

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-054

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-054

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Reviews / Information Included in this NDA Review.

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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-054

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 _____

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,

mmu 12/03/92

Murray M. Lumpkin, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Orig: NDA 16-620/S-054
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Buko
HFD-521/Dillon-Parker
HFD-520/Katague *sjk 11/30/92*
init. by SUPVCHEM/11/30/92 *WJ 11/30/92*
td:11/30/92
n16620.s54

APPROVAL

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CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW 1. ORGANIZATION 2. NDA NUMBER
 DAIDP (HFD-520) 16-620

3. NAME & ADDRESS OF APPLICANT 4. AF NUMBER
 Proctor & Gamble Pharmaceuticals
 P.O. Box 191
 Norwich, N.Y. 13815

5. SUPPLEMENTS
 NUMBER(S) DATE(S)

6. NAME OF DRUG 7. NONPROPRIETARY NAME
 Macrochantin Nitrofurantoin SCF-054 4/16/92

8. SUPPLEMENT(S) PROVIDES FOR: 9. AMENDMENTS AND OTHER
 (REPORTS, etc.) DATES

10. PHARMACOLOGICAL CATEGORY 11. HOW DISPENSED 12. RELATED
 IND/NDA/DMF(S)
 Antibacterial XXX Rx OTC

13. DOSAGE FORM(S) 14. POTENCY(ies)
 Capsules 25, 50, 100 mg

15. CHEMICAL NAME AND STRUCTURE $C_8H_8N_4O_5$
 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/Alpert
 HFD-520/Buko HFD-520/Dillon-Parker
 HFD-520/Katague HFD-520/WHDeCamp:R/D initialed

19. REVIEWER
 NAME SIGNATURE DATE COMPLETED
 David B. Katague, Ph.D. *David B. Katague* 11/09/92

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MM
12/03/92