconds and spit out. Do not swallow. Also look for relief with other *biotène*® products including *biotène*® Dry Mouth Toothpaste, *biotène*® oralbalance® Gel and *biotène*® Mouth Spray. *biotène*® is specially formulated for individuals experiencing dry mouth or having oral irritations.

**INGREDIENTS:** Purified Water, Propylene Glycol, Xylitol, Polyglycol, Poloxamer 407, Hydroxyethyl Cellulose, Sodium Benzoate, Benzoic Acid, Natural Peppermint, Sodium Phosphate, Zinc Gluconate, Lactoferrin, Calcium Lactate, Aloe Vera, Potassium Thiocyanate

**Enzyme System:** Lysozyme, Lactoperoxidase, Glucose Oxidase

Store Below 25°C (77°F)

**CONTAINS NO SACCHARIN**

Warning: Keep out of reach of children.  
**DO NOT USE IF SEAL ON CAP IS REMOVED**

Questions or comments?  
call toll-free 1-800-822-6856 weekdays  
[www.biotene.com](http://www.biotene.com)

©2009 GlaxoSmithKline  
Patent Pending  
62154XA

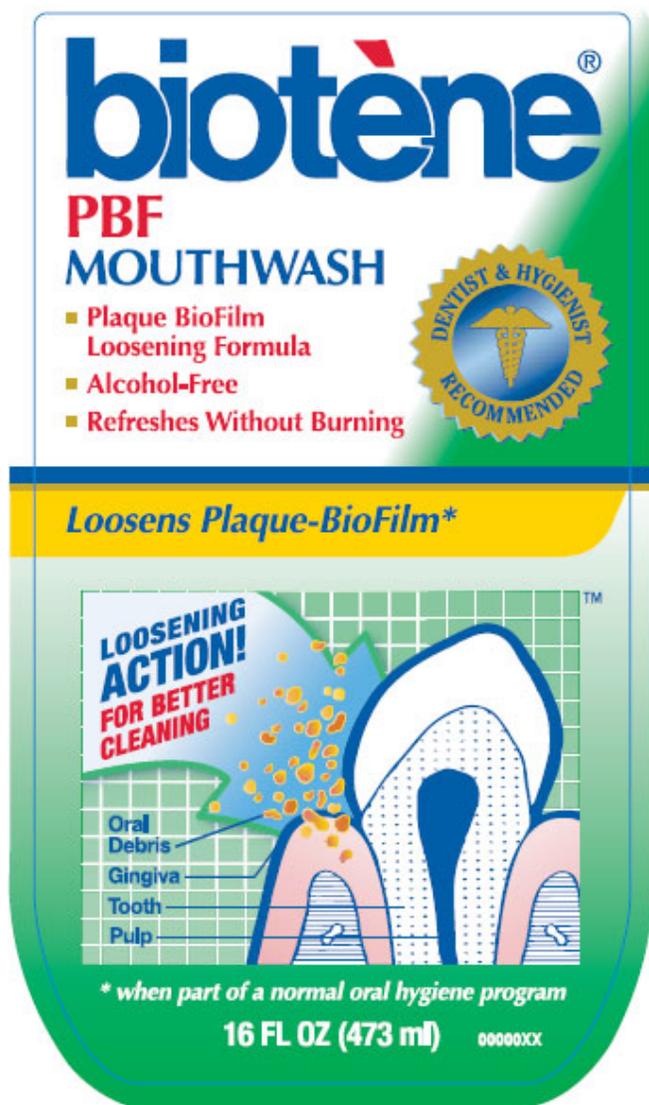
*biotène*® and various graphic elements are trademarks of the GlaxoSmithKline group of companies.

Clinically Tested and Used by Hospitals

Distributed By:  
GlaxoSmithKline  
Consumer Healthcare L.P.  
Moon Township, PA 15108  
©2009 GlaxoSmithKline

**128 FL OZ (3785.4 ml)**

**LABEL 13-2 Biotène PBF Dry Mouth Mouthwash (Front)**



**LABEL 13-2 Biotène PBF Dry Mouth Mouthwash (Back)**

biotène®

Dentist & Hygienist  
Recommended

PBF MOUTHWASH

**BioFilm is the bacterial film on your teeth often described as plaque. With oral dryness, saliva's natural ability to cleanse and control the BioFilm is reduced. Although brushing and flossing help you disrupt and remove BioFilm, this may not be enough.**

With 2 additional enzymes, **biotène® PBF Mouthwash** and regular brushing can help loosen and prevent excessive BioFilm formation for a cleaner, fresher mouth.

Like Original **biotène® Mouthwash**, **biotène® PBF Mouthwash** also contains the 3 bio-active enzymes to help provide protection against dry mouth symptoms.

Also look for relief with other **biotène®** products including **biotène® PBF Toothpaste**, **biotène® OralBalance® Gel** and **biotène® Mouth Spray**

**DIRECTIONS:** Use approximately one tablespoon. Swish thoroughly for 60 seconds and spit out. Do not swallow. Use up to 5 times daily. **Children under 12:** Consult a doctor. For best results: use after brushing with **PBF** toothpaste.

**INGREDIENTS:** Purified Water, Propylene Glycol, Xylitol, Hydrogenated Starch Hydrolysate, Poloxamer 407, Hydroxyethylcellulose, Sodium Benzoate, Flavor, Benzoic Acid, Mutanase, Disodium Phosphate, Zinc Gluconate, Lactoferrin, Lysozyme, Lactoperoxidase, Potassium Thiocyanate, Aloe Vera Gel, Calcium Lactate, Glucose Oxidase, Dextranase.

**CONTAINS NO SACCHARIN**  Naturally Sweetened with Xylitol™ 

Store Below 25°C (77°F)

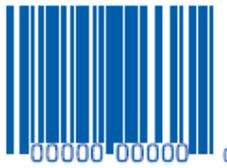
**DO NOT USE IF SHRINK SLEEVE IS MISSING**

**Warning:**  
Keep out of reach of children.

**Questions or comments?**  
call toll-free 1-800-822-5856 weekdays

[www.biotene.com](http://www.biotene.com)

Distributed By:  
**GlaxoSmithKline**  
Consumer Healthcare L.P.  
Moon Township, PA 15108  
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US Patent No. 5,741,487



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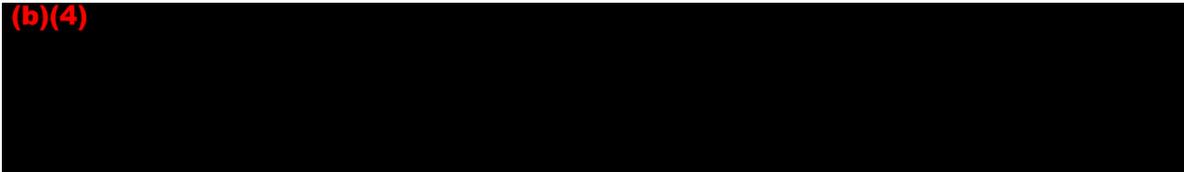
**SECTION 14: STERILIZATION AND SHELF LIFE**

**STERILIZATION**

*Not applicable to this device application.*

**SHELF LIFE**

**(b)(4)**



## **SECTION 15: BIOCOMPATIBILITY**

*Biocompatibility is essentially addressed in the Toxicology Statements provided in Section 21: Other.*

**SECTION 16: SOFTWARE**

*Not applicable to this device.*

**SECTION 17: ELECTROMAGNETIC COMPATIBILITY AND  
ELECTRICAL SAFETY**

*Not applicable to this device.*

**SECTION 18: PERFORMANCE TESTING – BENCH**

*Not Applicable - no bench testing was performed to support substantial equivalence.*

