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APPLICATION NUMBER:

NDA 19-422 / S-032

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-422 /S-032

Attention: Ram Chakroborty, Ph.D.
Vice President
415 West Pershing Road
Chicago, IL 60609

Dear Dr. Chakroborty:

Please refer to your supplemental drug application dated January 10, 2002, received February 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 2% (w/w) chlorhexidine gluconate solution.

We acknowledge receipt of your submissions dated July 2 and 18, 2002, August 7, 12, 15, and 30, 2002, September 12, 2002, October 7, 2002, November 6, 2002, February 10, 2003, March 26, 2003, August 22, 2003, September 3, October 22 and 31, 2003, and December 1, 2003.

Your submission of October 31, 2003, constitutes a complete response to our October 27, 2003, action letter.

This supplemental new drug application provides revised labeling for 2% (w/w) chlorhexidine gluconate solution.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the immediate container labels for the 16-ounce, 30-ounce, 32-ounce, and 1-gallon bottles submitted on September 3, 2003, and the 4-ounce and 8-ounce bottles submitted on October 31, 2003, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-422/S-032". Approval of this submission by FDA is not required before the labeling is used.

Additionally, in order to comply with 21 CFR 201.66, implement the following revisions at or before the time of the next printing:

1. Remove the extra subheading **Warnings**, on the fourth page of the 4-ounce container.

2. Remove the hairline just below that subheading.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,
{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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
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