# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-074**

# ADMINISTRATIVE DOCUMENTS

# 13.0 PATENT INFORMATION

SUBMISSION OF PATENT INFORMATION IN ACCORDANCE WITH 21 C.F.R. §314.53

In accordance with the requirements of 21 C.F.R. §314.53(c)(1), applicant 3M Health Care submits the following patent information.

**Patent Statement**

In accordance with Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, as codified at 21 CFR Section 314.53, the following information is provided:

U.S. Patent No. 5,897,031 is owned by 3M and expires June 21, 2016. This patent claims the drug product, 3M CHG Hand Prep, or a method of use of that product for which approval is sought. A claim of patent infringement could reasonable be asserted under this patent if a person not licensed by 3M engaged in the manufacture, use, or sale of the drug product for which approval has been granted.

Jeffrey J. Hohenshell
3M Office of Intellectual Property Counsel

5-6-99
Date

**EXCLUSIVITY SUMMARY for NDA #** 21-074 **SUPPL #** —

**Trade Name** AVAGARD™ **Generic Name** Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w

**Applicant Name** 3M Health Care **HFD-**520

**Approval Date** June 7, 2001

**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:

   _____

   _____

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?

_____

_____

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

YES /___/ NO /X/

**IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.**

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? (Rx to OTC) Switches should be answered No - Please indicate as such).

YES /___/ NO /X/

If yes, NDA # _____ Drug Name _____

**IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.**

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 9 (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 /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 # 17-768 Hibiclens (4% CHG) 19-422 Exidine 2% CHG

NDA # 19-125 Exidine 4% CHG 20-111 Dynahex .75% CHG

NDA # 19-127 Exidine Foam 4% CHG 20-832 Chloraprep 2% CHG/70% IPA

18-049 Hibistat .5 CHG/70% IPA

**IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9. IF "YES," GO TO PART III.**

**PART III: <u>THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS</u>**

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 /X/ NO /___/

**IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.**

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 /X/ 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 9:**

_____

_____

(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 /X/ (to literature (Part 1)) NO /X/ (to Statement (Part 2))

(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 /X/

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 /X/

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 # 7838 Surgical scrub study

Investigation #2, Study # 7957 Surgical scrub study

Investigation #3, Study # 7939 healthcare personnel wash 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 /___/ NO /X/

Investigation #2 YES /___/ NO /X/

Investigation #3 YES /___/ NO /X/

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

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 /___/ NO /X/

Investigation #2 YES /___/ NO /X/

Investigation #3 YES /___/ NO /X/

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

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

(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"):

Investigation #1, Study # 7838

Investigation #2, Study # 7957

Investigation #3, Study # 7939

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 # [redacted] YES /X/ NO /___/ Explain: _____

_____

_____

Investigation #2

IND # _____ 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? N/A

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 /X/

If yes, explain: _____

_____

_____

/S/ 6/7/01

Signature of Preparer Date

Title: Project Manager

/S/ 6/8/01

Signature of Office of Division Director Date

cc:
Archival NDA
HFD-520/Division File
HFD-520/RPM
HFD-093/Mary Ann Holovac
HFD-104/PEDS/T.Crescenzi

Form OGD-011347
Revised 8/7/95; edited 8/8/95; revised 8/25/98, edited 3/6/00

Copies sent to CC. list

## 16.0 DEBARMENT CERTIFICATION

3M Health Care hereby certifies that we did not and will not use in any capacity the services of any person debarred pursuant to the Federal Food, Drug and Cosmetic Act (306(k)(1)) in connection with this application.

