CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74759

BIOEQUIVALENCY REVIEW(S)

MAR 26 1996

Aminocaproic Acid, USP
1.25 g/ 5 ml, Syrup
ANDA # 74-759
Reviewer: A.P.Patel
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Mikart, Inc
Atlanta, Georgia
Submission Date:
Sept. 25, 1995
Nov.17, 1995

Review of a Waiver Request

Introduction:

Aminocaproic acid is useful in enhancing hemostasis when fibrinolysis contributes to bleeding.

Objective:

The firm has requested that the *in-vivo* Bioequivalence requirements for the test product be waived under the provisions of CFR 320.22(b)(3). The reference product is Amicar Syrup, 1.25 g/5ml, manufactured by Lederle Laboratories.

Comments:

1. The test product is an oral syrup containing the same active ingredient (6-aminocaproic acid) in the same concentration (1.25 g/ 5 ml) as the reference product.

2. The Firm was granted a waiver from in vivo Bioequivalency studies for this product (ANDA # 74-144). The proposed formulation is qualitatively and quantitatively similar to previously approved formulation except the proposed formulation does not contain sodium benzoate and potassium sorbate.

3. The test product contains no inactive ingredient known to significantly affect absorption of the active ingredient. The ingredients of the test and reference drugs are shown in Table 1.

4. The test product does not contain preservative. Division of Chemistry should address stability and microbial contamination issues.

Dificiencies: None

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Mikart, Inc. demonstrates [illegible] 320.22(b)(3). [illegible] bioequivalence study for aminocaproic acid, USP 1.25 g/5 ml syrup is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test syrup to be bioequivalent to Amicar Syrup, 1.25g / 5 ml manufactured by Lederle.

The firm should be advised of the recommendation.

/S/ 3/25/96

A.P.Patel
Division of Bioequivalence
Review Branch III

RD Initialed R.M. Mhatre
FT Initialed R.M. Mhatre /S/ Date: 3/26/96

Ramakant M. Mhatre, Ph.D.
Chief, Branch III
Division of Bioequivalence

ANDA# 74-786, HFD-600 (Hare), HFD-630, HFD-658 (R.M.Mhatre, A.P.Patel), Drug File, Division File.