**SECTION 19: PERFORMANCE TESTING – ANIMAL**

*Not Applicable - no animal testing was performed to support substantial equivalence.*

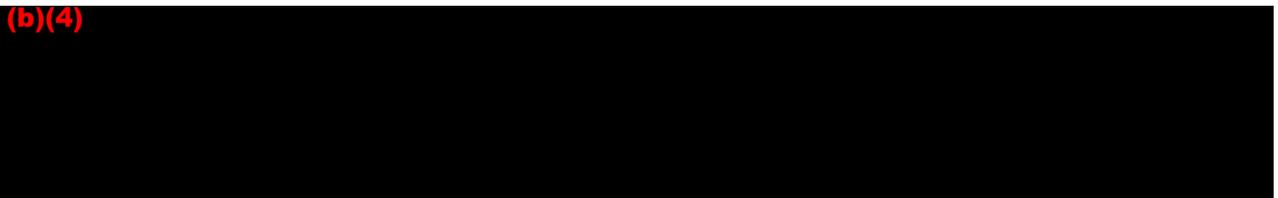
**SECTION 20: PERFORMANCE TESTING – CLINICAL**

*Not Applicable - no clinical testing was performed to support substantial equivalence.*

**SECTION 21: OTHER**

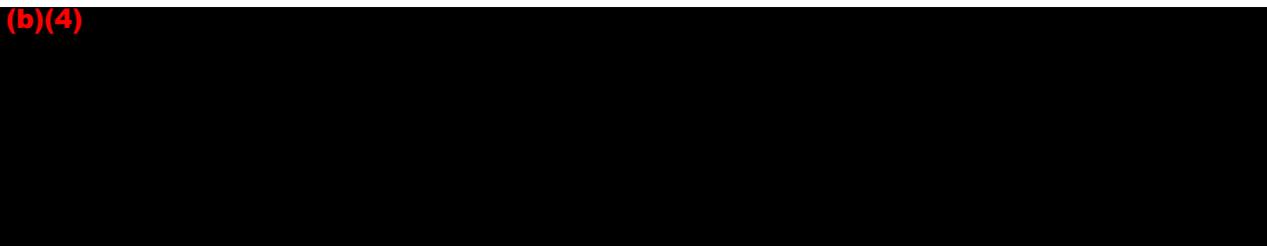
**Stability Tests:**

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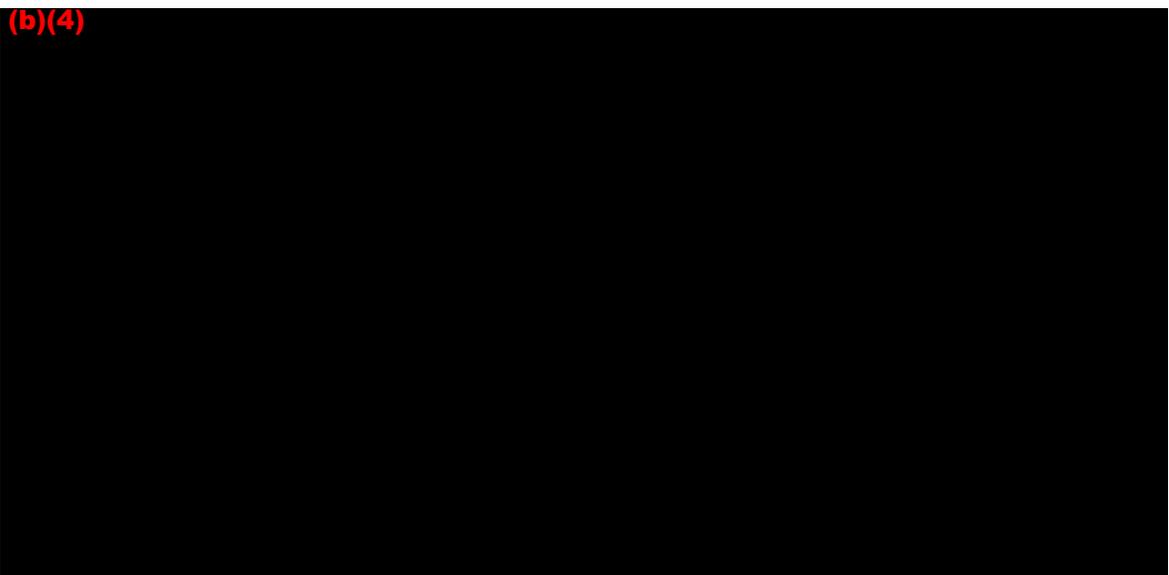
**Safety Tests:**

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A large black rectangular redaction box covering the content of the Safety Tests section.

