



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

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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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/s/

Janice Soreth

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