



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (ixg)
FOLDER: K123731 - 89 pages
COMPANY: GLAXOSMITHKLINE CONSUMER HEALTHCARE (GSKCH) (GLAXCONSHEALGSKC)
PRODUCT: SALIVA, ARTIFICIAL (LFD)
SUMMARY: Product: BIOTENE ORAL BALANCE GEL, BIOTENE DRY MOUTH ORAL RINSE, BIOTENE MOISTU
DATE REQUESTED: May 14, 2014
DATE PRINTED: May 14, 2014
Note: Printed





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 4, 2013

Mr. Paul Krumm
Regulatory Affairs Manager
GlaxoSmithKline Consumer Healthcare (GSKCH)
1500 Littleton Road
PARSIPPANY NJ 07054

Re: K123731

Trade/Device Name: Biotene Oral Balance Gel, Biotene Dry Mouth Oral Rinse, Biotene
Moisturizing Mouth Spray

Regulation Number: Unclassified

Regulation Name: Saliva, Artificial

Regulatory Class: Unclassified

Product Code: LFD

Dated: December 4, 2012

Received: December 10, 2012

Dear Mr. Krumm:

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.

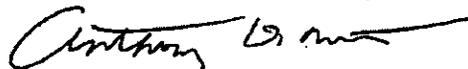
Page 2 – Mr. Krumm

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" (21 CFR 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (If known):

K123731

Devices Names: biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse, biotene Moisturizing Mouth Spray

Indications for Use: The biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse and biotene Moisturizing Mouth Spray intended use is to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____

Susan Runner DDS, MA 2013.01.04
12:41:11 -05'00'

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

510(k) Number: K123731

Biotene Artificial Saliva Products Modifications

Volume 1 Page 34 of 52

K123751

V.1



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Moisturizing Mouth Spray
Regulation Number: Unclassified
Regulation Name: Saliva, Artificial
Regulatory Class: Unclassified
Product Code: LFD
Dated: December 4, 2012
Received: December 10, 2012

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Director
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 3 – Mr. Krumm

Concurrence & Template History Page
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

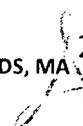
Full Submission Number: K123731

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	 Susan Runner DDS, MA 2013.01.04 14:29:56 -05'00'
Branch Chief Sign-Off	 Susan Runner DDS, MA 2013.01.04 14:29:37 -05'00'
Division Sign-Off	 Anthony D. Watson Anthony D. Watson 2013.01.04 14:14:08 -05'00'

Template Name: KI(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Indications for Use Statement

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K123731

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

510(k) Number: K123731

Biotene Artificial Saliva Products Modifications

Volume 1 Page 34 of 52

* * * COMMUNICATION RESULT REPORT (JAN. 7. 2013 9:55AM) * * *

FAX HEADER 1:
FAX HEADER 2:TRANSMITTED/STORED : JAN. 7. 2013 9:52AM
E MODE OPTION

ADDRESS

RESULT

PAGE

2326 MEMORY TX

9738892390

OK

3/3

REASON FOR ERROR OR LINE FAIL
E-1) HANG UP
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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10903 New Hampshire Avenue
Document Control Center - WO66-0609
Silver Spring, MD 20993-0002

January 4, 2013

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

COVER SHEET MEMORANDUM

From: Reviewer Name Mary Browne
Subject: 510(k) Number K23731
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE/SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

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 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<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, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<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 checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was		<input checked="" type="checkbox"/>	<input type="checkbox"/>

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.) ✓

Does this device include an Animal Tissue Source? ✓

All Pediatric Patients age ≤ 21 ✓

Neonate/Newborn (Birth to 28 days) ✓

Infant (29 days - < 2 years old) ✓

Child (2 years - < 12 years old) ✓

Adolescent (12 years - < 18 years old) ✓

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.) ✓

Transitional Adolescent B (18 - ≤ 21; No special considerations compared to adults ⇒ 21 years old) ✓

Nanotechnology ✓

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC. ✓

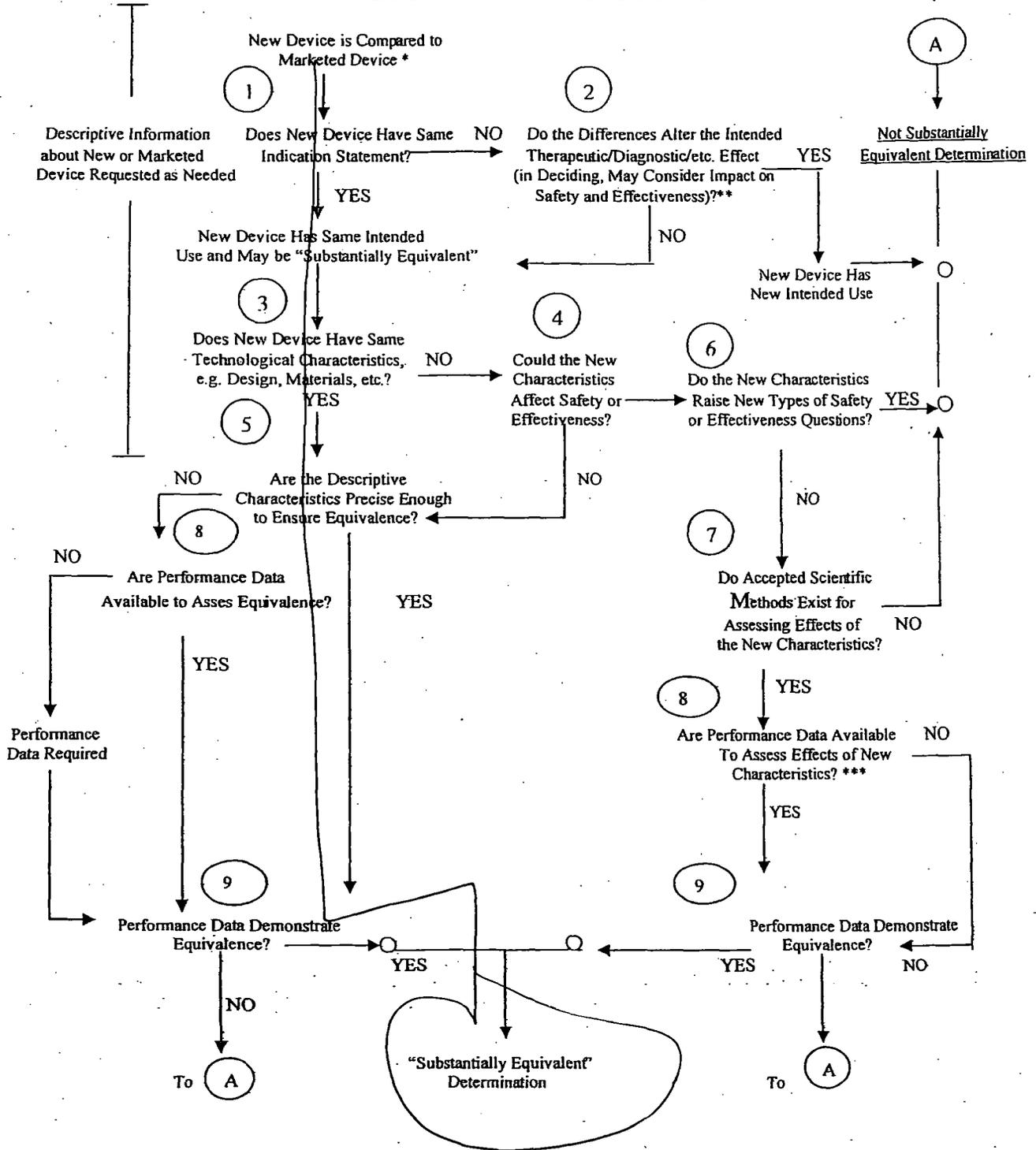
Regulation Number	Class*	Product Code
	<i>Unclassified</i>	<i>76LED</i>
	(*If unclassified, see 510(k) Staff)	

Additional Product Codes: _____

Review: *Susan Purne* *DEDB* *1/4/13*
 (Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* *1/4/13*
 (Division Director) (Date)

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



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

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

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

	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:

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Myra E. Browne <small>Digitally signed by Myra E. Browne DN: cn=Myra E. Browne, o=FDA, ou=CDRH, email=Myra.E.Browne@FDA.HHS.GOV, c=US</small>

Branch Chief Sign-Off	Susan Runner DDS, MA 2013.01.04 11:06:06 -05'00'
Division Sign-Off	Kwame O. Ulmer 2013.01.04 11:28:47 -05'00'

Revised: 8/1/03

10/16/2012 – MMJ placed in Digital Signature format

From: Browne, Myra E. [<mailto:Myra.Browne@fda.hhs.gov>]

Sent: Tuesday, December 18, 2012 11:33 AM

To: Paul Krumm

Subject: K123731

Dear Paul,

We have completed the administrative acceptance of your premarket notification (510(k)) submission K123731. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness.

Our Refuse to Accept (RTA) policy has not yet been implemented. Therefore, during this transitional phase, we have begun our substantive review of your 510(k) submission, and we are requesting the missing information interactively.

Please refer to the attached checklist and e-mail your response to me referencing the 510(k) number K123731 by December 26, 2012. Your response should address all of the elements identified as missing or inconsistent in the attached checklist. Failure to provide the requested information by December 26 may result in your submission being placed on hold.

Upon receipt of the requested information, FDA may have additional requests for information.

Please be advised that once our RTA policy is implemented, if your 510(k) submission does not meet the criteria established for administrative completeness, your file will not be accepted and we will not begin our substantive review until you submit the missing elements and your submission is accepted. Refer to the draft guidance document for information.

