DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22572/S-003

SUPPLEMENT APPROVAL

Mobius Therapeutics
Attention: Alan Beckman
Director of RA/QA
4041 Forest Park Avenue
St. Louis, MO 63108

Dear Mr. Beckman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 2, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mitosol (mitomycin for solution).

We also acknowledge your amendments dated May 7 and June 4, 2014.

This "Prior Approval" supplemental new drug application provides for revisions to the Instructions for Use (IFU) insert that is included in the Mitosol Kit. No changes are proposed to the product's approved package insert.

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.

LABELING REVISIONS

The following revisions in red text (noted with double underline) have been made to the Instructions for Use (IFU) insert that is included in the Mitosol Kit:

1. Under **2**. **Reconstituting Mitosol,** additional text following "b." and "e." is added as follows:

   b. **Press firmly** and screw the **blue end** of the vial adapter into the **blue end** of the syringe connector **(Fig. 2)**

   NOTE: For proper operation of the pre filled syringe, be sure it is fully and securely connected to a luer fitting. If it is not properly attached, the syringe will not operate. Excessive force applied to the plunger in this situation may force the contents to be expelled from the rear of the syringe.

e. Inject entire contents of sterile water (1 ml) into vial. **(Fig. 4)** *If syringe plunger does not operate see note following step 2b.*

2. Under **3. Preparing sponges,** additional text following the first bullet under "f." is added as follows:

f. **Mitosol must be used within 1 hour of reconstitution:**

- Inject medication into sponge container saturating sponges. Reconstituted Mitosol should remain undisturbed in sponge container for 60 seconds. **(Fig. 7)** *If syringe plunger does not operate, see note following step 2b.*

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 instruction for use), 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).

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 Ms. June Germain, Safety Regulatory Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Package Insert
Instructions For Use (IFU) insert

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

/s/

WILEY A CHAMBERS
09/25/2014