

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20905

CHEMISTRY REVIEW(S)

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

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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: Rx OTC

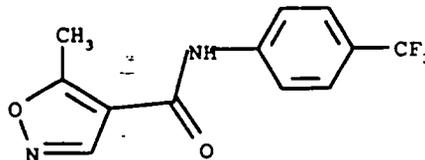
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:

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: C₁₂H₉N₂O₂F₃

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

Date

8/27/98

Vispi P. Bhavnagri Ph. D., Review Chemist

Date

8/27/98

CC:

NDA # 20-905

HFD-550/Division File

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APPROVE