Should you have questions about this email, you may contact me, the lead reviewer assigned to your 510(k) submission.

Sincerely,

Myra

Myra E. Browne, M.S.

Biologist

FDA

Center for Devices and Radiological Health

Dental Devices Branch

10903 New Hampshire Avenue

Silver Spring, MD 20993

301-796-6278

myra.browne@fda.hhs.gov

Browne, Myra E.

From: Paul Krumm [Paul.A.Krumm@gsk.com]
Sent: Thursday, December 20, 2012 1:59 PM
To: Browne, Myra E.
Subject: RE: Special 510(k) K123731
Attachments: Special 510k 123731 Responses.pdf

Dear Myra,

Thank you for your e:Mail of December 18.

Please see our responses below to the following items (in bold) that were highlighted in the checklist that you attached with your e:Mail:

Comments: Sponsor did not identify the risk analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA), specifically a Process FMEA.

Please see the attachment headed "Design Control" for further details.

Comments: All changes in proposed labeling resulting from device modification(s) have not been highlighted or prominently identified.

Response: Labeling Text Comparison Tables are hereby attached which show the differences in the proposed versus the current labels.

Comments: Sponsor did not submit a statement that the intended use of the modified device as described in the labeling, has not changed as a result of the modification.

Response: A "Statement of Intended Use" is hereby attached. It indicates that there is no change in the intended use of any of the devices that are the subjects of this submission.

We hope that these responses are satisfactory to enable the acceptance of our submission K123731. Would request that you please acknowledge upon your receipt of this response. Please contact me should you have any questions or require any further information.

Sincerely,

Paul

Paul Krumm
Regulatory Affairs Manager
GlaxoSmithKline Consumer Healthcare
973-889-7339

Design Controls

Special 510(k) # K123731

The risk analysis used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FEMA), specifically a Process FEMA.

The results of this risk analysis showed that the design verification tests required to verify the manufacturing process were those as listed in Table 1 below:

Table 1

Modification	Test Performed	Acceptance Criteria
Adjustment of pH (biotene Oral Balance Gel)	Test for pH	B4 [REDACTED]
Use of propylparaben preservative (biotene Oral Balance Gel)	Assay for propylparaben content	[REDACTED]
Adjustment of pH (biotene Dry Mouth Oral Rinse)	Test for pH	B4 [REDACTED]
Use of methylparaben and propylparaben as additional preservatives (biotene Dry Mouth Oral Rinse)	Assays for methylparaben and propylparaben content	[REDACTED] for both methylparaben and propylparaben
Adjustment of pH (biotene Moisturizing Mouth Spray)	Test for pH	B4 [REDACTED]
Use of methylparaben, propylparaben and cetylpyridinium chloride as additional preservatives (biotene Moisturizing Mouth Spray)	Assays for methylparaben, propylparaben and cetylpyridinium chloride content	[REDACTED] for both methylparaben and propylparaben, and a B4 [REDACTED] [REDACTED] cetylpyridinium chloride

The test method used for pH is similar to that referenced in the original submission.

The preservatives are assayed using validated test methodology.

These verification tests have been conducted on all of the products. The results have indicated that the manufacturing process is suitable for producing products that meet the new acceptance criteria resulting from the product modifications.

Labeling Text Comparison: biotene Oral Balance Gel: Differences of Proposed Formula versus Current Formula

	BIOTENE ORAL BALANCE GEL (Proposed Formula) 510(k) #K123731	BIOTENE ORAL BALANCE GEL (Current Formula) 510(k) #K061331
Marketing Statements	<ul style="list-style-type: none"> -Contains a mouth moisturizing system -Helps soothe and protect oral tissues -Helps maintain the oral environment - Helps provide protection against dry mouth symptoms -#1 Dentist & Hygienist Recommended Brand for Dry Mouth Symptoms 	<ul style="list-style-type: none"> -Contains a protein-enzyme system -Diminishes mouth odors -Helps maintain the oral environment - Helps provide protection against dry mouth symptoms -For moderate to severe dry mouth. Long lasting symptom relief. -#1 Dentist & Hygienist Recommended Brand for Dry Mouth
Usage	Helps soothe and protect dry mouth against discomfort. Contains a mouth moisturizing system to help relieve dry mouth symptoms	Soothes and protects dry mouth tissues against oral irritations and burning sensations. Contains a protein-enzyme system and diminishes mouth odor
Warnings	Keep out of reach of children. If symptoms of dry mouth persist, consult a healthcare professional. Do not use if you are allergic to any of the ingredients.	Keep out of reach of children. If symptoms of dry mouth persist, consult a healthcare professional.
Ingredient Listing	Reflects proposed formula	Reflects current formula

Labeling Text Comparison: biotene Moisturizing Mouth Spray: Differences of Proposed Formula versus Current Formula

	BIOTENE MOISTURIZING MOUTH SPRAY (Proposed Formula) 510(k) #123731	BIOTENE MOISTURIZING MOUTH SPRAY (Current Formula) 510(k) #K103745
Marketing Statements	<ul style="list-style-type: none"> -Experience a source of moisture for comfort -Supplements mouth moisture protection -Long lasting -Refreshes and moistens -Immediate relief -Helps keep mouth fresh -Soothing moisturization -Biotene contains a mouth moisturizing system to help maintain the oral environment and helps provide protection against dry mouth symptoms -#1 Dentist & Hygienist Recommended Brand for Dry Mouth Symptoms 	<ul style="list-style-type: none"> Experience a source of moisture for the comfort and health of your mouth Supplements mouth moisture protection -Refreshes and moistens instantly -Helps keep mouth fresh -With a protein-enzyme system -Biotene contains enzymes found in saliva. Biotene Mouth Spray helps maintain the oral environment and provides relief against dry mouth symptoms -#1 Dentist & Hygienist Recommended Brand for Dry Mouth
Usage	Use as needed for instant comfort. Biotene helps maintain the oral environment and helps provide protection against dry mouth symptoms.	Use as needed for instant comfort. Biotene contains enzymes found in saliva to help maintain the oral environment and help provide protection against dry mouth symptoms.
Warnings	If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children. Do not use if you are allergic to any of the ingredients.	If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children
Ingredient Listing	Reflects proposed formula	Reflects current formula

Labeling Text Comparison: biotene Dry Mouth Oral Rinse: Differences in Proposed Formula versus Current Formula

	BIOTENE DRY MOUTH ORAL RINSE (Proposed Formula) 510(k) #123731	BIOTENE DRY MOUTH ORAL RINSE (Current Formula) 510(k) #101477
Marketing Statements	-Soothing moisturization -New improved pH balance -#1 Dentist and Hygienist Recommended Brand for Dry Mouth Symptoms	-Protein-enzyme system -Refreshes without burning -#1 Dentist and Hygienist Recommended Brand for Dry Mouth
Warnings	If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children. Do not swallow. Do not use if you are allergic to any of the ingredients.	If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children. Do not swallow.
Other	An oral rinse with a soothing, gentle feel that cleans, refreshes and relieves dryness and soothes oral irritations. biotene contains a combination of moisturizers and humectants to help relieve dryness.	Imagine an oral rinse with a soothing gentle feel containing beneficial enzymes-an oral rinse that cleans, refreshes and relieves dryness and soothes oral irritations. That oral rinse is biotene, Only biotene contains beneficial enzymes found in saliva to help maintain the oral environment and help relieve dryness.
Ingredient Listing	Reflects proposed formula	Reflects current formula

Intended Use Statement

Statement

The intended use of the biotene Oral Balance Gel, Dry Mouth Oral Rinse and Moisturizing Mouth Spray, which are the subject of this Special 510(k) #123731, is for the relief of the symptoms of dry mouth: refresh, moisturize, clean, sooth oral irritation, and lubricate oral dryness. This is the same intended use as previously cleared for the biotene Oral balance Gel [510(k) Number K061331], biotene Dry Mouth Oral Rinse [510(k) Number K101477] and biotene Moisturizing Mouth Spray [510(k) Number K103745]. The intended use of these modified devices, as described in their labeling, has therefore not changed as a result of the modification(s) described in this submission.



Paul Krumm
Regulatory Affairs Manager
GlaxoSmithKline

19 December 2012

Date

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Refuse to Accept Checklist for Special 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: K123731 _____ Date Received: December 11, 2012 _____

Lead Reviewer Name: Myra E. Browne_ Branch: DEDB__ Division: DAGRID__ Office: ODE__

Special 510(k) Criteria		
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.		
	Yes	No
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4. The submission includes only summary-level information (i.e., NO test reports with performance data).	X	
Comments:		

Does the submission meet all 4 criteria above?

Yes; submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.

