

FDA Review Memo
Nov. 17, 1992

November 17, 1992 Amendment in Support of Pharmaceutical
Equivalence and Waiver Request:

In part, this amendment deals with the issue of whether Luitpold's iron dextran is pharmaceutically equivalent to either of the two available innovator products. The firm presents the 21CFR320.1(c) version of pharmaceutical equivalents which states that "pharmaceutical equivalents are drug products that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, in identical dosage forms, but not necessarily containing the same inactive ingredients, and that meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content, uniformity, disintegration times, and/or dissolution rates."

The firm also presents the definition of pharmaceutical equivalents as given in the Orange Book (12th Edition): "Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, and are identical in strength or concentration and route of administration."

The submitted information and arguments included in the amendment in support of another bioequivalence waiver request are basically a summary of previously submitted material.

Comments:

1. The FDA recently determined that Luitpold's iron dextran is pharmaceutically equivalent to the approved products. The firm may submit a protocol for a bioequivalence study.
2. Aside from molecular weight differences there might be other physicochemical differences resulting from probable different methods of production (as presented by Luitpold in the October 15, 1992 meeting with FDA) which might matter in terms of efficacy.

REF. 9

Deficiency:

The fact remains that the test product differs immensely in molecular weight and particle size from the innovator product. The test product (iron dextran injection, 50 mg/ml) manufactured by Luitpold Pharmaceuticals, Inc. has a weight average molecular weight of Luitpold determined that the reference product (Fisons' Imferon, Lot #/Batch MW303A) has a weight average molecular weight of

Recommendation:

The Division of Bioequivalence does not agree that the information submitted by Luitpold, Inc. demonstrates that

iron dextran injection, 50 mg/ml falls under 21 CFR Section 320.22 of the Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of in-vivo bioequivalence studies be denied. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable product not to be bioequivalent to Imferon manufactured by Fisons Pharmaceuticals.

The firm should be advised of comment 1, the deficiency and the recommendation.

James E Chaney

James E. Chaney, Ph.D.
Division of Bioequivalence
Review Branch I

RD INITIALED AJJackson
FT INITIALED AJJackson

a JJ

Date

3/18/93

Concur:

Agnes T. Wu

Date:

3/22/93

Agnes T. Wu
Acting Director
Division of Bioequivalence

cc: Anda 40-024 original, HFD-630, HFD-600 (OGD), HFD-604 (Hare), HFC-130 (JAllen), HFD-652 (Wu, Chaney), Drug File

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