

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-055

Trade Name: Macrochantin

Generic Name: Nitrofurantoin macrocrystals

Sponsor: Norwich Eaton Pharmaceuticals

Approval Date: December 8, 1992

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APPLICATION NUMBER:

16-620 / S-055

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Reviews / Information Included in this NDA Review.

Approval Letter	X
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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

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APPROVAL LETTER

NDA 16-620/S-055

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,

WHD 6/18/92

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 16-620/S-055
HFC-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/MO/Alpert
HFD-520/CHEM/Katague *DBK 6/18/92*
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)

JUN 15 1992

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 16-620
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3. NAME & ADDRESS OF APPLICANT Norwich Eaton Pharmaceuticals, Inc. P.O. Box 191 Norwich, N.Y. 13815	4. AF NUMBER
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5. SUPPLEMENTS

NUMBER(S) DATE(S)

6. NAME OF DRUG Macrochantin	7. NONPROPRIETARY NAME Nitrofurantoin	SCS-055	4/16/92
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8. SUPPLEMENT(S) PROVIDES FOR: S-055	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
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10. PHARMACOLOGICAL CATEGORY Antibacterial	11. HOW DISPENSED XXX Rx OTC	12. RELATED IND/NDA/DMF(S)
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13. DOSAGE FORM(S) Capsules	14. POTENCY(ies) 25, 50, 100 mg
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15. CHEMICAL NAME AND STRUCTURE C₈H₈N₄O₂
1[[[(5-Nitro-2-furanyl)Methylene]Amino]-2,4-Imidazolidinedione

m.w. 238.16
CAS Registry No. 67 -20 -9

16. RECORDS AND REPORTS	
CURRENT	
Yes	No
REVIEWED	
Yes	No

17. COMMENTS

[]

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 16-620
HFD-520
HFD-520/Buko
HFD-520/Katague

HFD-520/Alpert
HFD-520/Dillon-Parker
HFD-520/WHDeCamp:R/D initialed

WJ
WJ/KR

19. NAME David B. Katague, Ph.D.	REVIEWER SIGNATURE <i>D B Katague</i>	DATE COMPLETED 5/08/92
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