No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

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<u>Organizational Elements</u>		
<i>Failure to include these items along generally should not result in an RTA designation</i>		
	Yes	No
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	X	
Comments:		

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>						
Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			Yes	N/A	No
A.	Administrative					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X	<input type="checkbox"/>		
	Comments:					
	2.	510(k) Cover letter that identifies: at a minimum:	<input type="checkbox"/>	<input type="checkbox"/>		
	a.	Device trade name or proprietary name	X	<input type="checkbox"/>		
	b.	Device common name	X	<input type="checkbox"/>		
	c.	Device class and panel	X	<input type="checkbox"/>		
	Comments:					
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) <i>Submitter should use format appropriate for the reviewing</i>	X	<input type="checkbox"/>		

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Draft - Not for Implementation*

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
	<i>Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>			
	Comments:			
4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.</i>	X		<input type="checkbox"/>
	a. Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	b. Statement contains all elements per 21 CFR 807.93	X		<input type="checkbox"/>
	Comments:			
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format</i>	X		<input type="checkbox"/>
	Comments:			
6.	Submission contains Class III Summary and Certification <i>See recommended content</i> <i>Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature. "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:			
7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	<input type="checkbox"/>	X	<input type="checkbox"/>

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<p><i>There should be a completed form for each referenced national or international standard.</i></p> <p><i>"N/A" only if submission does not reference any standards.</i></p>			
	Comments:			
8.	<p>If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (Section 738 FD&C Act)]</p> <p><u>See Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission.</u></p> <p><i>"N/A" if not a bundled submission</i></p>	X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
9.	<p>The submission identifies related submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.</p>	X		<input type="checkbox"/>
	<p>a. If there are related submissions, within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.</p>	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
B.	Device Description			
10.	<p>If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable</p>	<input type="checkbox"/>	X	<input type="checkbox"/>

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
	statutory or regulatory criteria through an alternative approach. <i>Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.</i> <i>Select "N/A" if there is no device-specific guidance document</i>				
	Comments:				
	11.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
	a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	X		<input type="checkbox"/>
	b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		X	<input type="checkbox"/>
	c.	A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one model.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:				
	12.	A description of all device modification(s) including rationale for each modification.	X		<input type="checkbox"/>
	Comments:				
	13.	Identification of history of changes made to device since the previous 510(k) clearance	X		<input type="checkbox"/>
	Comments:				

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed:					
			Yes	N/A	No
		<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	14.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions	<input type="checkbox"/>	X	<input type="checkbox"/>
	a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	<input type="checkbox"/>	X	<input type="checkbox"/>
		Comments:			
	15.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		X	
	a.	A description (as detailed in item #12.a. and b. and 14 above) is provided for each component or accessory.	<input type="checkbox"/>		<input type="checkbox"/>
	b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			
C.	Substantial Equivalence Discussion				
	16.	Submitter has identified a predicate(s) device	X		<input type="checkbox"/>
	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		<input type="checkbox"/>
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing)	X		<input type="checkbox"/>

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
		Comments:			
	17.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a.	Indications for use	X		<input type="checkbox"/>
	b.	Technology, including features, materials, and principles of operation	X		<input type="checkbox"/>
		Comments:			
	18.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) <i>If there is no difference between the subject and predicate(s) with respect to the indications or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences.</i>	X		<input type="checkbox"/>
		Comments:			
D.	Design Control Activities				
	19.	Design Control Activities Summary includes all of the following:			
	a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	<input type="checkbox"/>		X
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	<input type="checkbox"/>		X

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<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>						
Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
			<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
		c.	Declaration of conformity with design controls, including: <i>All 3 must be present to answer "Yes"</i>	X		<input type="checkbox"/>
		i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.			
		ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30			
		iii.	Statement is signed by the individual responsible for these activities			
Comments: Sponsor did not identify the risk analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.						
E. Proposed Labeling (see also 21 CFR part 801)						
	20.		Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual) and advertisements that describe the device, its intended use, and the directions for use	X		<input type="checkbox"/>
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	<input type="checkbox"/>		X
Comments: All changes in proposed labeling resulting from device modification(s) have not been highlighted or prominently identified.						
	21.		Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	<input type="checkbox"/>		X
Comments: Sponsor did not submit a statement that the intended use of the modified device as described in the labeling, has not changed as a result of the modification(s).						

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Decision: Accept Refuse to Accept

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	<p>Myra E. Browne</p> <p><small>Digitally signed by Myra E. Browne DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Myra E Browne, 0.9.2342.19200300.1.00.1.1=1300013790 Date: 2012.12.18 11:13:54 -05'00'</small></p>
Branch Chief Sign-Off	<p>Susan Runner DDS, MA</p> <p>2012.12.18 12:12:54 -05'00'</p>
Division Sign-Off	<p>Kwame O. Ulmer</p> <p>2012.12.18 13:27:12 -05'00'</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 10, 2012

GLAXOSMITHKLINE CONSUMER HEALTHCARE (GSKCH)
 CONSUMER HEALTHCARE
 1500 LITTLETON ROAD
 PARSIPPANY, NEW JERSEY 07054
 ATTN: PAUL KRUMM

510k Number: K123731

Received: 12/10/2012

Product: BIOTENE ORAL BALANCE GEL, BIOT

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

Wilson, Kevin *

From: Wilson, Kevin *
Sent: Monday, December 10, 2012 5:25 PM
To: 'PAULA.KRUMM@GSK.COM'
Subject: K123731 ACKNOWLEDGMENT LETTER



CrystalViewerCA...



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

User Fee Hold Letter

December 05, 2012

Paul Krumm, Regulatory Affairs Manager
Glaxosmithkline Consumer Healthcare (Gskch)
Consumer Healthcare
1500 Littleton Road
Parsippany, NJ 07054
United States

Dear Paul Krumm:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K123731
Device: Biotene Oral Balance Gel, Biotene Dry Mouth Oral Rinse, Biotene Moisturizing Mouth Spray
Dated: 04-DEC-2012
Received: 05-DEC-2012

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), and the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain types of submissions. This submission cannot be accepted for review until the user fee is paid in full.

You have received this letter because we have not received your payment in full. Additional information on user fees, including how and where to submit your user fee payment and how to generate a User Fee Cover Sheet, may be found on our webpage entitled, "Premarket Notification [510(k)] Review Fees" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm>

In addition, please fax a completed copy of the User Fee Cover Sheet that includes the specific submission number above and the Payment Identification Number for this submission to our CDRH Document Control Center at (301) 847-8113.

You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to pay by check, make the check out to the Food and Drug Administration and reference the payment identification number, include a copy of the User Fee Cover sheet with the check, and mail them to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733

By Private Courier (e.g., Fed Ex, UPS)

U.S. Bank
Attn: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4821

When we have been notified that your user fee payment has been received, review of the submission will resume as of that date. Alternatively, you may request withdrawal of your submission.

If payment has not been received within 30 days, your 510(k) will be deleted from the system. If you have any questions concerning this letter, please contact Ms. Edwena Jones at (301) 796-6308 or by email at edwena.jones@fda.hhs.gov.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Pugh, Dominique *

From: Microsoft Outlook
To: paul.a.krumm@gsk.com
Sent: Wednesday, December 05, 2012 12:50 PM
Subject: Relayed: K123731 USER FEE HOLD LETTER

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

paul.a.krumm@gsk.com (paul.a.krumm@gsk.com)

Subject: K123731 USER FEE HOLD LETTER

CONFIDENTIAL



Biotene Artificial Saliva Products Modifications

Special 510k Premarket Notification

Published 12/4/2012

This submission is confidential and the property of GlaxoSmithKline. It contains proprietary information and trade secrets and is submitted to the Regulatory Authority for the sole purpose of licensing the identified product. Reproduction, disclosure or use of the submission or information contained therein in whole or in part otherwise than for the said purpose is forbidden unless at the express request or with the written consent of GlaxoSmithKline.

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Screening Checklist for Traditional/Abbreviated 510(k) Submission

Title	Related Information	Present	Not Adequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet (FDA Form3601)	X		
CDRH Premarkert Review Submission Cover Sheet	CDRH Premarkert Review Submission Cover Sheet (FDS Form 3514)	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)'s" updated November 17, 2005	X		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	X		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E	X		
Truthful & Accuracy Statement	Device Advice "Content of a 510(k)" Section G	X		
Class III Summary & Certification	Class III Summary & Certification Form			X
Financial Certification or Disclosure Statement	FORM FDA3454 Certif.:Financial Interests/Arrangements of Clin Invs FORM FDA3455, Disclosure: Financial Interests/Arrangements of Clin Invs			X
Dec of Conformity & Summary Reports [Abbrev. 510(k)s]	Use of Stds in Substantial Equivalence Determinations. FDA Standards program. Dec of Conformity. Required Elements for Dec of Conformity to Recognized Std.			X
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equival. Discuss.	Guidance on CDRH Premarket Notification Review Program 6/30/86 (K86-3)	X		
Proposed Labeling	Device Advice "Content of a 510(k)" Section H	X		
Sterilization/Shelf life	Updated 510(k) Sterility Review Guidance (K90-1), & see Guidance for Industry	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices part I: Evaluation and Testing"	X		
Software	Guidance for Premarket Submissions for Software contained in MedDevices			X
ElectromagComp./Elect Safety	CDRH Medical Device Electromagnetic Compatibility Program			X
Performance Testing - Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing - Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X

Performance Testing - Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for FORM FDA 3454, FORM FDA 3455, or Disclosure			X
<u>FORM FDA 3564, Standards Data Report for 510(k)s</u> OTHER: FDA Form 3674	Stds Data Report Form 3654. No standard used – No Stds Form Required Dec of Conformity OR - Std but no dec – Yes Stds Form Required Form FDA 3674	X		X

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: B4 Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) GLAXOSMITHKLINE CONSUMER HEALTHCARE 1500 Littleton Road Parsippany NJ 07054 US		2. CONTACT NAME Paul Krumm 2.1 E-MAIL ADDRESS paul.a.krumm@gsk.com 2.2 TELEPHONE NUMBER (include Area code) 973-889 7339 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) B4			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <u>Select an application type:</u>			
<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 <u>Supplement Types:</u> <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 http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population.	
<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 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 type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION B4		29-Nov-2012	

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.		
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission 12/04/2012	User Fee Payment ID Number B4	FDA Submission Document Number (if known)		
SECTION A TYPE OF SUBMISSION				
PMA <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	PMA & HDE Supplement <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	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <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):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards In your submission? <input checked="" type="checkbox"/> Yes <input 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) 3008316718		
Division Name (if applicable) Consumer Healthcare		Phone Number (including area code) 973-889-7339		
Street Address 1500 Littleton Road		FAX Number (including area code)		
City Parsippany	State / Province NJ	ZIP/Postal Code 07054	Country USA	
Contact Name Paul Krumm				
Contact Title Regulatory Affairs Manager.		Contact E-mail Address paul.a.krumm@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		

FORM FDA 3514 (12/10)

Page 1 of 5 Pages

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Biotene Artificial Saliva Products Modifications

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

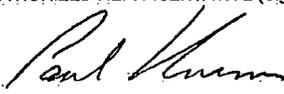
SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> 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"/> 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"/> 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"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Response to FDA correspondence:		
<input type="checkbox"/> Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> 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 type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change In Technology
<input checked="" type="checkbox"/> Other Reason (specify): Modifications to formulations.		