**Efficacy Tests:**

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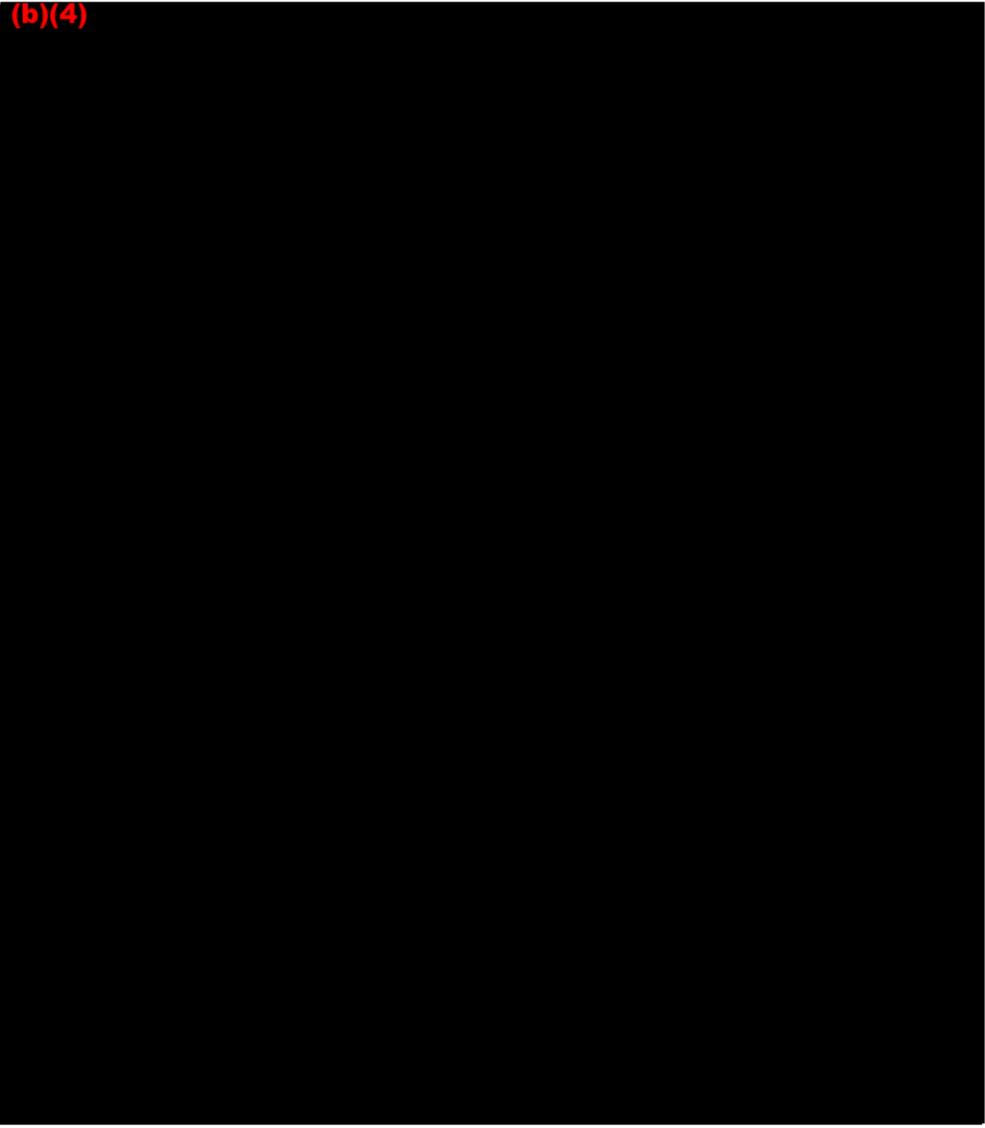
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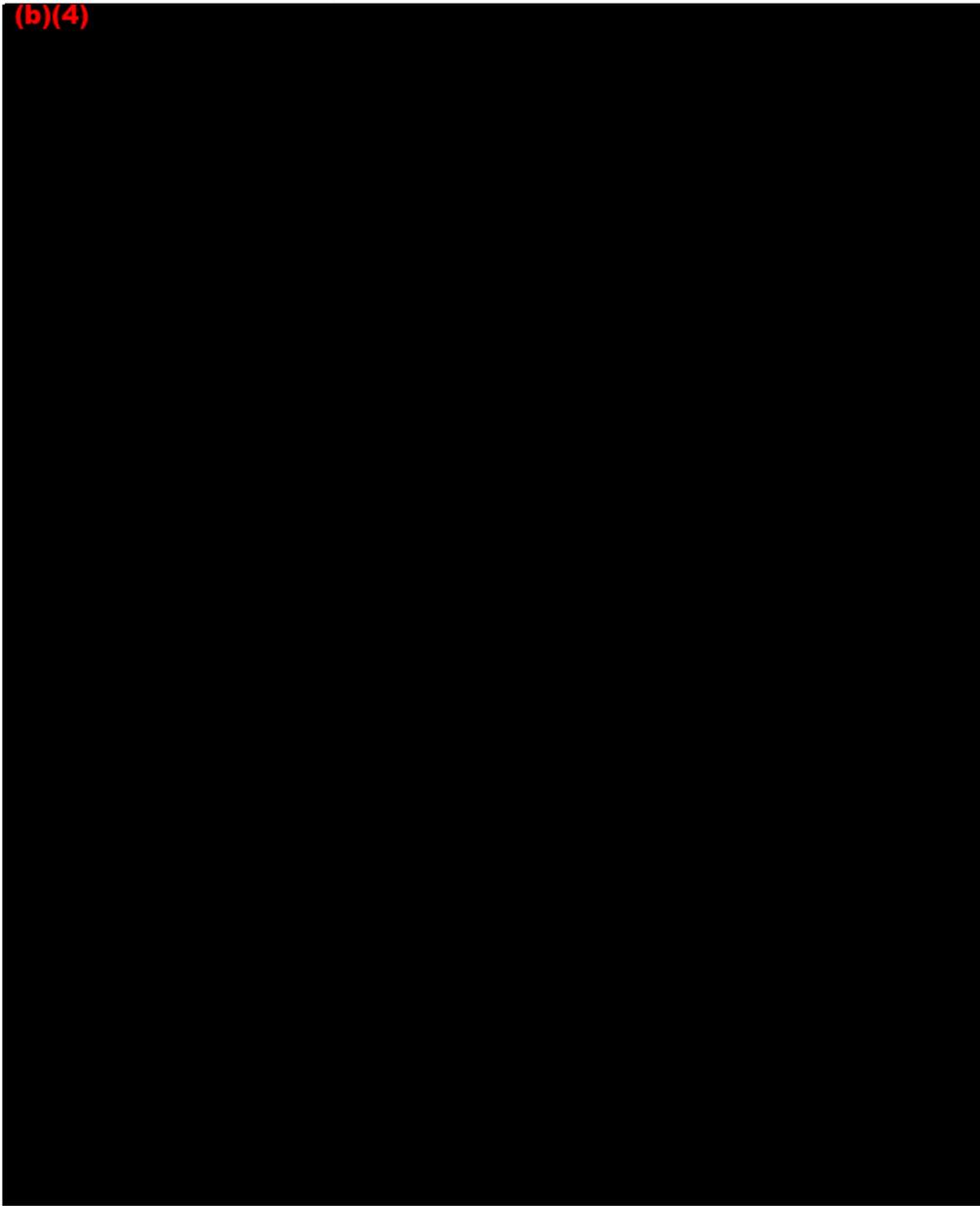
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### Statement of Toxicological Evaluation

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Signed: Tracey L. Spriggs Date: 4 May 2010

Tracey L. Spriggs, Ph.D., DABT  
Director Toxicology, Worldwide  
GlaxoSmithKline Consumer Healthcare

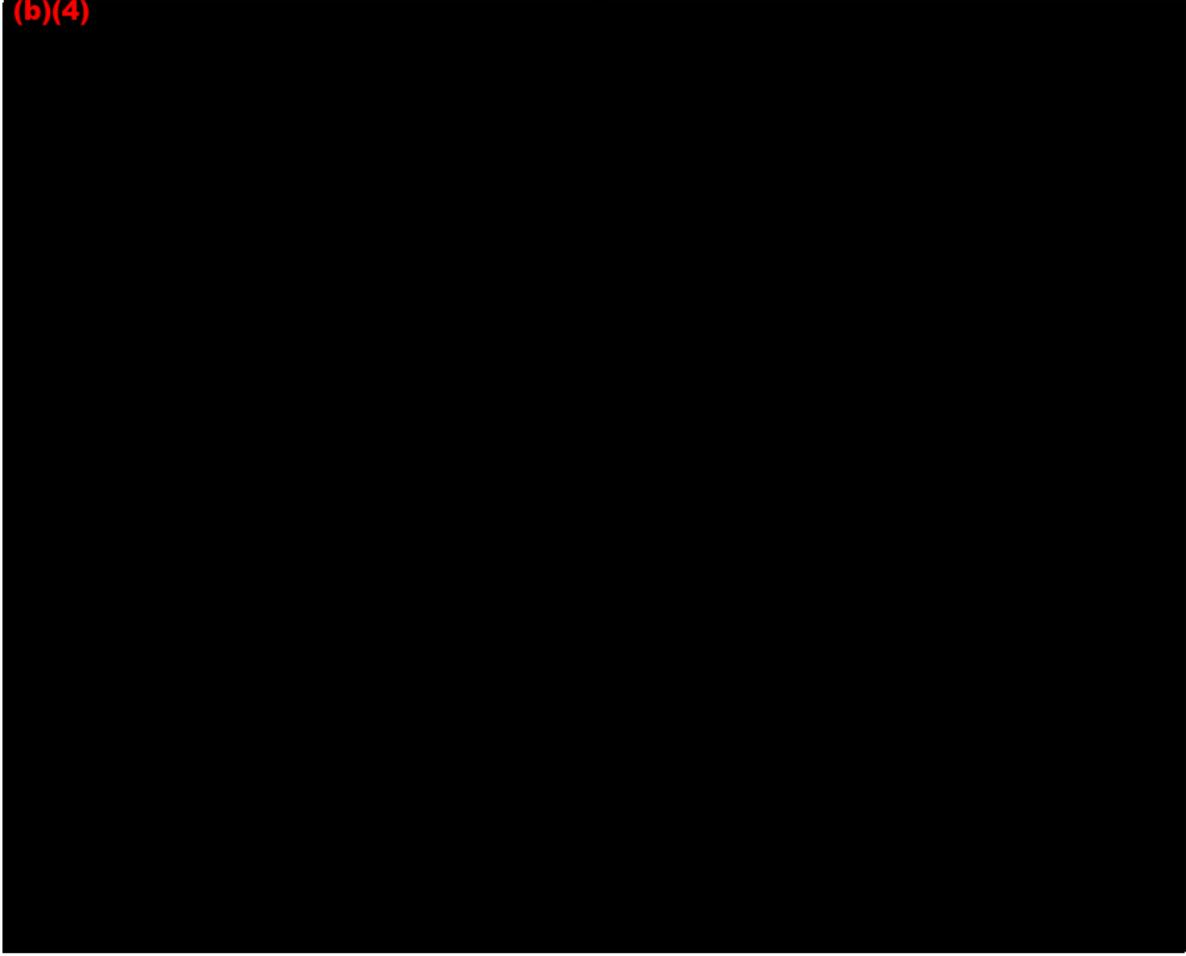
US PBF Biotène Mouthwash – Medical Device  
MFC 30602574L

