

# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

***APPLICATION NUMBER:***

**16-620 / S-020**

***Trade Name:*** Macrochantin

***Generic Name:*** (nitrofurantoin macrocrystals)

***Sponsor:*** Norwich Pharmacal Company

***Approval Date:*** March 21, 1977

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**16-620 / S-020**

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<b>Chemistry Review(s)</b>	<b>X</b>
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**APPROVAL LETTER**

NDA 16-620/S-020

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

MAR 21 1977

Gentlemen:

Reference is made to your supplemental new drug application of October 12, 1976, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrochantin (nitrofurantoin macrocrystals) Capsules.

The supplemental application provides for changes with respect to packaging and labeling.

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,

*M.L.G.*

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

cc: NYK-DO

✓ Orig. NDA

HFD-616

HFL-10

HFD-140

HFD-140/CSO

HFD-140/HZell, Ph.D./ar/3/15/77

R/D init. by: ACasola, Ph.D./3/8/77

H.C. 3/16/77

ARC 3/16/77

APPROVED

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**CHEMISTRY REVIEW(S)**

<b>CHEMIST'S REVIEW</b> <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION HFD-140	2. NDA NUMBER 16-620
3. NAME AND ADDRESS OF APPLICANT (City and State) Norwich Pharmacal Company Norwich, New York		4. AF NUMBER 9-700	
		5. SUPPLEMENT (S) NUMBER(S)	DATE(S)
6. NAME OF DRUG Macrofantin	7. NONPROPRIETARY NAME nitrofurantoin macrocrystals		8. SUPPLEMENT(S) PROVIDES FOR:  Changes with respect to packaging and labeling.
10. PHARMACOLOGICAL CATEGORY Antibacterial		11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	9. AMENDMENTS AND OTHER (Reports, etc.) DATES
13. DOSAGE FORM (S) Capsules	14. POTENCY (ies) 25, 50 and 100 mg.		12. RELATED IND/NDA/DMF(S)
15. CHEMICAL NAME AND STRUCTURE 1-[(5-Nitrofurfurylidene)amino]hydantoin		16. RECORDS AND REPORTS	
		CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO	
		REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS  The changes inaugurated give increased assurance of strict controls on the drug.  This NDA was approved 4/11/68.  The changes improve the drum labeling, and the use of control numbers and expiration dating, as well as, the handling of reject capsules.			
18. CONCLUSIONS AND RECOMMENDATIONS  The revised packaging and labeling controls are satisfactory.  The submission meets the requirements of 21 CFR 314.8(d)(3).  The supplement should be approved. <i>MCS 3/17/77</i> <i>AR Casola, Ph. D. 3/16/77</i>  cc: HFD-140 HFD-140/HCZell/sj/3/14/77 HFD 140/ARCasola/3/8/77 HFD-140/CSO			
19. NAME Howard C. Zell, Ph.D.		REVIEWER SIGNATURE <i>Howard C. Zell</i> DATE COMPLETED 3/8/77	
DISTRIBUTION		<input checked="" type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE	

CHEMIST'S REVIEW, Page 2 <i>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.</i>		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(e) (8f)	NC	
25. MANUFACTURING AND PROCESSING (8g,h,i,k)	NC	
26. CONTAINER (8i)	NC	
27. PACKAGING AND LABELING (8l,m)	Satisfactory  See Insert.	
28. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)	NC	
29. STABILITY (8p)	NA	
30. CONTROL NUMBERS (8c)	NC	
31. SAMPLES AND RESULTS (9)	a. VALIDATION                      NA                      b. MARKET PACKAGE                      NA	
32. LABELING (4)	NC	
33. ESTABLISHMENT INSPECTION	NA	
34. RECALLS	NA	

**WITHHOLD 3 PAGE(S)**

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Chemistry Review

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**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