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 type="checkbox"/> 510 (k) summary attached <input checked="" type="checkbox"/> 510 (k) statement															
1	LFD	2		3		4																	
5		6		7		8																	
Information on devices to which substantial equivalence is claimed (if known)																							
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer																		
1	K061331	1	biotene Oral Balance Gel	1																			
2	K101477	2	biotene Dry Mouth Oral Rinse	2																			
3	K103745	3	biotene Moisturizing Mouth Spray	3																			
4		4		4																			
5		5		5																			
6		6		6																			
SECTION F										PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS													
Common or usual name or classification name Saliva, Artificial (Dental)																							
	Trade or Proprietary or Model Name for This Device											Model Number											
1	biotene Oral Balance Gel										1												
2	biotene Dry Mouth Oral Rinse										2												
3	biotene Moisturizing Mouth Spray										3												
4											4												
5											5												
FDA document numbers of all prior related submissions (regardless of outcome)																							
1	K061331	2	K101477	3	K103745	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 Oral Balance Gel: Relieves and helps protect against symptoms of dry mouth; soothes and protects oral tissues. biotene Dry Mouth Oral Rinse: Relieves symptoms of dry mouth, cleans, refreshes, soothes oral irritations, relieves oral dryness. biotene Moisturizing Mouth Spray: Relieves symptoms of dry mouth, refreshes and moistens, helps keep mouth fresh.																							

<p><i>Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.</i></p>		<p>FDA Document Number (if known)</p>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number B4	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name B4		Establishment Registration Number B4	
Division Name (if applicable)		Phone Number (including area code) B4	
Street Address B4		FAX Number (including area code) B4	
City B4		State / Province B	ZIP Code B4
		Country B4	
Contact Name B4 B4		Contact Title B4	Contact E-mail Address B4
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number B4	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name B4		Establishment Registration Number B4	
Division Name (if applicable)		Phone Number (including area code) B4	
Street Address B4		FAX Number (including area code) B4	
City B4		State / Province B	ZIP Code B4
		Country B4	
Contact Name B4		Contact Title B4	Contact E-mail Address B4
<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 Sterilizer <input type="checkbox"/> Contract Manufacturer <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

SECCIÓN I		UTILIZATION OF STANDARDS			
<p>Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.</p>					
1	Standards No. 10993-1	Standards Organization ISO	Standards Title Biological evaluations of medical devices Part 1: Evaluation and testing within a risk management process.	Version 10	Date 11/30/2010
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
<p>Please include any additional standards to be cited on a separate page.</p>					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;"> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 </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>					

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

 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 GlaxoSmithKline Consumer Healthcare (GSKCH)	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Dec 4, 2012	
3. ADDRESS (Number, Street, State, and ZIP Code) 1500 Littleton Road Parsippany, NJ 07054	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 973-889-2100 (Fax) 973-889-2501	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)		
biotene Oral Balance Gel <hr/> biotene Dry Mouth Oral Rinse <hr/> biotene Moisturizing Mouth Spray <hr/>		
APPLICATION/SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned) K061331 K101477 K103745		
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)		
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial. <input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies. <input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s): _____		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Paul Krumm (Title) Regulatory Affairs Manager	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 1500 Littleton Road Parsippany, NJ 07054	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 973-889-7339 (Fax) 973-889-2501	15. DATE OF CERTIFICATION Dec 4, 2012

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 413-6740 EF

Biotene Artificial Saliva Products Modifications

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

K-18 K123731

FDA CDRH DMC

DEC 05 2012

Received



GlaxoSmithKline

Consumer Healthcare
1500 Littleton Road
Parsippany, NJ
07054-3884

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

December 4, 2012

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
Attn: Dr. Susan Runner

Subject: Special 510(k):Device Modification

References: 510(k) K061331 biotene Oral Balance Gel – Cleared July 25, 2006
510(k) K101477 biotene Dry Mouth Oral Rinse – Cleared Sept 28, 2010
510(k) K103745 biotene Moisturizing Mouth Spray – Cleared July 20, 2011

Dear Dr. Runner:

GlaxoSmithKline Consumer Healthcare (GSKCH) hereby submits this **Special 510(k): Device Modification** to request modifications for our three previously cleared artificial saliva products (K061331, K101477, K103745). GSKCH at 1500 Littleton Road, Parsippany, New Jersey 07054, with facility registration number 3008316718, is the current holder of the aforementioned 510(k)'s. As per an October 11, 2012 phone conversation between FDA (Dr. Susan Runner) and Ms. Sandra Binns of GSKCH, it was agreed that the submission of one Special 510(k) which "bundled" these three 510(k)'s would be sufficient.

The modifications to these products are as follows:

- A slight adjustment of the pH to bring the formulations closer to the pH of natural saliva.
- The removal of the enzymes in order to have standard global formulations. All references to enzymes will subsequently be removed from all product labeling.
- Slight modifications to some of the moisturizers/humectants in order to have standard global formulations.
- Slight modifications to some of the preservatives, necessitated by the pH adjustment.

We believe these modifications are eligible for the Special 510(k) process since they continue to have the same fundamental scientific technology and intended use as the predicate devices.

We consider our intent to market these devices as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q). One hard copy of the Special 510(k) submission is enclosed, along with a PDF copy of the submission on CD.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at 973-889-7339 or e:Mail at paul.a.krumm@gsk.com. As an alternate contact if I am unavailable, please contact Ms. Sandra Binns, Director of Regulatory Affairs, GlaxoSmithKline Consumer Healthcare, by phone at 973-889-2421, or e:Mail at sandra.r.binns@gsk.com.

Sincerely,



Paul Krumm
Regulatory Affairs Manager
GlaxoSmithKline Consumer Healthcare
1500 Littleton Road
Parsippany, NJ 07054-3884
(973) 889-7339

Labeling and Intended Use

Draft labels and instructions for use can be found in Attachment 1.

The following changes have occurred to the labels:

- All references to the enzyme ingredients have been removed
- Reference to the pH adjustment has been added
- The ingredient listings reflect the new formulations

No changes have occurred to the instructions for use.

Intended Use

The biotene Oral Balance Gel, Dry Mouth Oral Rinse and Moisturizing Mouth Spray intended use is for the relief of the symptoms of dry mouth: refresh, moisturize, clean, sooth oral irritation, and lubricate oral dryness. This is the same intended use as previously cleared for the biotene Oral balance Gel [510(k) Number K061331], biotene Dry Mouth Oral Rinse [510(k) Number K101477] and biotene Moisturizing Mouth Spray [510(k) Number K103745].

The Indications for Use Statement can be found in Attachment 2.

Device Description and Comparison

Comparisons of the modified formulas to the current formulas can be found in Attachment 3.

The main modifications are:

- Removal of the enzyme ingredients
- Some use of alternate moisturizer/humectants ingredients
- Some use of alternate preservatives

There are no changes to the formulas that will affect the efficacy or safety of the devices. All the ingredients in both the current and proposed formulas are commonly used in US OTC oral care products, and have acceptable local tolerance. When considering the requirements of ISO 10993-1, additional testing would not be necessary.

Device comparison tables are also included in Attachment 3.

Substantial Equivalence

The modified artificial saliva products have the following similarities to those which previously received 510(k) clearance:

- Have the same intended use
- Have the same instructions for use
- Have the same contraindications, warnings and precautions

- Incorporate similarly functioning ingredients
- Have the same shelf life

In summary, the biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse and biotene Moisturizing Mouth Spray described in this submission are, in our opinion, substantially equivalent to the predicate devices. Substantial equivalence tables are included in Attachment 4.

Shelf Life

The shelf life of the devices with the proposed new formulas will be the same as the devices with the current formulas.

Summary of Design Control Activities

The risk analysis used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FEMA). The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 1 below:

Modification	Test Performed	Acceptance Criteria
Adjustment of pH (biotene Oral Balance Gel)	Test for pH	B4 [REDACTED]
Use of propylparaben preservative (biotene Oral Balance Gel)	Assay for propylparaben content	[REDACTED]
Adjustment of pH (biotene Dry Mouth Oral Rinse)	Test for pH	[REDACTED]
Use of methylparaben and propylparaben as additional preservatives (biotene Dry Mouth Oral Rinse)	Assays for methylparaben and propylparaben content	[REDACTED] for both methylparaben and propylparaben
Adjustment of pH (biotene Moisturizing Mouth Spray)	Test for pH	B4 [REDACTED]
Use of methylparaben, propylparaben and cetylpyridinium chloride as additional preservatives (biotene Moisturizing Mouth Spray)	Assays for methylparaben, propylparaben and cetylpyridinium chloride content	[REDACTED] for both methylparaben and propylparaben, and a B4 [REDACTED] [REDACTED] cetylpyridinium chloride

The test method used for pH is similar to that referenced in the original submission.
The preservatives are assayed using validated test methodology.

A declaration of conformity with design controls is included in Attachment 5.

