CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-019

BIOEQUIVALENCE REVIEW(S)

#9

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # 76-019 SPONSOR : Abbott Laboratories

DRUG & DOSAGE FORM : Deferoxamine Mesylate for Injection USP,

STRENGTH : 500 mg/vial

TYPES OF STUDY: Waiver Request

SUMMARY:

Waiver Request: Granted per 21 CFR Section 320.22(b)(1)

PRIMARY REVIEWER :Lin-Whei Chuang BRANCH : I

INITIAL : LWC DATE : 12/28/00

BRANCH CHIEF : Yih-Chain Huang, Ph.D. BRANCH : I

INITIAL : YCH DATE : 1/5/2001

---

for DIRECTOR
DIVISION OF BIOEQUIVALENCE : Dale Conner, Pharm.D.

INITIAL : [signature] DATE: 1/10/2001

APPEARS THIS WAY
ON ORIGINAL

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 76-019 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Deferoxamine Mesylate for Injection USP,
500 mg/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,

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

CC: ANDA #75-019
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-652/ Lin-Whei Chuang

V:\FIRMSAM\ABBOTT\LTRS&REV\76019W.000

Endorsements: (Final with Dates)
HFD-652/ L. Chuang 12/28/00
HFD-652/ Y. Huang 1/4/2001
HFD-652/ K. Scardina
HFD-650/ D. Conner for 1/10/2001

BIOEQUIVALENCY - ACCEPTABLE

submission date: 10/31/00

WAIVER (WAI)

Strength: 500 mg/vial
~~Outcome:~~ **AC**

Outcome Decisions: **AC** - Acceptable

WinBio Comments:

APPEARS THIS WAY
ON ORIGINAL

Deferoxamine Mesylate for Injection USP
500 mg/Vial
ANDA #76-019
Reviewer: Lin-Whei Chuang
V:\FIRMSAM\ABBOTT\LTRS&REV\76019W.000

Abbott Laboratories
Abbott, IL
Submission Date:
Submission Date:
October 31, 2000

Review of a Waiver Request

Deferoxamine mesylate is indicated for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemia.

The firm is requesting a waiver of the *in-vivo* bioequivalence requirements for its deferoxamine mesylate for injection USP, 500 mg/vial.

The reference listed drug (RLD) is Desferal of Novartis, approved prior to 1/1/1982 through NDA #16267.

Both test drug and RLD are supplied as vials, each containing 500 mg of sterile, lyophilized deferoxamine mesylate. The labeling of RLD recommends, when preparing the solution for injection, to add 5 mL of sterile water for injection to each 500 mg vial resulting in a solution of 100 mg/mL.

Comments:

1. The active ingredient, indications, route of administration, dosage form, and strength of deferoxamine mesylate are all the same for both test drug and RLD.

2. The test drug meets the criteria for waiver of the in-vivo bioequivalence study requirements set forth in 21 CFR 320.22(b)(1).

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Abbott Laboratories demonstrates that its deferoxamine mesylate for injection USP, 500 mg/vial, falls under 21 CFR 320.22 (b)(1). Therefore, the waiver of *in vivo* bioequivalence study requirements for deferoxamine mesylate for injection USP, 500 mg/vial, is granted. The test product,

deferoxamine mesylate for injection USP, 500 mg/vial, is deemed bioequivalent to Desferal of Novartis.

The firm should be advised of the recommendation.

Lin-Whei Chuang 12/28/00

Lin-Whei Chuang
Division of Bioequivalence
Review Branch I

RD INITIALLED YHUANG
FT INITIALLED YHUANG 1/5/2001

Concur: _____ Date: 1/10/2001
Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence

V:\FIRMSAM\ABBOTT\LTRS&REV\76019W.000

APPEARS THIS WAY
ON ORIGINAL

2-1

Deferoxamine Mesylate for Injection USP
500 mg/vial & 2 g/vial
ANDA #76-019
Reviewer: Lin-Whei Chuang
V:\FIRMSAM\ABBOTT\LTRS&REV\76019W1101.doc

Abbott Laboratories
Abbott, IL
Submission Date:
November 7, 2001

Review of a Waiver Request for a Higher Strength

Reference Listed Drug (RLD):
Desferal of Novartis was approved prior to 1/1/1982 through NDA #16267 and is available in 500 mg/vial and 2 g/vial.

