



NDA 50-591/S-032
NDA 50-703/S-015
NDA 50-746/S-018

SUPPLEMENT APPROVAL

SmithKlineBeecham (Cork) Ltd d/b/a GlaxoSmithKline
c/o Stiefel, a GSK Company
Attention: Patricia D. Termini, M.S.
Manager Global Regulatory Affairs
20 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Termini:

Please refer to your Supplemental New Drug Applications (sNDAs) dated November 22, 2013, received November 22, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50-591/S-032 - Bactroban Ointment (mupirocin ointment, 2%)
NDA 50-703/S-015 - Bactroban Nasal (mupirocin calcium ointment, 2%)
NDA 50-746/S-018 - Bactroban Cream (mupirocin calcium cream, 2%)

We acknowledge your communications of May 20 and 22, 2014.

These "Prior Approval" supplemental new drug applications provide for consistent labeling across the three formulations, revisions to the **ADVERSE REACTIONS** and **WARNINGS** sections and minor editorial updates. In addition, the Microbiology subsection of the Bactroban Nasal labeling has also been revised.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package inserts), with the

addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Maureen Dillon-Parker, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling (3): Ointment, Nasal, Cream

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/s/

SUMATHI NAMBIAR
05/22/2014