CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-669

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-669

Sage Products, Inc.
Attention: Ajay Chawla
Product Development Compliance Manager
3909 Three Oaks Road
Cary, Illinois 60013

Dear Mr. Chawla:

Please refer to your new drug application (NDA) dated August 29, 2003, received September 4, 2003, submitted pursuant to section 505(b)(2) 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(s) dated October 21, and December 10, 2004; and February 25, April 4, 6, and 20, 2005.

The October 21, 2004 submission, received October 25, 2004, constituted a complete response to our July 1, 2004 action letter.

This new drug application provides for the use of 2% Chlorhexidine Gluconate* Cloth, *(equivalent to 500 mg chlorhexidine gluconate per cloth) as a patient preoperative skin preparation.

We completed our review of this application, as amended. It 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 labeling (immediate container label and outer container and carton labels) submitted April 20, 2005, and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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 NDA 21-669**." Approval of this submission by FDA is not required before the labeling is used.

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.

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. We are waiving the pediatric study requirement for children less than 2 months of age, as well as, for premature or low birth weight infants, and infants receiving phototherapy due to the potential for irritation and enhanced absorption.

You do not have any pediatric post-marketing study commitments.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Anti-Infective Drug Products, HFD-520 and the other copy, along with the labeling, to Division of Over-the-Counter Drug Products, HFD-560.

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

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

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

{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 – Labeling (2 pages)

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
4/25/05 01:45:28 PM

Janice Soreth
4/25/05 01:53:07 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-669

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-669

Sage Products, Inc.
Attention: Ajay Chawla
Product Development Compliance Manager
3909 Three Oaks Road
Cary, Illinois 60013

Dear Mr. Chawla:

Please refer to your new drug application (NDA) dated August 29, 2003, received September 4, 2003, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for [redacted] (chlorhexidine gluconate, 2%).

We acknowledge receipt of your submissions dated February 24, March 17 and 31, April 20, June 14 and 15, 2004.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

CHEMISTRY

1. An adequate analytical method to assess the quantity of chlorhexidine gluconate (CHG) and its impurities in the finished drug product has not been provided. The objective of the proposed revised analytical method is to quantitate the amount of CHG on each cloth in both the two-pack [redacted] configurations. In order for the stability data to be reliable and supportive of the NDA, both the revised assay [redacted] and added related impurities test [redacted] must first be validated. A minimum of [redacted] is requested on the finished drug product to support the proposed expiration period using the validated method.

2. The integrity of manufacturing controls to ensure content uniformity has not been developed for the two-pack or [redacted]. The claim that each cloth contains [redacted] is not supported by the data submitted in the NDA. Content uniformity is also a concern in each of the two finished drug product configurations and should be addressed.

3 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

Approvable

Withheld Track Number: ~~Approval~~ Ltrs- 1

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with the Division of Anti-Infective Drug Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/

Janice Soreth
6/29/04 12:31:54 PM

Charles Ganley
7/1/04 09:24:05 AM