

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-799

APPROVAL LETTER

NDA 20-799

520
Duvall
Miller

Daiichi Pharmaceutical Corporation
Attention: Amy Domanowski, Ph.D.
Senior Director, Regulatory Affairs
One Parker Plaza
Fort Lee, NJ 07024

DEC 16 1997

Dear Dr. Domanowski:

Please refer to your new drug application dated December 18, 1996, received December 18, 1996, 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 April 24, May 12, May 30, July 31, September 17, September 25, October 8, November 4, November 17, November 18, November 25, November 26, December 5, December 12, and December 15, 1997. The User Fee goal date for this application is December 18, 1997.

This new drug application provides for treatment of otitis externa, chronic suppurative otitis media, and acute otitis media in patients with tympanostomy tubes.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 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 "FINAL PRINTED LABELING" for approved NDA 20-799. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the

promotional material and the package insert directly to:

**Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857**

Validation of the regulatory methods has been completed. However, the Philadelphia District, HFR-MA160, has identified several problems in the regulatory methods. Therefore, we expect your continued cooperation to resolve the problems that have been identified. Please clarify the following items:

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

**/s/
Gary K. Chikami, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research**

ENCLOSURE