



NDA 50-789/S-027

SUPPLEMENT APPROVAL

APP Pharmaceuticals, Inc.
Attn: Tamira Wright, Regulatory Scientist
1501 East Woodfield Road
Suite 300E
Schamburg, IL 60173

Dear Ms. Wright:

Please refer to your supplemental new drug application dated January 28, 2009, received, January 30, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tobramycin for Injection, USP, 1.2 gram/50mL vial.

This "Changes Being Effected" supplemental new drug application provides for updates to the WARNINGS section and PRECAUTIONS/Information for Patients subsection in reference to *Clostridium difficile* associated disease (CDAD), and other minor editorial revisions.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the enclosed labeling submitted on January 28, 2009.

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 50-789/S-005.**"

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on January 28, 2009

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

/s/

KATHERINE A LAESSIG
08/10/2009