



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K101346 - 75 pages
COMPANY: GC AMERICA, INC. (GCAMER)
PRODUCT: SALIVA, ARTIFICIAL (LFD)
SUMMARY: Product: GC ORAL MOISTURIZING GEL

DATE REQUESTED: Aug 24, 2015

DATE PRINTED: Aug 24, 2015

Note: Printed





R101346

JAN 27 2011

GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

Section 6 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
Fax: (708) 897-4031

Date Prepared: May 7, 2010

2. Device Name:

Proprietary Name: GC Oral Moisturizing Gel
Classification Name: Saliva, Artificial
Device Classification: Unclassified
Produce Code: LFD

3. Predicate Devices:

Company	Device	K Number
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Lacled, inc.	K061331

4. Description of Device:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

GC Oral Moisturizing Gel is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

5. Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

6. Technological characteristics:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

7. Summary of Physical tests:

Summary of Performance Specification

	Consistency (mm)	pH
GC Oral Moisturizing Gel	32.5	7.2
BioXtra Moisturizing Gel	26.5	5.4
Oral Balance Gel	28.0	5.6

According to GC Corporation R & D test methods.

Moisture Desorption Assay

0.4g of products were placed on a weighing dish and weighed followed by incubation under the condition of humidity of 20% and a temperature of 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree. The results obtained are shown below.

GC Dry Mouth Gel: 6.9%

Biotene Oral Balance: 10.1%

8. Description of Safety and Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

All of the chemical components that constitute GC Oral Moisturizing Gel are previously used in the predicate devices which are legally marketed for the same indications and the same type of tissue contact. We believe that this fact well supports the compatibility of GC Oral Moisturizing Gel, and the safety of the applicant device is substantially equivalent to the predicate devices.

GC Oral Moisturizing gel is a wetting/moisturizing device.

Section 9 - Specifications and Substantial Equivalence Comparison

Specifications and Substantial Equivalence Comparison

1. Device description and Intended Use

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

The applicant device, GC Oral Moisturizing Gel, is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

2. Components and Mode of Action

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

All of the chemical components that constitute GC Oral Moisturizing Gel are:

Chemical Formulation

GC Oral Moisturizing Gel

Component	Weight %	Predicate devices in prior use
Polyglycerol (Diglycerol)	60	
Pure Water	36	GC MI Paste Plus (K070854)
Sodium carboxymethylcellulose	2.5	GC MI Paste Plus (K070854)
Carrageenan*	1.5	
Sodium Citrate	<0.5	
Flavour	<0.5	
Ethyl p-hydroxybenzoate	<0.1	GC MI Paste Plus (K070854)

*Carrageenan is a thickening agent, CAS# 9000-07-1



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

Dr. Mark Heiss
Director, Academic & Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

JAN 27 2011

Re: K101346
Trade/Device Name: GC Oral Moisturizing Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: December 8, 2010
Received: December 9, 2010

Dear Dr. Heiss:

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- Dr. Heiss

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

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

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

Sincerely yours,



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

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K101346

Device Name: GC Oral Moisturizing Gel

Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K101346

Smallwood, Senora F.

From: Smallwood, Senora F.
Sent: Wednesday, December 01, 2010 5:10 PM
To: 'mark_heiss@gcamerica.com'
Subject: 101346 - Extension Request

Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs
GC America, Inc.
3737 West 127th Street
Alsip, IL 60803

Re: K101346

Dear Dr. Heiss:

We granted you the maximum extension allowed (180 days) from the date of the additional information request June 23, 2010. The extension granted was until December 20, 2010. Unfortunately we can not grant another 90 day extension per the guidance document (below).

Please feel free to contact me with any questions at 301-796-5640. In addition, I have included an excerpt from our guidance document, Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment, below concerning extension request for additional information request responses.

D. Industry Requests an Extension of Time to Respond to an FDA Letter Requesting Additional Information

An industry request for an extension of time to respond to an AI letter informs the agency of the 510(k) submitter's wish to extend the response time identified in FDA's request.

1. Basis for the Request

In the past, FDA has not strictly enforced the 30 day timeframe identified in requests for AI and has allowed submitters additional time to respond to such requests. The agency intends to continue to allow additional time for responses. If the submitter needs more than 90 days to respond to the deficiencies in an AI letter, the submitter should send a letter requesting an extension to the Document Mail Center.

Note: FDA intends to issue a notice of withdrawal if it does not receive a request for additional time.¹⁵ (Refer to section IV. E. Issue a Notice of Withdrawal for additional discussion of FDA actions regarding requests for extension.) Even in those situations where a submitter does request an

extension, FDA does not intend to keep 510(k)s indefinitely on hold while awaiting the AI. Therefore, in general, FDA intends to issue a notice of withdrawal if the submitter, who has requested an extension, fails to provide a complete response within 180 days from the date of the AI request.

2. Effect on Review Clock

A request for an extension of time to respond to an AI request does not affect the FDA review clock because the 510(k) remains on hold.

3. Effect on MDUFMA Goals

Industry's submission of a request for an extension has no effect on the MDUFMA goals because this action does not affect the review clock.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of a request. As explained in Section IV. E., FDA generally permits submitters additional time to respond to such requests.

Best regards,

/s/

Senora F. Smallwood
Consumer Affairs Specialist
510(k) Staff
Office of Device Evaluation

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

*Senora F. Smallwood
510K Staff
Office of Device Evaluation*

K101346



GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

November 17, 2010

FDA CDRH DMC
NOV 23 2010
Received

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

RE: GC Oral Moisturizing Gel
510k Number : K101346

Document Mail Center:

GC America would like a 180 day cycle extension to the FDA's additional information request regarding flavoring.

This extension is necessary because not all of the information is readily available, and we require extra time to gather all the necessary information to properly respond to your request.

If you have any questions, please contact me at (708) 897-4042 or by e-mail at mark_heiss@gcamerica.com.

Sincerely,

GC AMERICA INC.

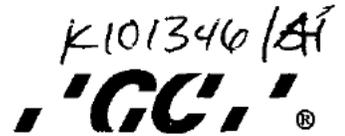
Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs

MH/II

cc: Myra Brown

K24





GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

August 24, 2010

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

FDA CDRH DMC

AUG 25 2010

Subject: GC Oral Moisturizing Gel
510(k) Number: K101346

Received

Dear Ms Shulman:

This letter is in response to the FDA notification dated June 23, 2010. Below are our responses to each of the five issues as presented to us by Ms Myra Browne, FDA Reviewer.