510(k) Statement

A 510(k) Statement for the biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse and biotene Moisturizing Mouth Spray is included in Attachment 6.

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy of the biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse and biotene Moisturizing Mouth Spray described in this submission is included in Attachment 7

Attachment 1

Proposed and Current Labels and Instructions for Use

Proposed Tube Labeling for New biotene Oral Balance Gel Formula

biotene® Helps Soothe & Protect Oral Tissues

oralbalance®
DRY MOUTH MOISTURIZING GEL

NET WT 1.5 OZ (42 g)

Usage: Helps soothe and protect dry mouths against discomfort.
Contains a mouth moisturizing system to help relieve dry mouth symptoms.
Directions: Place approximately a half inch of the gel directly on the tongue and spread thoroughly inside the mouth. Use as required. Children 12 years and under: not for use unless directed by a healthcare professional. If symptoms of dry mouth persist, consult a healthcare professional.
Store below 25°C (77°F).
Note: Should be used after rinsing mouth. Use within 3 months after opening. Keep out of reach of children.
Questions or comments? call toll-free 1-800-822-6856 weekdays www.biotene.com

Distributed by:
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108 ©2012 GlaxoSmithKline

Usage: Soothes and protects dry mouth (issues) against oral irritation and burning sensations. Contains a protein-enzyme system and dissolves in mouth. **oralbalance® gel** can also be used under dentures to improve retention and comfort.*

Directions: Place approximately a half inch length of the gel directly on the tongue and spread thoroughly inside the mouth. Use gel as required for symptom relief, especially at night or as directed by a dentist or physician.

Children: 12 years and under, not for use unless directed by a healthcare professional.

Note: Should be used after rinsing mouth. Use within 3 months after opening. Helps denture wearers, mouth breathers, and is safe to swallow.

Warnings: Keep out of reach of children. If symptoms of dry mouth persist, consult a healthcare professional.

Ingredients: Water, Hydrogenated Starch Hydrolyzate, Glycerin, Xylitol, Butylene Glycol, Sodium Polyacrylate, Polyacrylic Acid, Hydroxyethyl Cellulose, Sorbic Acid, Benzocaine, L-lysine, Lactoferrin, Lactoperoxidase, Disodium Phosphate, Glucose Oxidase, Potassium Thiocyanate. Contains milk and egg derivatives.

Other information: store below 25°C (77°F). **www.biotene.com**

Based on 2006 Dry Mouth Survey.

100% Naturally Sweetened with Xylitol!

BIOTENE, ORALBALANCE, and DRY MOUTH GUM are registered trademarks of the GlaxoSmithKline group of companies. XYLITOL is a registered trademark of Danisco Sweeteners Oy.

Contains a Protein-Enzyme System

- Diminishes mouth odors
- Helps maintain the oral environment
- Helps provide protection against dry mouth symptoms

Beneficial to people experiencing Dry Mouth caused by:

- Diabetes
- Medications*
- Stress & Depression
- Drug / Radiation Therapies
- Sjogren's Syndrome

100% PROTEIN-ENZYMES FOR LONG LASTING RELIEF

For Moderate to Severe Dry Mouth Long Lasting Symptom Relief*

biotène oralbalance® DRY MOUTH MOISTURIZING GEL

NET WT 1.5 OZ (42g)

102258XA

Look for relief and cleaning with other Biotène® products including Biotène® Dry Mouth® fluoride toothpaste, Biotène® Mouth Spray, Biotène® Oral Rinse, Biotène® Dry Mouth Gum®.

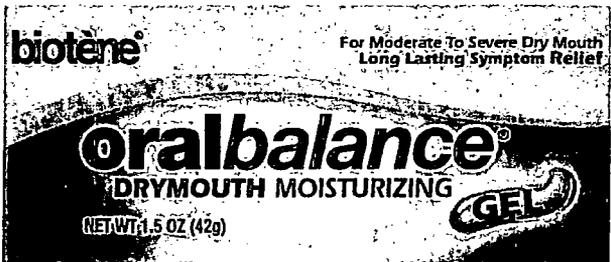
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 Moon Township, PA 15108
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Questions or comments? call toll free 1-800-922-5856 weekdays

0 48582 51201 6

Carton Labeling for Current biotene Oral Balance Gel Formula

Tube Labeling for Current biotene Oral Balance Gel Formula



The image shows a rectangular product label for Biotene Oral Balance Gel. At the top left is the 'biotene' logo. To the right, it says 'For Moderate To Severe Dry Mouth Long Lasting Symptom Relief'. The main product name 'Oralbalance' is in large, bold letters, with 'DRYMOUTH MOISTURIZING GEL' underneath. A small 'NET WT. 1.5 OZ (42g)' is printed at the bottom left of the product image area.

Usage: Soothes and protects dry mouth tissues against minor irritations and burning sensations. Contains Protein-Enzyme System and diminishes mouth odors.
Directions: Place approximately a half inch of the gel directly on the tongue and spread thoroughly inside the mouth. Use as required. Safe to swallow. Children 12 years and under: not for use unless directed by a healthcare professional. If symptoms of dry mouth persist, consult a healthcare professional. Store below 25°C (77°F).
Note: Should be used after rinsing mouth. Use within 3 months after opening. Keep out of reach of children. Contains milk and egg derivatives.
Questions or comments? call toll free 1-800-922-5858 weekdays www.biotene.com
Distributed by:
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Township, PA 15108 ©2011 GlaxoSmithKline 96848XC

Instructions for Use: Proposed New Biotene Oral Balance Gel Formula

Directions: Place approximately a half inch length of the gel directly on the tongue and spread thoroughly inside the mouth. Use gel as required for symptom relief, especially at night or as directed by a dentist or physician. Children 12 years and under: not for use unless directed by a healthcare professional.

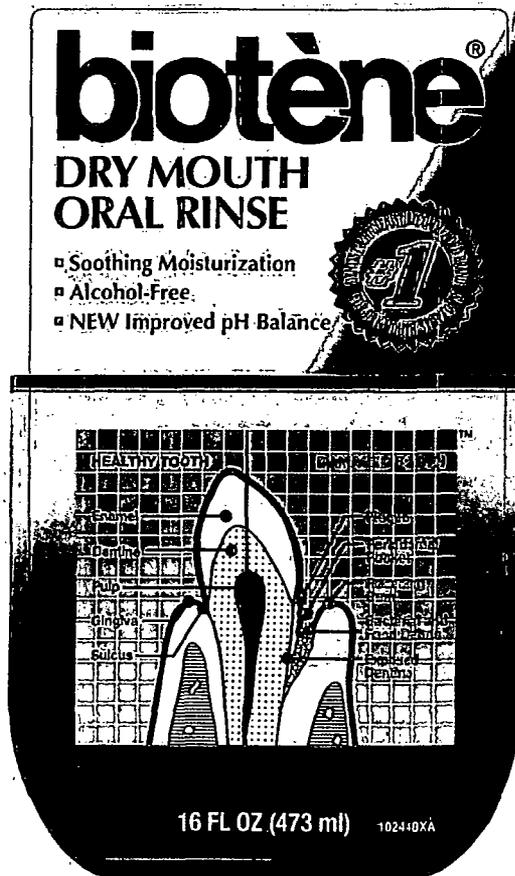
Note: Should be used after rinsing mouth. Use within 3 months after opening.

Instructions for Use: Current Biotene Oral Balance Gel Formula

Directions: Place approximately a half inch length of the gel directly on the tongue and spread thoroughly inside the mouth. Use gel as required for symptom relief, especially at night or as directed by a dentist or physician. Children 12 years and under: not for use unless directed by a healthcare professional.

Note: Should be used after rinsing mouth. Use within 3 months after opening.

Proposed Bottle Front Labeling for New biotène Dry Mouth Oral Rinse Formula



Proposed Bottle Back Labeling for New biotene Dry Mouth Oral Rinse Formula

biotene #1 Dentist & Hygienist Recommended Brand for Dry Mouth Symptoms

DRY MOUTH ORAL RINSE

An oral rinse with a soothing gentle feel that cleans, refreshes and relieves dryness and soothes oral irritations. *biotene* contains a combination of moisturizers and humectants to help relieve dryness.

Also look for other *biotene* products including *biotene* Toothpaste, *biotene* oralbalance Gel, *biotene* Mouth Spray, *biotene* oralbalance Liquid and *biotene* Gum. *biotene* is specially formulated for individuals who experience dry mouth symptoms.

DIRECTIONS:
Adults: Use approximately one tablespoon, rinse for 30 seconds then spit out. Use up to 5 times per day unless otherwise instructed by a healthcare professional.
Children 12 years and under: Do not use unless directed by a healthcare professional.

WARNINGS: If symptoms of dry mouth persist, consult a healthcare professional. **Keep out of reach of children.** Do not swallow. Do not use if you are allergic to any of the ingredients.