Page 1 of 4

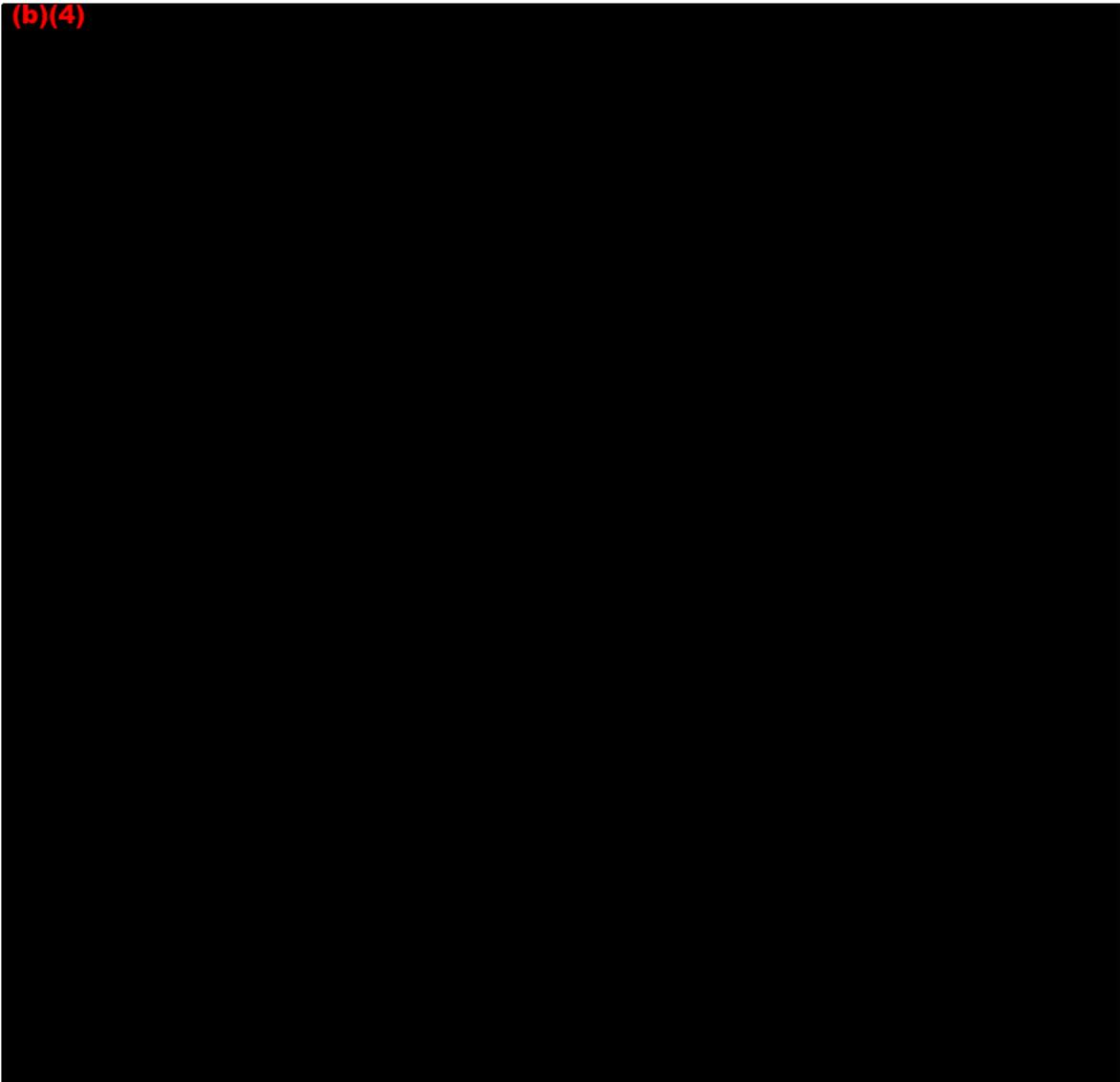


### Statement of Toxicological Evaluation

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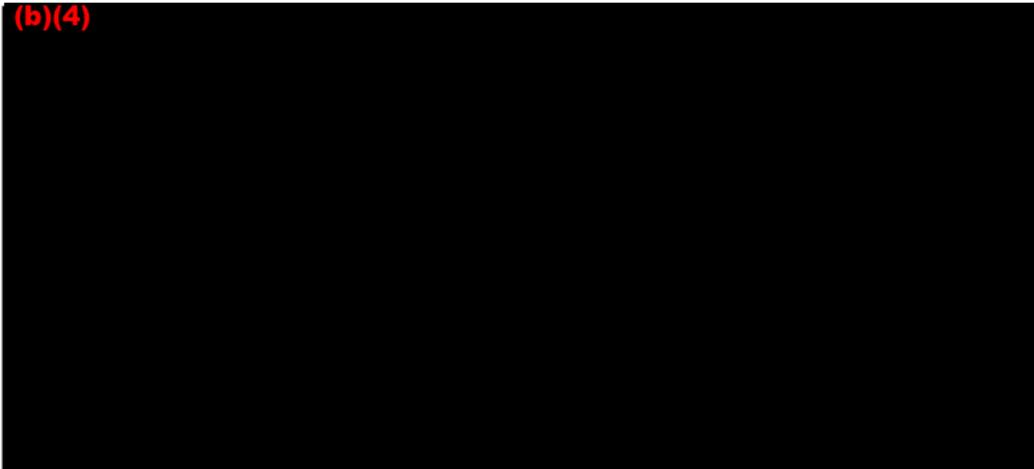


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(b)(4)





Joanna L Rowland B.Sc., Ph.D.  
Qualified Safety Assessor  
GlaxoSmithKline Consumer Healthcare

Signed: Tracey L Spriggs Date: 4 May 2010

Tracey L. Spriggs, Ph.D., DABT  
Director Toxicology, Worldwide  
GlaxoSmithKline Consumer Healthcare



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

**COVER SHEET MEMORANDUM**

From: Reviewer Name

*Marya E Brown*  
K101470/S1

Subject: 510(k) Number

To: The Record

*SE*

Please list CTS decision code

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

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

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC. ✓

Regulation Number \_\_\_\_\_ Class\* Unclassified Product Code 76-LFD  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: *Susan R...* *DEB3* *9/27/10*  
(Branch Chief) (Branch Code) (Date)

Final Review: *Anthony D. ...* *9/27/10*  
(Division Director) (Date)

6



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## MEMORANDUM

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

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

K101477

**Date:** August 6, 2010  
**To:** The Record  
**From:** Myra E. Browne, M.S., Biologist  
**Office/Division:** ODE/DAGID  
**510(k) Holder:** GlaxoSmithKline Consumer Healthcare  
**Device Name:** Biotene Dry Mouth Oral Rinse  
**Contact:** Ms. Wendy McManus  
**Phone:** 973-889-4415  
**Fax:** 973-889-2501  
**Email:** [wendy.a.mcmanus@gsk.com](mailto:wendy.a.mcmanus@gsk.com)

Purpose and Submission Summary

The 510(k) holder would like to introduce Biotene Dry Mouth Oral Rinse into interstate commerce.

