CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 085635Orig1s012

Name: Depo-Testosterone (Testosterone Cypionate Injection USP)
100 mg/mL and 200 mg/mL

Sponsor: The Upjohn Company

Approval Date: May 3, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 085635Orig1s012

CONTENTS

Reviews / Information Included in this Review

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Labeling Review(s)	
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Chemistry Review(s)	
Bioequivalence Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Other Review(s)	
Administrative & Correspondence Documents	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 085635Orig1s012

APPROVAL LETTER

ANDA 85-635/S-012

The Upjohn Company
Attention: Hendrik J. deKoning Gans
7000 Portage Road
Kalamazoo, MI 49001

MAY 3 1996

Dear Sir:

This is in reference to your supplemental new drug application dated December 20, 1994, submitted pursuant to 21 CFR 314.70(c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug application for Depo®-Testosterone (Testosterone Cypionate Injection, USP) 100 mg/mL and 200 mg/mL.

Reference is also made to your amendments dated June 8, 1995, October 6, 1995 and March 15, 1996.

The supplemental application provides for revised container labels (1 mL and 10 mL) and carton labeling (1 mL and 10 mL).

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 abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

Jerry Phillips 5/3/96

Jerry Phillips
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 85-635/S-012
Division File C Zimmermann 5/2/96
HFD-613/CZimmermann/JGrace (no cc:)
HFD-600/RF Johnson 5/2/96
njg/5/2/96/firmsnz/upjohn/ltrs&rev/85635S12.APL
Approval Letter - Single Supplement

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 085635s012

OTHER ACTION LETTERS

ANDA 85-635/S-012

The Upjohn Company
Attention: Donald A. Egge
7000 Portage Road
Kalamazoo, MI 49001-0199

MAR 28 1995

Dear Sir:

Reference is made to your supplemental new drug application dated December 20, 1994, submitted pursuant to Section 314.70(c) (Special Supplement - Changes Being Effected) of the Regulations, regarding your abbreviated new drug application for Depo®-Testosterone (Testosterone Cypionate Injection USP) 100 mg/mL and 200 mg/mL.

The supplemental application provides for revised carton labeling (1 x 10 mL).

We have completed our review of this supplemental application and it is approvable. However, before the supplemental application may be approved, it is necessary that you prepare and submit final printed container labels and carton labeling and revise the following:

1. Please differentiate the two strengths on both the container and carton, using different colors as seen in your previously approved labels and labeling. (Red ink for the 100 mg/mL and black ink for the 200 mg/mL).

2. Please insert a space between "100" and "mg" and "200" and "mg".

3. Please indicate that the vial is a multiple dose vial.

4. Container label - Relocate the statement "For IM Use Only" to the main panel and move the "Caution: Federal Law..." statement to the side panel.

Please note we believe this supplement was inappropriately submitted as a Special Supplement - Changes Being Affected. For future guidance, we refer you to 21 CFR 314.70(c). Materials must be submitted in **final print**.

In addition, we note that you have not submitted a properly signed and executed 356h form with this submission, as required by 21 CFR 314.50(a).

The changes provided for in this supplemental application may not be initiated until you have been notified in writing that the supplemental application is approved.

Sincerely,

Jerry Phillips for /

Yana Ruth Mille
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

3-28-95

cc: ANDA 85-635/S-012
Dup\Division File
HFD-613/AVezza/CZimmermann/JPhillips (nocc)
HFD-600/RF
FIELD COPY
njg/3/23/95/85635.S12
Approvable

avezza 3/24/95
czimmermann 3/23/95
JPhillips 3/28/95

ANDA 85-635/S-012

The Upjohn Company
Attention: Donald A. Egge
7000 Portage Road
Kalamazoo, MI 49001-0199

JUL 11 1995

Dear Sir:

This is in reference to your supplemental new drug application dated December 20, 1994, submitted pursuant to Section 314.70(c) (Special Supplement-Changes Being Effected) of the Regulations, regarding your abbreviated new drug application for Depo®-Testosterone (Testosterone Cypionate Injection USP) 100 mg/mL and 200 mg/mL.

Reference is also made to your amendment dated June 8, 1995.

The supplemental application provides for revised container labels (1 mL and 10 mL) and carton labeling (1 mL and 10 mL).

We have completed our review of this supplemental application and it is approvable. However, before the supplemental application may be approved, it is necessary that you prepare and submit final printed container labels as an amendment to this supplemental application. We consider the print quality of your computer generated container labels unacceptable.

The changes provided for in this supplemental application may not be initiated until you have been notified in writing that the supplemental application is approved.

Sincerely,

Yana Ruth Mille 7/11/95

Yana Ruth Mille
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 85-635/S-012
Dup/Division File
HFD-613/AVezza/APayne/JPhillips (no cc)
HFD-600/RF AVezza 7/7/95
FIELD COPY
aev/7/3/95/85635a.S12
Approvable

ANDA 85-635/S-012

The Upjohn Company
Attention: Donald A. Egge
7000 Portage Road
Kalamazoo, MI 49001

FEB 16 1996

Dear Sir:

This is in reference to your supplemental new drug application dated December 20, 1994, submitted pursuant to 21 CFR 314.70(c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug application for Depo®-Testosterone (Testosterone Cypionate Injection, USP) 100 mg/mL and 200 mg/mL.

