

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-047

CHEMISTRY REVIEW(S)

DEC 23 1988

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW		1. ORGANIZATION DAIDP	2. NDA NUMBER 16-620
3. NAME AND ADDRESS OF APPLICANT (CITY AND STATE) Norwich Eaton Pharmaceuticals, Inc. P. O. Box 191 Norwich, NY 13815 (607)-335-2572		4. AF NUMBER	
		5. SUPPLEMENT(s) NUMBER(s) DATE(s)	
6. NAME OF DRUG Macrochantin	7. NONPROPRIETARY NAME nitrofurantoin macrocrystals S-047		12/8/88
8. SUPPLEMENT(s) PROVIDES FOR: S-047 <u>contract packaging facilities</u>		9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES none	
10. PHARMACOLOGICAL CATEGORY antibacterial (urinary)	11. HOW DISPENSED XXX Rx OTC	12. RELATED IND/NDA/DMF(s)	
13. DOSAGE FORM(s) capsules	14. POTENCY(ies) 25, 50 & 100 mg		
15. CHEMICAL NAME AND STRUCTURE see USP/USAN 1-[[[(5-nitro-2-furanyl)-methylene]amino]- 2,4-imidazolinedione m.w. 238.16 (monohydrate, 256.17) CAS Registry No. 67-20-9 (monohydrate, 17140-81-7)			
		16. RECORDS AND REPORTS	
		CURRENT	
		Yes	No
		REVIEWED	
		Yes	No
17. COMMENTS This drug is the subject of a compendial monograph, USP XXI, pp. 734-735.			
18. CONCLUSIONS AND RECOMMENDATIONS Recommend approval letter to issue for this supplement.			
cc: Orig: NDA 16-620 HFD-520 HFD-520/Alpert HFD-520/Buko HFD-520/Fabritzky HFD-520/WHDeCamp HFD-520/ARCasola:R/D initialed <u>ARC 12/23/88</u> doc 0525w/349w			
19.		REVIEWER	
NAME Wilson H. De Camp, Ph. D.	SIGNATURE <i>Wilson H. De Camp, Ph. D.</i>	DATE COMPLETED 12/21/88	
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Chemistry review