Biotene Dry Mouth Oral Rinse is intended for the temporary relief of xerostomia which may result from an illness, chemotherapy, radiation, stress or aging.

Biotene Dry Mouth Oral Rinse are substantially equivalent (SE) to legally marketed artificial saliva products because the information submitted by GlaxoSmithKline Consumer Healthcare, demonstrates that the device has the same indication and technological characteristics as legally marketed artificial saliva products.

Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

**Indications for Use**

Biotene Dry Mouth Oral Rinse is intended for dryness of the mouth (i.e. hyposalivation, xerostomia, etc.).

The indication of Biotene Dry Mouth Oral Rinse does not differ from that of legally marketed artificial saliva products.

**Device Description/Formulation**

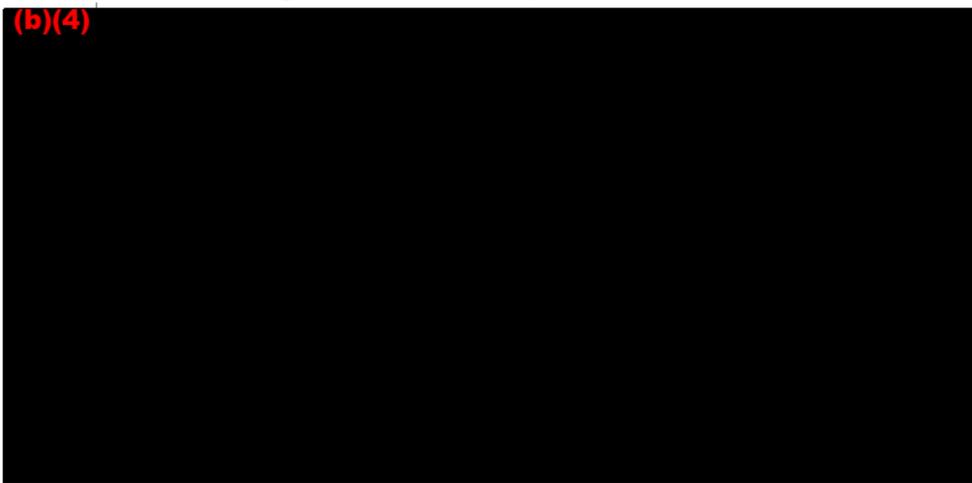
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The purpose of this 510(K) is to introduce a new product to market. No novel features have been introduced.

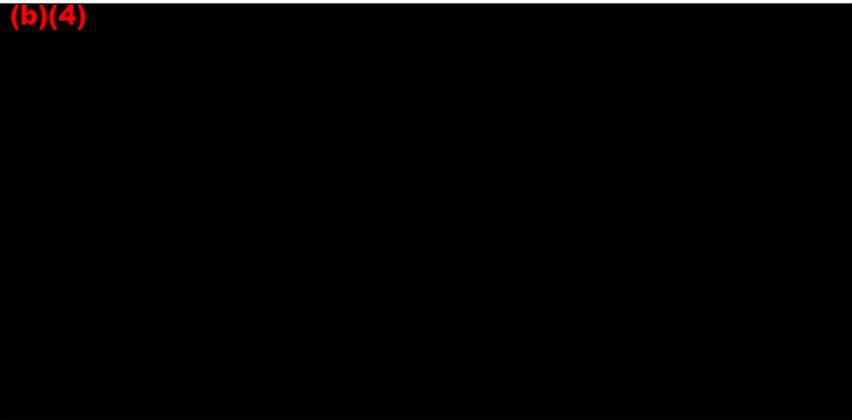
Biotene Dry Mouth Oral Rinse is an artificial saliva substitute which contain moisturizers, humectants, a protein, and patented salivary enzymes that when combined have lubricating, moisturizing, soothing, and refreshing properties to relieve and treat the symptoms of dry mouth. It is intended as a mouth rinse to moisten, lubricate and cleanse the oral cavity.

Biotene Dry Mouth Oral Rinse is supplied OTC in various sizes of PET bottles (8 ounces, 16 ounces, 33.8 ounces) and in a multi-layer laminated foil pouch (15 ml). Directions for use include the follow: use approximately one tablespoon. Swish thoroughly for 30 seconds and spit out, do not swallow. Directed for use up to 5 times daily. Only indicated for use with children under 12 years of age, if instructed by a physician.

The chemical composition Biotene Dry Mouth Oral Rinse is as follows:



(b)(4)



### Contact History

The reviewer contacted the submitter by telephone on August 18, 2010 to request that the sponsor submit the chemical composition, and a revised 510(k) summary. In addition, the reviewer notified the company that the Biotene PBF Mouthwash which makes claim for plaque loosening is considered a drug, and therefore they must the PBF version from this submission. The company submitted the requested information on September 21, 2010.

### Deficiencies

No deficiencies have been identified.

### Labeling

The labeling of Biotene Dry Mouth Oral Rinse has been provided which includes instructions for use. Biotene Dry Mouth Oral Rinse will only be sold OTC. No unsubstantiated claims are purported.

### Sterilization/Shelf Life/Reuse:

Biotene Dry Mouth Oral Rinse will be provided non-sterile and is not intended to be sterilized before use. Shelf-life was established at 36 months.

### Biocompatibility

The formulation of Biotene Dry Mouth Oral Rinse includes no new components. This basic formulation is known to be biocompatible for this intended use. Biocompatibility data was conducted with reference to ISO 10993-1, part 1. Based on the data submitted, there were no significant changes to the mucous membranes. This product has been demonstrated to be in compliance with ISO 10993-1, part 1.

### Software

Biotene Dry Mouth Oral Rinse contains no software.

### Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Biotene Dry Mouth Oral Rinse is not a mechanical or electrical device. Therefore, mechanical

safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering performance test results were not provided for Biotene Dry Mouth Oral Rinse.

