



NDA 22-055/S-002

SUPPLEMENT APPROVAL

Stiefel, a GSK Company
Attention: Maria C. Weber
Principal Labeling Coordinator, Regulatory Affairs
20 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Weber:

Please refer to your Supplemental New Drug Application (sNDA) dated September 1, 2009, received September 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALTABAX (retapamulin) Ointment, 1%.

We acknowledge receipt of your amendments dated August 4, 2011, and July 23, 2012.

The August 4, 2011, submission constituted a complete response to our August 5, 2010, action letter.

This supplemental new drug application provides for revisions to **HIGHLIGHTS OF PRESCRIBING INFORMATION**; Section 5, **WARNINGS AND PRECAUTIONS**; Section 6, **ADVERSE REACTIONS**; Section 7, **DRUG INTERACTIONS**; Section 8, **USE IN SPECIFIC POPULATIONS**; Section 12, **CLINICAL PHARMACOLOGY**, Section 15, **REFERENCES** of the labeling based on the results of study TOC106489. This study is a deferred pediatric study and a postmarketing commitment agreed to in the approval letter of April 12, 2007.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text [Content of Labeling] submitted July 23, 2012, with additional edits to **15 REFERENCES** section to reflect the current versions of the Clinical and Laboratory Standard Institute (CLSI) documents.

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 insert), 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 for this NDA, 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, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

SUMATHI NAMBIAR
12/21/2012