DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-822/S-006

K.W. Griffen Company {U.S. Agent for Biomed Systems, Incorporated}
Attention: James B. Brown
Director, Regulatory Affairs
100 Pearl Street
Norwalk, CT 06850

Dear Mr. Brown:

Please refer to your supplemental new drug application dated Februrary 21, 2000, received March 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pre-Scrub II™ (4% chlorhexidine gluconate) Solution.

We acknowledge receipt of your submissions dated July 18 and October 31, 2002, and January 3, 2003.

Your submission of July 18, 2002, constituted a complete response to our June 27, 2002, action letter.

This supplemental new drug application provides for revised labeling for revised labeling for Pre-Scrub II™ (4% 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, ***Drug Facts***, brush-sponge dispenser, and shipping carton labeling submitted on October 31, 2002, 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-822/S-006." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreement to make the following changes in the next printing of your label, as specified in your January 3, 2003, submission.

> In the ***Drug Facts*** section of your labeling for this supplement, under the subheading ***Active Ingredient***, revise the phrase "Chlorhexidine Gluconate 4% Solution" to read "Chlorhexidine gluconate 4% solution".

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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}

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

Enclosure

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

/s/

Charles Ganley
1/9/03 10:46:18 AM