

ESTTA Tracking number: **ESTTA673536**

Filing date: **05/21/2015**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91206212
Party	Defendant entrotech, inc.
Correspondence Address	LISA M. GRIFFITH FISH & RICHARDSON P O BOX 1022 MINNEAPOLIS, MN 55440 1022 UNITED STATES tmdoctc@fr.com, hickey@fr.com, martens@fr.com, dylan-hyde@fr.com, morris@fr.com
Submission	Defendant's Notice of Reliance
Filer's Name	Erin M. Hickey
Filer's e-mail	hickey@fr.com, ly@fr.com, reardon@fr.com, brenckman@fr.com, tm-doctc@fr.com, morris@fr.com
Signature	/Erin M. Hickey/
Date	05/21/2015
Attachments	2015-05-21 Applicant's Notice of Reliance + Exhibits (Official Records) RFS.pdf(2817484 bytes)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the matter of application Serial Nos.:

85/499,349 for the mark **CHLORADERM**
85/499,345 for the mark **CHLORABSORB**
85/499,337 for the mark **CHLORABOND**
85/499,332 for the mark **CHLORADRAPE**

Filed on December 19, 2011

Published in the *Official Gazette* on May 29, 2012

CAREFUSION 2200, INC.,

Opposer,

v.

ENTROTECH LIFE SCIENCES, INC.,

Applicant.

Combined Opposition Proceeding No. 91-206,212

United States Patent and Trademark Office
Trademark Trial and Appeal Board
P.O. Box 1451
Alexandria, Virginia 22313-1451

APPLICANT'S NOTICE OF RELIANCE

Pursuant to Rule 704.07 of the Trademark Trial and Appeal Board's Manual of Procedure and 37 C.F.R. § 2.122(e), Applicant Entrotech Life Sciences, Inc. ("Applicant" or "Entrotech") hereby notifies Opposer CareFusion 2200, Inc. ("Opposer" or "CareFusion") of its reliance upon the following official records (identified as Exhibits E1 – E20):

Exhibit No.	Document Description	Pages to Be Read
E1	CHLORASHIELD (Cancelled) TESS Record (Reg. No. 4,495,083)	All pages
E2	CHLORASHIELD (Cancelled) Statement of Use (Reg. No. 4,495,083)	All pages
E3	CHLORASHIELD (Cancelled) Specimen (Reg. No. 4,495,083)	All pages
E4	CHLORASHIELD PR- Section 7 Surrender of Registration for Cancellation dated Nov. 24, 2014 (Reg. No. 4,495,083)	All pages
E5	CHLORASHIELD PR - Section 7 Surrender of Registration for Cancellation dated Dec. 02, 2014 (Reg. No. 4,495,083)	All pages
E6	CHLORASHIELD Paper Correspondence Outgoing re Cancellation dated Dec. 31, 2014 (Reg. No. 4,495,083)	All pages
E7	CHLORASHIELD FDA 510(k) Premarket Notification (510K No. K133764)	All pages
E8	CHLORAPREP Consultation Response from FDA – Office of Post-Marketing Drug Risk Assessment (App. No. 20-832)	pp. 2-4 (relevant portions bracketed on right side)
E9	Center for Drug Evaluation and Research, Administrative and Correspondence Documents: Proprietary Name Review (App. No. 21-5224)	PDF pp. 23-33 (relevant portions bracketed on right side)
E10	CHLORADRAPE TESS Record (Serial No. 85/499,332)	All pages
E11	CHLORADRAPE Office Action (Serial No. 85/499,332)	All pages
E12	CHLORADRAPE Office Action Response (Serial No. 85/499,332)	All pages
E13	CHLORADERM TESS Record (Serial No. 85/499,349)	All pages
E14	CHLORADERM Office Action (Serial No. 85/499,349)	All pages
E15	CHLORADERM Office Action Response (Serial No. 85/499,349)	All pages

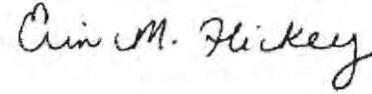
Exhibit No.	Document Description	Pages to Be Read
E16	CHLORABOND TESS Record (Serial No. 85/499,337)	All pages
E17	CHLORABSORB TESS Record (Serial No. 85/499,345)	All pages
E18	CHLORABSORB Office Action (Serial No. 85/499,345)	All pages
E19	CHLORABSORB Office Action Response (Serial No. 85/499,345)	All pages
E20	CHLORABOND Office Action (Serial No. 85/499,337)	All pages

Applicant will rely upon these official records to establish: (1) that confusion between Applicant’s CHLORADERM, CHLORABSORB, CHLORABOND, and CHLORADRAPE marks at issue in this Opposition, on the one hand, and Opposer’s CHLORAPREP and CHLORASHIELD marks at issue in this Opposition, on the other hand, is not likely; (2) the dissimilarity of the marks at issue in this Opposition; (3) the dissimilarity of the goods at issue in this Opposition; (4) the dissimilarity of the channels of trade and marketing/advertising at issue in this Opposition; (5) the purchasing conditions and the sophistication of the purchasers of the goods at issue in this Opposition; (6) the weakness of Opposer’s CHLORAPREP and CHLORASHIELD marks; and (7) the scope of Opposer’s use of its CHLORAPREP and CHLORASHIELD marks.

Dated: May 21, 2015

Respectfully submitted,

FISH & RICHARDSON P.C.



By: _____

Lisa M. Martens

Erin M. Hickey

P.O. Box 1022

Minneapolis, MN 55440-1022

Telephone: (858) 678-5070

Facsimile: (858) 678-5099

E-mail: martens@fr.com

E-mail: hickey@fr.com

Attorneys for Applicant,

ENTROTECH LIFE SCIENCES, INC.

EXHIBIT E1

**Trademarks > Trademark Electronic Search System (TESS)**

TESS was last updated on Wed May 6 03:21:32 EDT 2015

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [BOTTOM](#) | [HELP](#) Please logout when you are done to release system resources allocated for you.**Record 1 out of 1**[TSDR](#) | [ASSIGN Status](#) | [TTAB Status](#) (*Use the "Back" button of the Internet Browser to return to TESS*)

CHLORASHIELD

Word Mark	CHLORASHIELD
Goods and Services	(CANCELLED) IC 010. US 026 039 044. G & S: surgical incise drape. FIRST USE: 20131024. FIRST USE IN COMMERCE: 20131024
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85051477
Filing Date	June 1, 2010
Current Basis	1A
Original Filing Basis	1B
Published for Opposition	October 26, 2010
Registration Number	4495083
Registration Date	March 11, 2014
Owner	(REGISTRANT) CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130
Attorney of Record	Joseph R. Dreitler
Prior Registrations	1930248
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	DEAD
Cancellation Date	December 30, 2014

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [TOP](#) | [HELP](#)

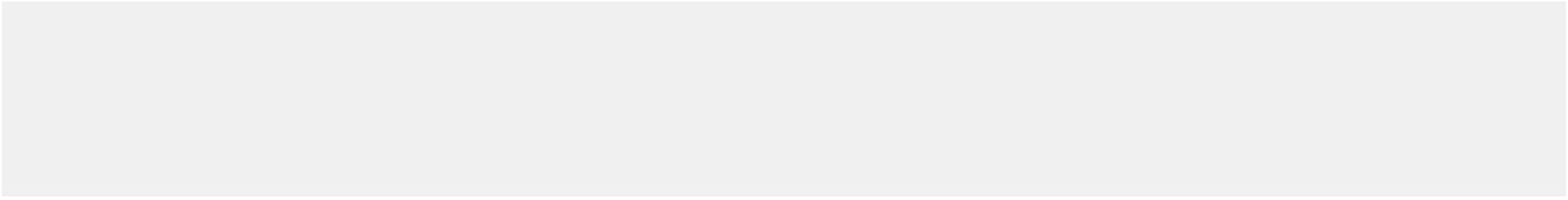


EXHIBIT E2

Trademark/Service Mark Statement of Use (15 U.S.C. Section 1051(d))

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85051477
LAW OFFICE ASSIGNED	LAW OFFICE 101
EXTENSION OF USE	NO
MARK SECTION	
MARK	CHLORASHIELD
OWNER SECTION	
NAME	CareFusion 2200, Inc.
STREET	3750 Torrey View Court
CITY	San Diego
STATE	California
ZIP/POSTAL CODE	92130
COUNTRY	United States
GOODS AND/OR SERVICES SECTION	
INTERNATIONAL CLASS	010
CURRENT IDENTIFICATION	surgical incise drape
GOODS OR SERVICES	KEEP ALL LISTED
FIRST USE ANYWHERE DATE	10/24/2013
FIRST USE IN COMMERCE DATE	10/24/2013
SPECIMEN FILE NAME(S)	\\TICRS\EXPORT16\IMAGEOUT 16\850\514\85051477\xml10 \SOU0002.JPG
SPECIMEN DESCRIPTION	The product's packaging
REQUEST TO DIVIDE	NO
PAYMENT SECTION	

NUMBER OF CLASSES IN USE	1
SUBTOTAL AMOUNT [ALLEGATION OF USE FEE]	100
TOTAL AMOUNT	100
SIGNATURE SECTION	
DECLARATION SIGNATURE	/Joseph R. Dreitler/
SIGNATORY'S NAME	Joseph R. Dreitler
SIGNATORY'S POSITION	Attorney of record, Ohio bar member
DATE SIGNED	12/12/2013
SIGNATORY'S PHONE NUMBER	614-545-6354
FILING INFORMATION	
SUBMIT DATE	Thu Dec 12 14:05:47 EST 2013
TEAS STAMP	USPTO/SOU-66.64.170.52-20 131212140547959270-850514 77-5003f30632677d627c7853 caf82b29596a2b011d1a01323 87aa8c4a6c8e41d-CC-1256-2 0131212140137471137

**Trademark/Service Mark Statement of Use
(15 U.S.C. Section 1051(d))**

To the Commissioner for Trademarks:

MARK: CHLORASHIELD
SERIAL NUMBER: 85051477

The applicant, CareFusion 2200, Inc., having an address of
3750 Torrey View Court
San Diego, California 92130
United States

is submitting the following allegation of use information:

For International Class 010:
Current identification: surgical incise drape

The mark is in use in commerce on or in connection with all goods or services listed in the application or Notice of Allowance or as subsequently modified for this specific class

The mark was first used by the applicant, or the applicant's related company, licensee, or predecessor in interest at least as early as 10/24/2013, and first used in commerce at least as early as 10/24/2013, and is now in use in such commerce. The applicant is submitting one specimen for the class showing the mark as used in commerce on or in connection with any item in the class, consisting of a(n) The product's packaging.

[Specimen File 1](#)

The applicant is not filing a Request to Divide with this Allegation of Use form.

A fee payment in the amount of \$100 will be submitted with the form, representing payment for the allegation of use for 1 class.

Declaration

Applicant requests registration of the above-identified trademark/service mark in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq., as amended). Applicant is the owner of the mark sought to be registered, and is using the mark in commerce on or in connection with the goods/services identified above, as evidenced by the attached specimen(s) showing the mark as used in commerce.

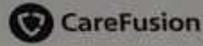
The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements may jeopardize the validity of the form or any resulting registration, declares that he/she is properly authorized to execute this form on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Signature: /Joseph R. Dreitler/ Date Signed: 12/12/2013
Signatory's Name: Joseph R. Dreitler
Signatory's Position: Attorney of record, Ohio bar member
Signatory's Phone: 614-545-6354

RAM Sale Number: 85051477
RAM Accounting Date: 12/13/2013

Serial Number: 85051477
Internet Transmission Date: Thu Dec 12 14:05:47 EST 2013
TEAS Stamp: USPTO/SOU-66.64.170.52-20131212140547959
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256-20131212140137471137

VANCIVE
MEDICAL TECHNOLOGIES



BeneHold™
CHG adhesive
technology by



200 per carton

410100

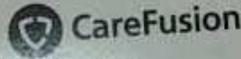
200 per carton

ChloraShield™

PIV Dressing with Chlorhexidine
Gluconate Antimicrobial

Apósito para IV periférica con gluconato
de clorhexidina antiséptico

Pansement pour perfusion intraveineuse
périphérique avec agent antimicrobien
digluconate de chlorhexidine



BeneHold™
CHG adhesive
technology by



FEE RECORD SHEET

Serial Number: 85051477



RAM Sale Number: 85051477

Total Fees: \$100

RAM Accounting Date: 20131213

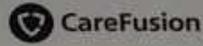
<u>Transaction</u>	<u>Fee Code</u>	<u>Transaction Date</u>	<u>Fee per Class</u>	<u>Number of Classes</u>	<u>Total Fee</u>
Statement of Use (SOU)	7003	20131212	\$100	1	\$100

Transaction Date: 20131212



EXHIBIT E3

VANCIVE
MEDICAL TECHNOLOGIES



BeneHold™
CHG adhesive
technology by



200 per carton

410100

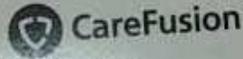
200 per carton

ChloraShield™

PIV Dressing with Chlorhexidine
Gluconate Antimicrobial

Apósito para IV periférica con gluconato
de clorhexidina antiséptico

Pansement pour perfusion intraveineuse
périphérique avec agent antimicrobien
digluconate de chlorhexidine



BeneHold™
CHG adhesive
technology by



EXHIBIT E4

Surrender of registration for cancellation

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85051477
REGISTRATION NUMBER	4495083
FORM TEXT	
Registration No. 4495083, CHLORASHIELD, is being surrendered in its entirety. Please see the attached signed petition.	
Contact information for the correspondent is as follows:	
Joseph R. Dreitler Dreitler True, LLC 19 E. Kossuth St. Columbus, OH 43206 jdreitler@ustrademarklawyer.com 614-449-6677	
ATTACHMENT(S)	
ORIGINAL PDF FILE	Chlorashield_Class_10_Voluntary_Cancellation_2014102431854830.pdf
CONVERTED PDF FILE(S) (1 page)	\\TICRS\EXPORT16\IMAGEOUT16\850\514\85051477\xml16\S7S0002.jpg
SIGNATURE SECTION	
SUBMISSION SIGNATURE	/Joseph R. Dreitler/
SIGNATORY'S NAME	Joseph R. Dreitler
SIGNATORY'S POSITION	Attorney of record, Ohio bar member
SIGNATORY'S PHONE NUMBER	614-449-6677
DATE SIGNED	11/24/2014
AUTHORIZED SIGNATORY	YES
FILING INFORMATION SECTION	

TEAS STAMP

USPTO/S7S-104.10.45.218-2
0141124152358399857-44950
83-20141124151806096297-N
/A-N/A-201411241518060962
97

Global Format; No Form Number (Rev 8/2009)
OMB No. 0651-0055 (Exp. 12/31/2011)

**Surrender of registration for cancellation
To the Commissioner for Trademarks:**

The following is submitted for registration number. **4495083** :

FORM INFORMATION

Registration No. 4495083, CHLORASHIELD, is being surrendered in its entirety. Please see the attached signed petition.

Contact information for the correspondent is as follows:

Joseph R. Dreitler
Dreitler True, LLC
19 E. Kossuth St.
Columbus, OH 43206
jdreitler@ustrademarklawyer.com
614-449-6677

FORM FILE NAME(S)

Original PDF file:

[Chlorashield Class 10 Voluntary Cancellation 2014102431854830.pdf](#)

Converted PDF file(s) (1 page)

[Attachments-1](#)

SIGNATURE(S)

Submission Signature

Signature: /Joseph R. Dreitler/ Date: 11/24/2014

Signatory's Name: Joseph R. Dreitler

Signatory's Position: Attorney of record, Ohio bar member

Signatory's Phone Number: 614-449-6677

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the

highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possession; and is currently the trademark owner's attorney or an associate thereof.

Serial Number: 85051477

Internet Transmission Date:

TEAS Stamp: USPTO/S7S-104.10.45.218-2014112415235839

9857-4495083-20141124151806096297-N/A-N/

A-20141124151806096297

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
To the Assistant Commissioner of Patents and Trademarks:**

Trademark: CHLORASHIELD

Registration Number: 4495083

International Class No.: 10

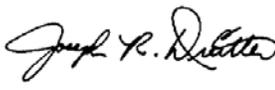
Registrant: CareFusion 2200, Inc.

**Petition for Voluntary Cancellation
Under Section 7(e)**

Box POST REG – NO FEE
Assistant Commissioner for Trademarks
Alexandria, VA

The above-identified Registrant, pursuant to Section 7(e) of the Lanham Act (15 U.S.C. 1057), through its attorney, hereby requests that the honorable Assistant Commissioner for Trademarks cancel Registration No. 4495083 for the mark CHLORASHIELD issued March 11, 2014.

Respectfully submitted,

By: 

Joseph R. Dreitler
Attorney for Registrant CareFusion 2200,
Inc.

EXHIBIT E5

Surrender of registration for cancellation

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85051477
REGISTRATION NUMBER	4495083
FORM TEXT	
<p>Registration No. 4495083, CHLORASHIELD, is being surrendered in its entirety. Pursuant to the filing of November 24, 2014, attached is a petition signed by the Registrant, CareFusion 2200, Inc.</p> <p>Contact information for the correspondent is as follows:</p> <p>Joseph R. Dreitler Dreitler True, LLC 19 E. Kossuth St. Columbus, OH 43206 jdreitler@ustrademarklawyer.com 614-449-6677</p>	
ATTACHMENT(S)	
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SIGNATURE SECTION	
SUBMISSION SIGNATURE	/Joseph R. Dreitler/
SIGNATORY'S NAME	Joseph R. Dreitler
SIGNATORY'S POSITION	Attorney of record, Ohio bar member
SIGNATORY'S PHONE NUMBER	614-449-6677
DATE SIGNED	12/02/2014
AUTHORIZED	

SIGNATORY	YES
FILING INFORMATION SECTION	
TEAS STAMP	USPTO/S7S-104.10.45.218-2 0141202104922213992-44950 83-20141202104325454933-N /A-N/A-201412021043254549 33

Global Format; No Form Number (Rev 8/2009)
OMB No. 0651-0055 (Exp. 12/31/2011)

Surrender of registration for cancellation To the Commissioner for Trademarks:

The following is submitted for registration number. **4495083** :

FORM INFORMATION

Registration No. 4495083, CHLORASHIELD, is being surrendered in its entirety. Pursuant to the filing of November 24, 2014, attached is a petition signed by the Registrant, CareFusion 2200, Inc.

Contact information for the correspondent is as follows:

Joseph R. Dreitler
Dreitler True, LLC
19 E. Kossuth St.
Columbus, OH 43206
jdreitler@ustrademarklawyer.com
614-449-6677

FORM FILE NAME(S)

Original PDF file:

[Chlorashield_RN4495083_Petition_VoluntaryCancellation_signed_2014112104417667.pdf](#)

Converted PDF file(s) (1 page)

[Attachments-1](#)

SIGNATURE(S)

Submission Signature

Signature: /Joseph R. Dreitler/ Date: 12/02/2014

Signatory's Name: Joseph R. Dreitler

Signatory's Position: Attorney of record, Ohio bar member

Signatory's Phone Number: 614-449-6677

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possession; and is currently the trademark owner's attorney or an associate thereof.

Serial Number: 85051477

Internet Transmission Date:

TEAS Stamp: USPTO/S7S-104.10.45.218-2014120210492221

3992-4495083-20141202104325454933-N/A-N/

A-20141202104325454933

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
To the Assistant Commissioner of Patents and Trademarks:**

Trademark: CHLORASHIELD

Registration Number: 4495083

International Class No.: 10

Registrant: CareFusion 2200, Inc.

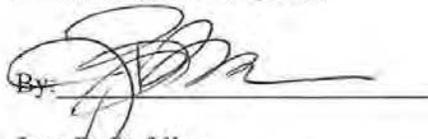
**Petition for Voluntary Cancellation
Under Section 7(e)**

Box POST REG – NO FEE
Assistant Commissioner for Trademarks
Alexandria, VA

The above-identified Registrant, pursuant to Section 7(e) of the Lanham Act (15 U.S.C. 1057), hereby requests that the honorable Assistant Commissioner for Trademarks cancel Registration No. 4495083 for the mark CHLORASHIELD issued March 11, 2014.

Respectfully submitted,

CAREFUSION 2200, INC.

By: 

Joan B. Stafslie
Executive VP, General Counsel and
Corporate Secretary

EXHIBIT E6



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451
www.uspto.gov

REGISTRATION NO. 4495083 SERIAL NO. 85/051477

PAPER NO.
MAILING DATE: DEC 31 2014

MARK: CHLORASHIELD (STD. CHAR)

REGISTRANT: CareFusion 2200, Inc.

CORRESPONDENCE ADDRESS:

TMPRU

JOSEPH R. DREITLER
DREITLER TRUE, LLC
19 E. KOSSUTH ST.
COLUMBUS, OH 43206

SEC. 7(e)
FEB 3 2015
CANCELED

In the United States Patent and Trademark Office

Ex Parte CareFusion 2200, Inc.

