CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-016

Trade Name: Macrodantin

Generic Name: (nitrofurantoin macrocrystals)

Sponsor: Norwich Pharmacal Company

Approval Date: July 15, 1976

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-016

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-016

APPROVAL LETTER

NDA 16-620/S-016

JUL 15 1976

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

Gentlemen:

Reference is made to your supplemental new drug application of February 3, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin (nitrofurantoin macrocrystals) Capsules, 25 mg.

We also acknowledge receipt of your additional communication dated June 3, 1976.

The supplemental application provides for a child-resistant closure for the container for 100 Macrodantin Capsules, 25 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: NYK-DO
Orig. NDA
HFD-140
HFD-140/CSO
HFD-140/HCZell/7/9/76/jmm/7/15/76 H.C.Z. 7/15/76
R/D init. by: ARCasola/7/9/76

APPROVED RLB for BRL 7-15-76

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APPLICATION NUMBER:

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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)*

Norwich Pharmacal Company
Norwich, New York 13815

4. AF NUMBER: 9-700

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-016	2/3/76

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

8. SUPPLEMENT(S) PROVIDES FOR:

A child-resistant closure for the container for 100 Macrodantin capsules, 25 mg.

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

6/3/76

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED
Antibacterial	[X] RX [ ] OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM (S)	14. POTENCY *(ies)*
Capsules	25 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 18 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.

ARCasola 7/14/76

cc: HFD-140 HFD-140/HCZell/sdj/7/12/76 HFD-140/CSO
HFD-140/ARCasola/7/9/76

MLG 7/15/76

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Howard C. Zell, Ph.D.	Howard C. Zell	7/9/76

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

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

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)*

See Insert

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

NC

31. CONTAINER *(8i)* Satisfactory

See Insert

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

NC

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

NC

34. STABILITY *(8p)* Adequate

See Insert

35. CONTROL NUMBERS *(8c)*

NC

36. SAMPLES AND RESULTS *(9)*

a. VALIDATION NA b. MARKET PACKAGE Submitted

37. LABELING *(4)*

NC

38. ESTABLISHMENT INSPECTION

NA

39. RECALLS

NA

WITHHOLD 12 PAGE(S)

B4

Chemistry Review 1a