DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-669/S-002

Sage Products, Inc.
Attention: John Brda
Regulatory Affairs Manager
3909 Three Oaks Road
Cary, Illinois 60013

Dear Mr. Brda:

Please refer to your supplemental new drug application dated July 14, 2005, received July 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 2% chlorhexidine gluconate* cloth (*equivalent to 500 mg chlorhexidine gluconate per cloth).

We acknowledge receipt of your submission dated October 25, 2005.

This supplemental new drug application provides for revised labeling for the 2% chlorhexidine gluconate* cloth (*equivalent to 500mg chlorhexidine gluconate per cloth).

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 submitted labeling (outer shipping carton labeling submitted October 25, 2005, and the immediate container and inner shipping carton labeling submitted July 14, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-669/S-002**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 Laura Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Andrea Segal

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