1. We have revised Section 6 – 510(k) Summary to adhere to 21 CFR 807.92. See attachment.
2. The only difference between the RX and OTC labeling is that the RX box label contains the required caution statement, the OTC version does not.
3. We have added a table comparing physical properties of GC Oral Moisturizing Gel to the predicate devices to both the 510(k) and the Summary. See attachment.
4. [REDACTED] (b)(4)
5. GC Moisturizing Gel is a wetting/moisturizing agent/device.

The above responses should now meet your requirements. Please let me know if you have any questions.

Sincerely,

GC AMERICA INC.

Mark A. Heiss, D.D.S.
Director – Academic and Regulatory Affairs

KSO

MAH/II
Enclosures

25





R101346

GC AMERICA INC.
 3737 WEST 127TH STREET
 ALSIP, ILLINOIS 60803
 TEL (708) 597-0900
 FAX (708) 371-5103

Section 6 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

GC AMERICA INC.
 3737 W. 127th Street
 Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
 Phone: (708) 897-4042
 Fax: (708) 897-4031

Date Prepared: May 7, 2010

2. Device Name:

Proprietary Name: GC Oral Moisturizing Gel
 Classification Name: Saliva, Artificial
 Device Classification: Unclassified
 Produce Code: LFD

3. Predicate Devices:

Company	Device	K Number
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Lacled, inc.	K061331

4. Description of Device:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

GC Oral Moisturizing Gel is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

26

5. Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

6. Technological characteristics:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

7. Summary of Physical tests:

Summary of Performance Specification

	Consistency (mm)	pH
GC Oral Moisturizing Gel	32.5	7.2
BioXtra Moisturizing Gel	26.5	5.4
Oral Balance Gel	28.0	5.6

According to GC Corporation R & D test methods.

Moisture Desorption Assay

0.4g of products were placed on a weighing dish and weighed followed by incubation under the condition of humidity of 20% and a temperature of 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree. The results obtained are shown below.

GC Dry Mouth Gel: 6.9%

Biotene Oral Balance: 10.1%

8. Description of Safety and Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

All of the chemical components that constitute GC Oral Moisturizing Gel are previously used in the predicate devices which are legally marketed for the same indications and the same type of tissue contact. We believe that this fact well supports the compatibility of GC Oral Moisturizing Gel, and the safety of the applicant device is substantially equivalent to the predicate devices.

GC Oral Moisturizing gel is a wetting/moisturizing device.

27

Section 9 - Specifications and Substantial Equivalence Comparison

Specifications and Substantial Equivalence Comparison

1. Device description and Intended Use

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

The applicant device, GC Oral Moisturizing Gel, is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

2. Components and Mode of Action

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

All of the chemical components that constitute GC Oral Moisturizing Gel are:

Chemical Formulation

GC Oral Moisturizing Gel

Component	Weight %	Predicate devices in prior use
Polyglycerol (Diglycerol)	60	
Pure Water	36	GC MI Paste Plus (K070854)
Sodium carboxymethylcellulose	2.5	GC MI Paste Plus (K070854)
Carrageenan*	1.5	
Sodium Citrate	<0.5	
Flavour	<0.5	
Ethyl p-hydroxybenzoate	<0.1	GC MI Paste Plus (K070854)

*Carrageenan is a thickening agent, CAS# 9000-07-1

28

3. Performance

1) Summary of Performance Specification (pH)

	Consistency (mm)	pH
GC Oral Moisturizing Gel	32.5	7.2
BioXtra Moisturizing Gel	26.5	5.4
Oral Balance Gel	28.0	5.6

According to GC Corporation R & D test methods.

2) Performance Specification-Moisture Desorption Assay

0.4g of products were placed on a weighing dish and weighed followed by incubation under the condition of humidity of 20% and a temperature of 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree. The results obtained are shown below.

GC Dry Mouth Gel: 6.9%

Biotene Oralbalance: 10.1%

3) Shelf Life Evaluation and Storage Conditions:

Shelf Life 3 years

Store in a cool dry low humidity area away from direct sunlight (8-25°C)
(46.4-77.0°F).



Re: K101346 
Mark Heiss to: Browne, Myra E.
Cc: Lori Lappo

08/06/2010 04:32 PM

Good Afternoon Myra,

I would like to take this opportunity to ask you for a informal review of our responses to your email of 6/23. If you feel we have addressed your questions, please let us know and we will formally submit the documents to the document center.

1. We have revised and added information as required to adhere to 21 CFR 807.92 (see attachment)
2. The only difference is in labeling: the RX box label contains the required caution statement, OTC version does not.
3. We have added physical properties: pH, Desorption Assay to the 510(k) and Summary page. (attachment)
4. Carrageenan is a thickening agent with CAS# 9000-07-1. This information was added to the formula as a footnote (attachment)
5. GC Moisturizing Gel is a wetting/moisturizing Agent/device.



Revised 510(k) Summary Oral Moist.Gel.doc



Revised Sect.9 Performance Specs.pdf Revised Sect.9 Formula.pdf

I hope the above response and attachments meet your requirements. If so please confirm and we will continue with the next steps outlined by your email of 6/23.

Regards,

Mark A. Heiss, D.D.S., F.A.D.I., F.I.A.D.F.E.
Director, New Business Development, Academic and Regulatory Affairs
Managing Director, GC Advanced Technologies
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
800.323.3386 x4042
708.897.4042
708.897.4031 (fax)

"Browne, Myra E." From: "Browne, Myra E." <Myra.Browne@fda.hhs.gov> 06/23/2010 01:17:06 PM

From: "Browne, Myra E." <Myra.Browne@fda.hhs.gov>
To: "Mark Heiss" <Mark_Heiss@gcamerica.com>
Date: 06/23/2010 01:17 PM
Subject: K101346

30

Hi Mark,

As per the messages I left on your answering machine today, the following additional information is needed for me to complete my review of GC Oral Moisturizing Gel:

1. Please re-write the Summary of Safety and Effectiveness so that it is in compliance with CFR 807.92. In addition the Indication for Use statement must be identical to the indication for use in the 510(k) summary.
2. Describe any differences, if any, between the Rx version and the OTC version of GC Oral Moisturizing Gel.
3. Compare the physical properties of your artificial saliva to the most appropriate predicate device (preferably in a table).
4. Explain the purpose/function of the carrageenan in your chemical composition (include a CAS #).
5. Please discuss any therapeutic claims that you intend to make for your artificial saliva.