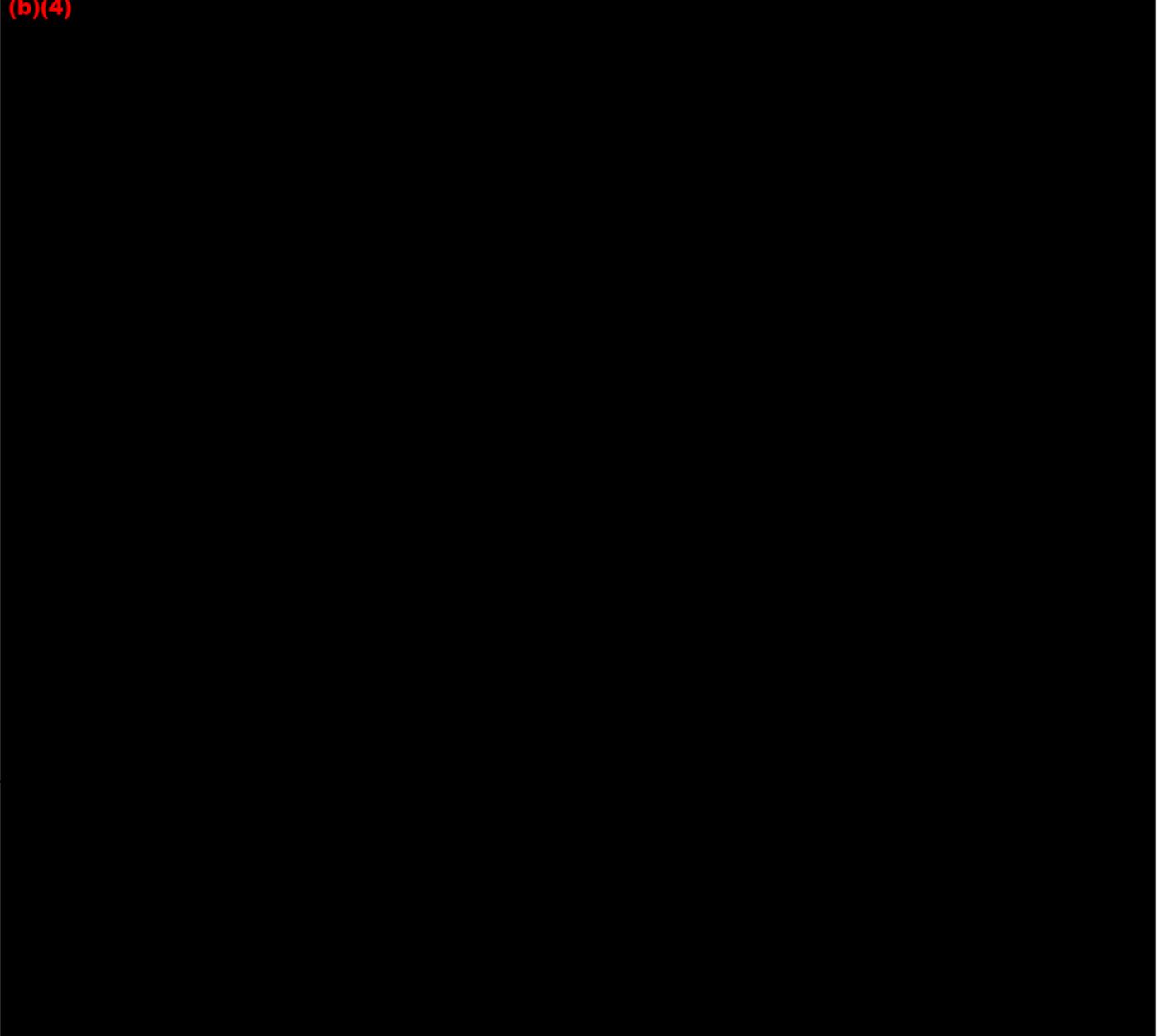
Performance Testing - Animal

Animal test results were not provided for Biotene Dry Mouth Oral Rinse.

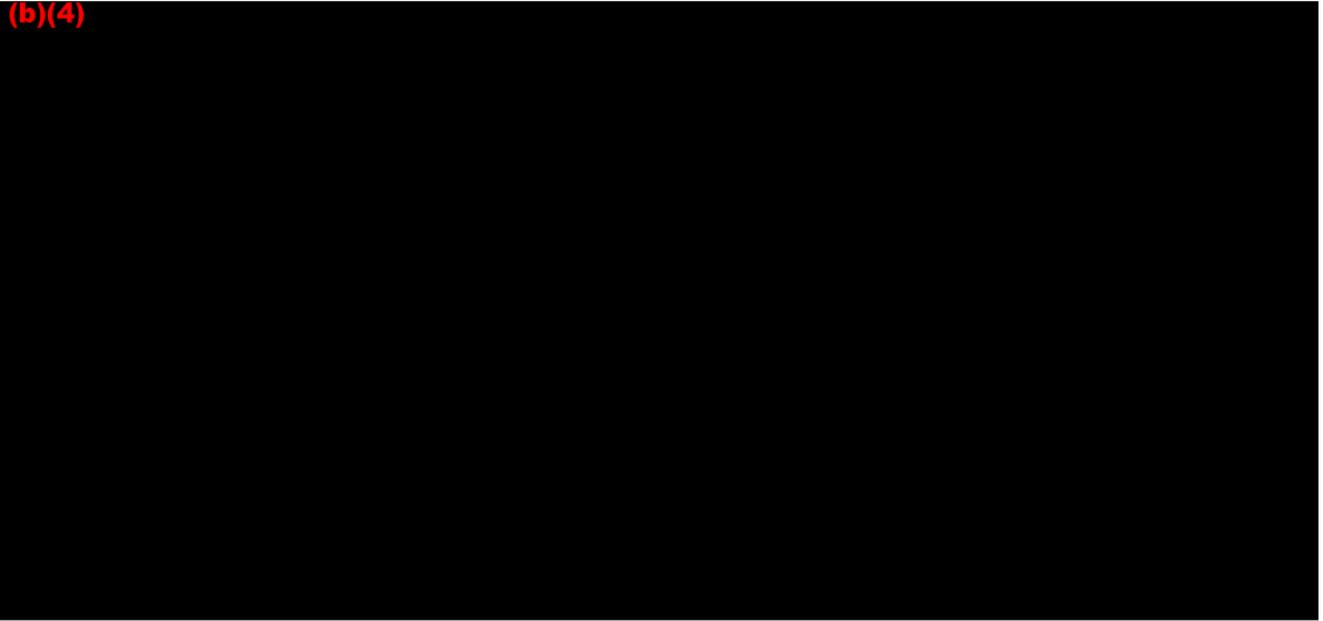
Performance Testing - Clinical

Human test results were not provided for Biotene Dry Mouth Oral Rinse.

(b)(4)



(b)(4)



12

**Substantial Equivalence Discussion**

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

**Recommendation**

Regulation Number: N/A  
 Regulation Name: Artificial Saliva  
 Regulatory Class: Unclassified  
 Product Code: LFD

