

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

16-620 / S-016

Trade Name: Macrochantin

Generic Name: (nitrofurantoin macrocrystals)

Sponsor: Norwich Pharmacal Company

Approval Date: July 15, 1976

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APPLICATION NUMBER:

16-620 / S-016

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APPROVAL LETTER

NDA 16-620/S-016

JUL 15 1976

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

Gentlemen:

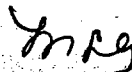
Reference is made to your supplemental new drug application of February 3, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrochantin (nitrofurantoin macrocrystals) Capsules, 25 mg.

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 Macrochantin 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,



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 Jb.C.J. 7/15/76

R/D init. by: ARCasala/7/9/76

APPROVED

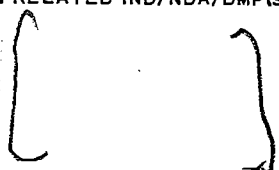

RCB for PDC 7-15-76

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CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		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. AF NUMBER 9-700	5. SUPPLEMENT (S) <table border="1"> <tr> <th>NUMBER(S)</th> <th>DATE(S)</th> </tr> <tr> <td>S-016</td> <td>2/3/76</td> </tr> </table>	NUMBER(S)	DATE(S)	S-016	2/3/76
NUMBER(S)	DATE(S)						
S-016	2/3/76						
6. NAME OF DRUG Macrochantin	7. NONPROPRIETARY NAME nitrofurantoin macrocrystals	9. AMENDMENTS AND OTHER (Reports, etc.) DATES 6/3/76					
8. SUPPLEMENT(S) PROVIDES FOR: A child-resistant closure for the container for 100 Macrochantin capsules, 25 mg.		12. RELATED IND/NDA/DMF(S) 					
10. PHARMACOLOGICAL CATEGORY Antibacterial	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	13. DOSAGE FORM (S) Capsules					
14. POTENCY (ies) 25 mg.		16. RECORDS AND REPORTS CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO					
15. CHEMICAL NAME AND STRUCTURE See Insert		17. COMMENTS <p>Samples of containers and closures were submitted, as well, as three month accelerated and 18 month room temperature stability data.</p> <p>A commitment to test two market batches for stability and to report as required in 21 CFR 314.8 (d)(5)(ii) was made.</p> <p>This NDA was approved 4/11/68.</p>					
18. CONCLUSIONS AND RECOMMENDATIONS Revisions of this nature are permitted under 21 CFR 314.8 (d) and (e). The supplement should be approved. cc: HFD-140 HFD-140/HCZell/sdj/7/12/76 HFD-140/CSO 7/14/76 HFD-140/ARCase1a/7/9/76 <i>mly 7/15/76</i>							
19. REVIEWER							
NAME Howard C. Zell, Ph.D.	SIGNATURE 	DATE COMPLETED 7/9/76					
DISTRIBUTION	<input checked="" type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE				

Enter evaluation or comments for each item. If necessary, continue on 8" x 10 1/2" 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(e) (8f)	See Insert
30. MANUFACTURING AND PROCESSING (8g,h,i,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)**

04

Chemistry Review 1a