Please contact my office if I can be of further assistance regarding this email. I will be placing your document on telephone hold until the above information is submitted to the Document Mail Center.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993
301-796-6278
myra.browne@fda.hhs.gov



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WQ66-G609
Silver Spring, MD 20993-0002

Dr. Mark Heiss
Director, Academic & Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

JAN 27 2011

Re: K101346
Trade/Device Name: GC Oral Moisturizing Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: December 8, 2010
Received: December 9, 2010

Dear Dr. Heiss:

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- Dr. Heiss

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

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

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

Sincerely yours,



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

Enclosure

Section 5 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K101346

Device Name: GC Oral Moisturizing Gel

Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K101346



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

November 19, 2010

GC AMERICA, INC.
3737 W. 127TH ST.
ALSIP, ILLINOIS 60803
UNITED STATES
ATTN: MARK HEISS

510k Number: K101346

Product: GC ORAL MOISTURIZING GEL

Extended Until: 12/20/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

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

Sincerely yours,

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

22



GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

November 17, 2010

FDA CDRH DMC

NOV 18 2010

Received K44

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

RE: GC Oral Moisturizing Gel
510k Number : K101346

Document Mail Center:

GC America would like a 180 day cycle extension to the FDA's additional information request regarding flavoring.

This extension is necessary because not all of the information is readily available, and we require extra time to gather all the necessary information to properly respond to your request.

If you have any questions, please contact me at (708) 897-4042 or by e-mail at mark_heiss@gcamerica.com.

Sincerely,

GC AMERICA INC.

Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs

MH/ll

cc: Myra Brown

23





U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 26, 2010

GC AMERICA, INC.
3737 W. 127TH ST.
ALSIP, ILLINOIS 60803
UNITED STATES
ATTN: MARK HEISS

510k Number: K101346

Product: GC ORAL MOISTURIZING GEL

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

24



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

June 24, 2010

GC AMERICA, INC.
3737 W. 127TH ST.
ALSIP, ILLINOIS 60803
UNITED STATES
ATTN: MARK HEISS

510k Number: K101346

Product: GC ORAL MOISTURIZING GEL

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

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

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

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

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

32

Revised Safe Medical Devices Act of 1990. Released by CDRH on 8/27/15.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 13, 2010

GC AMERICA, INC.
3737 W. 127TH ST.
ALSIP, ILLINOIS 60803
UNITED STATES
ATTN: MARK HEISS

510k Number: K101346

Received: 5/13/2010

Product: GC ORAL MOISTURIZING GEL

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

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

38

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

39

K101346


Section 3 - 510(k) Cover Letter

FDA CDRH DMC

MAY 13 2010

GC AMERICA INC.
 3737 WEST 127TH STREET
 ALSIP, ILLINOIS 60803
 TEL (708) 597-0900
 FAX (708) 371-5103

May 7, 2010

Received 

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

~~FDA CDRH DMC~~
~~MAY 13 2010~~
~~Received~~ 

Re: 510(k) Notification: GC Oral Moisturizing Gel

Dear Sir/Madam:

GC America Inc. hereby submits this traditional 510(k) pre-market notification for certain device claims for the **GC Oral Moisturizing Gel**, artificial saliva agent. The basis for the submission of this traditional 510(k) is that the **GC Oral Moisturizing Gel** is a new device.

This submission is also being submitted as an electronic copy and we attest to the fact that the electronic copy is an exact duplicate of the paper submission.

Relevant information related to the device and the medical claims for which clearance is sought is:

Proprietary name:	GC Oral Moisturizing Gel
Common name:	Artificial saliva agent
Classification name and class:	Saliva, Artificial, Class U
Product code:	LFD
Regulation:	Unclassified

Substantial equivalence for the medical device is based on comparison to the following devices:

Product	Applicant	510(k) No.
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Laclede, Inc.	K061331

K26



GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

The relevant parties are:

510(k) Sponsor / Applicant	GC America, Inc. 3737 W. 127th Street, Alsip, IL 60803 800.323.3386 x4042 708.897.4042 708.897.4031 (fax) Established registration No. 1410097
Device Manufacturer	GC CORPORATION 76 - 1 HASUNUMA - CHO, ITABASHI - KU TOKYO 174 - 8585 JAPAN Established registration No.96123000

The device will be manufactured by GC Corporation, and the Applicant will serve as the domestic distributor of the device.

Contact person: Mark Heiss

Sincerely,

GC AMERICA INC.



Mark Heiss, D.D.S.

Director- New Business Development, Academic and Regulatory Affairs

Section 8B – Instructions for Use

Bio-X Healthcare

Moisturizing Gel

- Immediate, long-lasting relief of dry mouth, especially at night.
- Forms a viscous barrier over dry oral surfaces.
- Slow-release of moisture to mucosal cells.
- Reduces trans-epidermal water loss.
- Improves mouth function and denture retention.
- Provokes the mouth's natural healing processes
- Promotes a healthy, comfortable mouth.

Gel Mouth Spray

- Instantly relieves dry mouth.
- Minerals help improve the mouth's moisture
- Non-drying formula coats mouth surfaces, lips and throat.
- Natural salivary components help promote better oral health.
- Convenient and easy to use during the day.

Sugar-free Chewing Gum

- Formulated to care for the dry mouth
- Stimulates and promotes the natural saliva issuing
- Pleasant to chew: gentle composition and light taste
- Helps to reduce plaque
- Promotes a fresh breath

Sucking Tablets

- Stimulate natural saliva
- Immediate refreshing, cooling sensation
- Mild lemon-mint flavour
- Help ease the discomfort of Dry Mouth
- 100% sweetened with Xylitol
- Contain oral enzymes
- Help guard against dental plaque

How to use

Three simple steps to a more comfortable mouth:

- **Step 1**
Cleansing: At least twice daily brush with BioXtra® Mild Toothpaste
- **Step 2**
Rinsing: Rinse with BioXtra® Alcohol-free Mouthrinse after brushing and, as desired, during the day for extra freshness.
- **Step 3**
Moisturizing: Apply BioXtra® Moisturizing Gel to gums or under dentures, for long lasting lubrication and comfort, especially at night. For convenience and moisture during the day, spray BioXtra® Gel Mouth Spray directly into the mouth as often as required. BioXtra® Sugar-free Chewing Gum and BioXtra® Sucking Tablet with Xylitol effectively relieves oral dryness by temporarily stimulating the flow of natural saliva.

