CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-290

Bioequivalence Review(s)

BIOEQUIVALENCY COMMENTS

ANDA:75-290 APPLICANT:Bedford Laboratories

DRUG PRODUCT: Pamidronate Disodium for Injection
30 mg/vial, 60 mg/vial and 90 mg/vial of lyophilized powder.

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 Conner

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

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Director, Division of Bioequivalence
Office of Generic Drugs
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Pamidronate Disodium for Injection
30 mg/vial
60 mg/vial
90 mg/vial
ANDA # 75-290
Reviewer:Andre Jackson
WP #: 75-290W.D97

Bedford Laboratories
Bedford, Ohio
Submission Date:
December 23, 1997

REVIEW OF A WAIVER REQUEST

OBJECTIVE:

The firm requests waivers of the requirement for submission of evidence demonstrating the in vivo bioavailability/ bioequivalence for Pamidronate Disodium for Injection 30 mg/vial, 60 mg/vial and 90 mg/vial. The product is a lyophilized powder to be reconstituted with sterile water. The innovator product is Aredia[R] Injection manufactured by Ciba Geigy as 30 mg/vial, 60 mg/vial and 90 mg/vial of lyophilized powder.

FORMULATIONS:

Table 1.The comparative formulations of the test and the reference products. Values are mg/vial.

Ingredient	Test 30 mg	Reference 30 mg	Test 60 mg	Reference 60 mg	Test 90 mg	Reference 90 mg
Pamidronate Disodium	30 mg	30 mg	60 mg	60 mg	90 mg	90 mg
Mannitol	470 mg	470 mg	400 mg	400 mg	375 mg	375 mg
Phosphoric Acid	used to adjust pH	used to adjust pH	used to adjust pH	used to adjust pH	used to adjust pH	used to adjust pH

Comments:

1. The product meets the criteria for waiver of the in vivo bioequivalence study requirements set forth in CFR 320.22(b)(1)(i)(ii).

   a. The test product is a parenteral solution intended solely for administration by injection.

   b. It contains the same active and inactive ingredients in the same concentrations as the drug product that is the subject of an approved full new application.

2. The comparative formulations for the 30 mg/vial, 60 mg/vial and 90 mg/vial of lyophilized powder for injection were presented in Table 1.

Recommendation:
The Division of Bioequivalence agrees that the information submitted by Bedford Laboratories demonstrates that Pamidronate Disodium for Injection lyophilized powder 30 mg/vial, 60 mg/vial and 90 mg/vial falls under 21 CFR Section 320.22(b)(1)(i)(ii) of the Bioavailability/Bioequivalence Regulations. The waiver of in vivo bioequivalence study for the 30 mg/vial, 60 mg/vial and 90 mg/vial of lyophilized powder for injection of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation to be bioequivalent to Aredia[R] Injection manufactured by Ciba Geigy as 30 mg/vial, 60 mg/vial and 90 mg/vial of lyophilized powder.

Andre Jackson
Review Branch I
Division of Bioequivalence

RD INITIALED YCHUANG
FT INITIALED YCHUANG Date 4/9/98

Concur: Date 4/9/98
Dale P. Conner, Pharm D.
Director
Division of Bioequivalence

ANDA