INGREDIENTS: Purified Water, Glycerin, Xylitol, Sorbitol, Propylene Glycol, Poloxamer 407, Sodium Benzoate, Hydroxyethyl Cellulose, Methylparaben, Propylparaben, Flavor, Sodium Phosphate, Disodium Phosphate

CONTAINS NO SACCHARIN
Sweetened with xylitol and sorbitol
Store Below 25°C (77°F)

DO NOT USE IF SHRINK SLEEVE IS MISSING

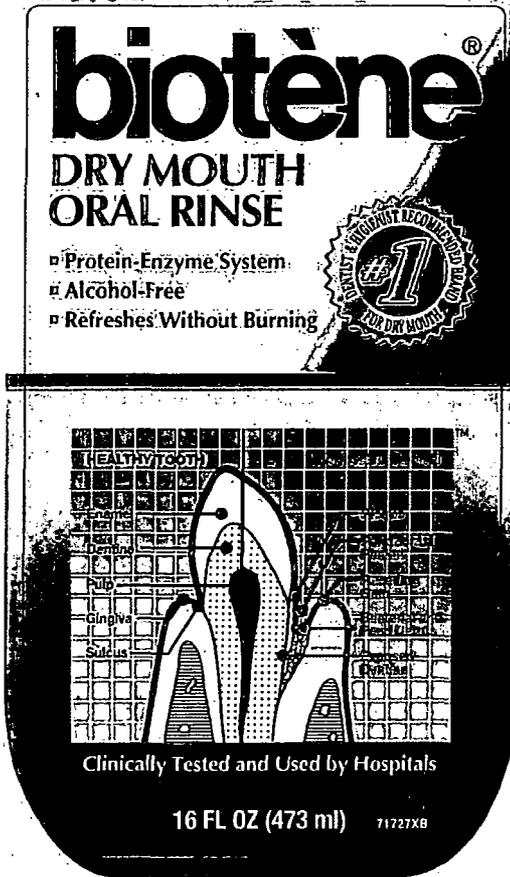
Questions or comments?
call toll-free 1-800-922-5856 weekdays
www.biotene.com

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Moon Township, PA 15108
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Bottle Front Labeling for Current biotene Dry Mouth Oral Rinse Formula



Bottle Back Labeling for Current biotene Dry Mouth Oral Rinse Formula

biotène #1 Dentist & Hygienist Recommended Brand for Dry Mouth

DRY MOUTH ORAL RINSE

Imagine an oral rinse with a soothing gentle feel containing beneficial enzymes - an oral rinse that cleans, refreshes and relieves dryness and soothes oral irritations. That oral rinse is *biotène*. Only *biotène* contains beneficial enzymes found in saliva to help maintain the oral environment and help relieve dryness.

Also look for relief with other *biotène* products including *biotène* Toothpaste, *biotène* oralbalance Gel and *biotène* Mouth Spray. *biotène* is specially formulated for individuals that experience dry mouth symptoms.

DIRECTIONS:
Adults: Use approximately one tablespoon, rinse for 30 seconds then spit out. Use up to 5 times per day unless otherwise instructed by a healthcare professional.
Children 12 years and under: Do not use unless directed by a healthcare professional.

WARNINGS: If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children. Do not swallow.

INGREDIENTS: Purified Water, Propylene Glycol, Xylitol, Hydrogenated Starch Hydrolysate, Poloxamer 407, Hydroxyethylcellulose, Sodium Benzoate, Flavor (Peppermint Oil), Benzoic Acid, Disodium Phosphate, Zinc Gluconate, Lactoferrin, Lysozyme, Lactoperoxidase, Potassium Thiocyanate, Aloe Vera Gel, Calcium Lactate, Glucose Oxidase. Contains milk & egg derivatives.

CONTAINS NO SACCHARIN
Store Below 25°C (77°F)

DO NOT USE IF SHRINK SLEEVE IS MISSING

Questions or comments?
call toll-free 1-800-922-5858 weekdays
www.biotene.com

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Moon Township, PA 15108
©2010 GlaxoSmithKline

Naturally Sweetened with Xylitol



0 48582 00330 9

68616XB

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Xylitol is a trademark of Danisco Sweeteners Oy

Instructions for Use: Proposed New Biotene Dry Mouth Oral Rinse Formula

Directions: **Adults:** Use approximately one tablespoon, rinse for 30 seconds then spit out. Use up to 5 times per day unless otherwise instructed by a healthcare professional.

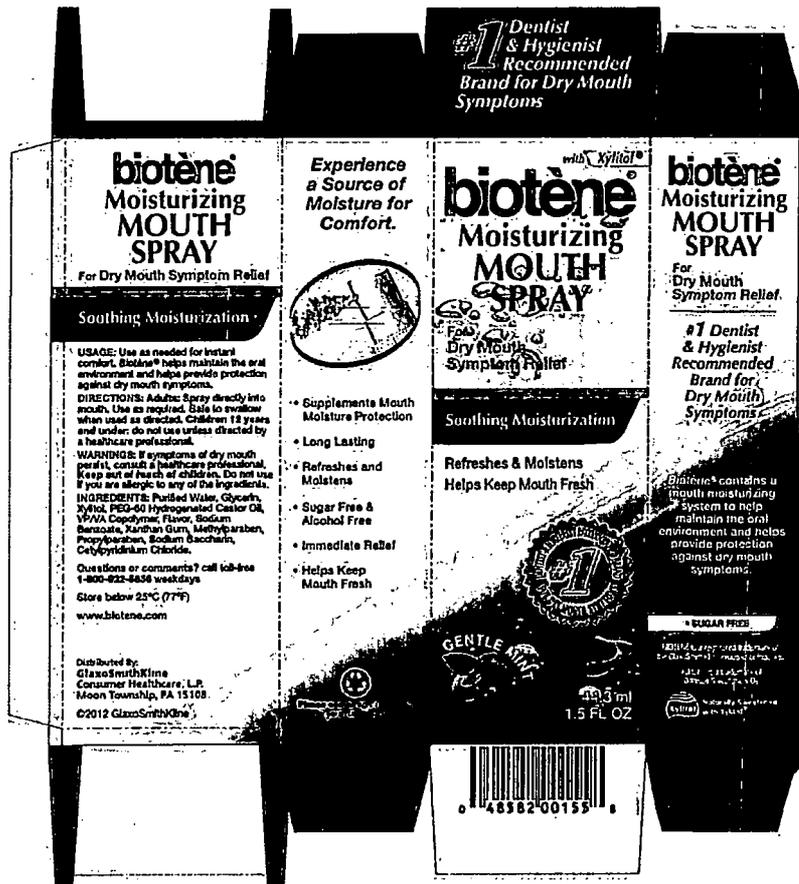
Children 12 years and under: Do not use unless directed by a healthcare professional.

Instructions for Use: Current Biotene Oral Balance Gel Formula

Directions: **Adults:** Use approximately one tablespoon, rinse for 30 seconds then spit out. Use up to 5 times per day unless otherwise instructed by a healthcare professional.

Children 12 years and under: Do not use unless directed by a healthcare professional.

Proposed Carton Labeling for New biotene Moisturizing Mouth Spray Formula



Proposed Bottle Front and Back Labeling for New biotène Moisturizing Mouth Spray Formula

with Xylitol®

biotène

Moisturizing MOUTH SPRAY

For Dry Mouth Symptom Relief

Soothing Moisturization

Refreshes & Moistens
Helps Keep Mouth Fresh

GENTLE MINT

44.3 ml / 1.5 FL OZ

† Dentist & Hygienist Recommended Brand For Dry Mouth Symptoms

DIRECTIONS: Adults: Spray directly into mouth. Use as required. Safe to swallow when used as directed. Children 12 years and under: consult a healthcare professional.

WARNINGS: If history of dry mouth persists, consult a healthcare professional. Keep out of reach of children. Do not use if you are allergic to any of the ingredients. Contains a mouth moisturizing system to help relieve dry mouth symptoms. Biotène® Mouth Spray helps maintain the oral environment and provides relief against dry mouth symptoms.

† SUGAR FREE †

Xylitol Naturally Sweetened with Xylitol®

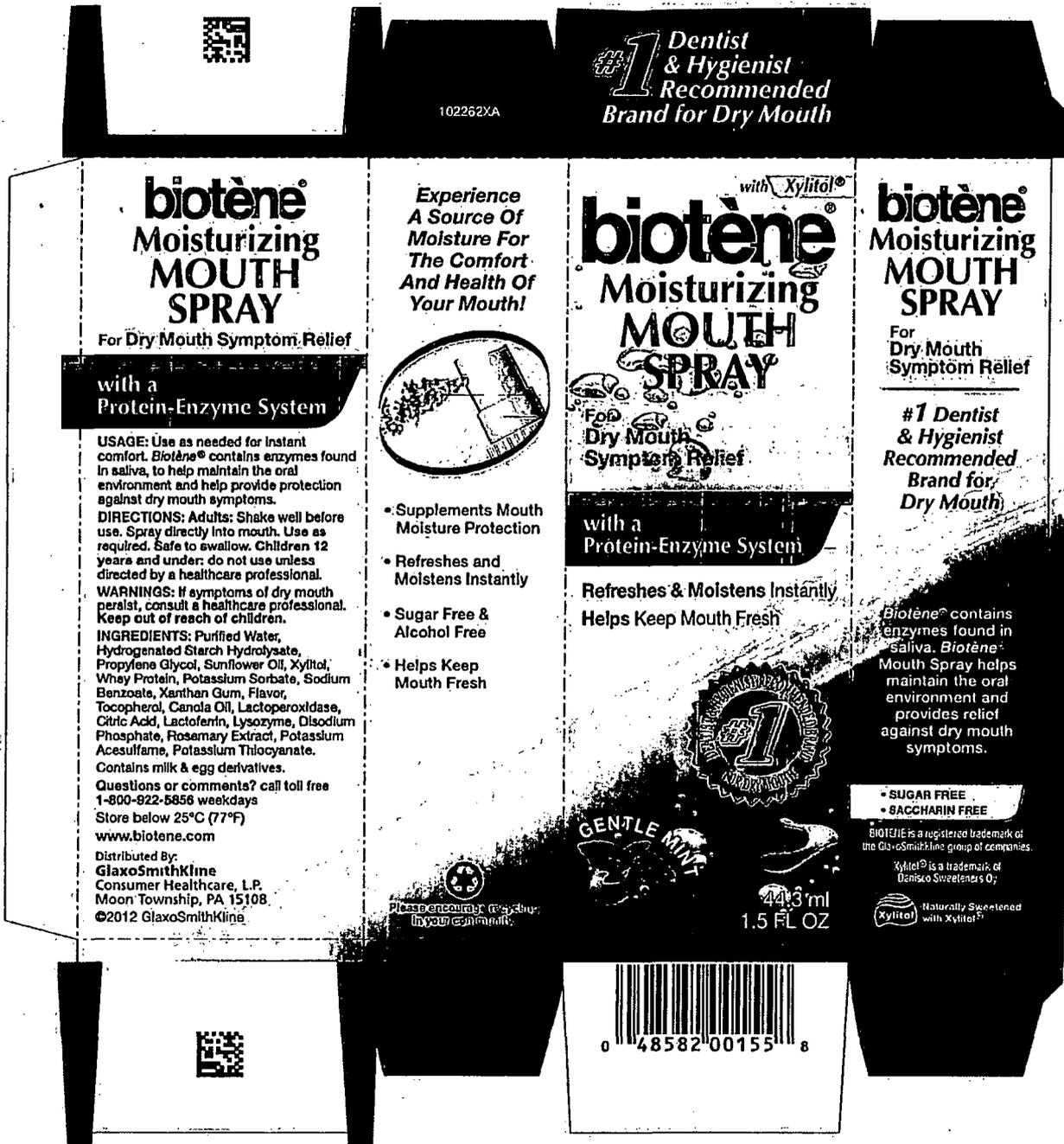
BIOTÈNE is a registered trademark of the GlaxoSmithKline group of companies. **Xylitol** is a trademark of Danisco Sweeteners Oy.

