



NDA 17-381/S-053

**APPROVAL LETTER**

Monarch Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc.  
Attention: Will Vogt  
Manager Worldwide Safety and Regulatory  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Mr. Vogt:

Please refer to your Supplemental New Drug Application (sNDA) dated February 1, 2016, received February 1, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Silvadene (silver sulfadiazine) Cream, 1%.

This “Changes Being Effected” supplemental new drug application provides for the following revisions to the package insert and carton/container labeling:

1. Addition of “Avoid contact with the eye” statement under the “For Topical Use Only” statement to prevent exposure to the eye when applied topically to eye area.
2. Addition of “Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)” to the HOW SUPPLIED Section.
3. Revises the storage temperature on the Carton and Container labels to read “Store at 20°- 25°C (68° to 77°F)”.

**APPROVAL & LABELING**

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**

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 include 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).

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *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 Carton and Container Labels for approved NDA 17-381/S-053.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maureen Dillon-Parker, Chief, Regulatory Project Management Staff, at (301) 796-0706.

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Acting Deputy Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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DMITRI IARIKOV  
08/01/2016