Whereas CareFusion 2200, Inc.

has surrendered Trademark Registration No. 4495083 for cancellation

and

Whereas it appears from the records of this office that the petitioner is the owner of Trademark Registration No. 4495083 and has complied with the provisions of Section 7(e) of the Trademark Act of 1946, and the Examiner of Trademarks has recommended the cancellation thereof;

now, therefore, Registration No. 4495083 is hereby cancelled.

DEC 22 2014

Date
Recommended

Deborah S. Cohn
Commissioner for Trademarks

7(e) Surrender

EXHIBIT E7

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

510(k) Premarket Notification



[510\(k\)](#)⁶ | [DeNovo](#)⁹ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [Classification](#)¹³ | [Standards](#)¹⁴
[CFR Title](#)²¹ | [Radiation-Emitting Products](#)¹⁶ | [X-Ray Assembler](#)¹⁷ | [Medsun Reports](#)¹⁸ | [CLIA](#)¹⁹ | [TPLC](#)²⁰ | [Inspections](#)²¹

[New Search](#)

[Back To Search Results](#)

Device Classification Name [Dressing, Wound, Drug](#)²²
510(K) Number K133764
Device Name CHLORASHIELD IV DRESSING WITH CHG ANTIMICROBIAL
Original Applicant AVERY DENNISON BELGIE, BVBA
 Tieblokkenlaan 1
 Turnhout, BE B-2300
Original Contact Lisa Bartakovics
Classification Product Code [FRO](#)²³
Date Received 12/11/2013
Decision Date 03/13/2014
Decision Substantially Equivalent (SESE)
510k Review Panel General & Plastic Surgery
Summary [Summary](#)²⁴
Type Special
Reviewed By Third Party No
Combination Product [Yes](#)²⁵

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
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23. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=FRO
24. http://www.accessdata.fda.gov/cdrh_docs/pdf13/K133764.pdf
25. <http://www.fda.gov/combinationproducts/default.htm>

Page Last Updated: 11/10/2014

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

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U.S. Department of **Health & Human Services**

Links on this page:

EXHIBIT E6

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-832

ADMINISTRATIVE DOCUMENTS

CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: 3/ 27/ 2000

DUE DATE: 5/ 30/ 2000

OPDRA CONSULT #: 00-0111

TO:

Gary Chikami, M.D.
Director, Division of Anti-Infective Drug Products
(HFD-520)

THROUGH:

Maureen Dillon-Parker
Project Manager
(HFD-520)

PRODUCT NAME: ChloraPrep One Step (chlorhexidine gluconate 2% (w/v) and isopropyl alcohol 70% (v/v))

MANUFACTURER: Mediflex Hospital Products, Inc.

NDA #: 20-832

SAFETY EVALUATOR: Lauren Lee, Pharm.D.

OPDRA RECOMMENDATION:

OPDRA has no objections to the use of the proprietary name, ChloraPrep. However, we do not recommend the use of the term, One-Step, as part of the proprietary name. See the checked box below.

- FOR NDA/ANDA WITH ACTION DATE BEYOND 90 DAYS OF THIS REVIEW**
This name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary names/NDA's from the signature date of this document. A re-review request of the name should be submitted via e-mail to "OPDRAREQUEST" with the NDA number, the proprietary name, and the goal date. OPDRA will respond back via e-mail with the final recommendation.
- FOR NDA/ANDA WITH ACTION DATE WITHIN 90 DAYS OF THIS REVIEW**
OPDRA considers this a final review. However, if the approval of the NDA is delayed beyond 90 days from the date of this review, the name must be re-evaluated. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary names/NDA's from this date forward.
- FOR PRIORITY 6 MONTH REVIEWS**
OPDRA will monitor this name until approximately 30 days before the approval of the NDA. The reviewing division need not submit a second consult for name review. OPDRA will notify the reviewing division of any changes in our recommendation of the name based upon the approvals of other proprietary names/NDA's from this date forward.

/S/ 6/2/2000
Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

/S/ - 6/5/00
Peter Honig, MD
Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

Office of Post-Marketing Drug Risk Assessment
HFD-400; Rm. 15B-03
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE RECEIVED: March 27, 2000
NDA#: 20-832
NAME OF DRUG: ChloraPrep One-Step (chlorhexidine gluconate 2% (w/v) and isopropyl alcohol 70% (v/v))
NDA HOLDER: Mediflex Hospital Products, Inc.

I. INTRODUCTION:

This consult is in response to a March 27, 2000 request by the Division of Anti-Infective Drug Products, to review the proposed proprietary drug name, ChloraPrep One-Step, regarding potential name confusion with other proprietary/generic drug names. The container label and carton labeling were reviewed for possible interventions in minimizing medication errors.

PRODUCT INFORMATION

ChloroPrep One-Step is an antiseptic proposed for patient preoperative skin preparation. It contains chlorhexidine gluconate 2% (w/v) and isopropyl alcohol 70% (v/v) for external use. This product is to be applied using a 3 mL single-use applicator. ChloroPrep One-Step is intended for professional use only without a prescription.

II. RISK ASSESSMENT

The medication error staff of OPDRA conducted a search of several standard published drug product reference texts^{1,2,3} as well as several FDA databases⁴ for existing drug names which sound-alike or look-alike ChloroPrep One-Step to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted⁵. An expert panel discussion was conducted to review all findings from the searches.

A. EXPERT PANEL DISCUSSION

[The expert panel consists of members of OPDRA's medication error Safety-Evaluator Staff and

¹ MICROMEDEX Healthcare Intranet Series, 2000, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes the following published texts: DrugDex, Poisindex, Martindale (Parfitt K (Ed), Martindale: The Complete Drug Reference. London: Pharmaceutical Press. Electronic version.), Emergindex, Reprodisk, Index Nominum, and PDR/Physician's Desk Reference (Medical Economics Company Inc, 2000).

² American Drug Index, online version, Facts and Comparisons, St. Louis, MO.

³ Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

⁴ Drug Product Reference File [DPR], the Established Evaluation System [EES], the AMF Decision Support System [DSS], the Labeling and Nomenclature Committee [LNC] database of Proprietary name consultation requests, and the electronic online version of the FDA Orange Book.

⁵ WWW location <http://www.uspto.gov/tmdb/index.html>.

a representative from the Division of Drug Marketing, Advertising and Communications (DDMAC)].

1. The panel identified Chloragel, Chloraseptic, Chloroptic, and Chlorafed, but concluded that these names do not have the potential for name confusion with ChloroPrep One-Step. Therefore, the proposed proprietary name does not pose a safety risk due to name confusion.
2. DDMAC – no comments.

B. SAFETY EVALUATOR RISK ASSESSMENT

The name, ChloroPrep, does not have the potential for name confusion with existing products since it lacks significant look-alike and sound-alike similarity with other drug names, thereby posing no significant safety risk. However, in reference to the term, One-Step, the directions for use of the applicator state that the user must pinch the wings on the barrel to break the ampule and release the antiseptic. Then the user has to wet the applicator sponge by repeatedly pressing and releasing the sponge against the skin of the treatment area until the liquid is visible on the skin. These steps indicate that more than one step is needed to apply the drug, and therefore, having the term, One-Step, as part of the proprietary name is misleading.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container label and carton labeling of ChloroPrep One-Step, OPDRA has attempted to focus on safety issues relating to possible medication errors. OPDRA has reviewed the current container label and carton labeling and has identified several areas of possible improvement, which might minimize potential user error.

A. CONTAINER LABEL (p 113)

1. The label reads, “3.0 mL Applicator.” Since the use of terminal zeros may lead to medication errors, we recommend deleting terminal zeros in all labels and labeling. In addition, we recommend relocating this phrase so that the statement of identity (the established name followed by the pharmacological category) is located immediately beneath the proprietary name.
2. We recommend including the statement,
3. We recommend that the inactive ingredients be listed on the label to be in accordance with 21 CFR 201.100 (b) (5).

B. CARTON LABELING (p 111 - 112)

1. We recommend that the established names be printed in letters that are at least half as large as the letters comprising the proprietary name to be in accordance with 21 CFR 201.10 (g) (2).
2. See comments under CONTAINER LABEL.

IV. RECOMMENDATIONS:

- A. OPDRA has no objections to the use of the proprietary name, ChloroPrep. However, we do not recommend the use of the term, One-Step, as part of the proprietary name.

EXCLUSIVITY SUMMARY for NDA # 20-832 SUPPL # —

Trade Name Chlorprep [Ⓢ] Generic Name 2'6-Chlorhexidine gluconate (CHA) / 70% isopropyl alcohol (IF)
Applicant Name Medi Flex Hospital Products HFD-520

Approval Date July 14, 2000

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it an original NDA?
YES /X/ NO /__/

b) Is it an effectiveness supplement?
YES /__/ NO /X/

If yes, what type? (SE1, SE2, etc.)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")
YES /X/ NO /__/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

CONFIDENTIAL

d) Did the applicant request exclusivity?

YES / / NO / X /

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use?

YES / / NO / X /

If yes, NDA # _____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES / / NO / X /

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

OR ORIGINAL

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES / / NO / X /

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____

NDA # _____

NDA # _____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES / X / NO / /

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # 19-422 Exidine 2%

NDA # _____

NDA # _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES / / NO / /

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

- (a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES / / NO / /

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

- (b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES / / NO / /

- (1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES / / NO / /

If yes, explain: _____

- (2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES / / NO / /

If yes, explain: _____

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # 990326.HTR

Investigation #2, Study # 990326.MBT

Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1	YES / <input type="checkbox"/> /	NO / <input checked="" type="checkbox"/> /
Investigation #2	YES / <input type="checkbox"/> /	NO / <input checked="" type="checkbox"/> /
Investigation #3	YES / <input type="checkbox"/> /	NO / <input type="checkbox"/> /

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____
 NDA # _____ Study # _____
 NDA # _____ Study # _____

b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1	YES / <input type="checkbox"/> /	NO / <input checked="" type="checkbox"/> /
Investigation #2	YES / <input type="checkbox"/> /	NO / <input checked="" type="checkbox"/> /
Investigation #3	YES / <input type="checkbox"/> /	NO / <input type="checkbox"/> /

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____
 NDA # _____ Study # _____
 NDA # _____ Study # _____

Investigation #2

YES / / Explain _____ ! NO / / Explain _____

- (c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES / / NO / X /

If yes, explain: _____

 / S /
Signature: _____ Date: 7-10-00
Title: Proj Manager

 / S /
Signature of Division Director _____ Date: 7/14/2000

cc: Original NDA

Division File

HFD-85 Mary Ann Holovac

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	<u>20832</u>	Trade Name:	<u>CHLORAPREP(CHLOROHEXIDINE GLUCONATE)2% W</u>
Supplement Number:		Generic Name:	<u>CHLORHEXIDINE GLUCONATE</u>
Supplement Type:		Dosage Form:	<u>SOL</u>
Regulatory Action:	<u>AP</u>	Proposed Indication:	<u>Patient preoperative skin preparation</u>

ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?

NO, Pediatric content not necessary because of pediatric waiver

What are the INTENDED Pediatric Age Groups for this submission?

NeoNates (0-30 Days) Children (25 Months-12 years)
 Infants (1-24 Months) Adolescents (13-16 Years)

Label Adequacy Adequate for SOME pediatric age groups
Formulation Status _____
Studies Needed _____
Study Status _____

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

The pediatric study requirement has been fulfilled for children 2 months of age and older. The pediatric study requirement has been waived for children under 2 months of age because of safety concerns with the use of the product in this age group. 7-14-00

Pediatric labeling will be extracted from adult labeling down to the age of 2 months. It is a patient pre-op preparation and no difference in the activity of adult vs pediatric skin (>2months) should be expected.

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, MAUREEN DILLON-PARKER

/S/
Signature

7/14/00
Date

Debarment Certification

Pursuant to section 306(K)(1) of the Federal Food, Drug and Cosmetic Act, the applicant certifies that, to the best of its knowledge and belief, the applicant did not and will not use in any capacity, in connection with this application, the services of any person listed pursuant to section 306(e) as debarred under subsections 306(a) or (b) of the Act.

Richard W. Holt
2-20-97

APPEARANCE ONLY
OR ORIGINAL

LAW OFFICES
HOVEY, WILLIAMS, TIMMONS & COLLINS

ROBERT D. HOVEY, P. C.*
WARREN N. WILLIAMS, P. C.
STEPHEN D. TIMMONS, P. C.
JOHN M. COLLINS, P. C.
STEVEN R. DICKET, P. C.
THOMAS H. VAN HOOZER, P. C.*
JOHN A. WERESH, P.C.

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*ADMITTED IN MISSOURI AND KANSAS

<http://www.hoveywilliams.com>
mailbox@hoveywilliams.com

November 21, 1996

Patrick D. McGrath, Ph.D.
Medi-Flex Hospital Products, Inc.
8717 W. 110th Street, Suite 750
Overland Park, KS 66210

RE: U.S. Patent Application; UNIT DOSE CHLORHEXADINE GLU-
CONATE (CHG) APPLICATOR HAVING EXTENDED CHG SHELF
LIFE; Docket No. 24799

Dear Pat:

The above application was filed in the U.S. Patent and Trademark Office on September 30, 1996 and assigned Serial No. 08/723,686. You may therefore commercialize the invention with the use of the notice "Pat. Pending" if you so desire. The Official Filing Receipt is being retained in our files for safekeeping.

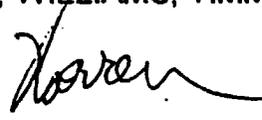
We will keep you advised as to the progress of the application, informing you when we receive the first action on your case from the Patent Office. In the meantime, if we can be of any further assistance, do not hesitate to advise.

Your attention is also called to the fact that if the subject matter of this application is to be validly covered in foreign countries under the provisions of the International Convention, applications must be lodged within one year from the U.S. filing date. We shall be happy to furnish you with additional information and quotations as to the cost of filing corresponding applications in foreign countries upon request.

Very truly yours,

HOVEY, WILLIAMS, TIMMONS & COLLINS

By


Warren N. Williams

WNW:jl

0274

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN
ANTIBIOTIC DRUG FOR HUMAN USE
(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000.
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT Medi-Flex Hospital Products, Inc.	DATE OF SUBMISSION February 3, 2000
TELEPHONE NO. (Include Area Code) 913-451-0880	FACSIMILE (FAX) Number (Include Area Code) 913-451-8509
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 8717 West 110 th Street, Suite 750 Overland Park, Kansas 66210	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE Beckloff Associates, Inc. Commerce Plaza II, Suite 720 7400 West 110th Street Overland Park, Kansas 66210 Telephone: 913-451-3955 Facsimile: 913-451-3846

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued) 20-832		
ESTABLISHED NAME (e.g. Proper name, USP/USAN name) Chlorhexidine Gluconate	PROPRIETARY NAME (trade name) IF ANY Chloraprep	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any) 1,6-di(4-chlorophenyl-diguanido) hexane	CODE NAME (if any)	
DOSAGE FORM: Solution	STRENGTHS: 2% w/v	ROUTE OF ADMINISTRATION: Topical
(PROPOSED) INDICATION(S) FOR USE: Patient Preoperative Skin Preparation		

APPLICATION INFORMATION

APPLICATION TYPE (check one) <input checked="" type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50) <input type="checkbox"/> ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR part 601)		
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b) (1) <input checked="" type="checkbox"/> 505 (b) (2) <input type="checkbox"/> 507		
IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug _____ Holder of Approved Application _____		
TYPE OF SUBMISSION (check one) <input type="checkbox"/> ORIGINAL APPLICATION <input checked="" type="checkbox"/> AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> SUPAC SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> OTHER		
REASON FOR SUBMISSION Response to February 20, 1998, FDA Complete Response Letter: Additional Requested Information		
PROPOSED MARKETING STATUS (check one) <input type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)		
NUMBER OF VOLUMES SUBMITTED <u>1</u>	THIS APPLICATION IS <input type="checkbox"/> PAPER <input checked="" type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether this site is ready for inspection or, if not, when it will be ready.

Medi-Flex Hospital Products, Inc., 19 Butterfield Trail, El Paso, Texas 79906
Contact: Beckloff Associates, Inc., 913-451-3955

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: (Check all that apply)

	1. Index
	2. Labeling (check one) <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))
X	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
X	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
	12. Case reports forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (i) (2) (A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.5 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, cautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE Michael C. Beckloff, President and Chief Executive Officer, Beckloff Associates, Inc.	DATE February 3, 2000
ADDRESS (Street, City, State, ZIP Code) 7400 West 110 th Street, Suite 720 Overland Park, Kansas 66210		Telephone Number (913) 451-3955

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
Independence Avenue, S.W.
Washington, DC 20201

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

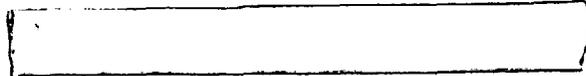
Please DO NOT RETURN this form to this address.

**Establishment Information
Medi-Flex Hospital Products, Inc.**

Corporate Offices:

8717 West 110th Street, Suite 750
Overland Park, Kansas 66210
Telephone: 913-451-0880
Toll Free: 800-523-0502
Telefax: 913-451-8509

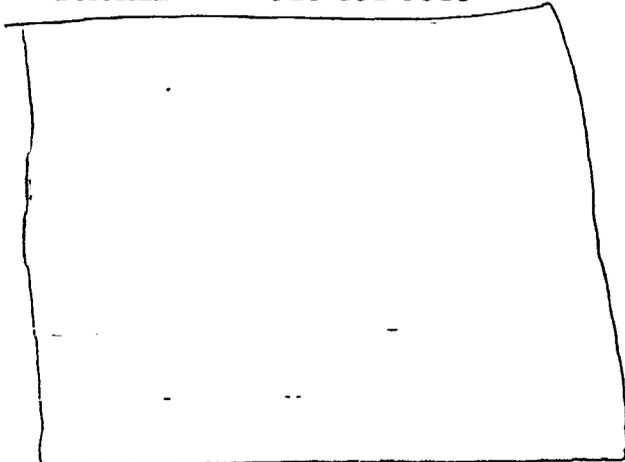
Site Functions:



Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

Manufacturing Facilities:



Establishment Registration Number:

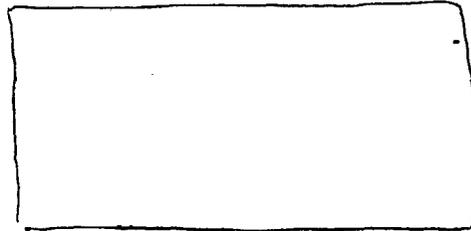
Site Functions:

Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

Warehouse Facilities:

Site Functions:



Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

Deficiency Summary

1. *There is no study to establish the contribution of each active ingredient (CHG and IPA) to the effect of the product. Specifically, no study contains a CHG alone arm.*

Response:

Two new pivotal clinical studies were designed and conducted in order to evaluate and compare the test drug (2% chlorhexidine gluconate in 70% isopropyl alcohol, CHG + IPA) to an active control (2% aqueous chlorhexidine gluconate, CHG) and reference drug (70% isopropyl alcohol, IPA) for use as a patient preoperative skin preparation as specified in the Tentative Final Monograph for Healthcare Antiseptic Drug Products published in the *Federal Register* on June 17, 1994. The protocols for these studies were submitted to the Agency for review as Protocol Amendments to IND No. (Serial No. 028, June 29, 1999, Protocol No. 990326.MBT; and Serial No. 029, July 26, 1999, Protocol No. 990326.HTR). MicroBioTest, Inc., Sterling, Virginia, performed Protocol No. 990326.MBT and Hill Top Research, Inc., Miamiville, Ohio, performed Protocol No. 990326.HTR. Both of these pivotal clinical studies were conducted using test product in a 3.0-mL swab stick applicator instead of the applicator used previously. The clinical statistical reports for these pivotal studies are included in Volumes 2-12 of this NDA Amendment.

All three test products (CHG + IPA, CHG, and IPA) met the criteria defined in the Tentative Final Monograph for patient preoperative skin preparation in both pivotal studies. A summary of the results for the CHG + IPA test product applied to the abdomen and groin compared to test day baseline for Protocol Nos. 990326.MBT and 990326.HTR is provided below:

CHG + IPA on Abdominal Sites

Protocol Number	Mean Log ₁₀ Reduction in CFU/cm ² from Test Day Baseline		
	At 10 Minutes	At 6 Hours	At 24 Hours
990326.MBT (n=39)	2.56	2.15	2.18
990326.HTR (n=42)	2.52	2.37	2.69

CHG + IPA on Groin Sites

Clinical Site	Mean Log ₁₀ Reduction in CFU/cm ² from Test Day Baseline		
	At 10 Minutes	At 6 Hours	At 24 Hours
990326.MBT (n=36)	4.20	3.50	2.67
990326.HTR (n=26)	3.54	3.74	3.82

In addition, the results from Protocol No. 990326.MBT demonstrated a significantly greater reduction in the CFU/cm² of skin on the groin ten minutes after application of CHG + IPA compared to ten minutes after application of IPA or CHG. The results

from Protocol No. 990326.HTR demonstrated a significantly greater reduction in the CFU/cm² of skin on the abdomen 24 hours after application of CHG + IPA compared to the IPA or CHG.

