CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-113

CLINICAL PHARMACOLOGY and BIOPHARMACEUTICS REVIEW(S)

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CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW

NDA 21-113 **SUBMISSION DATE**: February 26, 1999

Pamidronate Disodium Injection
3 mg per mL; 10 mL per vial

Bedford Laboratories **REVIEWER**: Hae-Young Ahn, Ph.D.

SUBMISSION TYPE: New Drug Application

The sponsor submitted an NDA for Pamidronate Disodium Injection, 3 mg per mL; 10 mL per vial.

The reference listed drug, Aredia® (Pamidronate disodium for injection) 30 mg per vial marketed by Novartis is a lyophilized powder to be reconstituted with 10 mL of water yielding a solution containing 3 mg/mL Pamidronate Disodium prior to use. However, the proposed drug product, Pamidronate Disodium Injection, 3 mg/mL; 10 mL per vial, is a ready to use solution.

Aredia® is currently marketed as a lyophilized powder, with the following formulation per vial:

Pamidronate Disodium	30 mg
Mannitol, USP	470 mg
Phosphoric Acid	To adjust pH

The proposed Pamidronate Disodium Injection, 3 mg/mL, 10 mL per vials has the following formulation:

Pamidronate Disodium	30 mg
Mannitol, USP	470 mg
Sodium Hydroxide, NF	To adjust pH
Phosphoric Acid, NF	To adjust pH
Water for Injection, USP	qs to 10 mL

The sponsor requests a waiver of the requirements for submission of evidence demonstrating the in vivo bioavailability/bioequivalence for the drug product under 21 CFR 320.22(b)(1). The drug product is intended for intravenous administration and it contains the active ingredient in the same concentration as in the listed drug product. Therefore, the Office of Clinical Pharmacology and Biopharmaceutics/Division of Pharmaceutical Evaluation II finds that request for a waiver of the requirements for submission of evidence demonstrating the in vivo bioavailability/bioequivalence for the drug product can be granted.

/S/

Hae-Young Ahn, Ph.D.
DPE II/OCPB

/S/

RD/FT initialed by J. Hunt, Deputy Director

CC: NDA 21-113, HFD-510 (Hedin), HFD-870 (M. Chen, Ahn), CDR (Murphy)
Code: AP