CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19322/S15

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date AUG 5 1996

NDA No. 20-340

J. Christopher Prue, R.Ph.
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Attention: J. Christopher Prue, R.Ph.

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Temovate (clobetasol propionate) Emollient, 0.05%

NDA Number: 20-340

Supplement Number: S-003

Date of Supplement: July 12, 1996

Date of Receipt: July 26, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 24, 1996 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Dermatologic and Ophthalmologic Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-540
Rockville, MD 20857

Sincerely yours, /S/

Chief, Project Management Staff
Division of Dermatologic and Ophthalmologic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date AUG 6 1996

NDA No. 20-337

J. Christopher Prue, R.Ph.
Miami Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Attention: J. Christopher Prue, R.Ph.

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Temovate (clobetasol propionate) Gel, 0.05%

NDA Number: 20-337

Supplement Number: S-001

Date of Supplement: July 12, 1996

Date of Receipt: July 26, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 24, 1996 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Dermatologic and Ophthalmologic Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-540
Rockville, MD 20857

Sincerely yours, /S/

Chief, Project Management Staff
Division of Dermatologic and Ophthalmologic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

FORM FDA 3217j (11/95)

ORIGINAL

GlaxoWellcome

Glaxo Dermatology

July 12, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUL 26 1996
HFD-

Jonathan K. Wilkin, M.D., Director
Division of Topical Drug Products
Attn: Document Control Room
FDA, CDER, ODEV
Food and Drug Administration
HFD-540
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 20340 REF. NO. S-003
NDA SUPPL FOR Manufacturing

Re: NDA 19-322; Temovate® (clobetasol propionate) Cream, 0.05%
NDA 19-323; Temovate® (clobetasol propionate) Ointment, 0.05%
NDA 19-966; Temovate® (clobetasol propionate) Scalp Application, 0.05%
NDA 20-337; Temovate® (clobetasol propionate) Gel, 0.05%
NDA 20-340; Temovate E® (clobetasol propionate) Emollient, 0.05% ? Cream.
Supplemental Application: Change in Location of the Synthesis of the Drug Substance

Dear Dr. Wilkin:

Reference is made to our approved NDAs listed above and to the synthesis of the drug substance which is fully described in NDA 19-322. This drug substance information is incorporated by reference into the rest of the above listed applications.

The drug substance, is manufactured at the Glaxo Wellcome Operations site in Montrose, Scotland. Approval is hereby requested to relocate the first two stages of the manufacture of is an established steroid manufacturing facility. As part of the general site development strategy, is intended to be replaced with a more modern facility. This change in location of the stages of the manufacture within the Montrose facility will not have any adverse impact on the quality of the drug substance produced.

Stages of the synthesis Included in this supplemental application are the following data:

1. Flow sheet diagram indicating the position of the stages in the manufacturing procedure due for relocation.

Glaxo Wellcome Inc.
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709
Telephone
919 248 2100

2. Comparisons of the equipment in Building

3. Process description of Stages

4. Comparative batch analysis data from Stages made in each facility and Stage which confirm that batch quality is unaffected by this change.

5. A stability commitment to incorporate the first three batches of

This supplemental application is being submitted in duplicate to each of the above referenced NDAs. We look forward to a prompt review and approval of this supplemental application. If there are any questions, please contact me at (919) 483-3034.

Sincerely,

J. Christopher Prue, R.Ph.
Director
Dermatology Regulatory Affairs

ORIGINAL

GlaxoWellcome

Glaxo Dermatology

July 12, 1996

CENTER FOR DRUG
REC'D
JUL 2 6 1996

Jonathan K. Wilkin, M.D., Director
Division of Topical Drug Products
Attn: Document Control Room
FDA, CDER, ODEV
Food and Drug Administration
HFD-540
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 20337 SUPPL. NO. S-001
NO. SUPPL. FOR Manufacturing

Re: NDA 19-322; Temovate® (clobetasol propionate) Cream, 0.05%
NDA 19-323; Temovate® (clobetasol propionate) Ointment, 0.05%
NDA 19-966; Temovate® (clobetasol propionate) Scalp Application, 0.05%
NDA 20-337; Temovate® (clobetasol propionate) Gel, 0.05%
NDA 20-340; Temovate E® (clobetasol propionate) Emollient, 0.05%
Supplemental Application: Change in Location of the Synthesis of the Drug Substance

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The drug substance, , is manufactured at the Glaxo Wellcome Operations site in Montrose, Scotland. Approval is hereby requested to relocate the first stages of the manufacture of manufacturing facility. As part of the general site development strategy, is intended to be replaced with a more modern facility. This change in location of the stages of the manufacture within the Montrose facility will not have any adverse impact on the quality of the drug substance produced.

Stages of the synthesis Included in this supplemental application are the following data:

1. Flow sheet diagram indicating the position of the stages in the manufacturing procedure due for relocation.

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A. ☐ MEMO
CSO INITIALS DATE

Glaxo Wellcome Inc.
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709
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J. Christopher Prue, R.Ph.
Director
Dermatology Regulatory Affairs