2. *There is no study which establishes the efficacy of the product at a "dry" skin site. Studies have been submitted using forearm, chest, or clavicle sites, but they are flawed by artificial elevation of resident bacteria, small numbers of subjects, or failure to test for the contribution of each active component to the total effect of the product. This is especially important because the testing submitted to date (i.e., with the 24-hour evaluation points) indicates that the product is intended for use in conjunction with peripheral catheters, which are commonly placed at "dry" sites.*

Response:

Protocol Nos. 990326.MBT and 990326.HTR compared the effect of CHG + IPA to its individual components in reducing the mean number of CFU/cm² of skin on the abdomen, which is a dry skin site. These studies did not artificially elevate the numbers of bacteria on the skin and did enroll a sufficient number of subjects to demonstrate a significant reduction in CFU/cm² of dry skin at the abdominal site. In addition, please note that the proposed indication for use of Chlorhexidine Gluconate 2% (w/v) Topical Solution is "patient preoperative skin preparation" per our NDA Amendment dated February 27, 1998.

Clinical

1. *The following summary lists the principal deficiencies / comments on the clinical efficacy studies submitted in support of this NDA.*
 - a. *Studies which did not include either a CHG arm (CXA 1002), or appropriate comparator(s) (CXA 1013); or a vehicle group (CXA1014).*

Response:

As stated in the response to Deficiency Summary Item No. 1 above, Protocol Nos. 990326.MBT and 990326.HTR compared the test drug (CHG + IPA) to appropriate comparators (i.e., treatment groups receiving CHG or IPA alone).

- b. *Studies in which bacterial levels were artificially elevated and which did not utilize the CHG/IPA formulation proposed for marketing: CXA 1005, CXA 1007, CXA 1009, and CXA 1010.*

Response:

Bacterial levels were not artificially elevated in Protocol Nos. 990326.MBT and 990326.HTR. In addition, the formulation proposed for marketing (2% [w/v] chlorhexidine gluconate in 70% isopropyl alcohol) was used in both of these new pivotal clinical studies.

- c. *Studies which did not include a "dry" test site or CHG alone group: CXA 1020 and CXA 1021.*

Response:

As stated in the response to Deficiency Summary Item No. 2, Protocol Nos. 990326.MBT and 990326.HTR included treatment of the abdomen as a "dry" skin site and CHG alone as one of the three treatment groups.

- d. *Studies in which there was no difference between the CHG/ IPA formulation and IPA alone or no treatment: CXA 1003, CXA 1011, and CXA 1019.*

Response:

Please refer to the clinical statistical reports for Protocol Nos. 990326.MBT and 990326.HTR included in Volumes 2-12 of this NDA Amendment.

The results from Protocol No. 990326.MBT demonstrated a significantly greater reduction in the CFU/cm² of skin on the groin ten minutes after application of CHG + IPA compared to ten minutes after application of IPA (p = 0.0096) or CHG (p = 0.0057).

The results from Protocol No. 990326.HTR demonstrated a significantly greater reduction in the CFU/cm² of skin on the abdomen 24 hours after application of CHG + IPA compared to the IPA (p = 0.0022) or CHG (p = 0.0272).

2. *Regarding the clinical simulation study (CXA 1021) that was submitted in partial fulfillment of the requirements for skin prepping prior to injection and to demonstrate persistent effect, the deficiencies are as follows:*
- a. *Four adjacent regions were used as test sites on the inguinal region test subjects (Addendum V, [REDACTED] February 17, 1997, Protocol No. 970101.01). Since the test and vehicle products were randomized to site but not randomized to region, data should be provided which demonstrate that*

the bacterial populations are not statistically different between regions 1 and 4 of test subjects at baseline.

Response:

As stated previously, two new pivotal clinical studies, Protocol Nos. 990326.MBT and 990326.HTR, were conducted to evaluate Chlorhexidine Gluconate 2% (w/v) Topical Solution for the indication of "patient preoperative skin preparation." In these studies, a computer-generated randomization schedule was used to randomize all three study drugs to treatment areas on the abdomen and groin (inguinal). Another computer-generated randomization schedule was used to randomize sample times to sampling sites within the treatment areas.

- b. *In the Final Study Report #970101 (August 8, 1997, submission), compliance with the randomization scheme (Appendix IV of Addendum 1) was assessed. Eight of the twenty-two subjects (36%) did not receive assignments as defined by the randomization scheme. Thus, the results of the study may have been influenced by this nonrandomization and may have an inherent bias. Please explain.*

Response:

As stated previously, two new pivotal clinical studies, Protocol Nos. 990326.MBT and 990326.HTR, were conducted to evaluate Chlorhexidine Gluconate 2% (w/v) Topical Solution for the indication of "patient preoperative skin preparation." In these studies, all subjects were screened for CFU/cm² of skin on the abdomen and groin prior to enrollment in the studies. All subjects who met the entry criterion for minimum number of CFU/cm² of skin on the abdomen and groin during the screening test were enrolled in the studies and randomized to treatment on the abdomen and/or groin with two of the three test products to eliminate bias.

- c. *Complete data sets for each test subject were not provided in Addendum II of the report. All raw data should be provided up until departure of the test subject from the study. The primary focus should be on subjects 10, 15, and 26. Please submit these data.*

Response:

Please refer to the Amendment to the Clinical Section of the NDA submitted to the Agency on August 8, 1997, for complete data sets for all subjects in CXA 1021 (Protocol No. 970101.01). Complete data sets for Subject Nos. 10, 15, and 26 are provided on pages 91-98, 123-130, and 227-234 of the August 1997 NDA Amendment.

3. *In any resubmission of this application, information / data must be presented which establish(es) the safety of such use, given that the irritancy and sensitization testing suggest that the product would be unacceptable to the patient when used under occlusion. Specifically, the resubmission should discuss the possibilities for sensitization and / or irritancy reactions under the proposed conditions of use*

Response:

Protocol Nos. 990326.MBT and 990326.HTR assessed skin irritation at the site of drug application before and 10 minutes, 6 hours, and 24 hours after application of the three test drugs. A Tegaderm™ dressing covered all treatment sites for 24 hours after topical application of the three test drugs. No clinically significant, drug-related skin irritation was observed on any test site treated with CHG + IPA, CHG, or IPA in these studies. Occasional mild skin irritation associated with the Tegaderm™ dressing was observed.

As stated previously, the indication for this NDA has been revised to "patient preoperative skin preparation." Thus, the comments regarding [redacted] are no longer applicable.

4. *If the [redacted] care indications are still desired, any new pivotal stud(ies) submitted should closely follow the outline [redacted]*

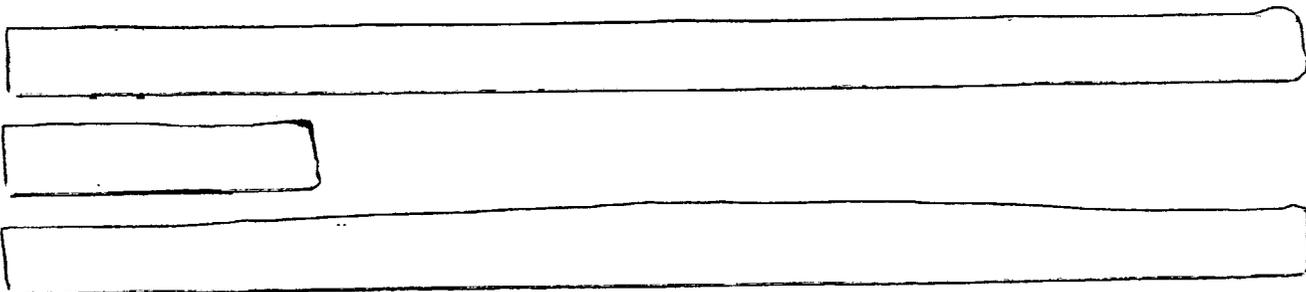
Response:

As stated previously, the indication for this NDA was officially changed to "patient preoperative skin preparation," and Protocol Nos. 990326.MBT and 990326.HTR were designed specifically to assess the efficacy and safety of Chlorhexidine Gluconate 2% (w/v) Topical Solution for this indication.

5. *If any of the indications specified in the Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products (health-care personnel hand wash, surgical scrub, patient preoperative skin preparation) are desired, the test methodology specified in the TFM for the selected indication should be used.*

Response:

Protocol Nos. 990326.MBT and 990326.HTR were designed specifically to evaluate Chlorhexidine Gluconate 2% (w/v) Topical Solution for the indication of "patient preoperative skin preparation," and the methodologies specified in the TFM for that indication were followed in these studies.



Microbiology

1. *The requirements described in the TFM for Health Care Antiseptic Drug Products regarding the studies needed to support the in vitro spectrum of activity for this product have not been met. The information provided is insufficient since it represents a single MIC value for a single species tested. In addition, it is not clear whether the MIC studies were conducted according to established methods in the TFM. The in vitro MIC studies as described in the TFM must be performed. The following modifications regarding the number of strains that should be tested can be made: (1) for the active ingredient (CHG alone) study, 10 strains of each species listed in the TFM should be tested (i.e., a reduction from the required 50 strains for each species); (2) the product, Chloraprep, should be tested with 50 strains of the listed nosocomial pathogens at a central laboratory experienced in the performance of MIC studies using the NCCLS protocols; and (3) the vehicle (70% IPA) requires no further testing.*

Response:

A new in vitro study (Protocol No. CMI 98-13R) was performed and previously submitted to the FDA as an Amendment to NDA No. 20-832 on April 1, 1999. In this study, the antimicrobial spectrum of a 2% CHG in 70% IPA, a 2% aqueous CHG solution, a 4% CHG solution, a povidone iodine solution, and a 70% IPA solution were compared. This study was performed by an experienced central laboratory [redacted] [redacted] using an NCCLS broth microdilution method to determine the minimum inhibitory concentration (MIC) of 1175 microbial isolates. This new in vitro study meets all requirements described in the TFM for Healthcare Antiseptic Drug Products to support the in vitro spectrum of activity of

Chlorhexidine Gluconate 2% (w/v) Topical Solution (2% chlorhexidine gluconate in 70% isopropyl alcohol).

- Validation of the neutralization system for the in vitro microbiology studies (MICs and time-kill kinetics) and the in vivo clinical simulation study could not be evaluated. The written presentation of the neutralizer validation studies should be consistent in content and format with those used to publish scientific articles. Thus, the report should contain an introduction which describes the purpose of the study, the material and methods used to perform the study, the results and raw data, the statistical methods used to analyze the data and the conclusions. The introduction and the conclusions should provide reference to the published literature in the development and support of the results and conclusions described in each study.*

Response:

The new in vitro MIC study report for Protocol No. CMI98-13R was written to be consistent in content and format with the requirements for publication in the *Journal of Clinical Microbiology*. It contains the following sections: Abstract, Introduction, Materials and Methods (with subsections for Microorganisms, Test Agents, Test Procedures, and Quality Control), Results, and Discussion. The microdilution method used in this study conformed to NCCLS guidelines.

In the new pivotal clinical studies, Protocol Nos. 990326.MBT and 990326.HTR, a neutralization study was performed at each site in accordance with the site's internal SOP in order to assure the validity of the neutralizers used in the recovery medium. The results of the neutralization study are included as an Appendix in each clinical statistical report.

- In general, the presentation of the data, the analysis of the data, and conclusions were provided in a manner that made evaluation difficult. It is recommended that all future reports be presented in a format suitable for publication in a journal (e.g., journals published by the American Society for Microbiology). Thus, the reports should include an abstract which summarizes the findings of the study as well as the specific items listed in #2 above. The discussion should include evidence from the published literature (if any) which supports the conclusions of the study submitted to the FDA.*

Response:

Please refer to the response provided in Microbiology, Item No. 2.

Chemistry/Microbiology

Your commitment to revise the specifications for [redacted] applicators containing chlorhexidine gluconate 2% (w/v) is noted.

Response:

Residual limits specifications have been revised to [redacted] and 3.0-mL swab stick applicators containing Chlorhexidine Gluconate 2% (w/v) Topical Solution.

Labeling

Response:

- The proposed labeling for Chlorhexidine Gluconate 2% (w/v) Topical Solution has been revised and is included in Appendix 1. Please note that this statement has been removed from the revised proposed labeling.
2. *Submit revised draft labeling (see attached prototype for reference if an OTC use is established) in accordance with:*
 - a. *Proposed rule for OTC healthcare antiseptic drug products published in the Federal Register of June 17, 1994 (59 FR 31402)*
 - b. *Proposed rule for OTC format and content requirements for OTC drug product labeling published in the Federal Register of February 27, 1997 (62 FR 9024 at 9050).*

Response:

The labeling for Chlorhexidine Gluconate 2% (w/v) Topical Solution has been revised in accordance with the proposed rule for OTC health-care antiseptic drug products published in the *Federal Register* of June 17, 1994, (59 FR 31402) and the proposed rule for OTC format and content requirements for OTC drug product labeling published in the *Federal Register* of February 27, 1997, (62 FR 9024 at 9050). The revised proposed labeling is included in Appendix 1.

3. *Revise the immediate container labels to contain the name of the manufacturer in typewritten text, not logo.*

Response:

The immediate container labels have been revised to contain the name of the manufacturer (Medi-Flex Hospital Products, Inc.) in typewritten text. The immediate container label is provided in Appendix 2.

4. *Provide draft labeling in color mock-up form for all labeling (primary packaging, carton, reformatted package insert) for both the [redacted]*

Response:

Draft labeling in color mock-up form is provided for all labeling (package insert, primary packaging, intermediate packaging, outer shipper packaging) for the 3.0-mL applicator containing Chlorhexidine Gluconate 2% (w/v) Topical Solution in Appendices 1-4, respectively.

5. *Explain the discrepancy between statements made in the [redacted] package insert and in the Standard Operating Procedure (S.O.P.) for packaging [redacted]*

Response:

Only cartons containing twenty-five (25) 3.0-mL applicators containing Chlorhexidine Gluconate 2% (w/v) Topical Solution will be commercially distributed.

6. *If two (or more) carton sizes are desired, labeling must be submitted for each.*

Response:

Only cartons containing twenty-five (25) 3.0-mL applicators containing Chlorhexidine Gluconate 2% (w/v) Topical Solution will be commercially distributed.

7. *Provide the packaging S.O.P. for the [redacted]*

Response:

The packaging SOP for the 3.0-mL applicators containing Chlorhexidine Gluconate 2% (w/v) Topical Solution is included in Appendix 5.

EXHIBIT E9

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-524

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



Les Entreprises SoluMed Inc.

NDA 21-524
July 26, 2004

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

Section 1: Administrative Documents

1.3 PATENT CERTIFICATION

In the opinion and to the best of knowledge of Les Entreprises SoluMed Inc. there are no patents that claim the drug or drug product or which claim a method for using the drug product on which investigations were conducted or that claim the use of such drug or drugs.

Stephane Levesque
Director of R&D
Les Entreprises SoluMed Inc.

Date



2109, Le Chatelier
Laval, Qc
H7L 5B3

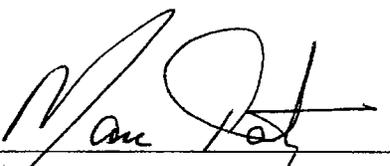
Tél.: (450) 682-6669
Fax: (450) 682-5777
info@solumed.biz

PATENT INFORMATION

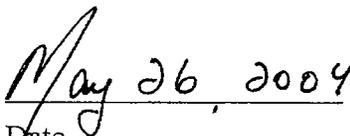
In the opinion and to the best of knowledge of Les Entreprises SoluMed Inc. there are no patents that claim the drug or drug product or which claim a method for using the drug product on which investigations were conducted or that claim the use of such drug or drugs.

An exhaustive search of the US patent data banks has been completed by:
Léger Robic Richard
Lawyers, Patents and Trademark Agents
1001 Victoria Square
Bloc E – 8th floor
Montreal Québec
Canada H2Z 2B7

Ref# 004620-0005 dated April 14, 2004



Marc Patry, B.Sc. Eng.
President
Les Entreprises SoluMed Inc.



Date



Les Entreprises SoluMed Inc.

NDA 21-524
July 26, 2004

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

Section 1: Administrative Documents

1.2 PATENT AND EXCLUSIVITY INFORMATION

1.2.1 Patent Information

In the opinion and to the best of knowledge of Les Entreprises SoluMed, Inc. there are no patents that claim the drug or drug products or which claim a method for using the drug product on which investigations were conducted or that claim the use of such drug or drugs.

An exhaustive search of the US patent data banks has been completed by:

Léger Robic Richard
Lawyers, Patents and Trademark Agents
1001 Victoria Square
Bloc E-8th floor
Montreal, Quebec
Canada H2Z 2B7

Ref# 004620-0005 dated April 14, 2004.

Stephane Levesque
Director of R&D
Les Entreprises SoluMed Inc.

July 26, 2004
Date



Les Entreprises SoluMed Inc.

NDA 21-524
July 26, 2004

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

Section 1: Administrative Documents

1.2.2 Claimed Exclusivity

According to the Electronic Orange Book of Approved Drug Products with Therapeutic Equivalents, updated July 27th, 2004, there are no prescription nor over-the counter drug products listed containing 3.15% (w/v) chlorhexidine Gluconate with 70% (v/v) isopropyl alcohol.

EXCLUSIVITY SUMMARY

NDA # 21-524

SUPPL #

HFD # 520

Trade Name

Chlorascrub Swab

Chlorascrub Swabstick

Chlorascrub Maxi Swabstick

Generic Name

[Chlorhexidine gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

*equivalent to 189 mg of Chlorhexidine Gluconate per pouch

[Chlorhexidine gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

*equivalent to 268 mg of Chlorhexidine Gluconate per pouch

[Chlorhexidine gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

*equivalent to 855 mg of Chlorhexidine Gluconate per pouch

Applicant Name Les Entreprises SoluMed, Inc (Canada)

Nice-Pak Products (US Agent)

Approval Date, If Known June 3, 2005

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505 (b)(2)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same

active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 20-832

Chloraprep

NDA# 21-669

Chlorhexidine Gluconate 2% Cloth

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)
IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

- (1) ~~020509-103~~
- (2) ~~-01-108607-11~~
- (3) 521-102

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

- (1) — 020509-103 —————
- (2) — 01-108607-11 —————
- (3) 521-102 —————

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !
IND # 59,446 YES ! NO
! Explain:

Investigation #2 !

IND # 59,446

YES

!
!
! NO
! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1

YES
Explain:

!
!
! NO
! Explain:

Investigation #2

YES
Explain:

!
!
! NO
! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES NO

If yes, explain:

=====
Name of person completing form: Maureen Dillon-Parker
Title: Chief, Project Manager
Date: 5-24-05

Name of Office/Division Director signing form: Janice Soreth, MD
Title: Division Director, Division of Anti-Infective and Ophthalmology Products

Name of Office/Division Director signing form: Curtis Rosenbraugh, MD, MPH
Title: Deputy Director, Office of Nonprescription Clinical Evaluation

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Curtis Rosebraugh,
6/14/05 04:04:44 PM

Janice Soreth
6/15/05 03:18:21 PM

PEDIATRIC PAGE

(Complete for all filed original applications and efficacy supplements)

DA #: 21-524 Supplement Type (e.g. SE5): NA Supplement Number: NA

Stamp Date: August 5, 2004 Action Date: June 3, 2005

HFD-520 Trade and generic names/dosage form: Chlorascerub (3.15% (w/v) chlorhexidine gluconate and 70% (v/v) isopropyl alcohol)

Applicant: Les Enterprises SoluMed, Inc. / Nice-Pak Products (US Agent) Therapeutic Class: 4020400

Indication(s) previously approved: None

Each approved indication must have pediatric studies: Completed, Deferred, and/or Waived.

Number of indications for this application(s): 2

Indication #1: Patient Preoperative Skin Preparation

Is there a full waiver for this indication (check one)?