Suzanne M. Danielson
Suzanne Danielson
Regulatory Affairs Manager

May 27, 1999
Date

LABELING REVIEW OF NDA AMENDMENT

| | | |
|---|---|---|
| **NDA**: 21-074<br>**AMENDMENT**: 017 | **Date Assigned to Reviewer**:<br>**Date Review Initiation**:<br>**Date Review Completed:**<br>**Date Review to Teamleader:** | June 6, 2001<br>June 6, 2001<br>June 6, 2001<br>June 6, 2001 |
| **Applicant**: | 3M Healthcare<br>3M Center 275-5W-06<br>St. Paul, MN 55144-1000 | |
| **Applicant's Representative:** | Dianne L. Gibbs, RAC<br>Regulatory Affairs Specialist<br>(651) 733-1110 | |
| **Drug**: | Avagard CHG Antiseptic Hand Prep<br>Chlorhexidine gluconate (CHG) 1% solution<br>Ethyl alcohol 61% w/w | |
| **Pharmacologic Category**: | Health-care antiseptic | |
| **Submitted to HFD-560**<br>from HFD-520**:** | Package insert | |
| **Reviewer**: | Michelle M. Jackson, Ph.D. | |

Reviewer's comments:
This amendment provided revised draft for Avagard CHG Antiseptic Hand Prep (chlorhexidine gluconate 1% solution, ethyl alcohol 61% w/w) labeling. This is in response to the December 18, 2000, fax from the Agency on the labeling and to the August 24, 2000, submission in the form of an amendment to the pending new drug application in conformance with 21 CFR 201.66. This is also in reference to the "Not Approvable" letter to the NDA 21-074 dated June 23, 2000.

In response to the package insert labeling comments relayed to the sponsor in the Agency's June 23, 2000, letter, the following revision has been made to its Avagard CHG Antiseptic Hand Prep product:

1. The sponsor has placed cosmetic "INFORMATION FOR THE USER" at the end of drug labeling before "REFERENCES."

Recommendation:
The submitted final printed labeling for the product container labeling and the package insert is satisfactory.

/S/
Michelle M. Jackson, Ph.D.
IDS Reviewer

/S/
Concurrance
Debbie L. Lumpkins
Team Leader, Microbiologist

HFD-520/Dillonparker

# TELECONFERENCE MINUTES

**Meeting Date**: July 20, 2000

**Time**: 11:00a.m.

**Drug Name**: AVAGARD™ (NDA 21-074)

**External Participant**: 3M Health Care

**Type of Meeting**: Labeling

**Meeting Chair**: David C. Bostwick, Clinical Reviewer

**External Participant Lead**: Dianne L. Gibbs, RAC
Regulatory Affairs Specialist

**Meeting Recorder**: Maureen Dillon-Parker
Regulatory Health Project Manager

**FDA Attendees:**

Division of Anti-Infective Drug Products (HFD-520):
Gary K. Chikami, M.D., Division Director
Alexander Rakowsky, M.D., Clinical Team Leader
David Bostwick, Clinical Reviewer
Maureen Dillon-Parker, Regulatory Health Project Manager

Division of Over-the-Counter Drug Products (HFD-560):
Linda M. Katz, M.D., M.P.H., Deputy Director
Debbie Lumpkins, Team Leader, Team 3
Daiva Shetty, M.D., Clinical Reviewer
Stephanie Mason, Interdisciplinary Scientist
Thomas Parmelee, Pharm.D., Project Manager

**External 3M Attendees:**
Dianne Gibbs, Regulatory Affairs
John Dell, Project Team Leader, Chemistry
Julie Stahl, Microbiology
Jim Heilman, Clinical Research
Pam Newcome, Marketing
Mardi Bentzen, Marketing

**A. Meeting Objectives (Topics):**

To discuss the FDA facsimile containing labeling comments on 3M's submission of June 15, 2000.

**B. Discussion Points:** See attached facsimile provided to 3M on 7-18-00 containing 21 comments in reply to their submission of June 15, 2000.

**COMMENTS ON POINT 2 (8 & 10)**

- 3M stated that all the changes requested were acceptable except points 2 (8 & 10) and 14.

- 3M explained that a study had been conducted which showed the product to be a mild irritant. Additionally, since the product would be for professional use and this population is more astute that the normal person, 3M felt that the statement "do not touch the eye with hands that have been treated with this preparation" is stronger than statements made in labels such as Hibiclens. FDA stated that the two products are not comparable because this is a leave-on product and people have a habit of touching their eyes.

- 3M agreed to the statement and further stated that the WARNING will be modified to a bolder color.

