



NDA 17-381/S-050

SUPPLEMENT APPROVAL

King Pharmaceuticals, Inc.
a wholly-owned subsidiary of Pfizer, Inc.
Attention: William C. Vogt
Manager, Worldwide Regulatory Strategy
501 Fifth Street
Bristol, TN 37620

Dear Mr. Vogt:

Please refer to your Supplemental New Drug Application (sNDA) dated September 14, 2012, received September 14, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Silvadene (silver sulfadiazine) Cream, 1%.

This "Prior Approval" supplemental new drug application provides for the following changes:

- (1) Revision of the current prescribing information text that reads "dermatologic and allergic reactions, including Stevens-Johnson syndrome and exfoliative dermatitis" to "dermatologic and allergic reactions, including life-threatening cutaneous reactions [Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and exfoliative dermatitis]".
- (2) Relocation of the current prescribing information text from the ADVERSE REACTIONS section to the WARNINGS section.

We have completed our review of this supplemental application. It is 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 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 that includes labeling changes 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).

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 and Regulatory Project Manager for this application, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
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
03/06/2013