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Approval Package for:

APPLICATION NUMBER:

16-620 / S-053

Trade Name: Macrochantin

Generic Name: Nitrofurantoin macrocrystals

Sponsor: Norwich Eaton Pharmaceuticals

Approval Date: December 8, 1992

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APPROVAL LETTER

NDA 16-620/S-053

Ms. Sandra M. Jones
Norwich Eaton Pharmaceuticals, Inc.
17 Eaton Avenue
Norwich, New York 13815-1799

DEC 8 1992

Dear Ms. Jones:

Reference is made to your supplemental New Drug Application (NDA) dated April 16, 1992, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrochantin (nitrofurantoin macrocrystals) Capsules.

The supplemental application provides for use of a _____

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

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,



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 16-620/S-053
HFC-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/MO/Alpert
HFD-520/CHEM/Katague *OK 6/10/92*
HFD-520/PHARM/Buko
HFD-520/CSO/Dillon-Parker
R/D initialed by SUPVCHEM/6/15/92
ndaltr.dbk

APPROVAL

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CHEMISTRY REVIEW(S)

