

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19322/S15**

**CHEMISTRY REVIEW(S)**

ORIGINAL

NOV 13 1996

## NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DAIDP (HFD-520)	19-322
		19-323
		19-966
		20-337
		20-340

3. NAME & ADDRESS OF APPLICANT  
Glaxo Wellcome Inc.  
Research Triangle Park, NC

4. AF NUMBER

5. SUPPLEMENT(s)  
NUMBER(s) DATE(s)

a) 19-322/S-015  
b) 19-323/S-016  
c) 19-966/S-005  
d) 20-337/S-001  
e) 20-340/S-003

6. NAME OF DRUG  
Temovate

7. NONPROPRIETARY NAME  
clobetasol propionate

8. SUPPLEMENT(s) PROVIDES FOR:

A change in the location  
manufacture of

9. AMENDMENTS AND OTHER  
(REPORTS, etc.) DATES  
stages of the

The supplements also provide for the following changes:

- \* Minor process changes associated with process optimization
- \* Deletion of the

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(s)
Anti-inflammatory Agent		

13. DOSAGE FORM(s)	Rx	x	OTC
a) Cream, b) Ointment &	0.05%		
c) Scalp Application			
d) Gel			
e) Emollient			

15. CHEMICAL NAME AND STRUCTURE

m.w.

CAS Registry No.

16. RECORDS AND REPORTS

CURRENT

x Yes No

REVIEWED

x Yes No

17. COMMENTS

These supplements provide for the relocation of the  
steps of the manufacturing process of the drug substance,

According to the firm,  
this change in location will not have any adverse impact on  
the quality of the drug substance produced.

Stages of the synthesis

In support of this request, the firm submitted following  
information:

- (1) Flow sheet to indicate stages of the  
relocation from during the
- (2) Comparisons of the equipment in buildings
- (3) Process description of stages
- (4) Comparative batch analysis data from stages  
to confirm that batch quality is unaffected by this  
change.
- (5) A stability commitment.

This information (above) was found acceptable to approve the  
supplements;

EER dated 8/12/96 from the Office of Compliance found the  
facilities for in  
compliance with CGMPs.

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#### 18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letters to issue for these  
supplements.

cc: Orig: NDAs 19-322, 19-323, 19-966, 20-337 & 20-340  
HFD-540 HFD-540/Walker  
HFD-540/Alam HFD-540/Kozma-Fornaro  
HFD-540/Pappas HFD-540/WHDeCamp:R/D initialed

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19.	REVIEWER
NAME	SIGNATURE ^ // / DATE COMPLETED
Ernest G. Pappas	11/13/96

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