Submission History:
The original ANDA submitted on 10/31/00 contained a waiver request for the 500 mg/vial strength which was granted by DBE per 21 CFR Section 320.22(b)(1).

Current submission is for an additional new strength of 2 g/vial.

Comments:

1. The active ingredient, indications, route of administration, dosage form, and strength of deferoxamine mesylate are all the same for both Abbott's 2 g/vial strength and the RLD, Desferal 2 g/vial.

2. According to the labeling of RLD, after dilution with Sterile Water for Injection (5 mL for the 500 mg/vial strength or 20 mL for the 2 g/vial strength), concentrations of the active ingredient, deferoxamine mesylate, in the reconstituted solution are the same for both strengths (100 mg/mL).

3. The test drug meets the criteria for waiver of the in-vivo bioequivalence study requirements set forth in 21 CFR 320.22(b)(1).

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Abbott Laboratories demonstrates that its deferoxamine mesylate for injection USP, 2 g/vial, falls under 21 CFR 320.22 (b)(1). Therefore, the waiver of *in vivo* bioequivalence study requirements for deferoxamine mesylate for injection USP, 2 g/vial, is granted. The test product,

deferoxamine mesylate for injection USP, 2 g/vial, is deemed bioequivalent to Desferal, 2 g/vial, of Novartis.

The firm should be advised of the recommendation.

Lin-Whei Chuang 2/15/02

Lin-Whei Chuang
Division of Bioequivalence
Review Branch I

RD INITIALLED YHUANG
FT INITIALLED YHUANG 7/19/2002

Concur: for Dale P. Conner, Pharm. D. Date: 2/20/2002
Director, Division of Bioequivalence

V:\FIRMSAM\ABBOTT\LTRS&REV\76019W1101.doc

APPEARS THIS WAY
ON ORIGINAL

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 76-019 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Deferoxamine Mesylate for Injection USP,
500 mg/Vial & 2 g/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,

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

CC: ANDA #75-019
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-652/ Lin-Whei Chuang

V:\FIRMSAM\ABBOTT\LTRS&REV\76019W1101.doc

Endorsements: (Final with Dates)
HFD-652/ L. Chuang 2/15/02
HFD-652/ Y. Huang
HFD-652/ K. Scardina
HFD-650/ D. Conner for 2/20/2002

BIOEQUIVALENCY - ACCEPTABLE submission date: 11/7/01

WAIVER (WAI) 0/C Strength: 2 g/vial
Outcome: AC

Outcome Decisions: **AC** - Acceptable

WinBio Comments:

APPEARS THIS WAY
ON ORIGINAL

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # 76-019 SPONSOR : Abbott Laboratories

DRUG & DOSAGE FORM : Deferoxamine Mesylate for Injection USP,
STRENGTH : 500 mg/vial & 2 g/vial
TYPES OF STUDY: Waiver Request

SUMMARY:

Waiver Request: Granted per 21 CFR Section 320.22(b)(1)

PRIMARY REVIEWER :Lin-Whei Chuang BRANCH : I

INITIAL : LWC DATE : 2/15/02

BRANCH CHIEF : Yih-Chain Huang, Ph.D. BRANCH : I

INITIAL : YCH DATE : 2/19/2002

DIRECTOR
DIVISION OF BIOEQUIVALENCE : Dale P. Conner, Pharm.D.

for

INITIAL : N Saluja DATE: 2/20/2002

APPEARS THIS WAY
ON ORIGINAL