

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20337/S1

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 & c) Scalp Application d) Gel e) Emollient	0.05%

14. POTENCY(ies)

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.

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

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

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