Used daily, the advanced formulation in BioXtra® products gently eases the sensations of dry mouth, helps reduce unwanted bacteria and leaves your mouth feeling fresh and comfortable, day and night.

K072306

510(k) SUMMARY

A. Submission Applicant Information and Correspondent:

Bio-X Healthcare S.A.,
21 Rue Herman Meganck
B-5032 Les Isnes
Belgium

NOV 15 2007

Registration Number: TBA

Contact: Dr. Jean-Paul Perraudin PhD
Email: jp.perraudiin@biopole.com
Telephone : 011-32- 81- 723- 460

US Agent and Correspondent:

Emalee G. Murphy
Kirkpatrick & Lockhart Preston Gates Ellis LLP
1601 K Street, NW
Washington, DC 20006

Email: emalee.murphy@klgates.com
Telephone: (202) 778-9428 (Direct)
Fax: (202) 778-9100

B. Name of Device: BioXtra® Moisturizing Gel

Trade Name: BioXtra® Moisturizing Gel
Common or Usual Name: BioXtra® Moisturizing Gel
Classification Name: Saliva, Artificial

C. Regulatory Information:

Product Code: LFD
Classification: Unclassified
Panel: Dental

D. Devices to Which New Device is Substantially Equivalent:

Parnell Pharmaceuticals Inc. Mouthkote Oral Moisturizer, cleared K062653
Laclede Inc. Oralbalance Gel and Liquid, cleared in K061331
Gebauer Company: Salivart Spray, cleared in K981693
Inpharma AB: Caphasol cleared in K030802
Sinclair Pharmaceuticals Salinum or Oraclair, cleared in K024148

Section 8B – Instructions for Use

Biotene Oral Balance

Apply Oral Balance Mouth Moisturizing Gel as often as needed for relief, especially at night or as directed by your dentist or physician. Place approximately a half inch length onto tongue and spread thoroughly. Effectively helps denture wearers and mouth breathers.

Note: Should be used after rinsing mouth. If condition persists, consult a physician.

Soothes and Protects Oral Tissues. Contains Bio-Active Enzymes: to inhibit harmful odor-causing bacteria and maintain a healthy, balanced oral environment.

- Sugar-Free
- Light Pleasant Taste
- Long-Lasting Relief
- Helps With Swallowing

Beneficial to individuals experiencing Dry Mouth caused by:

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

Oralbalance® long lasting lubricant relieves, soothes and protects dry mouth tissues against dry discomfort, minor irritations, and burning sensations. Contains Bio-Active Enzymes: to inhibit harmful odor-causing bacteria and maintain a healthy, balanced oral environment.

Section 8B – Instructions for Use

(Prescription)

GC Oral Moisturizing Gel

GC Oral Moisturizing Gel is designed to provide comfort for person suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth. GC Oral Moisturizing Gel is sugar free and alcohol free.

RECOMMENDED INDICATIONS

1. To provide comfort and relief for dry mouth conditions.
2. To provide a protective coating for teeth and oral tissue.
3. To help control bad breath.

CONTRAINDICATIONS

1. GC Oral Moisturizing Gel contains ethyl p-hydroxybenzoate. Do not use on people who have a hydroxybenzoates allergy.
2. In rare cases, the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

DIRECTIONS FOR USE

1. Use GC Oral Moisturizing Gel as often as required when the mouth feels dry. This can be anytime during the day or at night time.
2. Extrude a sufficient amount of gel from the tube on the finger or use a cotton swab to take the gel from the tube. Apply the gel to tongue, oral mucosa and or teeth.

FLAVOUR

Fruit Salad (F), Raspberry (R), Orange (O), Lemon (L), Mint (M). F, R, O, L and M in parentheses are abbreviations for each flavour.

These abbreviations are marked on the tubes after lot numbers to show the flavour of the contents. For example, 060815F Fruit Salad

Section 8B – Instructions for Use
(Over-the-counter)

GC Oral Moisturizing Gel helps provide comfort for people suffering from dry mouth. GC Oral Moisturizing Gel is sugar free.

RECOMMENDED INDICATIONS

1. To provide comfort and relief for dry mouth symptoms.
2. To provide a protective coating inside mouth.
3. To help control bad breath.

DIRECTIONS

EASY APPLICATION!

1. Squeeze a small amount onto clean finger and apply onto tongue.
2. Use tongue to spread around entire area of mouth and/or teeth.
3. Use GC Oral Moisturizing Gel as often as required when the mouth feels dry. This can be used anytime during the day or especially at night.



Cautions

- Do not use GC Oral Moisturizing Gel if you have a hydroxybenzoates allergy. GC Oral Moisturizing Gel contains ethyl p-hydroxybenzoate.
- In rare cases, the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

Table of Contents

Traditional 510(k): GC Oral Moisturizing Gel

Section	Title
01	Medical Device User Fee Cover Sheet
02	CDRH Premarket Review Submission Cover Sheet
03	510(k) Cover Letter
04	Certification of Compliance
05	Indications for Use Statement
06	510(k) Summary
07	Truthful and Accuracy Statement
08	Labels
08 A	Proposed Labeling
08 B	Instructions for Use
09	Specifications and Substantial Equivalence Comparison
10	Biological Compatibility Testing

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. 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) GC AMERICA INC 3737 W. 127th Street Alsip IL 60803 US	2. CONTACT NAME Lori Lappo 2.1 E-MAIL ADDRESS Lori_Lappo@gcamerica.com 2.2 TELEPHONE NUMBER (include Area code) 708-897-4036 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 708-897-4031	1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)
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)		
Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see 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"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		16-Feb-2010

Form FDA 3601 (01/2007)

"Close Window" [Print Cover sheet](#)

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission	User Fee Payment ID Number MD6047927-956733	FDA Submission Document Number (if known)
--------------------	--	---

SECTION A TYPE OF SUBMISSION

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

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name GC America Inc.		Establishment Registration Number (if known) 1410097	
Division Name (if applicable)		Phone Number (including area code) (708) 897-4042	
Street Address 3737 W. 127th Street		FAX Number (including area code) (708) 897-4031	
City Alsip	State / Province IL	ZIP/Postal Code 60803	Country USA
Contact Name Dr. Mark Heiss			
Contact Title Director - New Business Dev., Academic & Regulatory Affairs		Contact E-mail Address mark_heiss@gcamerica.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

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

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"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
	<input type="checkbox"/> 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"/> Other Reason (<i>specify</i>):					