- FDA agreed to allow 3M to revise the WARNING statement on the principal display panel only to read "WARNING: FLAMMABLE. DO NOT TOUCH THE EYE WITH HANDS WHICH HAVE BEEN TREATED WITH THIS PREPARATION". The WARNING statement in Drug Facts will not change.

**COMMENT ON POINT 14**

- FDA stated that they would not allow skin conditioning claims unless they are part of the products labeling. It was further stated that the Division of Drug Marketing, Advertising and Communications (DDMAC) no longer reviews Over-the-Counter (OTC) products launch materials. The Federal Trade Commission (FTC) regulates OTC advertising. Therefore, the FDA stated that the FTC would need to decide if the advertising materials were acceptable.

ADDITIONAL COMMENTS

- The OTC Division stated that 3M should review 21 CFR 201.66 for the appropriate formatting of the Drug Facts section of the labeling prior to submission of the revised draft copy. Specifically, the headings need to be in italics and the specifications for the fonts provided.

- 3M further stated that they are working with the manufacturer [redacted] issues and also exploring alternative manufacturing sites. 3M is targeting the 4th quarter of 2000 for responding to the not approvable letter. 3M stated that they may request a teleconference to discuss potential manufacturing sites and required stability data.

**C. Decisions (agreements) reached/Information to be submitted:**

- Revised labeling will be submitted inclusive of specifications as outlined in 21 CFR 201.66.

**D. Unresolved issues or issues requiring further discussion:**

- Alternative manufacturing sites and stability data requirements may need to be discussed in a future teleconference.

**Signature, minutes preparer:** /S/

**Concurrence, meeting chairperson:** /S/

**ATTACHMENT (2 pages)**

**Minutes for FDA/3M Label Negotiation Telecon**
**Avagard NDA 21-074**

Date: July 20, 2000

Participating in the Meeting:

**3M Health Care**
- John Dell, Chemistry
- Jim Heilman, Clinical Research
- Julie Stahl, Microbiology
- Dianne Gibbs, Regulatory Affairs
- Pam Newcome, Marketing
- Mardi Bentzen, Marketing

**FDA, Division of Anti-Infective Drug Products**
- Dr. Gary Chikami, Division Director
- Mr. David Bostwick, Clinical Reviewer
- Dr. Alexander Rakowsky, Clinical Team Leader
- Ms. Maureen Dillon-Parker, Project Manager

**FDA, Division of Over-the Counter Drug Products**
- Ms. Stephanie Mason, Interdisciplinary Scientist
- Ms. Debbie Lumpkins, Team Leader, Team 3
- Dr. Linda Katz, Deputy Director
- Dr. Daiva Shetty, Medical Reviewer
- Thomas Parmalee, Pharm.D., Project Manager

Key Discussion Points:

1. **The Agency's second comment to the revised draft labeling, as provided in the July 18, 2000 fax communication, states that the inclusion of the Warning statement "Do not touch the eye with hands that have been treated with this preparation." is required.**

3M feels that the inclusion of this Warning should not be required for the following reasons:
   1. As stated in our previous response, this is redundant to warning, "keep out of eyes, ears and mouth".
   2. Professional user (doctors and nurses) routinely practice good aseptic technique and are more astute than the casual user. They know not to touch their eyes.
   3. LIMS 7960, Ocular Irritation study, demonstrated low irritation, and was classified as a mild irritant.

**Agency Response:** Mr. Bostwick stated that due to the reported Adverse Event of the subject who rubbed their eye and developed conjunctivitis, this warning will be required. When asked if 3M could qualify the statement to indicate not to touch their eyes with hands while product is still wet, the Agency stated that we would have to support this with data. [This data is unavailable.]

**Resolution:** 3M agreed to include this Warning statement, as indicated in the Agency's comments #2 and #8.

2. **Comment #10 of the Agency's fax communication again relates to comment #2, above. In addition, we assume that shortening the Flammability warning is acceptable, since electrocautery is not of issue for this products indications.**

**Agency Response:** Mr. Bostwick stated that was correct. The additional flammability warning as it relates to electrocautery can be deleted.

