

**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 (b) (4)	5	5 (b) (4)

**Recommendations**

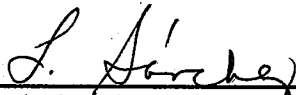
The Division of Bioequivalence agrees that the information submitted by Paddock Laboratories demonstrates that its test product, Testosterone Enanthate Injection USP, 200 mg/mL, 5 mL vial fall under the criteria set forth in 21 CFR 314.94(a)(9)(iii) and 320.22(b)(1) of the Bioavailability/Bioequivalence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



8/25/04

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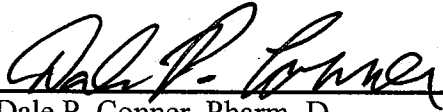
Steven Mazzella, R.Ph.  
Project Manager, Branch III  
Division of Bioequivalence



8/25/04

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



8/25/04

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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 *HW 8/25/04*  
HFD-655/ L. Sanchez  
HFD-650/ D. Conner *DM 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 <u>  No  </u>	Inspection requested: (date)	
New facility <u>      </u>	Inspection completed: (date)	
For cause <u>      </u>		
Other <u>      </u>		

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

INITIAL : SM                      DATE : 8/25/04

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

INITIAL : L. Sanchez                      DATE : 8/25/04

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

INITIAL : DP                      DATE : 8/25/04