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

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	LFD	2	LFD	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	K072306	BioXtra Moisturizing Gel	Bio-X Health S.A.
2	K061331	Oral Balance Gel	Laclede, Inc.
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Artificial saliva

	Trade or Proprietary or Model Name for This Device	Model Number
1	GC Oral Moisturizing Gel	1
2		2
3		3
4		4
5		5

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

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LFD	C.F.R. Section (if applicable)	Device Class
Classification Panel Saliva, Artificial, Class U		<input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Unclassified

Indications (from labeling)
 GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name GC Corporation			Establishment Registration Number 96123000		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address 76-1 Hasunuma-Cho			FAX Number (including area code) ()		
City Tokyo		State / Province Itabashi-Ku	ZIP/Postal Code 174-8585	Country Japan	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract 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/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract 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/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

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

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

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

Section 3 - 510(k) Cover Letter

May 7, 2010

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

Re: 510(k) Notification: GC Oral Moisturizing Gel

Dear Sir/Madam:

GC America Inc. hereby submits this traditional 510(k) pre-market notification for certain device claims for the **GC Oral Moisturizing Gel**, artificial saliva agent. The basis for the submission of this traditional 510(k) is that the **GC Oral Moisturizing Gel** is a new device.

This submission is also being submitted as an electronic copy and we attest to the fact that the electronic copy is an exact duplicate of the paper submission.

Relevant information related to the device and the medical claims for which clearance is sought is:

Proprietary name:	GC Oral Moisturizing Gel
Common name:	Artificial saliva agent
Classification name and class:	Saliva, Artificial, Class U
Product code:	LFD
Regulation:	Unclassified

Substantial equivalence for the medical device is based on comparison to the following devices:

Product	Applicant	510(k) No.
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Laclede, Inc.	K061331

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

The relevant parties are:

510(k) Sponsor / Applicant	GC America, Inc. 3737 W. 127th Street, Alsip, IL 60803 800.323.3386 x4042 708.897.4042 708.897.4031 (fax) Established registration No. 1410097
Device Manufacturer	GC CORPORATION 76 – 1 HASUNUMA – CHO, ITABASHI – KU TOKYO 174 – 8585 JAPAN Established registration No.96123000

The device will be manufactured by GC Corporation, and the Applicant will serve as the domestic distributor of the device.

Contact person: Mark Heiss

Sincerely,

GC AMERICA INC.

Mark Heiss, D.D.S.
Director- New Business Development, Academic and Regulatory Affairs

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 GC America Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES May 7, 2010
3. ADDRESS (Number, Street, State, and ZIP Code) 3737 W. 127th Street Alsip, IL 60803	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) (708) 897-4042 (Fax) (708) 897-4031

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)

APPLICATION / SUBMISSION INFORMATION

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(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.

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.

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) Mark Heiss, D.D.S. (Title) Director, New Businesses, Academic & Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 3737 W. 127th Street Alsip, IL 60803	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) (708) 897-4042 (Fax) (708) 897-4-31
15. DATE OF CERTIFICATION May 7, 2010	

Section 5 - Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: GC Oral Moisturizing Gel

Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 5.1 of 5.1

Section 6 - 510(k) Summary

Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
Fax: (708) 897-4031

Date Prepared: May 7, 2010

Device Name:

Proprietary Name: GC Oral Moisturizing Gel
Classification Name: Saliva, Artificial
Device Classification: Unclassified
Produce Code: LFD

Predicate Devices:

Company	Device	K Number
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Lacled, inc.	K061331

Description of Device:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

Indications for use:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

Description of Safety and Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

Section 7 - Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Director - New Business Development, Academic and Regulatory Affairs of GC America Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Mark Heiss, D.D.S.
GC America, Inc.
Director-New Business Development, Academic
and Regulatory Affairs

Date

Premarket Notification 510(k) Number

Section 8 – Labeling



Section 8 - Labeling



Section 9 - Specifications and Substantial Equivalence Comparison

Specifications and Substantial Equivalence Comparison

1. Device description and Intended Use

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

The applicant device, GC Oral Moisturizing Gel, is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

2. Components and Mode of Action

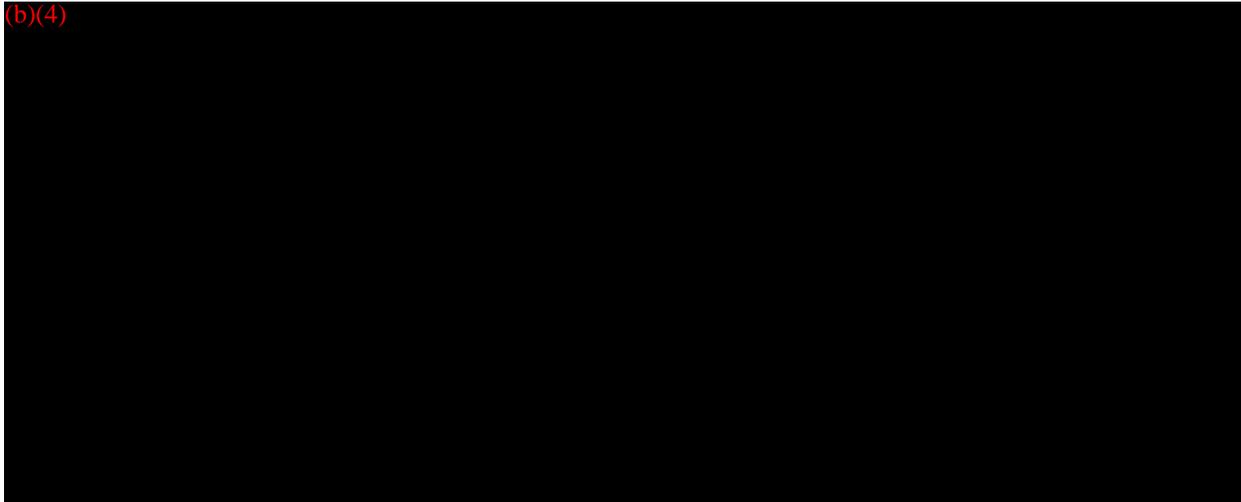
GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

All of the chemical components that constitute GC Oral Moisturizing Gel are:

