CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 040647

BIOEQUIVALENCE REVIEW

DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No.:	40-647
Drug Product Name	Testosterone Enanthate Injection, USP
Strength	200 mg/mL, 5 mL
Applicant Name	Synerx Pharma, LLC
Address	100 North State Street, Newtown, PA 18940-2048
Submission Date(s)	January 31, 2005
Amendment Date(s)	NA
Reviewer	Beth Fabian Fritsch, R.Ph., MBA
First Generic	No
File Location	V:\firmsnz\synerx\ltrs&rev\40647W0105

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	December 24, 1953
Indication	Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

B. Formulation

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

Recommendations

The Division of Bioequivalence agrees that the information submitted by Synerx Pharma, LLC demonstrates that its test product Testosterone Enanthate Injection USP, 200 mg/mL, 5 mL vial falls under the criteria set forth in 21 CFR 320.22(b)(1) of the Bioavailability/ Bioequivalence Regulations. The waiver is granted.

7/6/05

Beth Fabian Fritsch, R.Ph., MBA
Project Manager, Branch IV
Division of Bioequivalence

7/6/05

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

7/6/05

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

BIOEQUIVALENCE COMMENTS TO BE PROVIDED TO THE APPLICANT

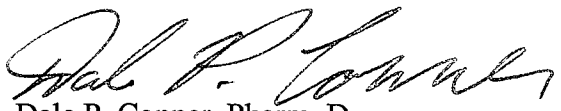
ANDA: 40-647 APPLICANT: Synerx Pharma, LLC

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

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

Please note that the bioequivalence 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 bioequivalence 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 40-647
ANDA DUPLICATE
DIVISION FILE

Printed in final on

Endorsements: (Final with Dates)
HFD-655/ B. Fritsch 7/6/05
HFD-655/ L. Sanchez 7/6/05
HFD-650/ D. Conner 7/6/05

BIOEQUIVALENCE - ACCEPTABLE Submission date: January 31, 2005

1. **WAIVER** (WAI) Strengths: 200 mg/mL
Outcome:AC

Outcome: AC- Acceptable

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA #: 40-647 SPONSOR: Synerx Pharma, LLC

DRUG AND DOSAGE FORM: Testosterone Enanthate Injection USP

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

TYPES OF STUDIES: NA

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)	

PROJECT MANAGER: Beth Fabian Fritsch, R.Ph., MBA BRANCH: IV

INITIAL: _____ DATE: 7/6/05

TEAM LEADER: Aida Lizzie Sanchez, Pharm.D.
Special Assistant to the Director, Division of Bioequivalence

INITIAL : _____ DATE : 7/6/05

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

INITIAL : _____ DATE : 7/6/05