- Yes: Please proceed to Section A.
X No: Please check all that apply: X Partial Waiver Deferred Completed
NOTE: More than one may apply
Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- Products in this class for this indication have been studied/labeled for pediatric population
Disease/condition does not exist in children
Too few children with disease to study
There are safety concerns
Other:

If studies are fully waived, then pediatric information is complete for this indication. If there is not a full indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be signed and DLS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min kg mo. yr. Tanner Stage
Max kg mo. yr. Tanner Stage

Reason(s) for partial waiver:

- Products in this class for this indication have been studied/labeled for pediatric population
Disease/condition does not exist in children
Too few children with disease to study
XX There are safety concerns
Adult studies ready for approval
Formulation needed

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

Min _____ kg _____ mo. _____ yr. _____ Tanner Stage _____
Max _____ kg _____ mo. _____ yr. _____ Tanner Stage _____

Reason(s) for deferral:

- Products in this class for this indication have been studied/labeled for pediatric population
- Disease/condition does not exist in children
- Too few children with disease to study
- There are safety concerns
- Adult studies ready for approval
- Formulation needed

Other: _____

Date studies are due (mm/dd/yy): _____

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section D: Completed Studies

Age/weight range of completed studies:

Min _____ kg _____ mo. _____ yr. _____ Tanner Stage _____
Max _____ kg _____ mo. _____ yr. _____ Tanner Stage _____

Comments:

If there are additional indications, please proceed to Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

cc: NDA 21-524
HFD-960/ Grace Carmouze

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE DIVISION OF PEDIATRIC DRUG DEVELOPMENT, HFD-960, 301-594-7337.

(revised 12-22-03)

Attachment A

(This attachment is to be completed for those applications with multiple indications only.)

Indication #2: Patient Preinjection Skin Preparation

Is there a full waiver for this indication (check one)?

Yes: Please proceed to Section A.

No: Please check all that apply: Partial Waiver Deferred Completed

NOTE: More than one may apply

Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- Products in this class for this indication have been studied/ labeled for pediatric population
- Disease/condition does not exist in children
- Too few children with disease to study
- There are safety concerns
- Other: _____

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min _____	kg _____	mo. <2 _____	yr. _____	Tanner Stage _____
Max _____	kg _____	mo. _____	yr. _____	Tanner Stage _____

Reason(s) for partial waiver:

- Products in this class for this indication have been studied/ labeled for pediatric population
- Disease/condition does not exist in children
- Too few children with disease to study
- There are safety concerns
- Adult studies ready for approval
- Formulation needed
- Other: _____

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

Min _____ kg _____ mo. _____ yr. _____ Tanner Stage _____
Max _____ kg _____ mo. _____ yr. _____ Tanner Stage _____

Reason(s) for deferral:

- Products in this class for this indication have been studied/labeled for pediatric population
- Disease/condition does not exist in children
- Too few children with disease to study
- There are safety concerns
- Adult studies ready for approval
- Formulation needed
- Other: _____

Date studies are due (mm/dd/yy): _____

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DfS.

Section D: Completed Studies

Age/weight range of completed studies:

Min _____ kg _____ mo. _____ yr. _____ Tanner Stage _____
Max _____ kg _____ mo. _____ yr. _____ Tanner Stage _____

Comments:

If there are additional indications, please copy the fields above and complete pediatric information as directed. If there are no other indications, this Pediatric Page is complete and should be entered into DfS.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

cc: NDA 21-524
HFD-960/ Grace Carmouze

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE DIVISION OF PEDIATRIC DRUG DEVELOPMENT, HFD-960, 301-594-7337.

(revised 10-14-03)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Maureen Dillon-Parker
5/24/05 01:43:30 PM
NDA 21-524; Pediatric Page

David Bostwick
5/24/05 02:13:51 PM

Jean Mulinde
5/24/05 04:24:32 PM



Les Entreprises SoluMed Inc.

NDA 21-524
July 26, 2004

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

Section 1: Administrative Documents

1.9.2 Request for Waiver of Pediatric Studies

NDA Number: 21-524
Product: Chlorascrub™
Sponsor: Les Entreprises Solumed Inc.
Indications: Skin antiseptic, patient preoperative skin preparation, patient preinjection skin preparation

What age ranges are included in your waiver request?

- We are requesting a waiver of the pediatric study requirement for children under two months of age.

Reason for waiving pediatric studies:

- The product would be unsafe in this pediatric age group.

Justification for waiver:

This waiver is based on a previous pediatric study requirement waiver granted by the Agency for the reference product, Chloraprep®. As noted previously, for the Chloraprep® product, the pediatric study requirement was waived for children under two months of age because of safety concerns with the use of the product in this age group (i.e., irritancy potential, possibility of enhanced absorption, etc.) The current labeling for the Chloraprep® product contains a statement that the drug product should not be used in children less than two months of age because of the potential for excessive skin irritation and increased drug absorption.

The Chlorascrub™ solution contains the identical concentration of IPA and a slightly higher concentration of CHG as the Chloraprep® solution (3.15% w/v versus 2% w/v, respectively). It is presumed that the safety considerations (i.e., possibility for excessive skin irritation and increased drug absorption) for the Chlorascrub™ solution will be identical to those for the Chloraprep® solution, thus forming the basis of the justification for the waiver for the Chlorascrub™ product.



Les Entreprises SoluMed Inc.

NDA 21-524

July 26, 2004

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

Section 1: Administrative Documents

Consequently, the labeling for Chloraprep® contains a statement that the drug product should not be used in children less than two months of age because of the potential for excessive skin irritation and increased drug absorption (see Attachment 3).

The Chlorascrub™ solution contains the identical concentration of IPA and a slightly higher concentration of CHG as the Chloraprep® solution (3.15% w/v versus 2% w/v, respectively). Therefore, we believe that it is acceptable to extrapolate the efficacy data to the pediatric population as was done for NDA No. 20-832.

It is our belief that this will fulfill the requirements specified in the Pediatric Research Equity Act of 2003 regarding submission of a pediatric use assessment.

In addition, we hereby request a waiver of the pediatric study requirement for children under two months of age. A formal Waiver Request is submitted on the following page.



Les Entreprises SoluMed Inc.

Chlorascrub™

3.15% (w/v) Chlorhexidine gluconate with 70% (v/v) Isopropyl alcohol
Swabstick, Maxi Swabstick, Swab

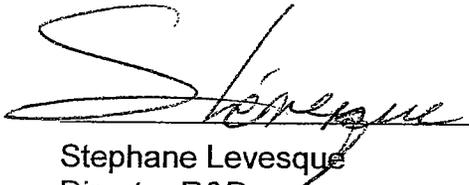
NDA 21-524

July 26, 2004

Section 1: Administrative Documents

1.4 DEBARMENT CERTIFICATION

On behalf of Les Entreprises SoluMed, Inc., I hereby certify that we did not and will not use in any capacity the services of an individual, partnership, corporation, or association debarred under subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act in connection with the NDA for Chlorascrub™.



Stephane Levesque
Director R&D
Les Entreprises SoluMed Inc.


Date

**Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research**

PROPRIETARY NAME REVIEW

DATE OF REVIEW: January 11, 2005

NDA#: 21-524

NAME OF DRUG: Chlorascrub™
Chlorhexidine Gluconate 3.125% (w/v)
and Isopropyl Alcohol 70%

NDA HOLDER: Les Enterprises SoluMed, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Anti-Infective Drug Products (HFD-520), for assessment of the proprietary name, Chlorascrub™, regarding potential name confusion with other proprietary or established drug names. Container labels and carton labeling were provided for review and comment.

PRODUCT INFORMATION

Chlorascrub™ is the name proposed for an over-the-counter (OTC) preparation of chlorhexidine gluconate and isopropyl alcohol topical solution. Chlorascrub is to reduce bacteria that potentially cause skin infection and is indicated for preparation of skin prior to surgery or prior to injection – Chlorascrub will be packaged with foam-tipped swabsticks premoistened with 1.6 mL of solution, “Maxi Swabsticks”, a larger swabstick, premoistened with 5.1 mL, and swabs each premoistened with 1 mL. Each swabstick or swab is to be applied to the procedure site and is for a single use only.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{1,2} as well as several FDA databases³ for existing drug names which sound-alike or look-alike to Chlorascrub to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of

¹ MICROMEDEX Integrated Index, 2005, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-05, and the electronic online version of the FDA Orange Book.

the U.S. Patent and Trademark Office’s Text and Image Database was also conducted⁴. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (requisition orders) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Chlorascrub. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary name Chlorascrub acceptable from a promotional perspective. Initially DDMAC had objected based on the concept that this is not a scrub and therefore the name is misleading. However, the medical consensus from the review division is that this may be used as a scrub and thus DDMAC changed their recommendation.
2. The Expert Panel identified two proprietary names that were thought to have the potential for confusion with Chlorascrub. These products are listed in Table 1 (see below), along with the dosage forms available and usual dosage. EPD participants commented that the proposed name sounds like a bathroom cleanser or contains Clorox (bleach) and questioned whether the product has a purely “chemical action” or does the swab “physically” remove or kill bacteria.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Chlorascrub	Chlorhexidine Gluconate 3.125% with 70% Isopropyl Alcohol (Packaged with “Swabsticks”)	Apply to procedure site.	
Chloraprep	Chlorhexidine Gluconate 2% with 70% Isopropyl Alcohol	Apply to procedure site.	SA/LA
Chloraseptic	Family Name for sore throat or sore mouth products in adult and pediatric formulations (see chart in Appendix B). Available in sprays and gargles (phenol 1.4% and 0.5%, pediatric), solutions and suspensions (acetaminophen), lozenges (procaine, benzocaine, butacaine), and strips (benzocaine/menthol).	Sprays: 3 sprays orally every 2 hours. Gargles: 1 capful for 15 seconds then spit. Lozenges: Suck one every 2 hours. Relief Strips: 2 strips every 2 hours. Adult liquid: 2 tablespoonfuls (1000 mg APAP every 6 hours) Pediatric Suspension: by age (160 mg APAP/teaspoonful)	LA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

⁴ WWW location <http://www.uspto.gov/tmdb/index.html>.

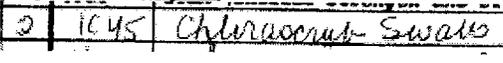
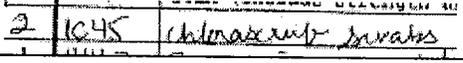
B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. The phonetic search module returns a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Chlorascrub were discussed by the Expert Panel (EPD).

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Chlorascrub with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten pharmacy requisition orders or verbal pronunciation of the drug name. These studies employed a total of 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. Two pharmacy requisition orders were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Chlorascrub (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, one of the requisitions was recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN REQUISITION	VERBAL ORDER
Requisition Sample 1: 	Chlorascrub swabs 2 boxes.
Requisition Sample 2: 	

2. Results:

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See Appendix A for the complete listing of interpretations from the verbal and written studies.

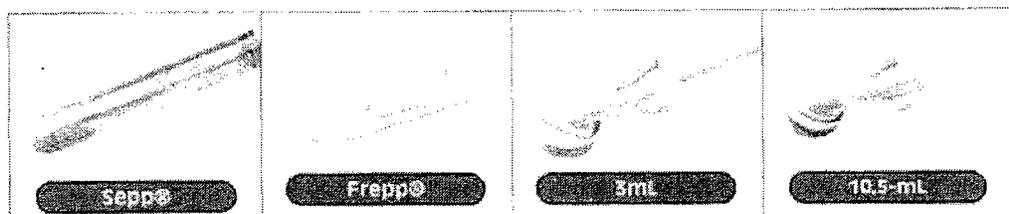
D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Chlorascrub, the primary concerns related to look-alike and sound-alike confusion with Chloraprep and Choraseptic. Additionally, DMETS is concerned with the use of the terminology swabstick. DMETS conducted prescription studies to simulate

the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Chlorascrub.

1. Sound-alike and or look-alike concerns

- a. Chloraprep may sound and look similar to Chlorascrub. Chloraprep is chlorhexidine gluconate, 2% and isopropyl alcohol, 70% used in the aseptic preparation of skin prior to surgical procedures and needle insertions. Chloraprep is available in ampules, scrubbing applicators, and 3 mL and 10.5 mL pen-like devices (see image below).



Chloraprep and Chlorascrub owe their look-alike properties to the shared initial letters, “Chlora”. The endings of the drug names look different, due to the down stroke of the letter “p” appearing twice in Chloraprep and the upstroke “b” in Chlorasacrub (see writing sample below).

Chlorascrub
Chloraprep

The initial two syllables of each contribute to the sound-alike properties. The “b” in Chlorascrub may also sound like the terminal “p” in Chloraprep as they are both stopped consonants. However, the “s” sound in Chlorascrub helps distinguish it from Chloraprep. Chloraprep and Chlorascrub have similar product characteristics including: route of administration, indication of use, active ingredients, dosage form, dosing regimen, and storage areas. Differences in product strength for the active ingredient, chlorhexidine gluconate may not suffice to distinguish the products since each product is only available in one strength and therefore the strength may not be written. However, it is not likely that inpatient practice settings will stock both of these products, primarily due to limited product formularies. DMETS finds it difficult to imagine a scenario in which confusion between these products would result in patient harm. For this reason and because of a lack of convincing orthographic and phonetic similarities, DMETS believes that these names may co-exist in the marketplace.

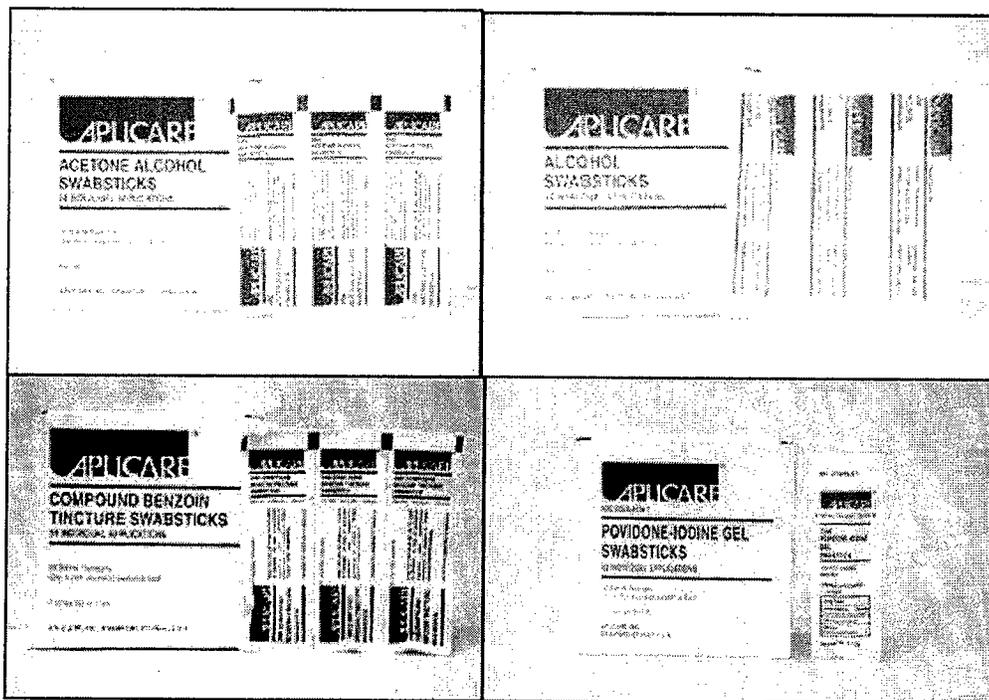
- b. Chloraseptic may look similar to Chlorasrub when written. Chloraseptic is a proprietary “family name” for OTC sore mouth/sore throat products (see Appendix B). Chloraseptic and Chlorasrub owe their look-alike properties to the shared initial letter, “Chloras”. The endings of the drug names look different, however, due to the down stroke “p” in Chloraseptic and the upstroke “b” in Chlorasrub (see writing sample below).

Chloraseptic
Chlorasrub

Despite some look-alike properties, Chloraseptic and Chlorasrub have differences including, route of administration (oral vs. topical), dosing intervals (every 2 hours or every 6 hours vs. one application before a procedure), and widely different indication for use (sore throat or mouth vs. topical antiseptic), respectively. Despite some look-alike properties, these differences and the lack of convincing orthographic similarities between the products will minimize the potential for error.

2. Nomenclature Concerns with the proposed “swabstick” and “maxi swabstick” terms

DMETS recognizes that the term “swabstick” has recognition in the marketplace as evidenced by the images appearing below.



In addition, Dorland’s Medical Dictionary defines “swabstick” as, a wad of cotton or other absorbent material firmly attached to the end of a wire or stick, used for applying medication, removing material, collecting bacteriological material, etc. This product

Monument
Don't have
much comment
ready
think for
most part
need to
run by
OTC folks

fits this definition since it has absorbent material firmly attached to the end of a stick and is used for applying medication. However, the term "Maxi Swabstick" most likely does not share the same user recognition. A search of the "Google" internet search engine for *maxi swabstick* yielded only 12 search results, none of which identified a device such as the one proposed with this product. DMETS believes that the term "Maxi" on this product labeling, should not be used unless it is clearly defined. Additionally, since this product is described as having a foam tip, the CDER Nomenclature and Standards Committee (NSC) was contacted regarding whether the tip best falls under the CDER defined terms "swab" or "sponge". Although the NSC is presently in the process of revising the definitions for the terms swab and sponge, committee members believe that the proposed products may be considered to be "swabsticks" because of the small size of the foam tip.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the container labels, carton and insert labeling of Chlorascrub, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. GENERAL

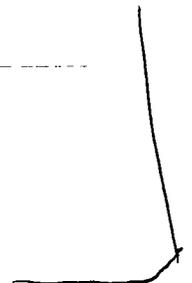
1.



2.



3.



1 Page(s) Withheld

 Trade Secret / Confidential

 ✓ Draft Labeling

 Deliberative Process

Withheld Track Number: Administrative- 1

IV. RECOMMENDATIONS:

- A. DMETS has no objections to the use of the proprietary name, Chlorascrub. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.
- B. DMETS recommends implementation of the label and labeling revisions outlined in Section III. of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.
- C. DDMAC finds the proprietary name Chlorascrub acceptable from a promotional perspective
- D. The CDER Labeling and Nomenclature Committee has made recommendations regarding the proper designation of the established name (see Section III.A. of this review).

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Sammie Beam, project manager, at 301-827-2102.

Charlie Hoppes, RPh, MPH
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Alina Mahmud, RPh, MS
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

Appendix A. Prescription Studies for Chlorascrub

Verbal	Pharmacy Requisition Sample 1.	Pharmacy Requisition Sample 2.
Chlorascrub swabs	Chlorascrub swabs	Chlorascrub swabs
Chlorascrub swabs	Chlirascrub swabs	Chlorascrub swabs
Chlorscrub swabs	Chlirascrub swabs	Chlorascrub swabs
Chloroscrub swabs	Chlorascrub swabs	Chlorascrub swabs
Corascrub swabs	Chlorascrub swabs	Chlorascrub sevabs
Chlorascrub Swabs	Chlorascrub swabs	Chlorascrub swabs
Chlor scrub swabs	Chlorascrub swabs	Chlorascrub swabs
Chlorscrub swabs	Chlorascrub swabs	Chlorascrub
Corscrub swabs	Chlorascrub	Chlorascruf swabs
Chlorscrub swabs	Chlorascrub	Chlorascrub swabs
Chloroscrub swabs	Chlirascrub	Chlorascrub
Chlorascrub swabs	Chlorascrub swabs	Chlorascrub swabs
	Chlorascrub swabs	Chloroscrub swabs
	Chlerascrub swab	Chlorascrub swabs
	Chlorascrub swabs	Chlorascrub swabs
	Chlirascrub swabs	
	Chlirascrub swabs	

Appendix B.