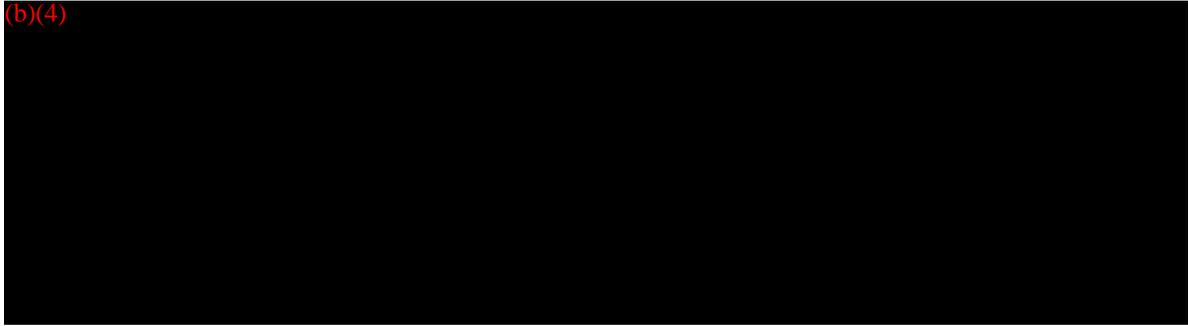
Chemical Formulation

(b)(4)



3. Performance

(b)(4)



2) Shelf Life Evaluation and Storage Conditions:

Shelf Life 3 years

Store in a cool dry low humidity area away from direct sunlight (8-25°C)
(46.4-77.0°F).

Section 10 - Biological Compatibility Testing

Biological Compatibility Testing

All of the chemical components that constitute GC Oral Moisturizing Gel are previously used in the predicate devices which are legally market ed for the same indications and the same type of tissue contact. We believe that this fact well supports the compatibility of GC Oral Moisturizing Gel, and the safety of the applicant device is substantially equivalent to the predicate devices.



COVER SHEET MEMORANDUM

From: Reviewer Name

Myra E. Brouse

Subject: 510(k) Number

K101346 | S2

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%20202%2007.doc)

Hold (Additional Information or Telephone Hold)

Final Decision (SE) SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input 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 checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

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

Additional Product Codes: _____

Review: [Signature] DEDB 1/24/11
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 1/27/11
(Division Director) (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

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

K101346

Date: January 21, 2011
To: The Record
From: Myra E. Browne, M.S., Biologist
Office/Division: ODE/DAGID
510(k) Holder: GC America, Inc.
Device Name: GC Oral Moisturizing Gel
Contact: Mark Heiss, D.D.S.
Phone: 708-897-4042
Fax: 708-897-4031
Email: mark-heiss@gcamerica.com

Purpose and Submission Summary

The 510(k) holder would like to introduce GC Oral Moisturizing Gel into interstate commerce.

GC Oral Moisturizing Gel is intended for the temporary relief of xerostomia which may result from an illness, chemotherapy, radiation, stress or aging.

GC Oral Moisturizing Gel is substantially equivalent (SE) to legally marketed artificial saliva products because the information submitted by GC America, Inc., demonstrates that the device has the same indication and technological characteristics as legally marketed artificial saliva products.

Administrative Requirements

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

Indications for Use

GC Oral Moisturizing Gel is intended for dryness of the mouth (i.e. xerostomia, etc.).

The indication of GC Oral Moisturizing Gel does not differ from that of legally marketed artificial saliva products.

Device Description/Formulation

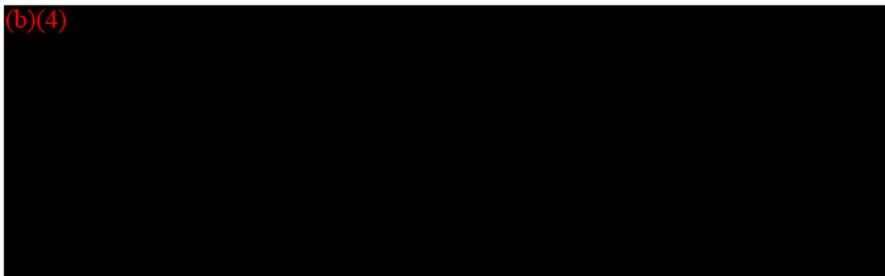
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end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

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

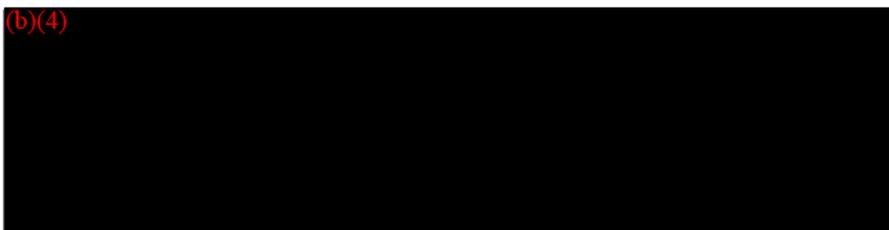
GC Oral Moisturizing Gel is an artificial saliva substitute which contain moisturizers, that when combined have lubricating, moisturizing, soothing, and refreshing properties to relieve and treat the symptoms of dry mouth. It is intended for use as an artificial saliva to moisten, lubricate and cleanse the oral cavity. Dry mouth very often leads to bad breath, therefore moistening can help relieve this symptom.

GC Oral Moisturizing Gel is supplied both by prescription and OTC in bottles of 35 ml. GC Oral Moisturizing Gel is both sugar and alcohol free. GC Oral Moisturizing Gel is available in five flavors: lemon, mint, raspberry, orange and fruit salad. Directions for use include the following: extrude a sufficient amount of gel from the tube on the finger or use a cotton swab to take gel from the tube. Apply the gel to tongue, oral mucosa and or teeth. Use GC Oral Moisturizing Gel as often as required when the mouth feels dry, to be used on an as needed basis. There is no difference in the chemical composition of the prescription or OTC versions of GC Oral Moisturizing Gel. The only difference between the two products is the labeling. The OTC version is indicated for the relief of dry mouth, and to control bad breath. The prescription version is indicated for individuals suffering from dry mouth, and experience difficulties in eating.

The chemical composition of GC Oral Moisturizing Gel is as follows:



(b)(4)

A large black rectangular redaction box covers the majority of the page content. The text "(b)(4)" is printed in red at the top left corner of this redacted area.

Contact History

The reviewer contacted the submitter by telephone on June 23, 2010 to request that the sponsor submit the chemical composition of the flavorings, any differences between the OTC and the prescription product, and a revised 510(k) summary. The company submitted the requested information on August 25 and December 9, 2010.

Deficiencies

No deficiencies have been identified.

