

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-007

APPROVAL LETTER

Isabel B. Drzewiecki
Director, Regulatory Affairs
The R.W. Johnson Pharmaceutical
Research Institute
Route 202, P.O. Box 300
Raritan, New Jersey 08869-0602

MAY 15 1992

Dear Ms. Drzewiecki:

Reference is made to your supplemental New Drug Application (NDA) dated January 2, 1992, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Floxin (ofloxacin) Tablets.

We also acknowledge your amendment dated February 27, 1992.

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We have completed our review of the supplemental application and it is approved effective as of the date of this letter.

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

Sincerely yours,

WA 5/13/92

Wilson H. De Camp, Ph.D.
Supervisory Chemist
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Orig: NDA 19-735/S-007
HFD-130/JAllen
~~HFD-520~~
HFD-520/Lumpkin (reading file)
HFD-520/Szarfman
HFD-520/Buko
HFD-521/Fogarty
HFD-520/Shetty BVS 4/22/92
init. by SUPVCHEM/3/10/92
th:3/10/92
n19735.s7