CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-018

Trade Name: Macrodantin

Generic Name: (nitrofurantoin macrocrystals)

Sponsor: Norwich Pharmacal Company

Approval Date: July 21, 1976

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-018

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**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-018

APPROVAL LETTER

JUL 21 1976

NDA 16-620/S-018

Norwich Pharmacal Company
Attention: Alexander B. Neill, Ph.D.
Norwich, New York 13815

Gentlemen:

Reference is made to your supplemental new drug application of March 17, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin (nitrofurantoin macrocrystals) Capsules, 25, 50 and 100 mg.

The supplemental application provides for _____ as an alternate packager.

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,

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

cc: NYK-DO
Orig NDA
HFD-140
HFD-140/CSO
HFD-140/HCZell/7/13/76/jmm/7/19/76 H.C.Z. 7/19/76
R/D init. by: ARCasola/7/14/76 ARC 7/20/76

APPROVED

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-018

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: HFD-140

2. NDA NUMBER: 16-620

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Norwich Pharmacal Company
Norwich, New York 13815

4. DATE NDA APPROVED:

5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY:

6. NAME OF DRUG: Macrodantin

7. NONPROPRIETARY NAME: nitrofurantoin macrocrystals

8. SUPPLEMENT
NUMBER: S-018
DATE: 3/17/76

9. PURPOSE OF SUPPLEMENT
[redacted] as an alternate packager.

10. AMENDMENT DATE(s):

11. OTHER DATE *(Report, etc.)*:

12. PHARMACOLOGICAL CATEGORY: Antibacterial

13. AF NUMBER: 9-700

14. DOSAGE FORM: Capsules

15. HOW DISPENSED
☒ Rx ☐ OTC

16. RELATED IND/NDA/MF(s)
DMF - [redacted]

17. POTENCY(ies): 25,50 and 100 mg.

18. DRUG REQUIRES
☐ NDA ☐ ANDA

19. CHEMICAL NAME: See Insert

20. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

21. CHEMICAL FORMULA
See Insert

22. REMARKS
See April 30, 1976, memo from HFD-322 indicating that the above named firm is in compliance and that there is no reason to withhold approval.

This NDA was approved 4/11/68.

23. CONCLUSIONS
Controls are adequate. The firm is in compliance with current GMP.

The submission meets the requirements of 21 CFR 314.8 (a)(b)(v).

The supplement should be approved.

Apr 7/20/76 AC Capsule 7/20/76

24. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Howard C. Zell, Ph.D.	Howard C. Zell	7/13/76

DISTRIBUTION ☐ ORIGINAL JACKET ☐ DUPLICATE JACKET ☐ REVIEWER

FORM FDH 2266 (11/73) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. 1

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

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

NC

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

NC

27. SYNTHESIS *(8c)*

NC

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

NC

b. OTHER INGREDIENTS

NC

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

[redacted] is to be an alternate packager.

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

NC

31. CONTAINER *(8i)*

NC

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

NC

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

NC

34. STABILITY *(8p)*

NA

35. CONTROL NUMBERS *(8c)*

NC

36. SAMPLES AND RESULTS *(9)*

a. VALIDATION NA

b. MARKET PACKAGE NA

37. LABELING *(4)*

NC

38. ESTABLISHMENT INSPECTION Satisfactory

See Insert

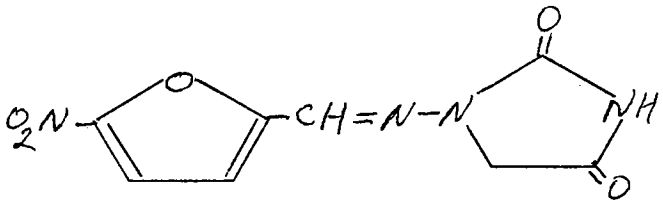
39. RECALLS

NA

Insert

19+21. Chemical Name and Structure:

1-[(5-Nitrofurfurylidene)amino] hydantoin



33. Establishment Inspection:

_____ was inspected 11/5-7/75 and found to be in compliance as indicated in a memo dated 4/30/76 (David H. Bryant HFD-322).

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-018

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Director, Division of Anti-Infective Drug Products (HFD-140)
Attn: R. C. Bieneman

DATE: April 30, 1976

FROM : Chief, Manufacturing Review Branch (HFD-322)
Division of Drug Manufacturing

SUBJECT: Approvable NDAs 8-693, Furadantin Tablets
16-620, Macrodantin Capsules

APPLICANT: Norwich Pharmacal Company
Norwich, N. Y.

PACKAGER: _____

We have evaluated the operations of _____ as they relate to compliance with Current Good Manufacturing Practice Regulations (21 CFR 211) and the referenced New Drug Applications. We conclude that there is no reason to withhold approval of the referenced pending NDAs insofar as they relate to this firm and the type of operations as specified in these pending new drug applications.

Our evaluation is based in part on an inspection conducted 11/5-11/75.

David H. Bryant
David H. Bryant

cc: BUF-DO (HFR-2200)
CHI-DO (HFR-5100)
HFV-210
HFD-322 Firm File
HFD-300 R/F
HFD-140 (NDA Orig)
HFA-226
WABrown:nct:4/30/76

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT .

NDA NUMBER: 16-620

DATE APPROVAL LETTER ISSUED: JUL 21 1976

TO: Press Relations Staff *(CE-300)*

FROM: [X] Bureau of ~~Medicine~~ 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 [ ] ABBREVIATED ORIGINAL NDA [X] SUPPLEMENT TO NDA

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	25 mg.
	50 mg.
	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

_____ as an alternate packager.

FORM PREPARED BY

NAME: Howard C. Zell, Ph.D. Howard C. Zell DATE: 7/13/76

FORM APPROVED BY

NAME: Armand R. Casola, Ph.D. Armand R Casola DATE: 7/20/76

FD FORM 1642 (7/69) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.