CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-057

Trade Name: **Macrodantin**

Generic Name: **Nitrofurantoin macrocrystals**

Sponsor: **Norwich Eaton Pharmaceuticals**

Approval Date: **August 9, 1993**

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APPLICATION NUMBER:

16-620 / S-057

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	**X**

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APPROVAL LETTER

NDA 16-620/S-057

AUG 9 1993

Sandra M. Jones
Regulatory Affairs
Proctor & Gamble Pharmaceuticals
P.O. Box 191
Norwich, New York 13815

Dear Ms. Jones:

Please refer to your supplemental New Drug Application (NDA) dated July 9, 1993, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin (nitrofurantoin) 25, 50 & 100 mg Capsules.

The supplemental application provides for centralization of all CMC information into the Macrobid NDA (#20-064), which contains the most up-to-date CMC information on nitrofurantoin macrocrystals bulk drug. Only CMC changes for drug substance are in effect for this supplement. A notification of changes with Form 356h will still be required for every supplement in the future.

We have completed our review of this supplemental application and it 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,

WH 8/9/93

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-057
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Buko
HFD-521/Dillon-Parker
HFD-520/Katague DBK 8/9/93
init. by SUPVCHEM/7/27/93
td:7/28/93/n16620.s57

APPROVED

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CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

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

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

4. **AF NUMBER**

5. SUPPLEMENTS NUMBER(s) DATE(s)

6. **NAME OF DRUG**	7. **NONPROPRIETARY NAME**	
Macrodantin	Nitrofurantoin	SCS-057 7/09/93

8. **SUPPLEMENT(s) PROVIDES FOR:**

9. **AMENDMENTS AND OTHER (REPORTS, etc.) DATES**

S-057 For centralization of all CMC information into the Macrobid NDA (# 20-064), which contains the most up-to-date CMC information on nitrofurantoin macrocrystals bulk drug.

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** $C_8H_6N_4O_5$
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		REVIEWED	
	Yes	No	Yes	No

17. **COMMENTS**
The supplement provides for an updated record of all CMC for the drug substance, nitrofurantoin macrocrystals, used in this drug product. For details, see attached page.

18. **CONCLUSIONS AND RECOMMENDATIONS**

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 16-620
HFD-520 HFD-520/Blum
HFD-520/Buko HFD-520/Dillon-Parker
HFD-520/Katague HFD-520/WHDeCamp:R/D initialed WH 7/27/93

19. **NAME**	**REVIEWER SIGNATURE**	**DATE COMPLETED**
David B.Katague, Ph.D.	D. B Katague	07/27/93

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JUL 19 1993

NDA No. 16-620

Procter & Gamble Pharmaceuticals
P.O. Box 191
Norwich, NY 13815-0191

Attention: Sandra M.Jones

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Macrodantin Capsules

NDA Number: 16-620

Supplement Number: S-057

Date of Supplement: July 9, 1993

Date of Receipt: July 12, 1993

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research