

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**16-620 / S-063**

**Trade Name: Macrochantin**

**Generic Name: Nitrofurantoin macrocrystals**

**Sponsor: Proctor and Gamble Pharmaceuticals, Inc.**

**Approval Date: October 21, 1998**

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**16-620 / S-063**

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### **Reviews / Information Included in this NDA Review.**

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**16-620 / S-063**

**APPROVAL LETTER**



DF

Food and Drug Administration  
Rockville MD 20857

NDA 16-620/S-063

OCT 21 1998

Proctor & Gamble Pharmaceuticals  
Attention: Leslie D. Carter  
Regulatory Affairs Manager  
114 Grooms Road  
Cincinnati, Ohio 45242-1434

Dear Ms. Carter:

Please refer to your supplemental new drug application dated April 29, 1998, received April 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrochantin( nitrofurantoin macrocrystals) Capsules.

The user fee goal date for this application is October 31, 1998.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effectuated' under 21 CFR 314.70(c).

This supplemental new drug application provides for a change in the storage statements for the Microchantin Capsules. Your submission stated that the implementation date for the change will be the second and third Quarters of 1998.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Beth Duvall-Miller, Project Manager , at (301) 827-2125.

Sincerely,

David B. Katague, Ph.D.  
Chemistry Team Leader for the  
Division of Anti-Infective Drug Products , (HFD-520)  
DNDC III, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

cc:

Archival NDA 16-620

HFD-520/Div. Files

HFD-520/B. Duvall-Miller

HFD-520/Yu

HFD-95/DDMS (with labeling)

HFD-830/DNDC Division Director

DISTRICT OFFICE

Drafted by: dbk/October 20, 1998

Initialed by:

final:

filename: 16620063

APPROVAL (AP)

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***APPLICATION NUMBER:***

**16-620 / S-063**

**CHEMISTRY REVIEW(S)**

DF

NDA SUPPLEMENT REVIEW

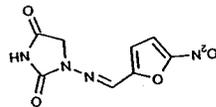
OCT 19 1998

CHEMIST'S REVIEW	1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 16-620
3. NAME & ADDRESS OF APPLICANT Leslie D Carter Proctor & Gamble Pharmaceuticals Sharon Woods Technical Center 11450 Grooms Road, Cincinnati, Ohio 45242-1434		4. AF NUMBER
5. SUPPLEMENT(s) NUMBER(s) DATE(s) SCS-063 4/29/98		

6. NAME OF DRUG Macrochantin Capsules	7. NONPROPRIETARY NAME Nitrofurantoin Capsules
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8. SUPPLEMENT(s) PROVIDES FOR: A change in the storage statements of Macrochantin Capsules.	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
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10. PHARMACOLOGICAL CATEGORY Anti-bacterial	11. HOW DISPENSED X Rx                      OTC	12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM(s) Capsule	14. POTENCY(ies) 25, 50 and 100 mg	
15. CHEMICAL NAME AND STRUCTURE 1-[(5-Nitrofurfurylidene)-amino]hydantoin		



16. RECORDS AND REPORTS		
CURRENT	X	
Yes		No
REVIEWED	X	
Yes		No

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS  
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 16-620            HFD-520/Garilovich  
       HFD-520                      HFD-520/Soreth  
       HFD-520/Osterberg        HFD-520/Duvall-Miller  
       HFD-520/Yu                HFD-520/DKatague:R/D initialed *DBK 10/19/98*

NAME Andrew Yu PhD	REVIEWER SIGNATURE <i>Andrew Yu</i>	DATE COMPLETED 7-OCT-1998
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DISTRIBUTION	ORIGINAL JACKET	REVIEWER	DIVISION FILE
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- 20. Components and Composition  
n/a
- 21. Facilities and Personnel  
n/a
- 22. Synthesis  
n/a
- 23. Raw Material Controls n/a
  - a. New Drug Substance
  - b. Other Ingredients
- 24. Other Firm(s)  
n/a
- 25. Manufacturing and Processing  
n/a
- 26. Container/Closure  
n/a
- 27. Packaging and Labeling  
n/a
- 28. Laboratory Controls (In-process and Finished Dosage Form) n/a
- 29. Stability**

The stability data submitted pertains to a site change associated with a previously approved supplement. They are re-cited here to provide background information for the





30. Control Numbers

n/a

31. Samples and Results

n/a

a. Validation

b. Market Package

32. Labeling            **ADEQUATE**



The new storage conditions for all Macrochantin Capsules requested will be consistent: "Store at controlled room temperature 20°-25°C (68°-77°F)."

33. Establishment Inspection  
n/a

34. Recalls  
n/a