Chloraseptic Products

Product Name	Active Ingredients/ Strengths	Directions for Use	Indications for Use	Notes	Product Image
Chloraseptic Sore Throat Spray	Phenol 1.4%	Spray 5 times to affected area. May repeat every 2 hours.	Sore Mouth Sore Throat Pain of Canker Sores	Available in cherry, cool mint, menthol, and grape	
Chloraseptic Sore Throat Lozenges	Benzocaine 6 mg Menthol 10 mg	Dissolve one lozenge in mouth for sore throat. May repeat every 2 hours.	Sore Mouth Sore Throat Pain of Canker Sores	Available in cherry, honey lemon, and menthol	
Chloraseptic Gargle	Phenol 1.4%	Gargle or swish one capful in mouth and throat for 15 seconds. May repeat every 2 hours.	Sore Mouth Sore Throat Pain of Canker Sores	Cool mint	
Chloraseptic Sore Throat Liquid	Acetaminophen 1000 mg/ 2 tablespoonfuls	Adults - two tablespoonfuls every six hours.	Sore throat, cold, fever, flu, headache, muscle aches	Cherry	
Kids Chloraseptic Sore Throat Suspension	Acetaminophen 160 mg/ teaspoonful	Dosing recommendations by age.	Sore throat, cold, fever, flu, headache, muscle aches	Grape	
Chloraseptic Sore Throat Relief Strips	Benzocaine 3 mg Menthol 3 mg	Use two strips per dose every 2 hours as needed.	Pain, sore throat and sore mouth	Cherry	

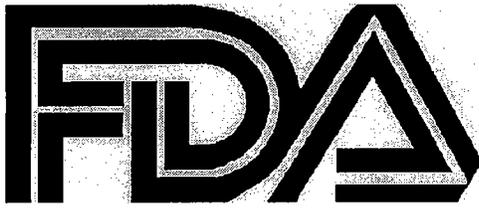
Kids Chloraseptic Sore Throat Spray	Phenol 0.5%	Spray five times in throat every 2 hours as needed.	Sore Mouth Sore Throat Pain of Canker Sores	Grape	
Chloraseptic Mouth Pain Rinse	Phenol 1.4 %	Gargle or swish one cupful in mouth and throat for 15 seconds. May repeat every 2 hours.	Pain due to minor injury or irritation of mouth or gums. Canker sores, dental procedures, or due to orthodontic appliances.	Cinnamon	
Chloraseptic Mouth Pain Spray	Phenol 1.4 %	Apply to affected area, let sit for 15 seconds then spit out. May repeat every 2 hours.	Tooth aches, canker sores, dental procedures, or due to orthodontic appliances.	Available in Cool mint and Cherry blast	

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Carol Holquist
5/4/05 11:23:13 AM
DRUG SAFETY OFFICE REVIEWER



**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV**

FACSIMILE TRANSMITTAL SHEET

DATE: June 1, 2005

To: Bob Reichman, US Agent, Nice-Pak Mark Patry/Anna Mallozzi, Les Entreprises Solumed	From: Maureen Dillon-Parker Regulatory Health Project Manager
Company: Nice-Pak Products Inc. and	Division of Division of Anti-Infective Drug Products
Fax number: #845-365-1602 (NP) #450-682-5777 (LES)	Fax number: #301-827-2325
Phone number: #845-365-1700 (NP) #450-682-6669 (LES)	Phone number: #301- 827-2125

Subject: Additional Labeling Comments for NDA 21-524

Total no. of pages including cover: 2

Comments: Please see attached additional changes to the labeling for NDA 21-524.

Document to be mailed: YES NO

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**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV**

FACSIMILE TRANSMITTAL SHEET

DATE: May 27, 2005

To: Bob Reichman, US Agent, Nice-Pak Mark Patry/Anna Mallozzi, Les Entreprises Solumed	From: Maureen Dillon-Parker Project Manager
Company: Nice-Pak Products Inc. and Les Entreprises Solumed	Division of Division of Anti-Infective Drug Products
Fax number: #845-365-1602 (NP) #450-682-5777 (LES)	Fax number: #301-827-2325
Phone number: #845-365-1700 (NP) #450-682-6669 (LES)	Phone number: #301- 827-2125

Subject: Additional Labeling Comments for NDA 21-524

Total no. of pages including cover: 2

Comments: Please see attached additional changes to the labeling for NDA 21-524 in follow-up to discussions with Mark Patry.

Document to be mailed: YES NO

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**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV**

FACSIMILE TRANSMITTAL SHEET

DATE: May 24, 2005

To: Bob Reichman, US Agent, Nice-Pak Mark Patry/Anna Mallozzi, Les Entreprises Solumed	From: Maureen Dillon-Parker Regulatory Health Project Manager
Company: Nice-Pak Products Inc. and	Division of Division of Anti-Infective Drug Products
Fax number: #845-365-1602 (NP) #450-682-5777 (LES)	Fax number: #301-827-2325
Phone number: #845-365-1700 (NP) #450-682-6669 (LES)	Phone number: #301- 827-2125
Subject: Additional Labeling Comments for NDA 21-524	

Total no. of pages including cover: 2

Comments: Please see attached additional changes to the labeling for NDA 21-524 per discussions with the Labeling and Nomenclature Committee and Chemistry staff as noted in the 5-18-05 facsimile.

Document to be mailed: YES NO

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**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV**

FACSIMILE TRANSMITTAL SHEET

DATE: May 18, 2005

To: Bob Reichman, US Agent, Nice-Pak Mark Patry/Anna Mallozzi, Les Entreprises Solumed	From: Maureen Dillon-Parker
Company: Nice-Pak Products Inc. and	Division of Division of Anti-Infective Drug Products
Fax number: #845-365-1602 (NP) #450-682-5777 (LES)	Fax number: #301-827-2325
Phone number: #845-365-1700 (NP) #450-682-6669 (LES)	Phone number: #301- 827-2125
Subject: Labeling Comments for NDA 21-524	

Total no. of pages including cover: 7

Comments: Please see attached recommended labeling changes for NDA 21-524. Please note these are preliminary comments and discussions with our Labeling and Nomenclature Committee and Chemistry staff are ongoing; Further changes to the labeling may be necessary once these meetings have concluded.

Document to be mailed: YES NO

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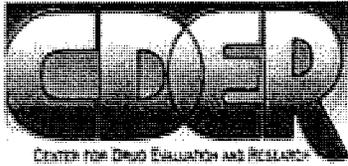
/s/

Maureen Dillon-Parker

5/18/05 02:54:28 PM

CSO

NDA 21-524; Preliminary Labeling comments facsimile of 5-18-05



OTC Drug Labeling Review

Division of Over-The-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE: July 26, 2004 **RECEIVED DATE:** August 5, 2004

REVIEW DATE: April 4, 2005

NDA/SUBMISSION TYPE: N21-524/ N 000

SPONSOR: Les Entreprises SoluMed, Inc.
2109, Le Chatelier
Laval, Quebec
Canada H7L 5B3
[U.S. Agent: Nice-Pak Products, Inc.]

CONTACT: Anna Mallozzi
Director, Regulatory Affairs
(450) 424-5115

DRUG PRODUCT: Chlorascrub™

DOSAGE FORMS: Swab, Swabstick, Maxi Swabstick

ACTIVE INGREDIENTS: 3.15% chlorhexidine gluconate with 70%
isopropyl alcohol

PHARMACOLOGICAL CATEGORY: Healthcare Antiseptic: Patient Preoperative
Skin Preparation, Pre-injection

LABELING SUBMITTED: For each dosage form (Swab, Swabstick, Maxi
Swabstick):
- Packet label
- Outer carton label
- Shipping label

PROJECT MANAGER: Maureen Dillon-Parker

REVIEWER: Colleen Kane Rogers, Ph.D.

BACKGROUND

On July 26, 2004, the sponsor submitted labeling for an NDA for a chlorhexidine gluconate/isopropyl alcohol combination antiseptic solution (Chlorascrub™) in three dosage forms. The three dosage forms are Swab (1.0 mL), Swabstick (1.6 mL), and Maxi Swabstick (5.1 mL). The sponsor requested the following indications for the Swabstick and Maxi Swabstick: “skin antiseptic”, “skin preparation prior to surgery”, and “skin preparation prior to injection _____”. Only “skin antiseptic” and “skin preparation prior to injection _____” were requested as indications for the Swab. The NDA contained draft labeling of the Outer carton label, Packet label (immediate container), and Shipping label for all three product sizes. Both the Carton label (back panel) and Shipping label contain **Drug Facts**.

REVIEWER'S COMMENT

For this review, comments on the Principal Display Panels of all three dosage forms are provided in one section (section A). Relevant dosage forms are indicated at the beginning of each comment in bold face type. **Drug Facts** for both the Swabstick and Maxi Swabstick are reviewed in section C. Due to differences in uses and directions, **Drug Facts** for the Swab is reviewed separately (section B). Packet labels and Shipping labels of all three dosage forms are reviewed in one section each (sections D and E, respectively).

A. Principal Display Panel (PDP) – Outer carton label, front panel

1. **Swabstick and Maxi Swabstick:** The statement of identity is incomplete and must be revised. 21 CFR 201.61(b) requires that the PDP include a statement of identity consisting of the established name of the drug, followed by the general pharmacological category of the drug. Both statements must be placed in direct conjunction with the most prominent display of the proprietary name. The appropriate established drug name for Chlorascrub™ is Chlorhexidine gluconate 3.15% (w/v) and Isopropyl alcohol 70% (v/v). The June 17, 1994, tentative final monograph for OTC Healthcare Antiseptic Drug Products (1994 TFM)(59 FR 31402 at 31443, § 333.460(a)) proposes the following as acceptable statements of the pharmacological category for patient preoperative preparations: _____ “patient preoperative skin preparation.” Given the intended use of this product, “patient preoperative skin preparation” seems more appropriate. Furthermore, 21 CFR 201.61(c) requires that the statement of identity be presented in bold face type on the PDP, in a size reasonably related to the most prominent printed matter on the panel. As advised by members of the Nonprescription Drugs Advisory Committee (NDAC) at its September 19, 2002, meeting, the statement of identity

should be 50 percent of the size of the trade name. See prototype of the statement of identity below.

Chlorascrub™
Swabstick
Chlorhexidine Gluconate 3.15% (w/v) and
Isopropyl Alcohol 70% (v/v)
Patient Preoperative Skin Preparation

2. **Swab:** The statement of identity must be revised. 21 CFR 201.61(b) requires that the PDP include a statement of identity consisting of the established name of the drug, followed by the general pharmacological category of the drug. Both statements must be placed in direct conjunction with the most prominent display of the proprietary name. The appropriate established drug name for Chlorascrub™ is Chlorhexidine gluconate 3.15% (w/v) and Isopropyl alcohol 70% (v/v). The 1994 TFM proposes the following as acceptable statements of the pharmacological category for patient preoperative preparations: "antiseptic" or ~~antiseptic~~. Given the intended use of this product, "antiseptic" seems more appropriate.
3. **Swab, Swabstick and Maxi Swabstick:** The net weight of contents must be revised. 21 CFR 201.62(b) requires the statements of weight of the contents to be expressed in terms of avoirdupois weight (e.g., fluid ounce). However, 21 CFR 201.62(p) allows for a separate statement of net quantity of contents in terms of metric units. Currently, only metric units are supplied. Finally, the statement must appear as a distinct item and must be placed within the bottom 30 percent of the area of the label (refer to 21 CFR 201.62(e)). Since the entire front panel of the outer carton is considered the PDP, this requirement has been met.
4. **Swab, Swabstick and Maxi Swabstick:** The first bulleted statement on the front panel of the Outer carton (PDP) of the Swab and the second bulleted statement on the PDPs of the Swabstick and Maxi Swabstick list skin antisepsis prior to ~~as a use~~ as a use. Currently, the only allowable indications are "for preparation of the skin prior to surgery," "for preparation of the skin prior to an injection," and "helps reduce bacteria that potentially can cause skin infection" (see 1994 TFM, § 333.460(b)). Therefore, ~~as a use~~ must be removed.
5. **Swabstick and Maxi Swabstick:** The first bulleted statement on the front panel of the Outer carton (PDP) should be reworded. Change the term ~~antiseptic~~. Also, the statement currently reads "~~antiseptic~~" (emphasis added). The meaning of this portion of the statement is unclear. The following revision of the statement is consistent with the definition of a patient preoperative skin preparation as described in the 1994 TFM, § 333.403(c)(2): "... ~~antiseptic~~ therefore, the first bullet should read: ~~antiseptic~~

- f. Modify the first two bulleted statements under **Directions** to enhance clarity. These statements are long and should be divided into two sentences (second and third bullets below). Refer to the following prototype **Directions** section for guidance.

Directions

- maximum treatment area for one swab is approximately 2.5 by 2.5 inches (6 by 6 cm)
- tear open packet and remove swab. Do not unfold swab.
- prior to injection, apply swab to the procedure site by holding swab between thumb and index finger. Apply swab to skin using repeated back-and-forth strokes for 15 seconds.
- allow the prepped area to air dry for 30 seconds
- do not blot or wipe dry
- discard after a single use

5. **Other information**

- a. Change the first letter of the first word in each bulleted statement to lower case. Also, remove periods from the end of each statement.
- b. The statement “for hospital and professional use only” may be added to this section.
- c. Remove the third bulleted statement: _____
_____ This statement is not pertinent to the safe and effective use of the product. Refer to 21 CFR 201.66(c)(7) for guidance.

6. **Questions?**

- a. _____

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 § 552(b)(4) Trade Secret / Confidential

 | § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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- f. Reorder the bulleted statements under the **Do not use** subheading so that they are consistent with approved labeling for other drugs in this product category. Refer to the box in B.3.f. for guidance.
- g. Add the subheading **When using this product** to follow the subheading **Do not use**. Move the statement “in the eyes, ears, mouth...” found under **Do not use** (second bullet) to the **When using this product** subheading. Modify the statement so that it is consistent with approved labeling for other drugs in this product category. It should read as follows:
When using this product keep out of eyes, ears, mouth, and mucous membranes. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.
- h. Add the subheading **Stop use and ask a doctor if** to follow the **When using this product** subheading. Move the statement _____ from the *Warnings* section to the subheading **Stop use and ask a doctor if**. Modify the statement so that it is consistent with labeling for other drugs in this product category. It should read as follows:
Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- i. Remove the bullet from the “**Keep out of reach of children**” statement.

5. *Directions*

- a. The maximum treatment areas and drying times are given in the *Directions* section. Please provide a justification (e.g., clinical data) for this information.
- b. Change the first letter of the first word in each bulleted statement to lower case. Also, statements comprised of a single sentence should not have periods at the end (i.e., all but the second bulleted statement).
- c. Remove the word _____ from the third bulleted statement. _____ is not an allowable indication.
- d. Remove _____ from the third bulleted statement. The final rule on Labeling Requirements for OTC drugs (64 FR 13254 at 13268) states that brand names may not appear in the *Drug Facts* enclosure, but may appear anywhere else on the labeling outside of the boxed area.

- e. Increase the prominence of the maximum treatment area information by moving the information toward the top of the bulleted list or by using bold face type.
- f. Emphasize that vigorous application of the antiseptic is recommended (especially for moist sites) by bolding the word “vigorous” in the directions.

6. *Other information*

- a. Change the first letter of the first word in each bulleted statement to lower case. Also, remove periods from the end of each statement.
- b. The statement “for hospital and professional use only” may be added to this section.
- c. Remove the third bulleted statement: _____
_____ This statement is not pertinent to the safe and effective use of the product. Refer to 21 CFR 201.66(c)(7) for guidance.

7. *Questions?*

- a. _____

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D. Packet Label (Immediate Container) – Swab, Swabstick, and Maxi Swabstick

1. Remove the word ~~————~~ ' from the front panel of the Packet label and from the Directions section on the back panel. ~~————~~ is not an allowable indication.
2. Add the statement “**For external use only.**” to the Warnings section of the back panel. The warnings on the Packet label should be the same as those listed under *Warnings* in *Drug Facts*. Therefore, this statement should be the first warning and should be in bold face type.
3. Add the statement “**IMPORTANT: See carton for complete *Drug Facts* information**” to the front and back panels of the Packet label to direct the user to the *Drug Facts* information.

E. Shipping Carton Label – Swab, Swabstick, and Maxi Swabstick

1. If included on the Shipping label, the *Drug Facts* information must be identical to the *Drug Facts* information on the Outer carton label. Refer to sections B and C for guidance on *Drug Facts* requirements.

RECOMMENDATIONS TO THE SPONSOR

Required Changes:

Note: the following changes apply to the Swab, Swabstick, and Maxi Swabstick unless otherwise noted. Please refer to the prototype *Drug Facts* label at the end of these recommendations.

1. Revise the statement of identity on the Principal Display Panel (PDP) of the Swabstick and Maxi Swabstick. The statement of identity must include the appropriate established name of the drug (Chlorhexidine gluconate 3.15% (w/v) and Isopropyl alcohol 70% (v/v)), followed by the general pharmacological category of the drug (Patient preoperative skin preparation). Refer to 21 CFR 201.61(b) for guidance.
2. Revise the statement of identity on the PDP of the Swab. The statement of identity must include the appropriate established name of the drug (Chlorhexidine gluconate 3.15% (w/v) and Isopropyl alcohol 70% (v/v)), followed by the general pharmacological category of the drug (Antiseptic). Refer to 21 CFR 201.61(b) for guidance.

3. Express the net weight of contents of the Swab, Swabstick, and Maxi Swabstick in terms of avoirdupois weight (e.g., fluid ounce). Metric weights are allowed, but the avoirdupois weight must precede the metric weight. Refer to 21 CFR 201.62(b) and (p) for guidance.
4. Remove the word " _____" from the PDP, *Drug Facts* (under *Uses* and *Directions*), and Packet label (front and back panels) of the Swab, Swabstick, and Maxi Swabstick. Currently, the only allowable indications are "for preparation of the skin prior to surgery," "for preparation of the skin prior to an injection," and "helps reduce bacteria that potentially can cause skin infection". Refer to the June 17, 1994, tentative final monograph (TFM) for OTC Healthcare Antiseptic Drug Products (59 FR 31402 at 31443, § 333.460(b)) for these allowable indications.
5. Change the first letter of the second word of the active ingredients (i.e., gluconate and alcohol) in the *Drug Facts* box of the Swabstick and Maxi Swabstick from upper case to lower case.
6. Change the first letter of the first word of each bulleted statement in the *Drug Facts* box (under the headings *Uses*, *Directions*, and *Other information*) from upper case to lower case.
7. Remove the periods from the ends of the statements in the *Drug Facts* box (under the headings *Uses*, *Warnings*, *Directions*, *Other information*, and _____). However, statements comprised of more than one sentence should have periods at the end of each sentence.
8. Move the statement "for hospital and professional use only" from the *Uses* section to the *Other information* section.
9. Remove the bullets from the statements immediately under the *Warnings* heading, unless more than one statement is placed on the same line.
10. Move the warning "**For external use only**" so that it is the first statement under the *Warnings* heading. Refer to 21 CFR 201.66(c) for guidance.
11. Move the statement "do not use under occlusive patch" to the **Do not use** subheading (see #13 below). Do not capitalize the word "occlusive".
12. Move the statement " _____ skin irritation and redness develop" to the **Stop use and ask a doctor if** subheading (see #15 below).

13. Reorder the bulleted statements under the **Do not use** subheading of the **Warnings** section of **Drug Facts** to make them consistent with approved labeling for other drugs in this product category. Reorder the bullets as follows:

Do not use

- on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser
- under occlusive patch

14. Modify the **Warnings** section of **Drug Facts**:
- a. Add the subheading **When using this product**, following the subheading **Do not use**.
 - b. Move the statement “in the eyes, ears, mouth...” from the _____ subheading to the **When using this product** subheading.
 - c. Modify the statement for consistency with approved labeling of other drugs in this product category. The statement should read as follows:
When using this product keep out of eyes, ears, mouth, and mucous membranes. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.
15. Modify the **Warnings** section of **Drug Facts**:
- a. Add the subheading **Stop use and ask a doctor if**, following the subheading **When using this product**.
 - b. Move the statement “_____ if skin irritation and redness develop” from the **Warnings** section to the subheading **Stop use and ask a doctor if**.
 - c. Modify the statement for consistency with approved labeling of other drugs in this product category. The statement should read as follows:
Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
16. Remove the bullet from the “**Keep out of reach of children**” statement.
17. Increase the prominence of the maximum treatment area information in the **Directions** section by moving the information toward the top of the bulleted list or by using bold face type (see #19 below).
18. Remove the _____ from the **Directions** section. The final rule on Labeling Requirements for OTC drugs (64 FR 13254 at 13268) states that _____ may not appear in the **Drug Facts** enclosure, but may appear anywhere else on the labeling outside of the boxed area.

19.



20.



21. Add the statement "**For external use only.**" to the Warnings section of the back panel of the Packet label. The warnings on the Packet label should be the same as those listed under *Warnings in Drug Facts*. Therefore, this statement should be the first warning and should be in bold face type, as described in 21 CFR 201.66(c).
22. Add the statement "IMPORTANT: See carton for complete *Drug Facts* information" to the front and back panels of the Packet label.

Recommended Changes:

1. Change the first bulleted statement on the front panel of the Outer carton (PDP) of the Swabstick and Maxi Swabstick to read: _____

2. Listed uses for the Swabstick and Maxi Swabstick can be combined to one bullet. *Uses* may read as follows:
Use for the preparation of the patient's skin prior to surgery or injection
3. Emphasize that vigorous application of the antiseptic is recommended by bolding the word "vigorous" in the directions.

