



NDA 20-799/S-016

Daiichi Pharmaceutical Corporation
Attention: Kenneth R. Palmer, M.Sc.
Director, Global Regulatory Affairs
11 Philips Parkway
Montvale, NJ 07645-1810

Dear Mr. Palmer:

Please refer to your supplemental new drug application dated March 16, 2005, received March 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FLOXIN[®] Otic (Ofloxacin Otic) Solution 0.3%.

This “Changes Being Effected” supplemental new drug application proposes to incorporate the additional word “transient” in front of the adverse event ‘loss of hearing’.

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

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-799/S-016.**" Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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
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/s/

Janice Soreth
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