



NDA 021669/S-019

SUPPLEMENT APPROVAL

Sage Products LLC
Attention: Christopher Markos
Director, Regulatory Affairs
3909 Three Oaks Road
Cary, IL 60013

Dear Mr. Markos:

Please refer to your Supplemental New Drug Application (sNDA) dated December 16, 2013, received December 17, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for 2% Chlorhexidine Gluconate Cloth.

This “Changes Being Effected” sNDA provides for the revision of product labels to indicate the sterility of your drug in accordance with the November 17, 2013 CBE-0 Supplement Request letter. This letter requested class labeling changes to inform consumers whether topical antiseptic drug products indicated for patient preoperative or preinjection skin preparation are sterile or non-sterile.

We have 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.

LABELING

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the 2-count immediate container labeling and outer carton labeling for product codes 9705/9706 and 9707 submitted on December 16, 2013, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021669/S-019.**” Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Kristen Hardin, Regulatory Project Manager, at (240) 402-4246.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

Carton and Container Labeling

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

/s/

THERESA M MICHELE
06/24/2014