Questions or comments? call toll-free 1-800-822-8658 weekdays
Store below 25°C (77°F)

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Moon Township, PA 15108

www.biotene.com
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Carton Labeling for Current biotene Moisturizing Mouth Spray Formula



102262XA

#1 Dentist & Hygienist Recommended Brand for Dry Mouth

biotene
Moisturizing
MOUTH SPRAY

For Dry Mouth Symptom Relief

with a
Protein-Enzyme System

USAGE: Use as needed for instant comfort. Biotene® contains enzymes found in saliva, to help maintain the oral environment and help provide protection against dry mouth symptoms.

DIRECTIONS: Adults: Shake well before use. Spray directly into mouth. Use as required. Safe to swallow. Children 12 years and under: do not use unless directed by a healthcare professional.

WARNINGS: If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children.

INGREDIENTS: Purified Water, Hydrogenated Starch Hydrolysate, Propylene Glycol, Sunflower Oil, Xylitol, Whey Protein, Potassium Sorbate, Sodium Benzoate, Xanthan Gum, Flavor, Tocopherol, Canola Oil, Lactoperoxidase, Citric Acid, Lactoferrin, Lysozyme, Disodium Phosphate, Rosemary Extract, Potassium Acesulfame, Potassium Thiocyanate. Contains milk & egg derivatives.

Questions or comments? call toll free 1-800-822-5858 weekdays

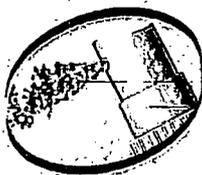
Store below 25°C (77°F)

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Moon Township, PA 15108
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Experience
A Source Of
Moisture For
The Comfort
And Health Of
Your Mouth!



- Supplements Mouth Moisture Protection
- Refreshes and Moistens Instantly
- Sugar Free & Alcohol Free
- Helps Keep Mouth Fresh

with Xylitol®
biotene
Moisturizing
MOUTH SPRAY

For Dry Mouth Symptom Relief

with a
Protein-Enzyme System

Refreshes & Moistens Instantly
Helps Keep Mouth Fresh



GENTLE MINT

44.3 ml
1.5 FL OZ

biotene
Moisturizing
MOUTH SPRAY

For Dry Mouth Symptom Relief

#1 Dentist & Hygienist Recommended Brand for Dry Mouth

Biotene® contains enzymes found in saliva. Biotene® Mouth Spray helps maintain the oral environment and provides relief against dry mouth symptoms.

- SUGAR FREE
- SACCHARIN FREE

BIOGENE is a registered trademark of the GlaxoSmithKline group of companies.

Xylitol® is a trademark of Danisco Sweeteners OJ.



Naturally Sweetened with Xylitol®



0 48582 00155 8



Bottle Front and Back Labeling for Current biotene Moisturizing Mouth Spray Formula

with Xylitol®

biotene
Moisturizing
**MOUTH
SPRAY**

For Dry Mouth Symptom Relief

with a Protein-Enzyme System

Refreshes & Moistens Instantly
Helps Keep Mouth Fresh

GENTLE MINT

44.3 ml / 1.5 FL OZ

#1 Dentist & Hygienist Recommended Brand For Dry Mouth

DIRECTIONS: Adults: Shake well before use. Spray directly into mouth, 3-5 times as required. Safe to swallow. Children 12 years and under: consult a healthcare professional.

WARNINGS: If symptoms of dry mouth persist, consult a healthcare professional. Keep out of reach of children.

Biotene® contains protein-enzymes found in saliva. Biotene® Mouth Spray helps maintain the oral environment and provides relief against dry mouth symptoms. Contains milk & egg derivatives.

SUGAR FREE • SACCHARIN FREE

Naturally Sweetened with Xylitol®

102261XA

www.biotene.com

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Moon, Township, PA 15108

BOTENE is a registered trademark of the GlaxoSmithKline group of companies.
Xylitol® is a trademark of Dantone Sweeteners Co.
Questions or comments? call toll free 1-800-822-8658, weekdays
9am to 5pm EST (774)

Instructions for Use: Proposed New Biotene Moisturizing Mouth Spray Formula

Directions: **Adults:** Spray directly into mouth. Use as required. Safe to swallow when used as directed.
Children 12 years and under: Do not use unless directed by a healthcare professional.

Instructions for Use: Current Biotene Moisturizing Mouth Spray Formula

Directions: **Adults:** Shake well before use. Spray directly into mouth. Use as required. Safe to swallow.
Children 12 years and under: Do not use unless directed by a healthcare professional.

Attachment 2

Indications for Use Statement

Indications for Use Statement

510(k) Number (If known): K123731

Devices Names: biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse, biotene Moisturizing Mouth Spray

Indications for Use: The biotene Oral Balance Gel, biotene Dry Mouth Oral Rinse and biotene Moisturizing Mouth Spray intended use is to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

AND/OR

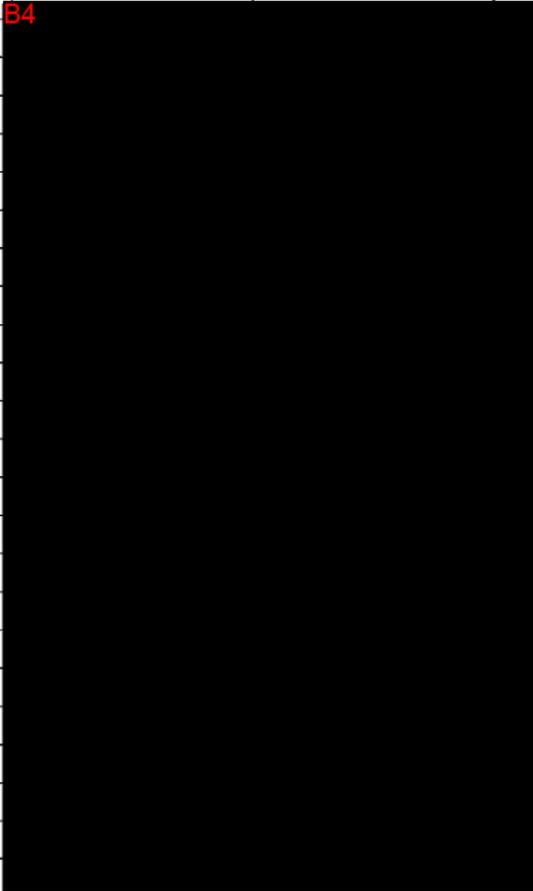
Over-The-Counter Use _____

Attachment 3

Formula and Device Comparisons

**Formula Comparison of Proposed New biotene Oral Balance Gel
Formula with Current biotene Oral Balance Gel Formula**

Ingredient	Proposed %w/w	Current %w/w
Water		
Glycerin		
Sorbitol Solution		
Hydrogenated Starch Hydrolysate		
Xylitol		
Butylene Glycol		
Carbomer		
Sodium Polyacrylate		
Polyacrylic Acid		
Hydroxyethyl Cellulose		
Sodium Hydroxide		
Propylparaben		
Sorbic Acid		
Benzoic Acid		
Lactoperoxidase		
Lysozyme		
Lactoferrin		
Glucose Oxidase		
Disodium Phosphate		
Potassium Thiocyanate		
TOTAL		



Device Comparison Table: biotene Oral Balance Gel: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

FUNCTION	BIOTENE ORAL BALANCE GEL (Proposed Formula)	BIOTENE ORAL BALANCE GEL (Current Formula) 510(k) # K061331	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
Solvent/Conditioning Agent	Water	Water	Water
Humectants and/or Moisturizers	Glycerin	Glycerin Hydrogenated Starch Hydrolysate*	Glycerin
Sweeteners/Humectants	Xylitol Sorbitol	Xylitol	Xylitol
Thickeners/Binders	Hydroxyethyl Cellulose Carbomer	Hydroxyethyl Cellulose Polyacrylic Acid	
Preservatives	Propylparaben	Benzoic Acid Sorbic Acid	Sodium Benzoate
Conditioning Agents and/or Emollients		Butylene Glycol Sodium Polyacrylate	
pH adjusters or Buffers	Sodium Hydroxide	Disodium Phosphate	Calcium Hydroxide
Protein or protein-like material		Lactoferrin	
Enzymes		Lactoperoxidase Lysozyme Glucose Oxidase	
Enzyme Substrate		Potassium Thiocyanate	
Flavor			Flavor
Color			Color

