CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-008

APPROVAL LETTER

NDA 19-735/S-008

JUN 23 1992

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

Dear Ms. Drzewiecki:

Reference is made to your supplemental New Drug Application (NDA) dated January 31, 1992, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Floxin (ofloxacin) Tablets.

The supplemental application provides for changes in the control procedures for the acceptance of the new drug substance, ofloxacin.

[redacted]

We have completed our review of the supplemental application and it is approved effective as of the date of this letter. However, please note that these kind of changes in the control procedures should have been submitted in your Annual Report and not as a supplement, per 21 CFR 314.70(d)(1).

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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 6/23/92

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-008
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Szarfman
HFD-520/Buko
HFD-521/Fogarty
HFD-520/Shetty BVS 6/22/92
init. by SUPVCHEM/6/22/92
th:6/23/92/n19735.s8

APPROVED