**Resolution:** Warning will read:

**WARNING: FLAMMABLE. DO NOT TOUCH THE EYE WITH HANDS WHICH HAVE BEEN TREATED WITH THIS PREPARATION**

Dr. Katz verified that this Warning is currently in bold caps on the principal display panel. The Warning statement on the back panel, Drug Facts Box, is currently in bold, upper/lower case. In addition the Flammability Warning in the Drug Facts Box should also remain as we currently have it, **"Flammable, keep away from fire or flame."** It was agreed that Warning statements on the principal display panel would be in contrasting color (purple on salmon background).

3. **Regarding Comment #14 of the Agency's fax communication, 3M understands that FDA cannot endorse the use of claims in our promotional/advertising materials that are based on our skin conditions studies, as these claims will not be included in final labeling. We further understand that FTC regulates OTC advertising and promotion.**

   **3M does intend to use these claims in product promotion and advertising. This is supported by Dr. Chikami's earlier comments at the End-of-Phase 2 meeting to the effect that if 3M has the data, we should be able to talk about it. However, will the inclusion of these types of claims in the launch materials, all of which are based on the NDA reviewed data, be problematic for DDMAC?**

**Response:** Dr. Katz concurred that the Agency cannot endorse the use of product claims unless they are part of approved labeling. DDMAC would not have a problem with their use in our launch materials, but FTC would look to ensure claims were supported by data.

**Resolution:** Skin condition claims supported by clinical data can be used in product advertising and promotion and will be regulated by FTC.

**Additional Agency Comments:**

1. Review Drug Facts Box for compliance with 21 CFR 201.66. Please italicize headings. Submit font/typesetting specifications with final revised labeling, along with color copies for Agency to review color contrasted Warning statements.

2. Dr. Rakowsky asked if we had information with respect to [redacted] or if we are in the process of pursuing alternate manufacturing sites. Dianne Gibbs informed him that 3M is working as best we are able with [redacted] to help them resolve their GMP issues. In addition Ms. Gibbs stated that she had been in contact with Ms. Debbie Pagano, Philadelphia District PAI Manager, regarding the procedural steps of getting the Avagard PAI approved. Per Ms. Pagano, the approval of the Avagard PAI would have to come before the approval of the sponge PAI. The approval of both these products hinges on the District's office verification, based on reinspection at [redacted] that the GMP issues have been resolved. Ms. Gibbs further stated that 3M is also looking at other manufacturing site options, and that once we had these options better defined that we would be requesting a telecon with the Agency to determine what information would be required in support of a manufacturing site change.

Ms. Gibbs asked the Agency if they had any information with respect to [redacted] current regulatory status, which they did not.

We thanked the Agency for taking the time to resolve these final labeling issues with us.

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

21-074

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| 3M Health Care | June 15, 2000 |
| **TELEPHONE NO.** *(Include Area Code)* (651) 737-9117 | **FACSIMILE (FAX) Number** *(Include Area Code)* (651) 737-5320 |
| **APPLICANT ADDRESS** *(Number, Street, City, State, Country, ZIP Code or Mail Code. and U.S. License number if previously issued):* 3M Center, Building 275-5W-06<br>St. Paul, MN 55105-1000 | **AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, Sta ZIP Code, telephone & FAX number)* IF APPLICABLE |

## PRODUCT DESCRIPTION

**NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER** (If previously issued)

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| 1% Chlorhexidine gluconate, 61% Ethyl alcohol | antiseptic hhand preparation Avagard |

| CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* | CODE NAME *(If any)* |
|---|---|
| Chlorhexidine gluconate BP, alcohol USP | HPD-5a |

| DOSAGE FORM: | STRENGTHS: | ROUTE OF ADMINISTRATION: |
|---|---|---|
| Lotion | CHG 1%, Ethyl alcohol 61% | Topical |

(PROPOSED) INDICATION(S) FOR USE:
Refer to Addendum I

## APPLICATION INFORMATION

APPLICATION TYPE (check one)
☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 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)
☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
Submission of revised draft labeling in response to Agency labeling comments

PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED _____ THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ 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 nam address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testin conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Refer to Addendum I

