DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-753/S-018

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Lori Ann Kneafsey
Associate Director, Drug Regulatory Affairs
One Health Plaza
Building 100
East Hanover, NJ 07936-1080

Dear Ms. Kneafsey:

Please refer to your Supplemental New Drug Application (sNDA) dated March 27, 2015, received March 27, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TOBI (tobramycin) solution for inhalation, 300 mg/5mL.

We also acknowledge receipt of your amendments dated April 7, and August 31, 2015.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the ***Metabolism and Nutrition disorders*** System Organ Class, in the **ADVERSE REACTIONS** section, **Postmarketing Experience** subsection and minor editorial changes.

APPROVAL & LABELING

We have completed our review of this supplemental application as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below and indicated in the enclosed labeling:

- Strike the term "weight loss" from the spontaneous reports subsection, as it is already included in Table 1.

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, including the revision listed above, 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 via 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 with the revisions 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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

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: 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
10/05/2015