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NDA REGULATORY FILING REVIEW
(Including Memo of Filing Meeting)

NDA # **21-524** Supplement # **NA** SE1 SE2 SE3 SE4 SE5 SE6 SE7 SE8

Trade Name: Chlorascrub™
 Generic Name: 3.15% (w/v) Chlorhexidine Gluconate with 70% (v/v) Isopropyl Alcohol (IPA)
 Strengths: Swab, Swabstick, Maxi Swabstick

Applicant: Les Entreprises SoluMed, Inc. (US Agent: Nice Pak Products, Inc. Orangeburg NY)

Date of Application: July 26, 2004
 Date of Receipt: August 5, 2004
 Date clock started after UN:
 Date of Filing Meeting: September 27, 2004
 Filing Date: October 4, 2004
 Action Goal Date (optional): May 30, 2004 User Fee Goal Date: **June 5, 2004**

Indication(s) requested: skin antiseptic, skin preparation prior to surgery, skin preparation prior to injection or puncture

Type of Original NDA: (b)(1) _____ (b)(2) X
 OR
 Type of Supplement: (b)(1) _____ (b)(2) _____

NOTE:

- (1) *If you have questions about whether the application is a 505(b)(1) or 505(b)(2) application, see Appendix A. A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). If the application is a (b)(2), complete Appendix B.*
- (2) *If the application is a supplement to an NDA, please indicate whether the NDA is a (b)(1) or a (b)(2) application:*
- _____ NDA is a (b)(1) application OR _____ NDA is a (b)(2) application

Therapeutic Classification: S X P _____
 Resubmission after withdrawal? _____ Resubmission after refuse to file? _____
 Chemical Classification: (1,2,3 etc.) 3
 Other (orphan, OTC, etc.) _____

Form 3397 (User Fee Cover Sheet) submitted: YES NO

User Fee Status: Paid _____ Exempt (orphan, government) _____
 Waived (e.g., small business, public health) X

NOTE: *If the NDA is a 505(b)(2) application, and the applicant did not pay a fee in reliance on the 505(b)(2) exemption (see box 7 on the User Fee Cover Sheet), confirm that a user fee is not required. The applicant is required to pay a user fee if: (1) the product described in the 505(b)(2) application is a new molecular entity or (2) the applicant claims a new indication for a use that has not been approved under section 505(b). Examples of a new indication for a use include a new indication, a new dosing regime, a new patient population, and an Rx to OTC switch. The best way to determine if the applicant is claiming a new indication for a use is to compare the applicant's proposed labeling to labeling that has already been approved for the*

product described in the application. Highlight the differences between the proposed and approved labeling. If you need assistance in determining if the applicant is claiming a new indication for a use, please contact the user fee staff.

- Is there any 5-year or 3-year exclusivity on this active moiety in an approved (b)(1) or (b)(2) application? YES NO

If yes, explain:

- Does another drug have orphan drug exclusivity for the same indication? YES NO

- If yes, is the drug considered to be the same drug according to the orphan drug definition of sameness [21 CFR 316.3(b)(13)]? YES NO

If yes, consult the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007).

- Is the application affected by the Application Integrity Policy (AIP)? YES NO

If yes, explain.

- If yes, has OC/DMPQ been notified of the submission? YES NO

- Does the submission contain an accurate comprehensive index? YES NO

- Was form 356h included with an authorized signature? YES NO

If foreign applicant, both the applicant and the U.S. agent must sign.

- Submission complete as required under 21 CFR 314.50? YES NO

If no, explain:

- If an electronic NDA, does it follow the Guidance? N/A YES NO

If an electronic NDA, all certifications must be in paper and require a signature.

Which parts of the application were submitted in electronic format?

The proposed labeling and SAS-transport files were submitted electronically

Additional comments: Entire NDA was submitted in paper except as noted above.

- If in Common Technical Document format, does it follow the guidance? N/A YES NO

- Is it an electronic CTD? N/A YES NO

If an electronic CTD, all certifications must be in paper and require a signature.

Which parts of the application were submitted in electronic format?

Additional comments:

- Patent information submitted on form FDA 3542a? YES NO
- Exclusivity requested? YES, _____ years NO
NOTE: An applicant can receive exclusivity without requesting it; therefore, requesting exclusivity is not required.
- Correctly worded Debarment Certification included with authorized signature? YES NO
If foreign applicant, both the applicant and the U.S. Agent must sign the certification.
NOTE: Debarment Certification should use wording in FD&C Act section 306(k)(1) i.e., "[Name of applicant] hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application." Applicant may not use wording such as "To the best of my knowledge"
- Financial Disclosure forms included with authorized signature? YES NO
(Forms 3454 and 3455 must be used and must be signed by the APPLICANT.)
- Field Copy Certification (that it is a true copy of the CMC technical section)? YES NO

Refer to 21 CFR 314.101(d) for Filing Requirements

- PDUFA and Action Goal dates correct in COMIS? YES NO
 If not, have the document room staff correct them immediately. These are the dates EES uses for calculating inspection dates.
- Drug name/Applicant name correct in COMIS? If not, have the Document Room make the corrections.
- List referenced IND numbers: **IND 59,446**
- End-of-Phase 2 Meeting(s)? Date(s) _____ NO
 If yes, distribute minutes before filing meeting.
- Pre-NDA Meeting(s)? Date(s) 3/11/02 NO
 If yes, distribute minutes before filing meeting.

Project Management

- All labeling (PI, PPI, MedGuide, carton and immediate container labels) consulted to DDMAC? Professional use product; DDMAC does not review YES NO
- Trade name (plus PI and all labels and labeling) consulted to ODS/DMETS? YES NO
- MedGuide and/or PPI (plus PI) consulted to ODS/DSRCS? N/A YES NO

- If a drug with abuse potential, was an Abuse Liability Assessment, including a proposal for scheduling, submitted? N/A YES NO

If Rx-to-OTC Switch application:

- OTC label comprehension studies, all OTC labeling, and current approved PI consulted to ODS/DSRCS? N/A YES NO
- Has DOTCDP been notified of the OTC switch application? YES NO

Clinical

- If a controlled substance, has a consult been sent to the Controlled Substance Staff? N/A YES NO

Chemistry

- Did applicant request categorical exclusion for environmental assessment? YES NO
- If no, did applicant submit a complete environmental assessment? YES NO
- If EA submitted, consulted to Florian Zielinski (HFD-357)? YES NO
- Establishment Evaluation Request (EER) submitted to DMPQ? YES NO
- If a parenteral product, consulted to Microbiology Team (HFD-805)? YES NO

ATTACHMENT

MEMO OF FILING MEETING

DATE: September 27, 2004 (11:00am)

BACKGROUND: This NDA is for Chlorascrub™ Swabstick, Maxi Swabstick and Swab. This is a 3.15% (w/v) chlorhexidine gluconate and 70% (v/v) isopropyl alcohol product. The applicant seeks the following indications: skin antiseptic; skin preparation prior to surgery; and skin preparation prior to injector —

This application will be jointly reviewed between the Division of Anti-Infective Drug Products and the Division of Over-the-Counter Drug Products.

Additionally, this NDA was filed as a 505(b)(2) application because it is relying on the Agency's findings of safety for NDA 20-832 (Mediflex; ChloraPrep (2% Chlorhexidine Gluconate/70% Isopropyl Alcohol)).

ATTENDEES:

Division of Anti-Infective Drug Products

Janice Soreth, MD, Division Director
Jean Mulinde, MD, Clinical Team Leader
David Bostwick, Clinical Reviewer
Connie Mahon, M.S., Microbiology Reviewer
Fred Marsik, Ph.D., Microbiology Team Leader (acting)
Sue Bell, Ph.D., Statistical Reviewer
Daphne Lin, Ph.D., Statistical Team Leader
Milton Sloan, Ph.D., Chemistry Reviewer
James Vidra, Ph.D., Chemistry Team Leader
Maureen Dillon-Parker, Project Manager

Office of Drug Evaluation IV

David Roeder, Associate Director for Regulatory Affairs

Office of Drug Evaluation V

Jonca C. Bull, MD, Director
Terri Rumble, Associate Director for Regulatory Affairs

Division of Over-the-Counter Drug Products

Charles Ganley, MD, Division Director
David Hilfiker, MS, Supervisory Project Manager
Steve Osborne, MD., Medical Officer
Andrea Leonard-Segal, M.D., M.S., Medical Team Leader
Tia Frazier, RN, MS, Project Manager
Debbie Lumpkins, Team Leader, Interdisciplinary Scientist, Team 3
Colleen Kane, Ph.D., Microbiology Reviewer

ASSIGNED REVIEWERS:

<u>Discipline</u>	<u>Reviewer</u>
Medical:	David Bostwick
Secondary Medical:	Jean Mulinde
Statistical:	Sue Bell.
Pharmacology:	Amy Ellis
Statistical Pharmacology:	NA
Chemistry:	Milton Sloan.
Environmental Assessment (if needed):	NA
Biopharmaceutical:	Venkateswar Jarugula
Microbiology, sterility:	NA
Microbiology, clinical (for antimicrobial products only):	Connie Mahon
DSI:	Mathew Thomas/Brenda Friend
Regulatory Project Management:	Maureen Dillon-Parker
Other Consults: <u>OTC</u>	<u>Clinical:</u> Steve Osborne & Andrea Leonard-Segal
	<u>PM:</u> Tia Frazier
	<u>IDS/Labeling:</u> Debbie Lumpkins & Colleen Kane

Per reviewers, are all parts in English or English translation? YES NO
 If no, explain:

CLINICAL FILE X REFUSE TO FILE _____

- Clinical site inspection needed: YES NO
- Advisory Committee Meeting needed? YES, date if known _____ NO
- If the application is affected by the AIP, has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance? N/A YES NO

CLINICAL MICROBIOLOGY NA _____ FILE X REFUSE TO FILE _____

STATISTICS FILE X REFUSE TO FILE _____

BIOPHARMACEUTICS FILE X REFUSE TO FILE _____

- Biopharm. inspection needed: YES NO

PHARMACOLOGY NA _____ FILE X REFUSE TO FILE _____

- GLP inspection needed: YES NO

CHEMISTRY FILE X REFUSE TO FILE _____

- Establishment(s) ready for inspection? YES NO

- Microbiology

N/A

YES

NO

ELECTRONIC SUBMISSION:

Any comments: SAS Data sets and Labeling submitted electronically.

REGULATORY CONCLUSIONS/DEFICIENCIES:

_____ The application is unsuitable for filing. Explain why:

_____ The application, on its face, appears to be well organized and indexed. The application appears to be suitable for filing.

_____ No filing issues have been identified.

 X Filing issues to be communicated by Day 74. List (optional):

ACTION ITEMS:

Document filing issues conveyed to applicant by Day 74. Letter issued 10-18-04.

Regulatory Project Manager, HFD-520

Appendix A to NDA Regulatory Filing Review

An application is likely to be a 505(b)(2) application if:

- (1) it relies on literature to meet any of the approval requirements (unless the applicant has a written right of reference to the underlying data)
- (2) it relies on the Agency's previous approval of another sponsor's drug product (which may be evidenced by reference to publicly available FDA reviews, or labeling of another drug sponsor's drug product) to meet any of the approval requirements (unless the application includes a written right of reference to data in the other sponsor's NDA)
- (3) it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)
- (4) it seeks approval for a change from a product described in an OTC monograph and relies on the monograph to establish the safety or effectiveness of one or more aspects of the drug product for which approval is sought (see 21 CFR 330.11).

Products that may be likely to be described in a 505(b)(2) application include combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations), OTC monograph deviations, new dosage forms, new indications, and new salts.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, please consult with the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007).

**Appendix B to NDA Regulatory Filing Review
Questions for 505(b)(2) Applications**

1. Does the application reference a listed drug (approved drug)? YES NO

If "No," skip to question 3.

2. Name of listed drug(s) referenced by the applicant (if any) and NDA/ANDA #(s):

NDA 20-832; Medi-Flex, Inc., ChloroPrep®
[chlorhexidine gluconate 2% (w/v) and isopropyl alcohol 70% (v/v)]

3. The purpose of this and the questions below (questions 3 to 5) is to determine if there is an approved drug product that is equivalent or very similar to the product proposed for approval and that should be referenced as a listed drug in the pending application.

- (a) Is there a pharmaceutical equivalent(s) to the product proposed in the 505(b)(2) application that is already approved?

YES NO

(Pharmaceutical equivalents are drug products in identical dosage forms that: (1) contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; (2) do not necessarily contain the same inactive ingredients; and (3) meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. (21 CFR 320.1(c))

If "No," skip to question 4. Otherwise, answer part (b).

- (b) Is the approved pharmaceutical equivalent(s) cited as the listed drug(s)? YES NO
(The approved pharmaceutical equivalent(s) should be cited as the listed drug(s).)

If "Yes," skip to question 6. Otherwise, answer part (c).

- (c) Have you conferred with the Director, Division of Regulatory Policy II, Office of Regulatory Policy (ORP) (HFD-007)?

YES NO

If "No," please contact the Director, Division of Regulatory Policy II, ORP. Proceed to question 6.

4. (a) Is there a pharmaceutical alternative(s) already approved? YES NO

(Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates. (21 CFR 320.1(d)) Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate- or standard-release formulations of the same active ingredient.)

If "No," skip to question 5. Otherwise, answer part (b).

- (b) Is the approved pharmaceutical alternative(s) cited as the listed drug(s)? YES NO
(The approved pharmaceutical alternative(s) should be cited as the listed drug(s).)

NOTE: If there is more than one pharmaceutical alternative approved, consult the Director, Division of Regulatory Policy II, Office of Regulatory Policy (ORP) (HFD-007) to determine if the appropriate pharmaceutical alternatives are referenced.

If "Yes," skip to question 6. Otherwise, answer part (c).

- (c) Have you conferred with the Director, Division of Regulatory Policy II, ORP? YES NO

If "No," please contact the Director, Division of Regulatory Policy II, ORP. Proceed to question 6.

5. (a) Is there an approved drug product that does not meet the definition of "pharmaceutical equivalent" or "pharmaceutical alternative," as provided in questions 3(a) and 4(a), above, but that is otherwise very similar to the proposed product?

YES NO

If "No," skip to question 6.

If "Yes," please describe how the approved drug product is similar to the proposed one and answer part (b) of this question. Please also contact the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007), to further discuss.

The approved product (NDA 20-832) is indicated for the same indications as this Sponsor is seeking and contains both chlorhexidine gluconate (CHG) and isopropyl alcohol. The approved product contains 2% CHG/70% IPA whereas, this NDA contains 3.15% CHG/70% IPA..

- (b) Is the approved drug product cited as the listed drug? YES NO

6. Describe the change from the listed drug(s) provided for in this (b)(2) application (for example, "This application provides for a new indication, otitis media" or "This application provides for a change in dosage form, from capsules to solution").

This product provides for an increase in the amount of CHG in the product and the addition of a swab applicator.

7. Is the application for a duplicate of a listed drug and eligible for approval under section 505(j) as an ANDA? (Normally, FDA will refuse-to-file such NDAs (see 21 CFR 314.101(d)(9)). YES NO

8. Is the extent to which the active ingredient(s) is absorbed or otherwise made available to the site of action less than that of the reference listed drug (RLD)? (See 314.54(b)(1)). If yes, the application should be refused for filing under 21 CFR 314.101(d)(9). YES NO
9. Is the rate at which the product's active ingredient(s) is absorbed or otherwise made available to the site of action unintentionally less than that of the RLD (see 21 CFR 314.54(b)(2))? If yes, the application should be refused for filing under 21 CFR 314.101(d)(9). YES NO
10. Are there certifications for each of the patents listed for the listed drug(s)? YES NO*
***Application contains a certification that states "there are no patents that claim the drug or drug product, or claim a method for using the drug product".**

11. Which of the following patent certifications does the application contain? (Check all that apply and identify the patents to which each type of certification was made, as appropriate.)

21 CFR 314.50(i)(1)(i)(A)(1): The patent information has not been submitted to FDA. (Paragraph I certification)

21 CFR 314.50(i)(1)(i)(A)(2): The patent has expired. (Paragraph II certification)

21 CFR 314.50(i)(1)(i)(A)(3): The date on which the patent will expire. (Paragraph III certification)

21 CFR 314.50(i)(1)(i)(A)(4): The patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. (Paragraph IV certification)

IF FILED, and if the applicant made a "Paragraph IV" certification [21 CFR 314.50(i)(1)(i)(A)(4)], the applicant must subsequently submit a signed certification stating that the NDA holder and patent owner(s) were notified the NDA was filed [21 CFR 314.52(b)]. The applicant must also submit documentation showing that the NDA holder and patent owner(s) received the notification [21 CFR 314.52(e)].

21 CFR 314.50(i)(1)(ii): No relevant patents.

21 CFR 314.50(i)(1)(iii): The patent on the listed drug is a method of use patent and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent as described in the corresponding use code in the Orange Book. Applicant must provide a statement that the method of use patent does not claim any of the proposed indications. (Section viii statement)

21 CFR 314.50(i)(3): Statement that applicant has a licensing agreement with the patent owner (must also submit certification under 21 CFR 314.50(i)(1)(i)(A)(4) above).

Written statement from patent owner that it consents to an immediate effective date upon approval of the application.

12. Did the applicant:

- Identify which parts of the application rely on information (e.g. literature, prior approval of another sponsor's application) that the applicant does not own or to which the applicant does not have a right of reference?

YES NO
- Submit a statement as to whether the listed drug(s) identified has received a period of marketing exclusivity?

YES NO
- Submit a bioavailability/bioequivalence (BA/BE) study comparing the proposed product to the listed drug?

N/A YES NO
- Certify that it is seeking approval only for a new indication and not for the indications approved for the listed drug if the listed drug has patent protection for the approved indications and the applicant is requesting only the new indication (21 CFR 314.54(a)(1)(iv).?

N/A YES NO

13. If the (b)(2) applicant is requesting 3-year exclusivity, did the applicant submit the following information required by 21 CFR 314.50(j)(4): No exclusivity requested.

- Certification that at least one of the investigations included meets the definition of "new clinical investigation" as set forth at 314.108(a).

YES NO
- A list of all published studies or publicly available reports that are relevant to the conditions for which the applicant is seeking approval.

YES NO
- EITHER
The number of the applicant's IND under which the studies essential to approval were conducted.

IND # 59,446 NO

OR
A certification that the NDA sponsor provided substantial support for the clinical investigation(s) essential to approval if it was not the sponsor of the IND under which those clinical studies were conducted?

YES NO

14. Has the Associate Director for Regulatory Affairs, OND, been notified of the existence of the (b)(2) application?

YES NO

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Maureen Dillon-Parker
10/26/04 01:30:00 PM
CSO
NDA 21-524; NDA Regulatory Filing Review

OTC Division Comments on Chlorascrub Labeling

1. The CDER Labeling and Nomenclature Committee was contacted regarding the correct designation of the established name for this drug product. The committee concurs that the established name of this product should be Chlorhexidine Gluconate and Isopropyl Alcohol. ~~Revise labels and labeling to reflect the correct designation of the established name. Relocate the drug strength information to the space after the names of the product's active ingredients to provide more prominence. We suggest the following established name format:~~

**Chlorhexidine Gluconate 3.15% (w/v)
and Isopropyl Alcohol 70% (v/v)**

2. Please define the term "Maxi" as part of "Maxi Swabstick" where it appears on product labeling, if necessary using an asterisks to locate the definition to a less prominent location on the labeling. FDA's Division of Medication Errors and Technical Support reported that the phrase "maxi" in your proposed tradename needs to be more clearly defined.

3. Delete the terminal zero where it appears with "1.0 mL" on labels and labeling of the Clorascrub Swab product. Postmarketing experience has shown confusion resulting in ten-fold errors as a result of terminal zero notation. We note that the Joint Commission for Accreditation of Hospitals (JCAHO), 2005 Hospitals National Patient Safety Goals includes the goal: Improve the effectiveness of communication among caregivers. A requirement to meet this goal is that each hospital must 'Standardize a list of abbreviations, acronyms and symbols that are not to be used throughout the organization. The use of trailing zeroes is specifically listed as a dangerous abbreviation, acronym, or symbol. Other healthcare organizations, such as ISMP have also published similar lists containing symbols that can lead to medication errors.



FILING COMMUNICATION

NDA 21-524

Nice-Pak Products, Inc. [U.S. Agent for Les Enterprises SoluMed Inc.]
Attention: Bob Reichman
Vice President, Quality and Production
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Mr. Reichman:

Please refer to your August 5, 2004 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chlorascrub™ Swabstick, Maxi Swabstick and Swab [3.15% (w/v) chlorhexidine gluconate and 70% (v/v) isopropyl alcohol].

We also refer to your submission dated August 19, 2004.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application has been filed under section 505(b) of the Act on October 5, 2004 in accordance with 21 CFR 314.101(a).

In our filing review, we have identified the following potential review issues:

Microbiology:

With regard to the report on the “*In vitro* antimicrobial spectrum and time-kill studies on Chlorascrub 3.15% chlorhexidine gluconate with 70% isopropyl alcohol” Study SLM: ITSSSTK-01, the following information is requested:

Time Kill Studies

- 1) The time kill studies results show microbial reductions in the tubes that contain phosphate buffered saline and organism inoculum that served as viability controls. Please explain or clarify the microbial reduction of up to 70% of the microbial population in the absence of an active ingredient. Please explain the results that show variable % reductions in the viability control tubes over the course of test time (0-30 minutes). (Table 3 Time Kill Studies, Section 7.3.8.3 page 239).
- 2) Explain why *M. luteus* ATCC 7468 failed to grow in this experiment.
- 3) In testing EC 11229, the viability control plates were reportedly dropped. Was the test procedure for this organism repeated?