*Myra E. Browne*

Myra E. Browne, M.S., Biologist

Reviewer

*9/21/10*

Date

*Susan Runner*

M. Susan Runner, DDS

Branch Chief

*9/27/10*

Date

*Am...*

*9/27/10*



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

COVER SHEET MEMORANDUM

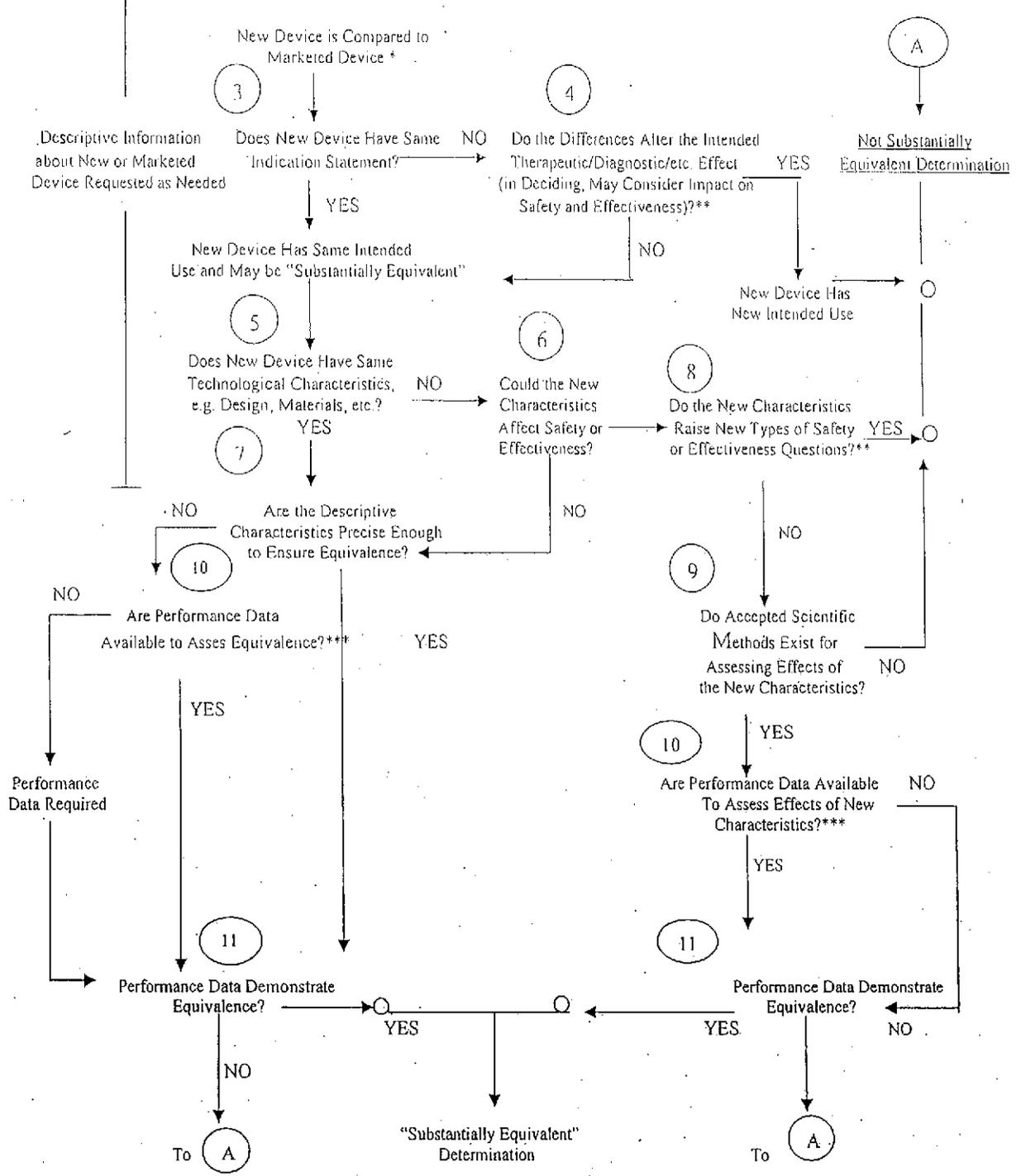
From: Reviewer Name Murphy  
Subject: 510(k) Number K101470  
To: The Record

- Please list CTS decision code TH
- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
  - Hold (Additional Information or Telephone Hold)
  - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

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



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.



To: The Record

From: Biologist, DEDB, DAGID, ODE, CDRH

Subject: K101477

Date: August 18, 2010

Background

GlaxoSmithKline Consumer Health Care submitted a 510(k) for Biotene Dry Mouthwash and Biotene PBF Dry Mouthwash. I spoke to Wendy McManus to request the following additional information:

1. Revise the 510(k) summary as per CFR807.92
2. Submit the complete chemical composition for both mouthwashes;
3. Indicate if any standards were used for establishing biocompatibility;
4. Indicate the differences between the 2 mouthwashes; and
5. Submit a chart comparing these mouthwashes to the predicate device, the Laclede product.

I informed Ms. McManus that this document will be placed on telephone hold until the additional information is submitted

Recommendation

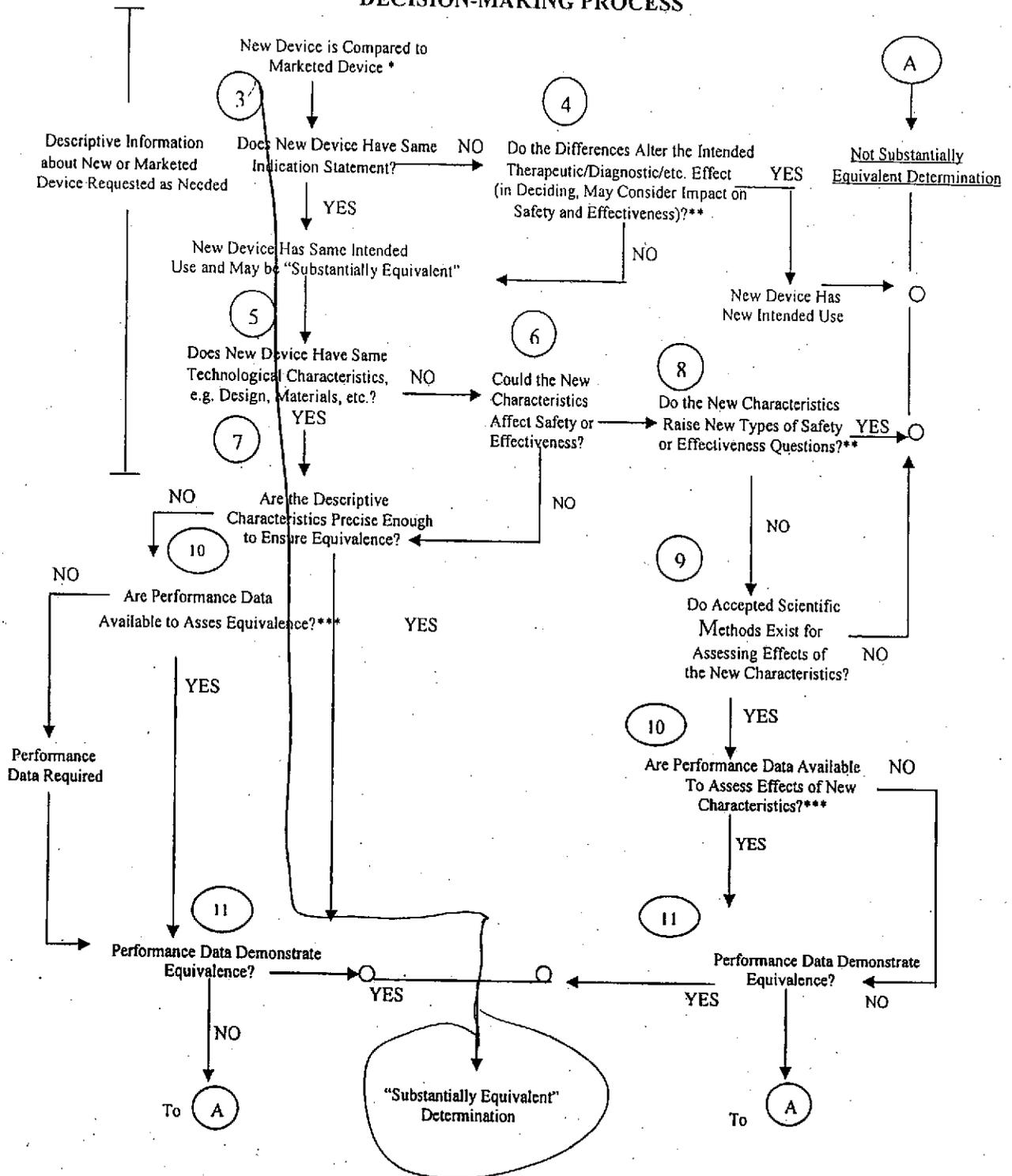
Place on telephone hold

A handwritten signature in black ink that reads "Myra E. Browne". The signature is written in a cursive, flowing style.