Reference is also made to your amendments dated June 8, 1995 and October 6, 1995.

The supplemental application provides for revised container labels (1 mL and 10 mL) and carton labeling (1 mL and 10 mL).

We have completed the review of this supplemental application and it is approvable. However, before the supplemental application may be approved, it is necessary that you prepare and submit final printed container labels as an amendment to this supplemental application. We do not accept photocopies as final printed labeling.

The changes provided for in this supplemental application may not be initiated until you have been notified in writing that the supplemental application is approved.

Sincerely Yours,

Jerry Phillips 2/16/96

Jerry Phillips
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 85-635/S-012
Division File C.Zimmermann 2/08/96
HFD-613/CZimmermann/JGrace (no cc:) JGrace 2-15-96
HFD-600/RF
njg/2/8/96/X:/new/firmsnz/upjohn/ltrs&rev/85635S12.NA1
Approvable Letter - Single Supplement

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 085635Orig1s012

LABELING

Original

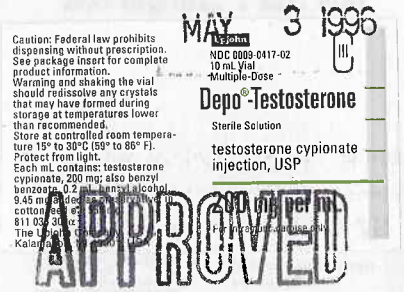
March 15, 1996

ANDA 85-635/S-012
DEPO-TESTOSTERONE® Sterile Solution

Final Printed Container Labeling

100 mg/mL, 10 mL vial

200 mg/mL, 1 mL vial



200 mg/mL, 10 mL vial

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 085635Orig1s012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

THE UPJOHN COMPANY

7000 PORTAGE ROAD
KALAMAZOO, MICHIGAN 49001-0199, U.S.A.

Office of:
DONALD A. EGGE, *Director*
Regulatory Affairs - Marketed Products
Telephone No. (616) 329-8097
Facsimile No. (616) 329-5409

approvable letter
Allegra 3/3/95

December 20, 1994

NDA NO. _____ REF. NO. SL-012

NDA SUPPL FOR Labeling Revision SL-012/11

Office of Generic Drugs, HFD-630
Center for Drug Evaluation and Research
Metro Park North
7500 Standish Place
Rockville, Maryland 20855

Re: ANDA 85-635
DEPO®-Testosterone Sterile Solution
SUPPLEMENT - Carton Labeling

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED > not appropriate since submitted in draft. Notify in letter 1-4-95 SMiller

Sir/Madam:

Reference is made to the FDA Division of Metabolism and Endocrine Drug Products' letter dated July 25, 1994 (Attachment 1) regarding carton labeling for DEPO-PROVERA Contraceptive Injection (NDA 20-246) and DEPO-Testosterone Sterile Solution (ANDA 85-635).

> In response to FDA DMEDP's letter, and as provided for in 21 CFR 314.70(3)(c), we are submitting the attached draft carton labeling for DEPO-Testosterone Sterile Solution (Attachment 2) as a **SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED.**

We plan to implement this new carton labeling for DEPO-Testosterone Sterile Solution in production runs beginning on or after March 1, 1995. We do not intend to make any changes to the current carton labeling for DEPO-PROVERA Contraceptive Injection.

If you have any questions, please contact Michael D. Burdick at (616) 329-8041.

Sincerely,

THE UPJOHN COMPANY
Michael Burdick for

Donald A. Egge, Director
Regulatory Affairs - Marketed Products

DAE:MDB:carton.le

RECEIVED
DEC 27 1994
GENERIC DRUGS
1-3-95

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1-4-95

FROM: Jerry Phillips, Consumer Safety Officer

SUBJECT: Special Supplement - Changes Placed into Effect

TO: Document Room

Please make the following entry in the MIS concerning the status of this Special Supplement - Changes Placed into Effect.

ANDA(s)	SUPPLEMENT(s)	GRANTED	DENIED
85-635	SL-012		

This form is to accompany the action package/jacket.

Thank you,

Jerry Phillips 1/4/95
Signature of CSO and Date

CC:
ANDA
DIVISION FILE

THE UPJOHN COMPANY

7000 Portage Road
Kalamazoo, Michigan 49001-0199, U.S.A.

Office of:
Donald A. Egge
Director, Worldwide Regulatory Affairs - Marketed Products

Telephone No. (616) 329-8097
Facsimile No. (616) 329-5409

June 8, 1995

DRAFT
AMENDMENT
container/label
+ carton labeling
Satisfactory
approvable letter SLO 12
AL
approvable ltr 7/3/95

Dr. Yana Ruth Mille, Acting Director
Division of Labeling and Program Support
Office of Generic Drugs, HFD-611
Food and Drug Administration
Center for Drug Evaluation and Research
Metropark North 2, Room 286
7500 Standish Place
Rockville, Maryland 20857

RE: ANDA 85-635/S-012, Amendment to DEPO-TESTOSTERONE® Sterile Solution Labeling Change

Dear Dr. Mille,

Reference is made to your letter dated March 28, 1995, which was issued in response to our supplemental new drug application dated December 20, 1994. Your March 28 letter (Attachment 1) indicated that the supplement was approvable, but requested certain modifications be made before final approval could be granted.