MIC Analysis:

In accordance with the Tentative Final Monograph (TFM) FR 333.470 (1)(ii) (Testing of health-care antiseptic drug products), 25 fresh clinical isolates and 25 laboratory strains of the organisms listed in the section are to be included in the *in vitro* testing to determine the *in vitro* antimicrobial spectrum of the antiseptic ingredient, vehicle, and the finished product. For the following organisms, please provide a rationale for not being able to meet the number of test isolates.

Staphylococcus epidermidis (29)
Staphylococcus haemolyticus (28)
Staphylococcus hominis (5)
Micrococcus luteus(3)
Staphylococcus saprophyticus (11)

Additional information requests:

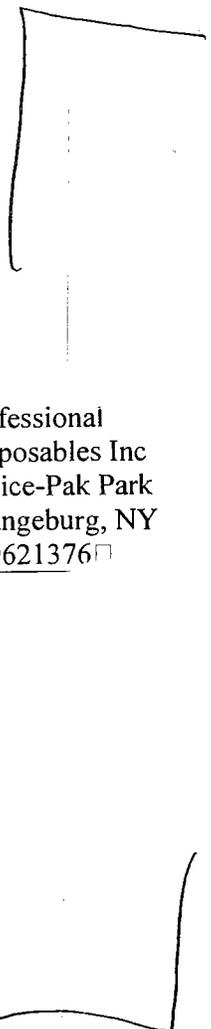
- 1) Provide a copy of the ASTM procedure used in performing the *in vitro* neutralization validation studies and time kill studies mentioned in the report. If the document is included in the submission, please provide the volume number or section. Please include the formula used or how the microbial log reductions in the time kill studies were derived.
- 2) In the time kill study procedure #4 (page 255) it states that “100 µl was removed and transferred to 0.9 ml of neutralizer. This was repeated for each of the four tubes.” Does this imply that the viability control tubes also contained the neutralizer? If this was the case, were there additional viability or microbial growth control tubes included in the experiment that only contained the phosphate buffered saline and microbial inoculum to assure that the organisms in the inoculum were viable?
- 3) In the time kill study procedure #5 (page 225) where it states that the “suspension was serially diluted and duplicate 0.1ml samples were plated onto _____ agar plates without neutralizer (the plating method)”, please provide the worksheets or logsheets used that show the serial dilutions and the colony counts on each of the dilutions of the tested substances (SoluPrep 1:10, SoluPrep 1:100, Hibiclens 1:100, and Microbial population) for the each of the organisms tested.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application.

We also request that you submit the following information as requested in the facsimile of October 1, 2004:

Chemistry:

These establishments were included in NDA 21-524. Please verify that the list of establishments below is correct and that the sites are ready for inspection. Please also supply missing CFN (Central File Number) or FEI (Form Establishment Indicator) for the indicated sites.

Establishments:		Responsibilities		Establishment information found in FDA database	
CFN _____ FEI _____		Drug Substance Manufacturer	DMF No: None	Yes	
CFN _____ FEI _____		Finished Dosage Release Tester And Stability Tester		Yes	
CFN _____ FEI _____		Drug Substance Manufacturer	DMF No: _____	Yes	
CFN 2411192 FEI _____		Professional Disposables Inc 2 Nice-Pak Park Orangeburg, NY 109621376	Finished Dosage Manufacturer And Packager		Yes
CFN _____ FEI _____			Drug Substance Manufacturer	DMF No: None	No
CFN _____ FEI _____			Finished Dosage Manufacturer And Packager		No
CFN _____ FEI _____			Finished Dosage Manufacturer And Packager		No

Statistics:

If possible, the reviewer requests that the datasets be provided or revised as follows:

- 1) To include the demographic information (age, sex, race) for each subject for both efficacy and safety studies.
- 2) Provide data for safety study SC-02 mentioned in letter dated July 26, 2004 and safety data for SC-03 and SC-08.
- 3) Provide analysis datasets that are as consistent in format as possible across the studies. For studies SC-03 and SC-04 we would prefer the efficacy data be provided as row per subject as was provided for in SC-08. Include the measurement units in the file definitions and convert SC-04 to CFU per square centimeter to be consistent with the Tentative Final Monograph's outcome measure and with the other studies.

Please respond only to the above requests for additional information. While we anticipate that any response submitted in a timely manner will be reviewed during this review cycle, such review decisions will be made on a case-by-case basis at the time of receipt of the submission.

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc: Les Entreprises Solumed, Inc.
Attention: Anna Mallozzi, B. Chem. Eng.
Regulatory Affairs
2109 Le Chatelier
Laval QUEBEC
H7L 5B3 CANADA

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Janice Soreth
10/18/04 03:53:50 PM



**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV**

FACSIMILE TRANSMITTAL SHEET

DATE: October 1, 2004

To: Bob Reichman, US Agent, Nice-Pak Anna Mallozzi, Les Entreprises Solumed	From: Maureen Dillon-Parker
Company: Nice-Pak Products Inc. and	Division of Division of Anti-Infective Drug Products
Fax number: #845-365-1602 (NP) #450-682-5777 (LES)	Fax number: #301-827-2325
Phone number: #845-365-1700	Phone number: #301- 827-2125
Subject: Request for Information on NDA 21-524	

Total no. of pages including cover: 3

Comments: Please see attached request from the Chemistry and Statistical reviewer. We request that you submit this information to your NDA file.

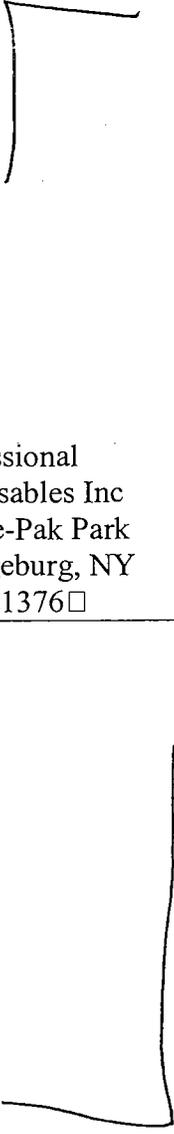
Document to be mailed: YES NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this 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 notify us immediately by telephone at (301) 827-2125. Thank you.

Chlorascrub™ (chlorhexidine gluconate and isopropyl alcohol) Swabstick, Maxi Swabstick and Swab

Chemistry Request: These establishments were included in NDA 21-524. Please verify that the list of establishments below is correct and that the sites are ready for inspection. Please also supply missing CFN (central file numbers) or FEI (facility establishment identification) for the indicated sites.

Establishments:		Responsibilities		Establishment information found in FDA database	
CFN _____ FEI _____		Drug Substance Manufacturer	DMF No: None	Yes	
CFN _____ FEI _____ 3		Finished Dosage Release Tester And Stability Tester		Yes	
CFN _____ FEI _____		Drug Substance Manufacturer	DMF No: _____	Yes	
CFN 2411192 FEI _____		Professional Disposables Inc 2 Nice-Pak Park Orangeburg, NY 109621376□	Finished Dosage Manufacturer And Packager		Yes
CFN _____ FEI _____			Drug Substance Manufacturer	DMF No: None	No
CFN _____ FEI _____			Finished Dosage Manufacturer And Packager		No
CFN _____ FEI _____			Finished Dosage Manufacturer And Packager		No

Statistics Request:

If possible, the reviewer requests that the datasets be provided or revised as follows:

- 1) To include the demographic information (age, sex, race) for each subject for both efficacy and safety studies.
- 2) Provide data for safety study SC-02 mentioned in letter dated July 26, 2004 and safety data for SC-03 and SC-08.
- 3) Provide analysis datasets that are as consistent in format as possible across the studies. For studies SC-03 and SC-04 we would prefer the efficacy data be provided as row per subject as was provided for in SC-08. Include the measurement units in the file definitions and convert SC-04 to CFU per square centimeter to be consistent with the Tentative Final Monograph's outcome measure and with the other studies.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Document Room N-111
9201 Corporate Blvd
Rockville, Maryland 20850

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Frances V. LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Cc: Les Entreprises SoluMed, Inc.
Attention: Anna Mallozzi
Director, Regulatory Affairs
2109 Le Chatelier
Laval, Quebec
CANADA H7L 5B3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-524

Nice-Pak Products, Inc. [U.S. Agent for Les Enterprises SoluMed Inc.]
Attention: Bob Reichman
Vice President, Quality and Production
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Mr. Reichman:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Chlorascrub™ Swabstick, Maxi Swabstick and Swab
[3.15% (w/v) chlorhexidine gluconate and 70% (v/v) isopropyl alcohol]

Review Priority Classification: Standard (S)

Date of Application: July 26, 2004

Date of Receipt: August 5, 2004

Our Reference Number: NDA 21-524

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on October 4, 2004 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be June 5, 2005.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirements. We acknowledge receipt of your request for a waiver of pediatric studies for this application. Once the application has been filed we will notify you whether we have waived the pediatric study requirement for this application.

NDA 21-524

Page 2

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Document Room N-111
9201 Corporate Blvd
Rockville, Maryland 20850

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Frances V. LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Cc: Les Entreprises SoluMed, Inc.
Attention: Anna Mallozzi
Director, Regulatory Affairs
2109 Le Chatelier
Laval, Quebec
CANADA H7L 5B3

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Frances LeSane
8/13/04 12:40:45 PM

EXHIBIT E10

**Trademarks > Trademark Electronic Search System (TESS)**

TESS was last updated on Wed May 6 03:21:32 EDT 2015

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [BOTTOM](#) | [HELP](#) Please logout when you are done to release system resources allocated for you.**Record 1 out of 1**[TSDR](#) | [ASSIGN Status](#) | [TTAB Status](#) (Use the "Back" button of the Internet Browser to return to TESS)

CHLORADRAPE

Word Mark	CHLORADRAPE
Goods and Services	IC 010. US 026 039 044. G & S: Surgical drapes
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85499332
Filing Date	December 19, 2011
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	May 29, 2012
International Registration Number	1121161
Owner	(APPLICANT) ENTROTECH LIFE SCIENCES, INC. CORPORATION DELAWARE 409 ILLINOIS STREET SAN FRANCISCO CALIFORNIA 94158
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Lisa M. Griffith
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [TOP](#) | [HELP](#)[HOME](#) | [SITE INDEX](#) | [SEARCH](#) | [eBUSINESS](#) | [HELP](#) | [PRIVACY POLICY](#)

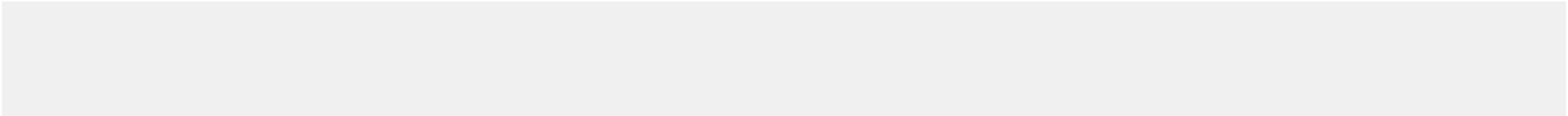


EXHIBIT E11

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499332 - CHLORADRAPE - entrotech 11
Sent: 3/26/2012 11:24:46 AM
Sent As: ECOM105@USPTO.GOV
Attachments: [Attachment - 1](#)
[Attachment - 2](#)
[Attachment - 3](#)
[Attachment - 4](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85499332

MARK: CHLORADRAPE

85499332

CORRESPONDENT ADDRESS:

LISA M. GRIFFITH
THE GRIFFITH LAW FIRM, A P.C.
991C LOMAS SANTA FE DR STE 450
SOLANA BEACH, CA 92075-2125

CLICK HERE TO RESPOND TO THIS LETTER:

http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: entrotech, inc.

CORRESPONDENT'S REFERENCE/DOCKET

NO:

entrotech 11

CORRESPONDENT E-MAIL ADDRESS:

Lgriffith@griffithpc.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: **3/26/2012**

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See 37*

C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

SEARCH OF OFFICE DATABASE:

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no similar registered mark that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d). However, marks in prior-filed pending applications may present a bar to registration of applicant's mark.

POTENTIAL 2(d) REFUSALS:

The filing dates of pending Application Serial Nos. **85051474 & 85051477** precede applicant's filing date. See attached referenced applications. If one or more of the marks in the referenced applications register, applicant's mark may be refused registration under Trademark Act Section 2(d) because of a likelihood of confusion with the registered mark(s). *See* 15 U.S.C. §1052(d); 37 C.F.R. §2.83; TMEP §§1208 *et seq.* Therefore, upon receipt of applicant's response to this Office action, action on this application may be suspended pending final disposition of the earlier-filed referenced applications.

In response to this Office action, applicant may present arguments in support of registration by addressing the issue of the potential conflict between applicant's mark and the marks in the referenced applications. Applicant's election not to submit arguments at this time in no way limits applicant's right to address this issue later if a refusal under Section 2(d) issues.

SIGNIFICANCE INQUIRY:

Applicant must specify whether the wording "**CHLORADRAPE**", "**CHLORA DRAPE**", and "**CHLORA**" has any significance in the health, medical, and medical equipment field, trade, or industry and as applied to the goods described in the application, or if such wording is a "term of art" within applicant's industry. *See* 37 C.F.R. §2.61(b); TMEP §§808.01(a), 814.

Failure to respond to a request for information is an additional ground for refusing registration. *See In re Cheezwhse.com, Inc.*, 85 USPQ2d 1917, 1919 (TTAB 2008); *In re DTI P'ship LLP*, 67 USPQ2d 1699, 1701 (TTAB 2003); TMEP §814.

If applicant has questions about its application or needs assistance in responding to this Office action, please telephone the assigned trademark examining attorney directly at the number below.

Simon Teng
/Simon Teng/

Trademark Examining Attorney - USPTO
Law Office 105
Tel: 571-272-4930; simon.teng@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

DESIGN MARK

Serial Number

85051474

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 005. US 006 018 044 046 051 052. G & S: antimicrobial catheter patch dressing.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

Print: Mar 26, 2012

85051477

DESIGN MARK

Serial Number

85051477

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 010. US 026 039 044. G & S: surgical incise drape.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499332 - CHLORADRAPE - entrotech 11
Sent: 3/26/2012 11:24:46 AM
Sent As: ECOM105@USPTO.GOV
Attachments:

**IMPORTANT NOTICE REGARDING YOUR
U.S. TRADEMARK APPLICATION**

USPTO OFFICE ACTION HAS ISSUED ON **3/26/2012 FOR
SERIAL NO. 85499332**

Please follow the instructions below to continue the prosecution of your application:

TO READ OFFICE ACTION: Click on this [link](#) or go to <http://portal.uspto.gov/external/portal/tow> and enter the application serial number to [access](#) the Office action.

PLEASE NOTE: The Office action may not be immediately available but will be viewable within 24 hours of this e-mail notification.

RESPONSE IS REQUIRED: You should carefully review the Office action to determine (1) how to respond; and (2) the applicable [response time period](#). Your response deadline will be calculated from **3/26/2012** (or sooner if specified in the office action).

Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System [Response Form](#).

HELP: For *technical* assistance in accessing the Office action, please e-mail TDR@uspto.gov. Please contact the assigned examining attorney with questions about the Office action.

WARNING

Failure to file the required response by the applicable deadline will result in the [ABANDONMENT](#) of your application.

EXHIBIT E12

Response to Office Action

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85499332
LAW OFFICE ASSIGNED	LAW OFFICE 105
MARK SECTION (no change)	
ARGUMENT(S)	
<p>The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCRUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORADRAPE" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORADRAPE" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.</p>	
ADDITIONAL STATEMENTS SECTION	
SIGNIFICANCE OF MARK	CHLORADRAPE appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.
MISCELLANEOUS STATEMENT	CHLORA DRAPE and CHLORA have no significance nor are they terms of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance. However, as noted above in response to the asserted potential Trademark Act Section 2(d) refusal, the prefix CHLORA is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry.
SIGNATURE SECTION	
RESPONSE SIGNATURE	/Lisa M. Griffith/

SIGNATORY'S NAME	Lisa M. Griffith
SIGNATORY'S POSITION	Attorney of record, CA bar member
SIGNATORY'S PHONE NUMBER	8587566935
DATE SIGNED	03/29/2012
AUTHORIZED SIGNATORY	YES
FILING INFORMATION SECTION	
SUBMIT DATE	Thu Mar 29 12:53:40 EDT 2012
TEAS STAMP	USPTO/ROA-75.32.224.63-20 120329125340815212-854993 32-490c0fdee543251cb3e6ac 2a3bdaf628b2-N/A-N/A-2012 0329124545906865

PTO Form 1957 (Rev 9/2005)
OMB No. 0651-0050 (Exp. 07/31/2017)

Response to Office Action To the Commissioner for Trademarks:

Application serial no. **85499332** has been amended as follows:

ARGUMENT(S)

In response to the substantive refusal(s), please note the following:

The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCRUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORADRAPE" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORADRAPE" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.

ADDITIONAL STATEMENTS

Significance of wording, letter(s), or numeral(s)

CHLORADRAPE appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.

Miscellaneous Statement

CHLORA DRAPE and CHLORA have no significance nor are they terms of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance. However, as noted above in response to the asserted potential Trademark Act Section 2(d) refusal, the prefix CHLORA is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry.

SIGNATURE(S)

Response Signature

Signature: /Lisa M. Griffith/ Date: 03/29/2012

Signatory's Name: Lisa M. Griffith

Signatory's Position: Attorney of record, CA bar member

Signatory's Phone Number: 8587566935

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possessions; and he/she is currently the applicant's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S. attorney or a Canadian attorney/agent not currently associated with his/her company/firm previously represented the applicant in this matter: (1) the applicant has filed or is concurrently filing a signed revocation of or substitute power of attorney with the USPTO; (2) the USPTO has granted the request of the prior representative to withdraw; (3) the applicant has filed a power of attorney appointing him/her in this matter; or (4) the applicant's appointed U.S. attorney or Canadian attorney/agent has filed a power of attorney appointing him/her as an associate attorney in this matter.

Serial Number: 85499332

Internet Transmission Date: Thu Mar 29 12:53:40 EDT 2012

TEAS Stamp: USPTO/ROA-75.32.224.63-20120329125340815

212-85499332-490c0fdee543251cb3e6ac2a3bd

af628b2-N/A-N/A-20120329124545906865

EXHIBIT E13



Trademarks > Trademark Electronic Search System (TESS)

TESS was last updated on Thu May 7 03:21:33 EDT 2015

TESS HOME | NEW USER | STRUCTURED | FREE FORM | BROWSE DICT | SEARCH OG | BOTTOM | HELP

Logout Please logout when you are done to release system resources allocated for you.

Record 1 out of 1

TSDR | ASSIGN Status | TTAB Status (Use the "Back" button of the Internet Browser to return to TESS)

CHLORADERM

Word Mark	CHLORADERM
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Medical and surgical dressings
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85499349
Filing Date	December 19, 2011
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	May 29, 2012
International Registration Number	1120296
Owner	(APPLICANT) ENTROTECH LIFE SCIENCES, INC. CORPORATION DELAWARE 409 ILLINOIS STREET SAN FRANCISCO CALIFORNIA 94158
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Lisa M. Griffith
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

TESS HOME | NEW USER | STRUCTURED | FREE FORM | BROWSE DICT | SEARCH OG | TOP | HELP



EXHIBIT E14

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499349 - CHLORADERM - entrotech 11
Sent: 3/26/2012 11:20:20 AM
Sent As: ECOM105@USPTO.GOV
Attachments: [Attachment - 1](#)
[Attachment - 2](#)
[Attachment - 3](#)
[Attachment - 4](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85499349

MARK: CHLORADERM

85499349

CORRESPONDENT ADDRESS:

LISA M. GRIFFITH
THE GRIFFITH LAW FIRM, A P.C.
991C LOMAS SANTA FE DR STE 450
SOLANA BEACH, CA 92075-2125

CLICK HERE TO RESPOND TO THIS LETTER:

http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: entrotech, inc.

CORRESPONDENT'S REFERENCE/DOCKET

NO:

entrotech 11

CORRESPONDENT E-MAIL ADDRESS:

Lgriffith@griffithpc.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: **3/26/2012**

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See 37*

C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

SEARCH OF OFFICE DATABASE:

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no similar registered mark that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d). However, marks in prior-filed pending applications may present a bar to registration of applicant's mark.

POTENTIAL 2(d) REFUSALS:

The filing dates of pending Application Serial Nos. **85051474 & 85051477** precede applicant's filing date. See attached referenced applications. If one or more of the marks in the referenced applications register, applicant's mark may be refused registration under Trademark Act Section 2(d) because of a likelihood of confusion with the registered mark(s). *See* 15 U.S.C. §1052(d); 37 C.F.R. §2.83; TMEP §§1208 *et seq.* Therefore, upon receipt of applicant's response to this Office action, action on this application may be suspended pending final disposition of the earlier-filed referenced applications.

