CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-918

OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-918

Parexel International
Attention: Alberto Grignolo, Ph.D.
Corporate VP and General Manager, DDC
195 West Street
Waltham, MA 02451-1163

Dear Dr. Grignolo:

Please refer to your June 9, 2005 new drug application (NDA) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for CETRAXAL (ciprofloxacin otic solution) 0.2%.

We acknowledge receipt of your submissions dated July 13, August 3 and August 24, September 6, 2005, January 31, March 20, and March 27, 2006.

We completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit a new vial configuration, stability information for the new vial and any applicable carton and labeling changes.

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 the Division of Anti-Infective and Ophthalmology Products 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 a meeting or telephone conference with Division of Anti-Infective and Ophthalmology Products 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 this application is approved.

If you have any questions, call Susmita Samanta, MD, Regulatory Project Manager, at 301-796-1400.

Sincerely,

{See appended electronic signature page}

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

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
4/6/2006 02:46:56 PM