Labeling

The labeling of GC Oral Moisturizing Gel has been provided which includes instructions for use. GC Oral Moisturizing Gel will be sold both OTC and by prescription. The prescription packaging includes the appropriate Rx statement. No unsubstantiated claims are purported.

Sterilization/Shelf Life/Reuse:

GC Oral Moisturizing Gel will be provided non-sterile and is not intended to be sterilized before use. Shelf Life was established at 3 years.

Biocompatibility

The formulation of GC Oral Moisturizing Gel includes no new components. This basic formulation is known to be biocompatible for this intended use. Therefore, no additional testing is required.

Software

GC Oral Moisturizing Gel contains no software.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

GC Oral Moisturizing Gel is not a mechanical or electrical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering performance test results were provided for GC Oral Moisturizing Gel (see Section III, Device Comparison).

Performance Testing - Animal

Animal test results were not provided for GC Oral Moisturizing Gel. This type of information is not needed for the assessment of safety and effectiveness of this product.

Performance Testing - Clinical

Human test results were not provided for GC Oral Moisturizing Gel. This type of information is not needed for the assessment of safety and effectiveness of this product.

Device Comparison

Predicate Device: BioXtra Moisturizing Gel (K072306) of Bio-X Healthcare, S.A.

Physical Property	GC Oral Moisturizing Gel	BioXtra Moisturizing Gel (K072306)
(b)(4)		
Dosage	Sold both OTC and prescription; for use on an as needed basis	Sold both OTC and prescription; for use on an as needed basis
Packaging	Tube, 40g	Tube 40ml
Consistency	32.5 mm	26.5 mm
pH	7.2	5.4

GC Oral Moisturizing Gel is comparable to other legally marketed artificial saliva products on the market, especially BioXtra Moisturizing Gel by Bio-X Healthcare, S.A. These devices have essentially the same intended use, composition and physical properties. The differences between the GC Oral Moisturizing Gel and the predicate device is that the predicate product makes extensive claims for the relief of the effects of xerostomia (dry mouth, bad breath) that may result from an illness, chemotherapy, radiation, stress or aging. GC Oral Moisturizing Gel only makes claims for the relief of patients suffering from dry mouth. The predicate product contains amino acids and salivary enzymes, and the GC product does not. In addition the GC Oral Moisturizing Gel does not include and sugar or artificial sweeteners. Both products do have lubricating and moistening properties, are both sold OTC and Rx, and are intended for use on an as needed basis.

No new technological characteristics have been introduced in GC Oral Moisturizing Gel that could affect its safety or effectiveness.

Substantial Equivalence Discussion

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

Recommendation

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

Myra E. Browne, M.S., Biologist
 Reviewer

 Date

M. Susan Runner, DDS
 Branch Chief



1/27/15
 Date

Section 5 - Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: GC Oral Moisturizing Gel

Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

12



COVER SHEET MEMORANDUM

From: Reviewer Name M. Brone
Subject: 510(k) Number K101346
To: The Record

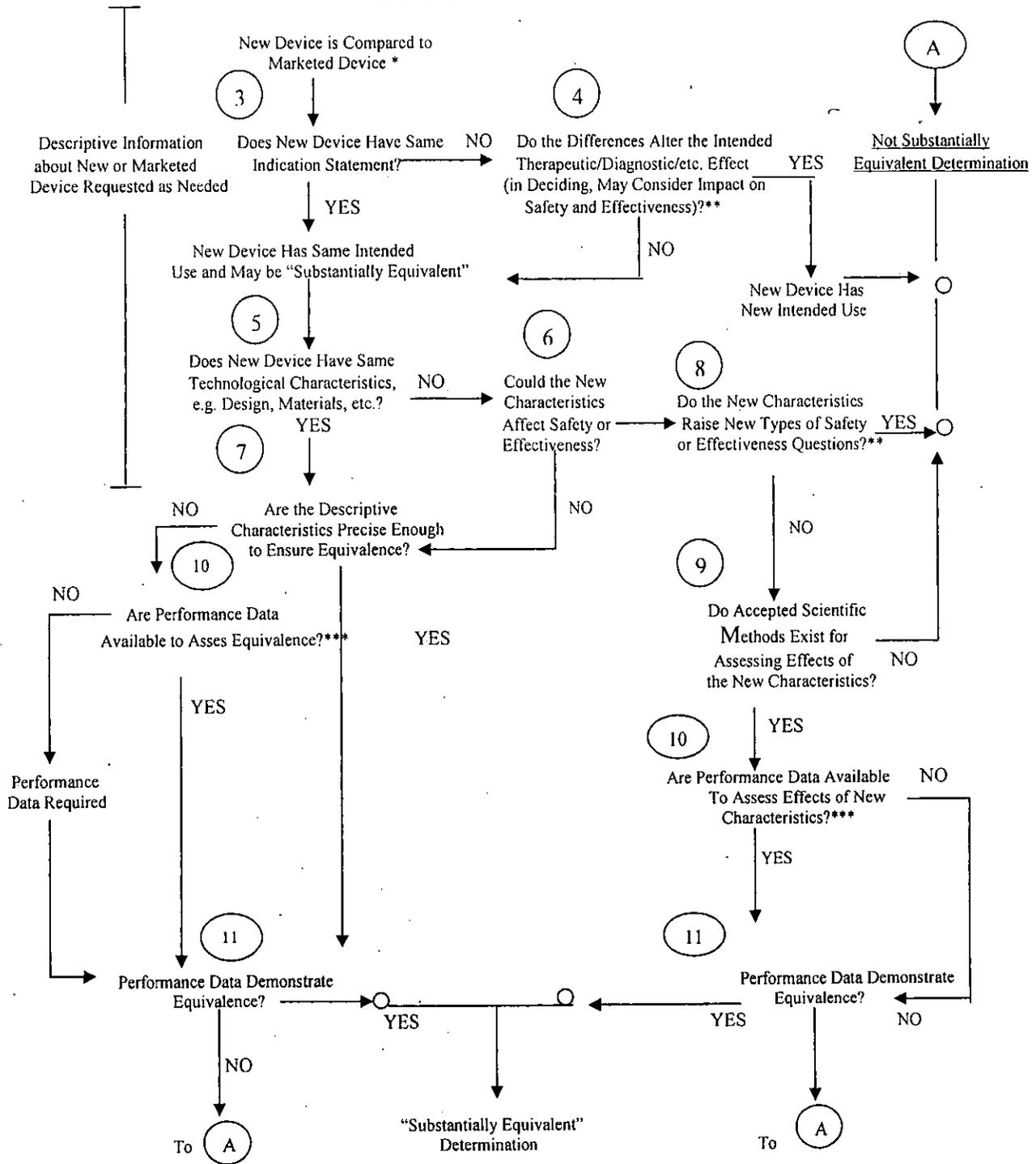
Please list CTS decision code TJL

- 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%20%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
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)			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

34

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.

