DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-300/S-014

SSL Americas, Incorporated
Attention: Kathleen Harris, M.B.A.
Manager, Regulatory Affairs
3585 Engineering Drive
Suite 200
Norcross, GA 30092

Dear Ms. Harris:

Please refer to your supplemental new drug application dated February 22, 2002, received February 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hibistat® (0.5% chlorhexidine gluconate) Solution and 5 mL Towelettes.

We acknowledge receipt of your submissions dated July 18 and December 3, 2002; January 9, 14 and 30, 2003; June 9 and 19, 2003; July 18 and 31, 2003; August 20, 2003; and November 27, 2003.

Your submission of July 31, 2003, constituted a complete response to our July 23, 2003, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application proposes a change in the location for the manufacture, packaging and testing of the Hibiclens solution in 4- and 8-ounce bottles to a new site,(b)(4)----------. This supplemental new drug application also provides for new Drug Fa----------e bottles of Hibistat Solution.

We have 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 draft immediate container labeling submitted November 27, 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 18-300/S-014." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
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

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
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