CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 040575

BIOEQUIVALENCE REVIEW

DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No.	40-575
Drug Product Name	Testosterone Enanthate Injection, USP
Strength	200 mg/mL, 5 mL vial
Applicant Name	Paddock Laboratories, Inc.
Address	Minneapolis, MN
Submission Date(s)	December 30, 2003
Amendment Date(s)	
Reviewer	Steven Mazzella
First Generic	No
File Location	V:\firmsnz\paddock\ltrs&rev\40575W1203

I. Submission Summary

A. Drug Product Information

Test Product	Testosterone Enanthate Injection USP, 200 mg/mL, 5 mL vial
Reference Product	Delatestryl® (Testosterone Enanthate) Injection USP, 200 mg/mL, 5 mL vial
RLD Manufacturer	Savient Pharmaceuticals
NDA No.	009165
RLD Approval Date	Prior to January 1, 1982 (per Orange Book)
Indication	Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

B. Formulation

Ingredient	Test mg/mL	Reference mg/mL
Testosterone Enanthate, USP	200	200
Sesame Oil, NF	q.s. to 1 mL	q.s. to 1 mL
Chlorobutanol, NF	5	5
(b) (4)		(b) (4)

Recommendations

The Division of Bioequivalence agrees that the information submitted by Paddock Laboratories demonstrates that its test product, Testosterone Enanthate Injection USP, 200 mg/mL, 5 mL vial fall under the criteria set forth in 21 CFR 314.94(a)(9)(iii) and 320.22(b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver is granted.

8/25/04

Steven Mazzella, R.Ph.
Project Manager, Branch III
Division of Bioequivalence

8/25/04

Lizzie Sanchez, Pharm.D.
Special Assistant to the Director
Division of Bioequivalence

8/25/04

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs

BIOEQUIVALENCE COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 40-575 APPLICANT: Paddock Laboratories

DRUG PRODUCT: Testosterone Enanthate Injection USP, 200 mg/mL, 5 mL vial

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner, Pharm. D.
Director,
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 40-575
ANDA DUPLICATE
DIVISION FILE

Printed in final on
8/25/04
Endorsements: (Final with Dates)
HFD-655/ Steven Mazzella 8/25/04
HFD-655/ L. Sanchez
HFD-650/ D. Conner 8/25/04
BIOEQUIVALENCE - ACCEPTABLE Submission date: December 30, 2003

1. **WAIVER** (WAI)

Strengths:
200 mg/mL
Outcome:AC

Outcome: AC- Acceptable

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # : 40-575 SPONSOR : Paddock Laboratories

DRUG AND DOSAGE FORM : Testosterone Enanthate Injection, USP

STRENGTH(S) : 200 mg/mL, 5 mL vial

TYPES OF STUDIES : N/A

STUDY SUMMARY : The test drug product is a parenteral solution intended solely for administration by injection and contains the same active and inactive ingredients in the same concentration as the approved reference listed product. A waiver of the in-vivo bioavailability/bioequivalence study requirements is granted [21 CFR 320.22(b)(1)].

DSI INSPECTION STATUS

Inspection needed: No	Inspection status:	Inspection results:
First Generic __No_ New facility _____ For cause ____ Other ____	Inspection requested: (date) Inspection completed: (date)	

Steven Mazzella, R.Ph.
Project Manager, Branch III, Division of Bioquivalence

INITIAL : _____ DATE : 8/25/04

Lizzie Sanchez, Pharm.D.
Special Assistant to the Director, Division of Bioequivalence

INITIAL : _____ DATE : 8/25/04

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm.D.

INITIAL : _____ DATE : 8/25/04