36

Browne, Myra E.

From: Browne, Myra E.
Sent: Wednesday, June 23, 2010 2:17 PM
To: 'Mark Heiss'
Subject: K101346

Hi Mark,

As per the messages I left on your answering machine today, the following additional information is needed for me to complete my review of GC Oral Moisturizing Gel:

1. Please re-write the Summary of Safety and Effectiveness so that it is in compliance with CFR 807.92. In addition the Indication for Use statement must be identical to the indication for use in the 510(k) summary.
2. Describe any differences, if any, between the Rx version and the OTC version of GC Oral Moisturizing Gel.
3. Compare the physical properties of your artificial saliva to the most appropriate predicate device (preferably in a table).
4. (b)(4)
5. Please discuss any therapeutic claims that you intend to make for your artificial saliva.

Please contact my office if I can be of further assistance regarding this email. I will be placing your document on telephone hold until the above information is submitted to the Document Mail Center.

Sincerely,
Myra Browne

Myra E. Browne, M.S.
Biologist
FDA
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-Rm. 2610
Silver Spring, MD. 20993
301-796-6278
myra.browne@fda.hhs.gov

*Re: Only for RFP
6/23/10*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 10, 2010

GC AMERICA, INC.
3737 W. 127TH ST.
ALSIP, ILLINOIS 60803
UNITED STATES
ATTN: MARK HEISS

510k Number: K101346

Product: GC ORAL MOISTURIZING GEL

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

13



FDA CDRH DMC

DEC 09 2010

Received K7

GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

December 8, 2010

K101346/S2

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

RE: GC Oral Moisturizing Gel
510k Number : K101346

Document Mail Center:

We are attaching a revised formula change for GC Oral Moisturizing Gel. Where applicable, a CAS number has been provided.

Additional information regarding the flavoring was received from our supplier. The information shown on the ingredient list addresses possible allergens.

If you have any questions, please contact me at (708) 897-4042 or by e-mail at mark_heiss@gcamerica.com.

Sincerely,

GC AMERICA INC.

Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs

MH/ll

cc: Myra Brown

14

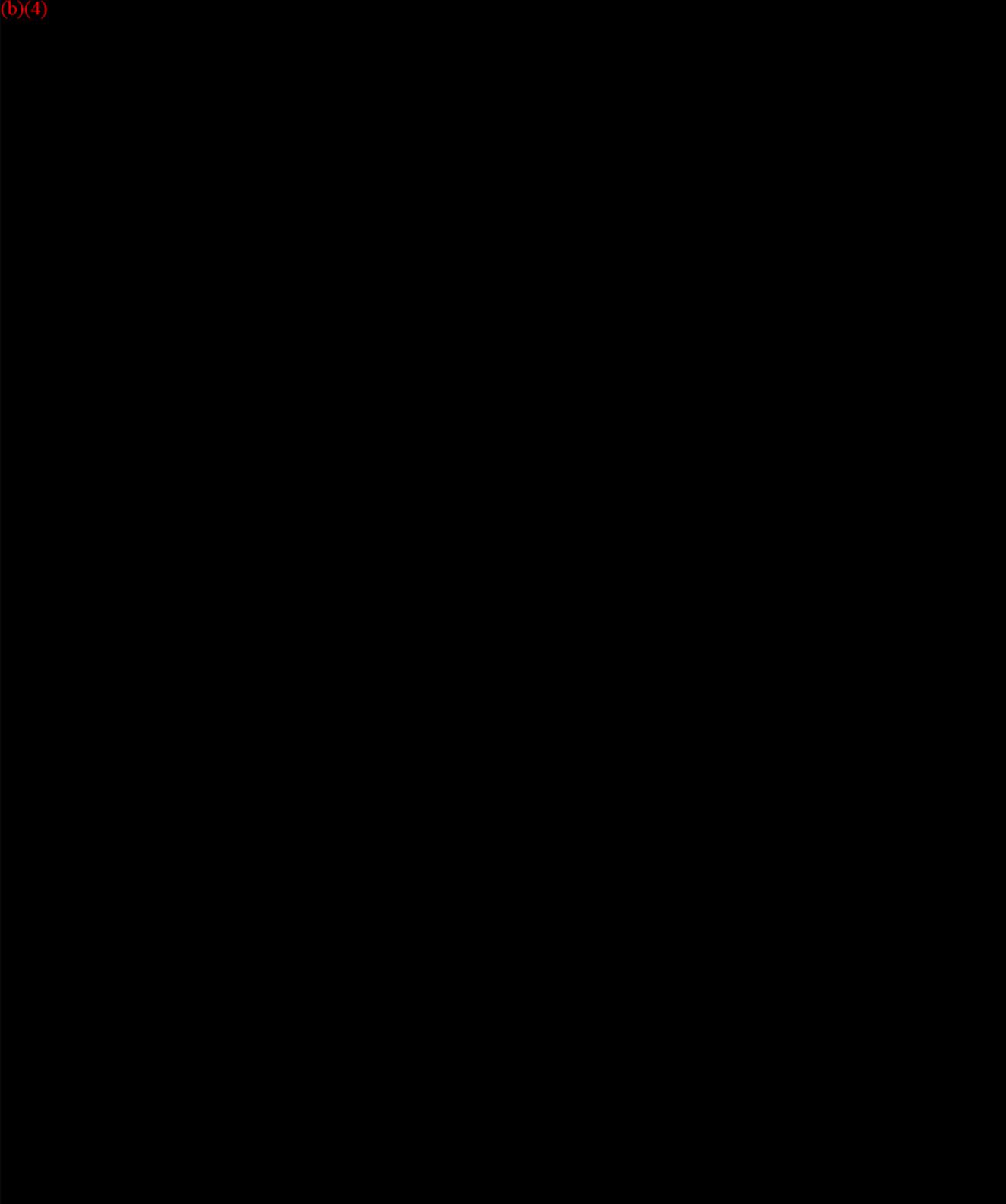


15

Chemical Formula

GC Oral Moisturizing Gel - #K101346

(b)(4)



15

(b)(4)