Myra E. Browne

Handwritten text in black ink that reads "See Myra 8/18/10" followed by the number "20".

### 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.



K101477/5001

GlaxoSmithKline

**GlaxoSmithKline**  
1500 Littleton Road  
Parsippany, NJ  
07054-3884

Tel. 973 889 2100  
Fax 973 889 2390  
www.gsk.com

September 17, 2010

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

FDA CDRH DMC

SEP 20 2010

Received

**Re: 510(k) Notification K101477**  
**Trade Name: Biotène Dry Mouth Oral Rinse**  
**Common Name: Saliva, Artificial**

Dear Myra Browne,

Attached are the requested final revisions for **Biotène Dry Mouth Oral Rinse K101477**:

*Section 4 Indications for Use Statement*  
*Section 5 510K Summary*

Please do not hesitate to contact the undersigned by telephone at 973-889-4415 or by fax at 973-889-2501 if you have any questions or need additional information.

Sincerely,

Wendy A. McManus  
Regulatory Associate, US Regulatory Affairs  
GlaxoSmithKline Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884  
(973) 889-4415

14-8



**GlaxoSmithKline**

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Fax 973 889 2390  
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September 17, 2010

U.S. Food and Drug Administration  
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10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Re:** 510(k) Notification K101477  
**Trade Name:** Biotène Dry Mouth Oral Rinse  
**Common Name:** Saliva, Artificial

Dear Myra Browne,

Attached are the requested final revisions for **Biotène Dry Mouth Oral Rinse K101477:**

*Section 4 Indications for Use Statement*  
*Section 5 510K Summary*

Please do not hesitate to contact the undersigned by telephone at 973-889-4415 or by fax at 973-889-2501 if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy A. McManus", with a long horizontal line extending to the right.

Wendy A. McManus  
Regulatory Associate, US Regulatory Affairs  
GlaxoSmithKline Consumer Healthcare  
1500 Littleton Road  
Parsippany, NJ 07054-3884  
(973) 889-4415

**SECTION 4: INDICATIONS FOR USE STATEMENT**

**510(k) Number (if known):** N/A

**Device Name:** Biotène Dry Mouth Oral Rinse

**Indications for Use:**

Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness.

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

**Concurrence of CDRH, Officers of Device Evaluation (ODE)**

**Prescription Use** \_\_\_\_\_ **OR** **Over-The-Counter Use** \_\_\_\_\_

**(Per 21 CFR 801.109)**

**SECTION 5: 510(K) SUMMARY**

**1. SUBMITTER INFORMATION**

Name: GlaxoSmithKline Consumer Healthcare  
Address: 1500 Littleton Road  
Parsippany, NJ 07054-3884  
Contact Person: Wendy A. McManus  
Telephone/Fax: 973-889-4415  
973-889-2501 (fax)  
Date Summary Prepared: May 25, 2010

**2. DEVICE NAME**

Device Name: Biotène Dry Mouth Oral Rinse  
Trade or Proprietary Name: Biotène Dry Mouth Oral Rinse  
Common or Usual Name: Saliva, Artificial  
Classification Name (if known): Saliva, Artificial

**3. IDENTIFICATION OF EQUIVALENCE**

Laclede, Inc. *Oral Balance Gel* cleared in K061331  
Laclede, Inc. *Oral Balance Liquid* cleared in K061331

**4. DEVICE DESCRIPTION**

Biotène Dry Mouth Oral Rinse is a specially formulated artificial saliva substitute which contain moisturizers, humectants, a protein, and patented salivary enzymes, that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of Dry Mouth. The liquid products are supplied in PET

510K Notification

Biotène Dry Mouth Oral Rinse  
GlaxoSmithKline Consumer Healthcare, L.P.

bottles of various sizes, including an 8 oz., 16 oz., and 33.8 oz., and also 15 ml. multi-layer laminated foil pouches.

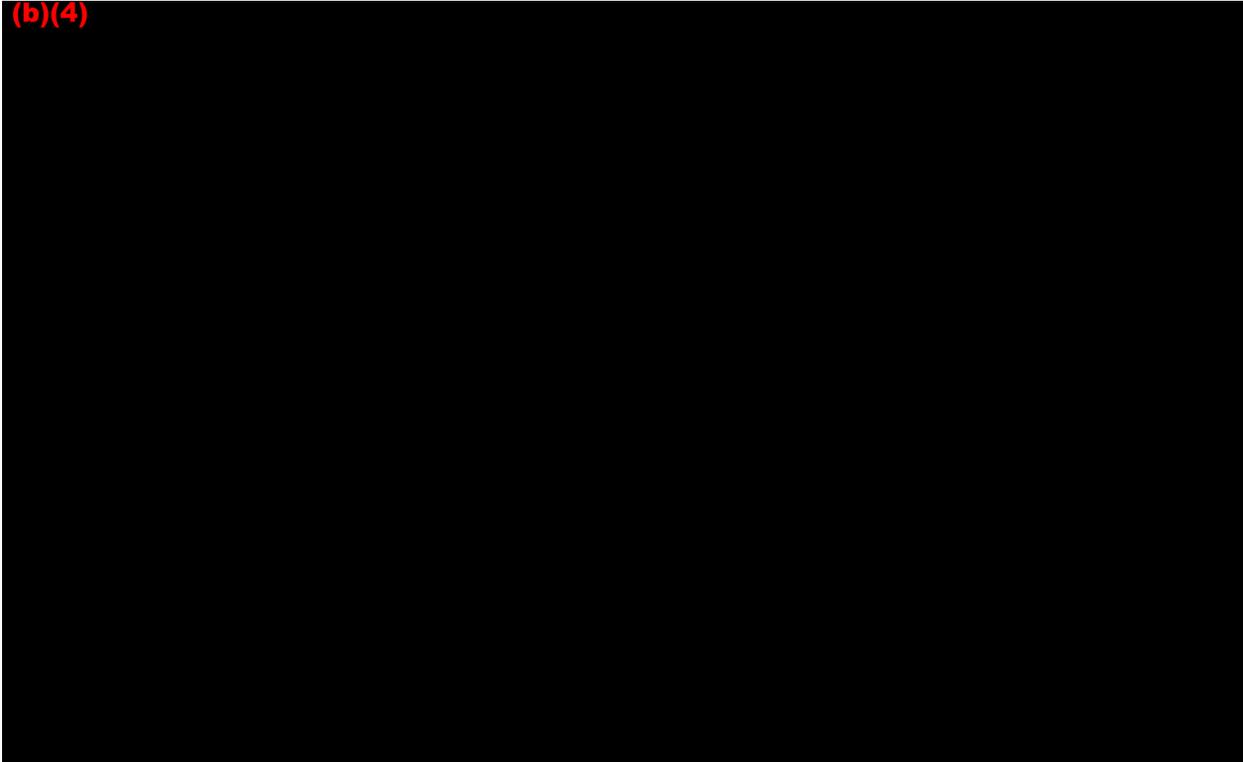
## 5. STATEMENT OF INTENDED USE

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

The *Indication for Use*: Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritations, and lubricates oral dryness.

## 6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

(b)(4)



## 7. Discussion and conclusions from the nonclinical and clinical tests

(b)(4)

