DIVISION OF ANTI-INFLAMMATORY, ANALGESIC AND OPHTHALMIC DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-905

REVIEW # 2

DATE REVIEWED: August 26, 1998

SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE
Fax 21 August, 1998 None 21 August, 1998

NAME & ADDRESS OF APPLICANT:
Hoechst Marion Roussel, Inc.
10236 Marion Park Drive
Kansas City, Mo 64137

DRUG PRODUCT NAME
Proprietary: ARAVA™ Tablets
Established: N-(4’ Trifluoromethylphenyl)-5-methylisoxazole-4-carboxamide Tablets
Code Name/#: HWA 486, A771486, Cas Number: 75706-12-6
Chem Type/Ther. Class:

PHARMACOL. CATEGORY: Antiinflammatory

DOSAGE FORM: Tablets

STRENGTHS: 10, 20 and 100 mg.

ROUTE OF ADMINISTRATION: Oral

DISPENSED: X Rx __ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:

CHEMICAL NAME: N-(4’ Trifluoromethylphenyl)-5-methylisoxazole-4-carboxamide
5-Methylisoxazole-4-carboxylic acid 4-trifluoromethyl anilide
α, α, α - Tifluoro-5-methyl-4-isoxazolecarboxy-p-toluidine

MOLECULAR WEIGHT: 270.2

MOLECULAR FORMULA: C_{12}H_{9}N_{2}O_{2}F_{3}

STRUCTURAL FORMULA:
SUPPORTING DOCUMENTS:

Chemistry Review #1

RELATED DOCUMENTS

None

REMARKS:

This is a review of the responses the company has furnished via fax (attached) for the deficiencies cited.

CONCLUSIONS & RECOMMENDATIONS:

The information provided in the CMC section and the responses to the deficiencies are now considered to be satisfactory. The company proposes to tighten the dissolution specification to Q 75% in 30 minutes, which is acceptable from the CMC standpoint, but should also be acceptable to the pharmacokineticist.

It is recommended that the NDA from the CMC standpoint be approved.

Hasmukh Patel Ph. D., Team Leader

8/27/98

Date

Vispi P. Bhavnagri Ph. D. / Review Chemist

8/27/98

Date

CC:

NDA # 20-905
HFD-550/Division File
HFD-550/V.Bhavnagri
HFD-550/H.Patel
HFD-550/S.Cook

HFD-550/J.Hyde
HFD-550/V.Tandon
HFD-550/K.Johnson
HFD-550/A.Mukherjee
HFD-830/Chi Wan Chen

APPROVE