CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-019

Trade Name: Macrodantin

Generic Name: (nitrofurantoin macrocrystals)

Sponsor: Norwich Pharmacal Company

Approval Date: November 22, 1976

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-019

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	**X**

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APPLICATION NUMBER:

16-620 / S-019

APPROVAL LETTER

NOV 2 2 1976

NDA 16-620/S-019

Norwich Pharmacal Company
Attention: William L. Davies, Ph.D.
Norwich, New York 13815

Gentlemen:

Reference is made to your supplemental new drug application of July 29, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin (nitrofurantoin macrocrystals) Capsules, 50 and 100 mg.

The supplemental application provides for child-resistant closures for the containers for Macrodantin Capsules, 50 and 100 mg.

We have completed the review of this supplemental application and it is approved. Our letter of April 11, 1968, detailed the conditions relating to the approval of this application.

Sincerely yours,

MLG

Merle L. Gibson, M.D.
Director
Division of Anti-Infective
Drug Products
Bureau of Drugs

cc:
Orig. NDA
HFD-140
HFD-140/CSO
HFD-616
HFL-10
HFD-140/HCZell/11/9/76/es/11/15/76 HCZ 11/17/76
R/D init by: ARCasola/11/9/76 ARC 11/18/76

APPROVED LETTER

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-019

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW (If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)	1. ORGANIZATION	2. NDA NUMBER
	HFD-140	16-620

3. NAME AND ADDRESS OF APPLICANT (City and State)	4. AF NUMBER	5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
Norwich Pharmacal Company Norwich, New York 13815	9-700	S-019	7/29/76

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Macrodantin	nitrofurantoin macrocrystals

8. SUPPLEMENT(S) PROVIDES FOR:

Child-resistant closures for the containers for Macrodantin capsules, 50 and 100 mg.

9. AMENDMENTS AND OTHER (Reports, etc.) DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Antibacterial	[X] RX [ ] OTC	

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

15. CHEMICAL NAME AND STRUCTURE

See Insert

16. RECORDS AND REPORTS

CURRENT [ ] YES [ ] NO

REVIEWED [ ] YES [ ] NO

17. COMMENTS

Samples of containers and closures were submitted, as well as, three month accelerated and 24 month room temperature stability data.

A commitment to test two market batches for stability and to report as required in 21 CFR 314.8(d)(5)(ii) was made.

This NDA was approved 4/11/68.

18. CONCLUSIONS AND RECOMMENDATIONS

Revisions of this nature are permitted under 21 CFR 314.8(d) and (e).

The supplement should be approved.

AR Casola mds 11/9/76

cc: HFD-140 HFD-140/HCZell/sj/11/16/76 HFD-140/CSO
HFD-140/ARCasola/11/9/76

19. REVIEWER		
NAME	SIGNATURE	DATE COMPLETED
Howard C. Zell, Ph.D.	Howard C. Zell	11/9/76

DISTRIBUTION [X] ORIGINAL JACKET [ ] REVIEWER [ ] DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. 1

CHEMIST'S REVIEW, Page 2 *Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.*	NDA NUMBER 16-620

20. COMPONENTS AND COMPOSITION *(6, 7)*

NC

21. FACILITIES AND PERSONNEL *(8a,b)*

NC

22. SYNTHESIS *(8c)*

NC

23. RAW MATERIAL CONTROLS *(8d,e)*
a. NEW DRUG SUBSTANCE

NC

b. OTHER INGREDIENTS

NC

24. OTHER FIRM(s) *(8f)*

See Insert

25. MANUFACTURING AND PROCESSING *(8g,h,j,k)*

NC

26. CONTAINER *(8i)* Satisfactory

See Insert

27. PACKAGING AND LABELING *(8l,m)*

NC

28. LABORATORY CONTROLS *(In-Process and Finished Dosage Form) (8n)*

NC

29. STABILITY *(8p)* Adequate

See Insert

30. CONTROL NUMBERS *(8c)*

NC

31. SAMPLES AND RESULTS *(9)*

a. VALIDATION NA

b. MARKET PACKAGE Submitted

32. LABELING *(4)*

NC

33. ESTABLISHMENT INSPECTION

NA

34. RECALLS

NA

WITHHOLD 18 PAGE(S)

Chemistry Review
B4

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-019

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 16-620

DATE APPROVAL LETTER ISSUED: NOV 22 1976

TO: Press Relations Staff (HFI-40)

FROM:
- [X] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [X] SUPPLEMENT TO NDA
- [ ] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

TRADE NAME *(or other designated name)* AND ESTABLISHED OR NONPROPRIETARY NAME *(if any)* OF DRUG

Macrodantin Nitrofurantoin Macrocrystals

DOSAGE FORM: Capsules

HOW DISPENSED
- [X] RX
- [ ] OTC

ACTIVE INGREDIENT(S) *(as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)*

Nitrofurantoin Macrocrystals 50 and 100 mg.

NAME OF APPLICANT *(Include City and State)*

Norwich Pharmacal Company
Norwich, New York 13815

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Antibacterial

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

Child-resistant closures for the containers for Macrodantin Capsules, 50 and 100 mg.

FORM PREPARED BY

NAME Howard C. Zell, Ph.D. Howard C. Zell DATE 11/9/76

FORM APPROVED BY

NAME Armand R. Casola, Ph.D. Armand R. Casola DATE 11/18/76