We are amending ANDA 85-635/S-012 to incorporate the changes requested in your March 28, 1995 letter, and are providing revised draft vial and carton labeling for DEPO-TESTOSTERONE 100 mg/ml (Attachment 2) and DEPO-TESTOSTERONE 200 mg/ml (Attachment 3).

Please note that **draft** labeling is being provided at this time for FDA review, due to the time and expense involved in preparing final printed cartons and labels. This was discussed and agreed to in a telephone conversation on May 4, 1995 between Michael Burdick of The Upjohn Company, and OGD Division CSO Jerry Phillips.

Please contact Michael D. Burdick at (616) 329-8041 if you have any questions.

Sincerely,

RECEIVED
JUN 21 1995
GENERIC DRUGS

THE UPJOHN COMPANY

Michael Burdick for

Donald A. Egge, Director
Regulatory Affairs - Marketed Products

DAE:MDB:mdb\depotest\carton.le2

23 Jun 95
Phillips

THE UPJOHN COMPANY

7000 Portage Road
Kalamazoo, Michigan 49001-0199, U.S.A.

Office of:
Donald A. Egge
Director, Worldwide Regulatory Affairs - Marketed Products

Telephone No. (616) 329-8097
Facsimile No. (616) 329-5409

October 6, 1995

Dr. Yana Ruth Mille, Acting Director
Division of Labeling and Program Support
Office of Generic Drugs, HFD-611
Food and Drug Administration
Center for Drug Evaluation and Research
Metropark North 2, Room 286
7500 Standish Place
Rockville, Maryland 20857

NDA SUPPL AMENDMENT
SLO12 AZ

Not FPL - Photocopies Approvable C-Summaries 2/7/96

RE: ANDA 85-635/S-012
DEPO-TESTOSTERONE® Sterile Solution

Labeling Change -- Amendment

Dear Dr. Mille,

Reference is made to your letter dated July 11, 1995, which in response to our supplemental new drug application dated December 20, 1994, and our amendment dated June 8, 1995. Your July 11 letter (Attachment 1) indicated that this supplement was approvable, but requested that we prepare and submit final printed container labels.

In response to your July 11 letter, we are amending ANDA 85-635/S-012 to provide 15 copies each of final printed container labels for the following:

DEPO-TESTOSTERONE Sterile Solution 100 mg/mL, 10 mL vial (Attachment 2)
DEPO-TESTOSTERONE Sterile Solution 200 mg/mL, 1 mL vial (Attachment 3)
DEPO-TESTOSTERONE Sterile Solution 200 mg/mL, 10 mL vial (Attachment 4)

Please contact Michael D. Burdick at (616) 329-8041 if you have any questions.

Sincerely,

THE UPJOHN COMPANY

Donald A. Egge, Director
Regulatory Affairs - Marketed Products

DAE:MDB:mdb\depotest\carton.le3

RECEIVED
OCT 10 1995
GENERIC DRUGS

FPL satisfactory Ogwumeasan 5/2/96

THE UPJOHN COMPANY

7000 Portage Road
Kalamazoo, Michigan 49001-0199, U.S.A.

Office of:
Hendrik J. de Koning Gans, M.D.
Director, Worldwide Regulatory Liaison

Telephone No. (616) 329-8516
Facsimile No. (616) 329-5409

March 15, 1996

Mr. John Grace, Acting Director
Division of Labeling and Program Support
Office of Generic Drugs, HFD-611
Food and Drug Administration
Center for Drug Evaluation and Research
Metropark North 2, Room 286
7500 Standish Place
Rockville, MD 20857

SUPPL AMENDEMENT FPL
SL-012/AL

Re: ANDA 85-635/S-012
DEPO-TESTOSTERONE® Sterile Solution

Labeling Change - Amendment

Dear Mr. Grace:

Reference is made to your letter of February 16, 1996 that requested final printed container labels associated with the above cited supplement. Our supplement amendment of October 6, 1995 inadvertently provided photocopies of the labeling rather than actual printed labels as requested in your letter of July 11, 1995.

Final printed labels for the following products are attached:

DEPO-TESTOSTERONE Sterile Solution 100 mg/mL, 10 mL vial
DEPO-TESTOSTERONE Sterile Solution 200 mg/mL, 1 mL vial
DEPO-TESTOSTERONE Sterile Solution 200 mg/mL, 10 mL vial

Fifteen copies of each label (1 of each of the 3 labels per page) are provided.

Please contact Karolee J. Bruzewski at (616) 329-5672 if you have any questions regarding this labeling.

Very truly yours,

THE UPJOHN COMPANY

Karolee J. Bruzewski for

Hendrik J. de Koning Gans, MD
Director, Worldwide Regulatory Liaison

HJD:KJB:pjv
Attachment