*Hydrogenated Starch Hydrolysate = polyglycitol syrup, consisting mainly of sorbitol/maltitol

**Formula Comparison of Proposed biotene Dry Mouth Oral Rinse
Formula with Current biotene Dry Mouth Oral Rinse Formula**

Ingredient	Proposed %w/w	Current %w/w
	B4	
Water		
Glycerin		
Xylitol		
Sorbitol Solution		
Propylene Glycol		
Hydrogenated Starch Hydrolysate		
Poloxamer 407		
Sodium Benzoate		
Hydroxyethyl Cellulose		
Methylparaben		
Propylparaben		
Benzoic Acid		
B4		
Sodium Phosphate		
Disodium Phosphate		
Lysozyme		
Lactoferrin		
Lactoperoxidase		
Glucose Oxidase		
Zinc Gluconate		
Potassium Thiocyanate		
Aloe Vera		
Calcium Lactate		
TOTAL		

Device Comparison Table: biotene Dry Mouth Oral Rinse: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

FUNCTION	BIOTENE DRY MOUTH ORAL RINSE (Proposed Formula)	BIOTENE DRY MOUTH ORAL RINSE (Current Formula) 510(k) # K101477	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
Solvent/Conditioning Agent	Water	Water	Water
Humectants and/or Moisturizers	Glycerin Propylene Glycol	Hydrogenated Starch Hydrolysate* Propylene Glycol Aloe Vera	Glycerin
Sweeteners/Humectants	Xylitol Sorbitol	Xylitol	Xylitol
Thickeners/Binders	Hydroxyethyl Cellulose	Hydroxyethyl Cellulose	
Surfactant	Poloxamer 407	Poloxamer 407	
Preservatives	Sodium Benzoate Methylparaben Propylparaben	Sodium Benzoate	Sodium Benzoate
Flavor	Flavor	Flavor	Flavor
pH adjusters or Buffers	Disodium Phosphate Sodium Phosphate	Disodium Phosphate Benzoic Acid Zinc Gluconate Calcium Lactate	Calcium Hydroxide
Protein or protein-like material		Lactoferrin	
Enzymes		Lysozyme Lactoperoxidase Glucose Oxidase	
Enzyme Substrate		Potassium Thiocyanate	
Color			Color

*Hydrogenated Starch Hydrolysate = polyglycitol syrup, consisting mainly of sorbitol/maltitol

Formula Comparison of Proposed biotene Moisturizing Mouth Spray Formula with Current biotene Moisturizing Mouth Spray Formula

Ingredient	Proposed %w/w	Current %w/w
Water	B4	
Glycerin		
Hydrogenated Starch Hydrolysate		
Xylitol		
Propylene Glycol		
Sunflower Oil		
PEG-60 Hydrogenated Castor Oil		
Whey Protein		
VP/VA Copolymer		
B4		
Sodium Benzoate		
Xanthan Gum		
Methylparaben		
Propylparaben		
Sodium Saccharin		
Cetylpyridinium Chloride		
Potassium Sorbate		
Tocopherols in Canola Oil		
Lysozyme		
Lactoferrin		
Lactoperoxidase		
Citric Acid		
Disodium Phosphate		
Rosemary Extract		
Potassium Acesulfame		
Potassium Thiocyanate		
TOTAL		

Device Comparison Table: biotene Moisturizing Mouth Spray: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

FUNCTION	BIOTENE MOISTURIZING MOUTH SPRAY (Proposed Formula)	BIOTENE MOISTURIZING MOUTH SPRAY (Current Formula) 510(k) # K103745	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
Solvent/Conditioning Agent	Water	Water	Water
Humectants and/or Moisturizers	Glycerin	Hydrogenated Starch Hydrolysate* Propylene Glycol Sunflower Oil Tocopherol Canola Oil Rosemary Extract	Glycerin
Sweetener/Humectant	Xylitol	Xylitol	Xylitol
Thickeners/ Binders		Xanthan Gum	
Surfactant	PEG-60 Hydrogenated Castor Oil		
Lubricating Agents	Copovidone (VP/VA Copolymer) Xanthan Gum		
Preservatives	Sodium Benzoate Cetylpyridinium Chloride Methylparaben Propylparaben	Sodium Benzoate Potassium Sorbate	Sodium Benzoate
Flavor	Flavor	Flavor	Flavor
pH adjusters or Buffers		Disodium Phosphate Citric Acid	Calcium Hydroxide
Protein or protein-like material		Lactoferrin Whey Protein	
Enzymes		Lysozyme Lactoperoxidase	
Enzyme Substrate		Potassium Thiocyanate	
Sweetener	Sodium Saccharin	Potassium Acesulfame	
Color			Color

*Hydrogenated Starch Hydrolysate = polyglycitol syrup, consisting mainly of sorbitol/maltitol

Attachment 4

Substantial Equivalence Comparisons

Substantial Equivalence Table: biotene Oral Balance Gel: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

PRODUCT	BIOTENE ORAL BALANCE GEL (Proposed Formula)	BIOTENE ORAL BALANCE GEL (Current Formula) 510(k) # K061331	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
INTENDED USE	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia
METHOD OF USE	Ready to use gel	Ready to use gel	Ready to use gel, liquid, spray
APPLICATIONS PER DAY	As needed	As needed	As needed
DISEASE STATE	Xerostomia	Xerostomia	Xerostomia
AREA OF USE	Oral cavity	Oral cavity	Oral cavity
TYPE OF PRODUCT	Gel	Gel	Gel, liquid, spray
PRESENTATION	Non-sterile	Non-sterile	Non-sterile
CONTAIN ENZYMES	No	Yes	No

Substantial Equivalence Table: biotene Dry Mouth Oral Rinse: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

PRODUCT	BIOTENE DRY MOUTH ORAL RINSE (Proposed Formula)	BIOTENE DRY MOUTH ORAL RINSE (Current Formula) 510(k) # K101477	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
INTENDED USE	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia
METHOD OF USE	Ready to use liquid	Ready to use liquid	Ready to use liquid, gel spray
APPLICATIONS PER DAY	Up to 5 times a day	Up to 5 times a day	As needed
DISEASE STATE	Xerostomia	Xerostomia	Xerostomia
AREA OF USE	Oral cavity	Oral cavity	Oral cavity
TYPE OF PRODUCT	Liquid	Liquid	Liquid, gel, spray
PRESENTATION	Non-sterile	Non-sterile	Non-sterile
CONTAINS ENZYMES	No	Yes	No

Substantial Equivalence Table: biotene Moisturizing Mouth Spray: Proposed Formula versus Current (Predicate) Formula and Oral Neutralizer Predicate Formula

PRODUCT	BIOTENE MOISTURIZING MOUTH SPRAY (Proposed Formula)	BIOTENE MOISTURIZING MOUTH SPRAY (Current Formula) 510(k) # K103745	ORAL NEUTRALIZER (Predicate) 510(k) # K071617
INTENDED USE	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia	Symptomatic treatment of Xerostomia
METHOD OF USE	Ready to use spray	Ready to use spray	Ready to use spray, liquid, gel
APPLICATIONS PER DAY	As needed	As needed	As needed
DISEASE STATE	Xerostomia	Xerostomia	Xerostomia
AREA OF USE	Oral cavity	Oral cavity	Oral cavity
TYPE OF PRODUCT	Spray	Spray	Spray, liquid, gel
PRESENTATION	Non-sterile	Non-sterile	Non-sterile
CONTAINS ENZYMES	No	Yes	No

Attachment 5

Declaration of Conformity with Design Controls

Declaration of Conformity with Design Controls

**Verification
Activities**

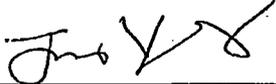
To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.


PAUL KRUMM
RA MANAGER
GLAXOSMITHKLINE

29 Nov 2012

**Manufacturing
Facility**

The manufacturing facility, Ultradent Products, Inc./Oratech LLC, a contract manufacturer for GlaxoSmithKline Consumer Healthcare, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.


[Print Name] JENNA YANG [Date]
[Title] PRINCIPAL SCIENTIST
[Company] GLAXOSMITHKLINE

29 Nov 2012

Declaration of Conformity with Design Controls

**Verification
Activities**

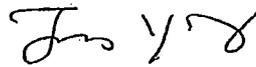
To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.


PAUL KRUMM
RA MANAGER
GLAXOSMITHKLINE

29 NOV 2012

**Manufacturing
Facility**

The manufacturing facility, Marietta Corporation, a contract manufacturer for GlaxoSmithKline Consumer Healthcare, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.


[Print Name] JENNA YANG
[Title] PRINCIPAL SCIENTIST
[Company] GLAXOSMITHKLINE

29 NOV 2012
[Date]

Attachment 6

510(k) Statement

510(k) Statement

Statement

I certify that, in my capacity as Regulatory Affairs Manager of GlaxoSmithKline Consumer Healthcare, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the devices described in the premarket notification are determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61



Paul Krumm

30 Nov 2012

Date

Attachment 7

Certificate of Truthfulness and Accuracy

Certification of Truthfulness and Accuracy

Pursuant to 21 CFR 807.87(j), I Paul Krumm, certify that to the best of my knowledge and belief, and based upon the data and information submitted to me in the course of my responsibilities as Regulatory Affairs Manager of GlaxoSmithKline Consumer Healthcare, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate, and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Paul Krumm

30 Nov 2012

Date