CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-004

APPROVAL LETTER

NDA 19-735/S-004

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

DEC 13 1991

Dear Ms. Drzewiecki:

Reference is made to your supplemental New Drug Application (NDA) dated April 8, 1991, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Floxin (ofloxacin) Tablets.

The supplemental application provides for additional firms to serve as packagers of the drug products, Floxin Tablets.

We have completed our review of the supplemental application and only _____ are approved.

_____ is not approved as it was found to be inactive.

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,

WD 12/12/91

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-004
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Szarfman
HFD-520/Buko
HFD-521/Fogarty
HFD-520/Shetty BVS 12/4/91
init. by SUPVCHEM/12/4/91
th:12/4/91
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