CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-789

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-789

American Pharmaceutical Partners, Inc.
Attention: Toni A. Glinsey
Senior Regulatory Scientist
2045 North Cornell Avenue
Melrose Park, IL 60160

Dear Ms. Glinsey:

Please refer to your new drug application (NDA) dated December 20, 2002, received December 24, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tobramycin for Injection, USP. This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated October 31, 2003, January 12, and June 28, 2004. Your submission of January 12, 2004 constituted a complete response to our October 24, 2003 action letter.

This new drug application provides for the use of Tobramycin for Injection for the treatment of septicemia, lower respiratory tract infections, serious central nervous system infections, intra-abdominal infections, skin, bone, and skin structure infections, and complicated and recurrent urinary tract infections (UTIs).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on January 12, 2004, and the immediate container and carton labeling submitted June 28, 2004.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Frances LeSane, Chief, Project Management Staff, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: package insert, immediate container, and carton label

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We acknowledge receipt of your submissions dated August 20, October 8, 10, 13, 15, 16, and 17, 2003.

We have completed our review of this application, as submitted, with draft labeling, and it is approvable. However, the Drug Master File (DMF) [redacted] for the drug substance is inadequate. Before the application may be approved, it will be necessary for the DMF holder to correct these deficiencies.

In addition, you must submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed labeling (text for the package insert, immediate container and carton labels).

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment or follow one of your other options under 21 CFR 314.110. If you do not

follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call LT Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosed: text for the package insert, immediate container and carton labels

13 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

✓ § 552(b)(5) Draft Labeling

Withheld Track Number: Approvable Letter 1 of 1

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

/s/

Janice Soreth
10/24/03 04:20:26 PM