DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-799/S-006

Daiichi Pharmaceutical Corporation
Attention: Amy S. Domanowski, Ph.D.
Vice President, Regulatory Affairs
11 Philips Parkway
Montvale, New Jersey 07645-1810

Dear Dr. Domanowski:

Please refer to your supplemental new drug application dated January 25, 2001, received January 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FLOXIN® Otic (ofloxacin otic solution) 0.3%.

We acknowledge receipt of your submissions dated March 28, May 28, June 5, 2003 and September 26, 2003. Your submission of March 28, 2003 constituted a complete response to our November 27, 2001 action letter.

This supplemental new drug application proposes once-a-day dosing of FLOXIN® Otic for the treatment of adults and pediatric patients (ages 6 months and older) with Otitis Externa (OE) caused by susceptible strains of *Escherichia coli, Pseudomonas aeruginosa, and Staphylococcus aureus*.

We have completed the review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, patient information, and the carton labeling must be revised as agreed on September 26, 2003), and must be formatted in accordance with the requirements of 21 CFR 201.66. Please submit the FPL electronically according to the Guidance for Industry titled "Providing Regulatory Submissions in Electronic Format – NDA". Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-799/S-006". Approval of this submission by FDA is not required before the labeling is used.

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, HFD-520, and two copies of both the promotional materials and the package inserts directly to:

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

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, HF-2
FDA
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 Susmita Samanta, M.D., Regulatory 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

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

9/30/03 03:35:50 PM