In response to this Office action, applicant may present arguments in support of registration by addressing the issue of the potential conflict between applicant's mark and the marks in the referenced applications. Applicant's election not to submit arguments at this time in no way limits applicant's right to address this issue later if a refusal under Section 2(d) issues.

SIGNIFICANCE INQUIRY:

Applicant must specify whether the wording "**CHLORADERM**" and "**CHLORA DERM**" has any significance in the health, medical, and medical equipment field, trade, or industry and as applied to the goods described in the application, or if such wording is a "term of art" within applicant's industry. *See* 37 C.F.R. §2.61(b); TMEP §§808.01(a), 814.

Failure to respond to a request for information is an additional ground for refusing registration. *See In re Cheezwhse.com, Inc.*, 85 USPQ2d 1917, 1919 (TTAB 2008); *In re DTI P'ship LLP*, 67 USPQ2d 1699, 1701 (TTAB 2003); TMEP §814.

If applicant has questions about its application or needs assistance in responding to this Office action, please telephone the assigned trademark examining attorney directly at the number below.

Simon Teng
/Simon Teng/

Trademark Examining Attorney - USPTO
Law Office 105
Tel: 571-272-4930; simon.teng@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

DESIGN MARK

Serial Number

85051474

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 005. US 006 018 044 046 051 052. G & S: antimicrobial catheter patch dressing.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

DESIGN MARK

Serial Number

85051477

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 010. US 026 039 044. G & S: surgical incise drape.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499349 - CHLORADERM - entrotech 11
Sent: 3/26/2012 11:20:21 AM
Sent As: ECOM105@USPTO.GOV
Attachments:

IMPORTANT NOTICE REGARDING YOUR U.S. TRADEMARK APPLICATION

USPTO OFFICE ACTION HAS ISSUED ON **3/26/2012** FOR
SERIAL NO. 85499349

Please follow the instructions below to continue the prosecution of your application:

TO READ OFFICE ACTION: Click on this [link](#) or go to <http://portal.uspto.gov/external/portal/tow> and enter the application serial number to [access](#) the Office action.

PLEASE NOTE: The Office action may not be immediately available but will be viewable within 24 hours of this e-mail notification.

RESPONSE IS REQUIRED: You should carefully review the Office action to determine (1) how to respond; and (2) the applicable [response time period](#). Your response deadline will be calculated from **3/26/2012** (or sooner if specified in the office action).

Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System [Response Form](#).

HELP: For *technical* assistance in accessing the Office action, please e-mail TDR@uspto.gov. Please contact the assigned examining attorney with questions about the Office action.

WARNING

Failure to file the required response by the applicable deadline will result in the [ABANDONMENT](#) of your application.

EXHIBIT E15

Response to Office Action

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85499349
LAW OFFICE ASSIGNED	LAW OFFICE 105
MARK SECTION (no change)	
ARGUMENT(S)	
<p>The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCRUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORADERM" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORADERM" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.</p>	
ADDITIONAL STATEMENTS SECTION	
SIGNIFICANCE OF MARK	CHLORADERM appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.
MISCELLANEOUS STATEMENT	CHLORA DERM has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.
SIGNATURE SECTION	
RESPONSE SIGNATURE	/Lisa M. Griffith/
SIGNATORY'S NAME	Lisa M. Griffith
SIGNATORY'S POSITION	Attorney of record, CA bar member

SIGNATORY'S PHONE NUMBER	8587566935
DATE SIGNED	03/29/2012
AUTHORIZED SIGNATORY	YES
FILING INFORMATION SECTION	
SUBMIT DATE	Thu Mar 29 12:43:32 EDT 2012
TEAS STAMP	USPTO/ROA-75.32.224.63-20 120329124332151185-854993 49-4909dd3d3e11834604b2e1 9dacce95bd812-N/A-N/A-201 20329123530009386

PTO Form 1957 (Rev 9/2005)
OMB No. 0651-0050 (Exp. 07/31/2017)

Response to Office Action To the Commissioner for Trademarks:

Application serial no. **85499349** has been amended as follows:

ARGUMENT(S)

In response to the substantive refusal(s), please note the following:

The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORADERM" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORADERM" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.

ADDITIONAL STATEMENTS

Significance of wording, letter(s), or numeral(s)

CHLORADERM appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.

Miscellaneous Statement

CHLORA DERM has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.

SIGNATURE(S)**Response Signature**

Signature: /Lisa M. Griffith/ Date: 03/29/2012

Signatory's Name: Lisa M. Griffith

Signatory's Position: Attorney of record, CA bar member

Signatory's Phone Number: 8587566935

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possessions; and he/she is currently the applicant's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S. attorney or a Canadian attorney/agent not currently associated with his/her company/firm previously represented the applicant in this matter: (1) the applicant has filed or is concurrently filing a signed revocation of or substitute power of attorney with the USPTO; (2) the USPTO has granted the request of the prior representative to withdraw; (3) the applicant has filed a power of attorney appointing him/her in this matter; or (4) the applicant's appointed U.S. attorney or Canadian attorney/agent has filed a power of attorney appointing him/her as an associate attorney in this matter.

Serial Number: 85499349

Internet Transmission Date: Thu Mar 29 12:43:32 EDT 2012

TEAS Stamp: USPTO/ROA-75.32.224.63-20120329124332151

185-85499349-4909dd3d3e11834604b2e19dacc

e95bd812-N/A-N/A-20120329123530009386

EXHIBIT E16



Trademarks > Trademark Electronic Search System (TESS)

TESS was last updated on Thu May 7 03:21:33 EDT 2015

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Please logout when you are done to release system resources allocated for you.

Record 1 out of 1

[TSDR](#) | [ASSIGN Status](#) | [TTAB Status](#) (Use the "Back" button of the Internet Browser to return to TESS)

CHLORABOND

Word Mark	CHLORABOND
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Topical antimicrobial solutions for dermatologic use
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85499337
Filing Date	December 19, 2011
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	May 29, 2012
International Registration Number	1122821
Owner	(APPLICANT) ENTROTECH LIFE SCIENCES, INC. CORPORATION DELAWARE 409 ILLINOIS STREET SAN FRANCISCO CALIFORNIA 94158
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Lisa M. Griffith
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [TOP](#) | [HELP](#)



EXHIBIT E17

**Trademarks > Trademark Electronic Search System (TESS)**

TESS was last updated on Thu May 7 03:21:33 EDT 2015

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [BOTTOM](#) | [HELP](#) Please logout when you are done to release system resources allocated for you.**Record 1 out of 1**[TSDR](#) | [ASSIGN Status](#) | [TTAB Status](#) (Use the "Back" button of the Internet Browser to return to TESS)

CHLORABSORB

Word Mark	CHLORABSORB
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Medical and surgical dressings
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85499345
Filing Date	December 19, 2011
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	May 29, 2012
International Registration Number	1120580
Owner	(APPLICANT) ENTROTECH LIFE SCIENCES, INC. CORPORATION DELAWARE 409 ILLINOIS STREET SAN FRANCISCO CALIFORNIA 94158
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Lisa M. Griffith
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

[TESS HOME](#) | [NEW USER](#) | [STRUCTURED](#) | [FREE FORM](#) | [BROWSE DICT](#) | [SEARCH OG](#) | [TOP](#) | [HELP](#)

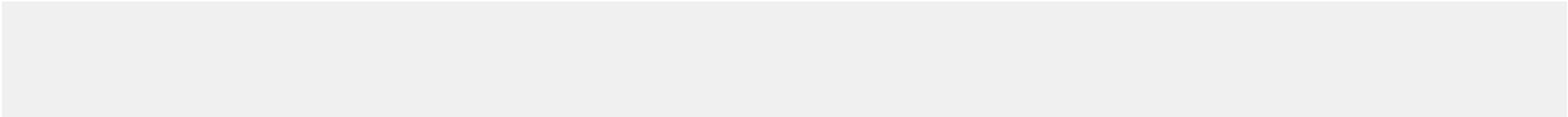


EXHIBIT E18

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499345 - CHLORABSORB - entrotech 11
Sent: 3/26/2012 11:17:26 AM
Sent As: ECOM105@USPTO.GOV
Attachments: [Attachment - 1](#)
[Attachment - 2](#)
[Attachment - 3](#)
[Attachment - 4](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85499345

MARK: CHLORABSORB

85499345

CORRESPONDENT ADDRESS:

LISA M. GRIFFITH
THE GRIFFITH LAW FIRM, A P.C.
991C LOMAS SANTA FE DR STE 450
SOLANA BEACH, CA 92075-2125

CLICK HERE TO RESPOND TO THIS LETTER:
http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: entrotech, inc.

CORRESPONDENT'S REFERENCE/DOCKET

NO:

entrotech 11

CORRESPONDENT E-MAIL ADDRESS:

Lgriffith@griffithpc.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: **3/26/2012**

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See 37*

C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

SEARCH OF OFFICE DATABASE:

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no similar registered mark that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d). However, marks in prior-filed pending applications may present a bar to registration of applicant's mark.

POTENTIAL 2(d) REFUSALS:

The filing dates of pending Application Serial Nos. **85051474 & 85051477** precede applicant's filing date. See attached referenced applications. If one or more of the marks in the referenced applications register, applicant's mark may be refused registration under Trademark Act Section 2(d) because of a likelihood of confusion with the registered mark(s). *See* 15 U.S.C. §1052(d); 37 C.F.R. §2.83; TMEP §§1208 *et seq.* Therefore, upon receipt of applicant's response to this Office action, action on this application may be suspended pending final disposition of the earlier-filed referenced applications.

In response to this Office action, applicant may present arguments in support of registration by addressing the issue of the potential conflict between applicant's mark and the marks in the referenced applications. Applicant's election not to submit arguments at this time in no way limits applicant's right to address this issue later if a refusal under Section 2(d) issues.

SIGNIFICANCE INQUIRY:

Applicant must specify whether the wording "**CHLORABSORB**" has any significance in the health, medical, and medical equipment field, trade, or industry and as applied to the goods described in the application, or if such wording is a "term of art" within applicant's industry. *See* 37 C.F.R. §2.61(b); TMEP §§808.01(a), 814.

Failure to respond to a request for information is an additional ground for refusing registration. *See In re Cheezwhse.com, Inc.*, 85 USPQ2d 1917, 1919 (TTAB 2008); *In re DTI P'ship LLP*, 67 USPQ2d 1699, 1701 (TTAB 2003); TMEP §814.

If applicant has questions about its application or needs assistance in responding to this Office action, please telephone the assigned trademark examining attorney directly at the number below.

Simon Teng
/Simon Teng/

Trademark Examining Attorney - USPTO
Law Office 105
Tel: 571-272-4930; simon.teng@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

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WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

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TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

DESIGN MARK

Serial Number

85051474

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 005. US 006 018 044 046 051 052. G & S: antimicrobial catheter patch dressing.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

DESIGN MARK

Serial Number

85051477

Status

SECOND EXTENSION - GRANTED

Word Mark

CHLORASHIELD

Standard Character Mark

Yes

Type of Mark

TRADEMARK

Register

PRINCIPAL

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Owner

CareFusion 2200, Inc. CORPORATION DELAWARE 3750 Torrey View Court San Diego CALIFORNIA 92130

Goods/Services

Class Status -- ACTIVE. IC 010. US 026 039 044. G & S: surgical incise drape.

Prior Registration(s)

1930248

Filing Date

2010/06/01

Examining Attorney

CONNOLLY, KATHERINE

Attorney of Record

Joseph R. Dreitler

CHLORASHIELD

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499345 - CHLORABSORB - entrotech 11
Sent: 3/26/2012 11:17:27 AM
Sent As: ECOM105@USPTO.GOV
Attachments:

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SERIAL NO. 85499345

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HELP: For *technical* assistance in accessing the Office action, please e-mail TDR@uspto.gov. Please contact the assigned examining attorney with questions about the Office action.

WARNING

Failure to file the required response by the applicable deadline will result in the [ABANDONMENT](#) of your application.

EXHIBIT E19

Response to Office Action

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85499345
LAW OFFICE ASSIGNED	LAW OFFICE 105
MARK SECTION (no change)	
ARGUMENT(S)	
<p>The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCRUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORABSORB" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORABSORB" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.</p>	
ADDITIONAL STATEMENTS SECTION	
SIGNIFICANCE OF MARK	CHLORABSORB appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.
SIGNATURE SECTION	
RESPONSE SIGNATURE	/Lisa M. Griffith/
SIGNATORY'S NAME	Lisa M. Griffith
SIGNATORY'S POSITION	Attorney of record, CA bar member
SIGNATORY'S PHONE NUMBER	8587566935
DATE SIGNED	03/29/2012
AUTHORIZED SIGNATORY	YES

FILING INFORMATION SECTION

SUBMIT DATE	Thu Mar 29 12:31:26 EDT 2012
TEAS STAMP	USPTO/ROA-75.32.224.63-20 120329123126340270-854993 45-4907267e92fea6290453c5 2e8794fa250c3-N/A-N/A-201 20329115352346119

PTO Form 1957 (Rev 9/2005)
OMB No. 0651-0050 (Exp. 07/31/2017)

Response to Office Action To the Commissioner for Trademarks:

Application serial no. **85499345** has been amended as follows:

ARGUMENT(S)

In response to the substantive refusal(s), please note the following:

The prefix "CHLORA" is widely used to indicate the presence of an antiseptic in the health, medical, and medical equipment industry. As exemplary evidence of this fact, reference is made to registered marks associated with antiseptic goods from several different sources, most of them also classified in International Class 005, including U.S. Trademark Registration Nos. 4052849 and 1930248 for the mark "CHLORAPREP," 4071394 for the mark "CHLORAG+ARD," 4012226 for the mark "CHLORASEB," 3608454 for the mark "CHLORADINE," 1530509 for the mark "CHLORAZENE," and 1494769 for the mark "CHLORASCUB." The asserted potential conflicting "CHLORASHIELD" marks identified in the Office Action are believed to be no more significant to registration of the subject "CHLORABSORB" mark than these exemplary registered "CHLORA" marks. Applicant respectfully submits that, among other arguments to be presented if necessary, in view of the widespread use of marks containing the "CHLORA" prefix in the health, medical, and medical equipment industry, the applied-for "CHLORABSORB" mark would not lead to a likelihood of confusion based on the pending registrations for the "CHLORASHIELD" marks.

ADDITIONAL STATEMENTS

Significance of wording, letter(s), or numeral(s)

CHLORABSORB appearing in the mark has no significance nor is it a term of art in the relevant trade or industry or as applied to the goods/services listed in the application, or any geographical significance.

SIGNATURE(S)

Response Signature

Signature: /Lisa M. Griffith/ Date: 03/29/2012

Signatory's Name: Lisa M. Griffith

Signatory's Position: Attorney of record, CA bar member

Signatory's Phone Number: 8587566935

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possessions; and he/she is currently the applicant's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S. attorney or a Canadian attorney/agent not currently associated with his/her company/firm previously represented the applicant in this matter: (1) the applicant has filed or is concurrently filing a signed revocation of or substitute power of attorney with the USPTO; (2) the USPTO has granted the request of the prior representative to withdraw; (3) the applicant has filed a power of attorney appointing him/her in this matter; or (4) the applicant's appointed U.S. attorney or Canadian attorney/agent has filed a power of attorney appointing him/her as an associate attorney in this matter.

Serial Number: 85499345

Internet Transmission Date: Thu Mar 29 12:31:26 EDT 2012

TEAS Stamp: USPTO/ROA-75.32.224.63-20120329123126340

270-85499345-4907267e92fea6290453c52e879

4fa250c3-N/A-N/A-20120329115352346119

EXHIBIT E20

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499337 - CHLORABOND - entrotech 11
Sent: 3/28/2012 10:37:15 AM
Sent As: ECOM105@USPTO.GOV
Attachments:

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85499337

MARK: CHLORABOND

85499337

CORRESPONDENT ADDRESS:

LISA M. GRIFFITH
THE GRIFFITH LAW FIRM, A P.C.
991C LOMAS SANTA FE DR STE 450
SOLANA BEACH, CA 92075-2125

CLICK HERE TO RESPOND TO THIS LETTER:
http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: entrotech, inc.

CORRESPONDENT'S REFERENCE/DOCKET

NO:

entrotech 11

CORRESPONDENT E-MAIL ADDRESS:

Lgriffith@griffithpc.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: 3/28/2012

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

NO CONFLICTING MARKS:

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no conflicting marks that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d).

IDENTIFICATION OF GOODS:

Class 5 -

In Class 5, applicant's identification is: "topical antimicrobial solutions."

The above wording is unacceptable because it is indefinite and could fall in multiple classes. The functionality of the solution must be further specified. *See below for suggestions.*

Taking the above together, applicant may adopt the following:

Class 3: Non-medicated topical antimicrobial skin cleanser solutions

Class 5: ***Medicated*** topical antimicrobial solutions ***for dermatological use on humans***

TMEP §1402.01.

For assistance with identifying and classifying goods and/or services in trademark applications, please see the online searchable *Manual of Acceptable Identifications of Goods and Services* at <http://tess2.uspto.gov/netahtml/tidm.html>. *See* TMEP §1402.04.

An applicant may amend an identification of goods and services only to clarify or limit the goods and services; adding to or broadening the scope of the goods and/or services is not permitted. 37 C.F.R. §2.71(a); *see* TMEP §§1402.06 *et seq.*, 1402.07 *et seq.*

MULTI-CLASS REQUIREMENTS:

If applicant prosecutes this application as a combined, or multiple-class application, then applicant must comply with each of the following for those goods and/or services based on an intent to use the mark in commerce under Trademark Act Section 1(b):

- (1) Applicant must list the goods and/or services by international class; and
- (2) Applicant must submit a filing fee for each international class of goods and/or services not covered by the fee already paid (current fee information should be confirmed at <http://www.uspto.gov>).

See 15 U.S.C. §§1051(b), 1112, 1126(e); 37 C.F.R. §§2.34(a)(2)-(3), 2.86(a); TMEP §§1403.01, 1403.02(c).

FEES FOR ADDITIONAL CLASSES:

The filing fee for adding classes to an application is as follows:

(1) \$325 per class, when the fees are submitted with a response filed online via the Trademark Electronic Application System (TEAS) at <http://www.uspto.gov/teas/index.html>; or

(2) \$375 per class, when the fees are submitted with a paper response.

37 C.F.R. §2.6(a)(1)(i)-(a)(1)(ii); TMEP §810.

SIGNIFICANCE INQUIRY:

Applicant must specify whether the wording “**CHLORABOND**” has any significance as applied to the goods described in the application, or if such wording is a “term of art” within applicant’s industry. See 37 C.F.R. §2.61(b); TMEP §§808.01(a), 814.

Failure to respond to a request for information is an additional ground for refusing registration. See *In re Cheezwhse.com, Inc.*, 85 USPQ2d 1917, 1919 (TTAB 2008); *In re DTI P’ship LLP*, 67 USPQ2d 1699, 1701 (TTAB 2003); TMEP §814.

If applicant has questions about its application or needs assistance in responding to this Office action, please telephone the assigned trademark examining attorney directly at the number below.

Simon Teng
/Simon Teng/
Trademark Examining Attorney - USPTO
Law Office 105
Tel: 571-272-4930; simon.teng@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

To: entrotech, inc. (Lgriffith@griffithpc.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85499337 - CHLORABOND - entrotech 11
Sent: 3/28/2012 10:37:16 AM
Sent As: ECOM105@USPTO.GOV
Attachments:

IMPORTANT NOTICE REGARDING YOUR U.S. TRADEMARK APPLICATION

USPTO OFFICE ACTION HAS ISSUED ON **3/28/2012** FOR
SERIAL NO. 85499337

Please follow the instructions below to continue the prosecution of your application:

TO READ OFFICE ACTION: Click on this [link](#) or go to <http://portal.uspto.gov/external/portal/tow> and enter the application serial number to [access](#) the Office action.

PLEASE NOTE: The Office action may not be immediately available but will be viewable within 24 hours of this e-mail notification.

RESPONSE IS REQUIRED: You should carefully review the Office action to determine (1) how to respond; and (2) the applicable [response time period](#). Your response deadline will be calculated from **3/28/2012** (or sooner if specified in the office action).

Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System [Response Form](#).

HELP: For *technical* assistance in accessing the Office action, please e-mail TDR@uspto.gov. Please contact the assigned examining attorney with questions about the Office action.

WARNING

Failure to file the required response by the applicable deadline will result in the [ABANDONMENT](#) of your application.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of May, 2015, a true and correct copy of **APPLICANT'S NOTICE OF RELIANCE** has been served by electronic mail upon Opposer's attorneys of record in this proceeding at the following electronic addresses:

Joseph R. Dreitler, Esq.
Mary R. True, Esq.
Dreitler True, LLC
jdreitler@ustrademarklawyer.com
mtrue@ustrademarklawyer.com

/s/ April R. Morris
April R. Morris