CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-669/S-006

Name: 2% Chlorhexidine Gluconate Cloth
(equivalent to 500 mg chlorhexidine gluconate per cloth)

Sponsor: Sage Products Inc.

Approval Date: February 1, 2007

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-669/S-006

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-669/S-006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-669/S-006

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

Dear Mr. Brda:

Please refer to your supplemental new drug application dated September 15, 2006, received October 3, 2006, 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).

This "Prior Approval" supplemental new drug application provides for an alternate manufacturing site, (b) (4) ((b) (4)) for the drug substance (b) (4)% w/v chlorhexidine gluconate solution) and Sage Products (Cary, Illinois) as an alternate manufacturing site for the bulk drug product (2% w/w chlorhexidine gluconate solution).

We completed our review of this supplemental new drug application. This supplement is approved.

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

If you have any questions, call Robert Hummel, Regulatory Project Manager for Quality, at (301) 796-1981.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel
2/1/2007 11:44:05 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-669/S-006

CHEMISTRY REVIEW

Review of Chemistry, Manufacturing, and Controls

Clinical Review Division: Office of Non-Prescription Products

NDA #: 21-669 **CHEM. REVIEW #:** 1 **REVIEW DATE:** 01/30/07

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
N 21669/SCM–006 (PA)	09/15/06	09/29/06	10/18/06

NAME & ADDRESS OF APPLICANT: Sage Products Inc.
3909 Three Oaks Rd.
Cary, IL 60013

DRUG PRODUCT NAME

Proprietary: Chlorhexidine Gluconate Cloth, 2%
Nonproprietary/USAN: Chlorhexidine gluconate
Code Name/#:
Other Names:
Chem.Type/Ther.Class:

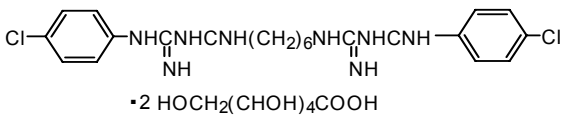
Patent Status: NA

PHARMACOLOGICAL CATEGORY/INDICATION:

DOSAGE FORM: Cloth
STRENGTHS: Chlorhexidine gluconate, 2% (equivalent to 500 mg/cloth)
ROUTE OF ADMINISTRATION: Topical
DISPENSED: Rx
PACKAGE SIZES:
SPECIAL PRODUCTS: ☐ Yes ☒ No (If yes, ill out the form for special products and deliver to TIA through team leader for data entry)

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT:

Chemical Name: 2,4,11,13-Tetraazatetradecane-dimidamide, N,N"-bis(4-chlorophenyl)-3,12-diimino-, di-D-gluconate
CAS Registry No.: CAS-18472-51-0
Molecular Formula: $C_{22}H_{30}C_{l2}N_{10}\cdot 2C_6H_{12}O_7$
Molecular Weight: 897.76



CHLORHEXIDINE GLUCONATE

SUPPORTING DOCUMENTS: NA

CONSULTS: NA

REMARKS/COMMENTS: This Prior Approval supplement requests approval for [redacted] as an alternate manufacturer of the drug substance [redacted]% w/v chlorhexidine gluconate solution) as well as for Sage Products (Cary, Illinois) as an alternate manufacturer of the bulk drug product (2% w/w chlorhexidine gluconate solution) used in the manufacture of the 2% Chlorhexidine Gluconate Cloth (equivalent to 500 mg chlorhexidine gluconate per cloth) product. The [redacted] DMFs referenced for the manufacture of the [redacted]% chlorhexidine gluconate solution (DMF [redacted]) and the [redacted] (DMF [redacted]) have been reviewed by Dr. Y. Sun (in ONDQA) and found to be Acceptable. The same manufacturing equipment and processes appear to be used by the approved and proposed facilities to manufacture of the bulk drug product. No changes have been made to the bulk product composition or component specifications and their testing. The specifications for in-process, release, and stability testing of the bulk product have undergone minor changes to reflect the fact that the bulk product does not undergo transfer to the approved manufacturing facility for the finished drug product (also performed at Sage Products).

Three different lots of the (b) (4)% chlorhexidine gluconate solution were used to manufacture the three lots of bulk drug product for stability studies. All lots satisfied specifications for testing at release and during 12 months of storage at 25°C and 60% RH. The requested re-test period of (b) (4) months can be recommended. The three different lots of the bulk product (b) (4)% chlorhexidine gluconate solution) were then used to manufacture three lots of finished drug product (2% Chlorhexidine Gluconate Cloth) for stability studies. All lots satisfied specifications for testing at release and during 18 months of storage at 25°C and 60% RH. The requested expiry period of 18 months can be recommended for the 2-pack configuration of 2% Chlorhexidine Gluconate Cloth.

The proposed sites have been recommended by the Office of Compliance as Acceptable (on 30-JAN-2007) based on District recommendation for (b) (4) and profile for Sage Products.

CONCLUSIONS & RECOMMENDATIONS:

The CMC information presented in the submission is sufficient to recommend APPROVAL of this amendment.

cc: Orig. NDA 21-669
DMIHP/Division File
DMIHP/CSO/R.Hummel

filename: n21669s.006.doc

Allan Fenselau, Ph.D., Review Chemist

DRAFT LETTER

There are no CMC–specific deficiencies, therefore no draft was generated.

8 Pages have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

Allan Fenselau
1/30/2007 01:04:53 PM
CHEMIST

EER completed!

Hasmukh Patel
1/30/2007 03:31:11 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-669/S-006

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

SAGE PRODUCTS INC

NDA NO. 21-669 006
SCM-006

RECEIVED
OCT 03 2006
CDER White Oak DR 1

ORIGINAL

RECEIVED
OCT 03 2006
CDR / CDER

September 15, 2006

Ms. Laura Shay
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Product
Division of Nonprescription Clinical Evaluation
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA 21-669 – Supplement 006 – Alternate Bulk Drug Product Manufacturing Site

Dear Ms. Shay:

Enclosed please find information regarding an alternate manufacturing site Sage Products plans to use for the bulk drug product used in the manufacture of the 2% Chlorhexidine gluconate Cloth product (*equivalent to 500mg chlorhexidine gluconate per cloth). We are submitting this change as a Prior-Approval Supplement. In addition, we are submitting a complete copy of this Prior Approval Supplement to the Food and Drug Administration at the Chicago District Office.

If you have any questions or comments, please do not hesitate to contact me by phone at (815) 444-5310, or by e-mail at jbrda@sageproducts.com. Thank you in advance for your assistance with this matter.

Sincerely,

John Brda
Manager, Regulatory Affairs