DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-074

3M Health Care
Attention: Suzanne M. Danielson, RAC
Regulatory Affairs Manager
3M Center, Building 275-3E-08
St. Paul, MN 55144-1000

Dear Ms. Danielson:

Please refer to your new drug application (NDA) dated June 25, 1999, received June 25, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AVAGARD™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w).

We acknowledge receipt of your submissions dated June 26, July 18, July 20 (2), August 9, August 24, October 17, 2000; and January 10, February 21, March 14, and May 22, 2001. Your submission of February 21, 2001 constituted a complete response to our June 23, 2000 action letter.

This new drug application provides for the use of AVAGARD™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w) for the following indications:

- Surgical Hand Scrub
- Healthcare Personnel Hand Wash

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (patient package insert submitted May 22, 2001, immediate container and carton labels submitted February 21, 2001) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-074." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

Additionally, we note the facsimile provided to you on June 5, 2001 (copy attached) which provided comments on the promotional materials submitted January 10, 2001. Please provide a response to these comments so that the materials can be further evaluated.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with the Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Ms. Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

(See appended electronic signature page)

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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