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

Refer to Addendum I

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

| | |
|---|---|
| | 1. Index |
| X | 2. Labeling (check one) ☒ Draft Labeling ☐ 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)) |
| | 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) |
| | 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 (j) (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 314.50 (k) (3)) |
| | 18. User Fee Cover Sheet (Form FDA 3397) |
| | 19. OTHER (Specify) |

CERTIFICATION

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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 | DATE |
|---|---|---|
| Suzanne Danielson RS | Suzanne M. Danielson, Reg. Aff. Mgr. | 6-15-00 |

| ADDRESS *(Street, City, State, and ZIP Code)* | Telephone Number |
|---|---|
| 3M Center, Building 275-5W-06, St. Paul, MN 55144-1000 | ( 651) 733-4365 |



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**FORM FDA 356h (7/97)**

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
NDA 21-074

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| 3M Health Care | August 9, 2000 |
| **TELEPHONE NO. *(Include Area Code)*** | **FACSIMILE (FAX) Number *(Include Area Code)*** |
| (651) 737-9117 | (651) 737-5320 |

**APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:**
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

**AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE**

## PRODUCT DESCRIPTION

**NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued)**

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| 1% Chlorhexidine Gluconate, 61% Ethyl alcohol | antiseptic hand preparation Avagard |
| **CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(if any)*** | **CODE NAME *(if any)*** |
| Chlorhexidine gluconate BP, alcohol USP | HPD-5a |
| **DOSAGE FORM:** | **STRENGTHS:** | **ROUTE OF ADMINISTRATION:** |
| Lotion | CHG 1.0%, Ethyl alcohol 61% | Topical |

**(PROPOSED) INDICATION(S) FOR USE:**
Refer to Addendum I

## APPLICATION INFORMATION

**APPLICATION TYPE** (check one) ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

**IF AN NDA, IDENTIFY THE APPROPRIATE TYPE** ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 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) ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

**REASON FOR SUBMISSION**
Intent to file amendment

**PROPOSED MARKETING STATUS** (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

**NUMBER OF VOLUMES SUBMITTED** _____ **THIS APPLICATION IS** ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ 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 the site is ready for inspection or, if not, when it will be ready.

Refer to Addendum I

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

Refer to Addendum I

| | This application contains the following items: *(Check all that apply)* |
|---|---|
| | 1. Index |
| | 2. Labeling (check one) ☐ Draft Labeling ☐ 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)) |
| | 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) |
| | 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 (j) (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 314.50 (k) (3)) |
| | 18. User Fee Cover Sheet (Form FDA 3397) |
| X | 19. OTHER (Specify) Minutes to 7/20/00 teleconference |

CERTIFICATION

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| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE |
|---|---|---|
| Suzanne Danielson | Suzanne M. Danielson | 8/9/00 |

| ADDRESS (Street, City, State, and ZIP Code) | Telephone Number |
|---|---|
| 3M Center, Building 275-5W-06, St. Paul, MN 55144-1000 | (651) 733-4365 |



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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
NDA 21-074

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| 3M Health Care | August 24, 2000 |
| **TELEPHONE NO. *(Include Area Code)*** | **FACSIMILE (FAX) Number *(Include Area Code)*** |
| (651) 737-9117 | (651) 737-5320 |

**APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):***

3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

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|---|---|
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| **CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*** | **CODE NAME *(If any)*** |
| Chlorhexidine gluconate BP, alcohol USP | HPD-5a |

| DOSAGE FORM: | STRENGTHS: | ROUTE OF ADMINISTRATION: |
|---|---|---|
| Lotion | CHG 1.0%, Ethyl alcohol 61% | Topical |

**(PROPOSED) INDICATION(S) FOR USE:**
Refer to Addendum I

## APPLICATION INFORMATION

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| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE |
|---|---|---|
| Suzanne Danielson (for) | Suzanne M. Danielson | 8/24/00 |

| ADDRESS *(Street, City, State, and ZIP Code)* | Telephone Number |
|---|---|
| 3M Center, Building 275-5W-06, St. Paul, MN 55144-1000 | ( 651 ) 733 4365 |

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

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