APPLICATION NUMBER: 20763

CHEMISTRY REVIEW(S)
DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA#: 20-763

CHEMISTRY REVIEW: # 3

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NAME & ADDRESS OF APPLICANT:
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

DRUG PRODUCT NAME:
Proprietary: AMERGET™
Nonproprietary/Established/USAN: naratriptan (hydrochloride) [USAN, 1993]
Code Name#: GR85548(A)
Chem. Type/Ther. Class: 1S
no DESI issues; patent expires August 12, 2008

PHARMACOLOGICAL CATEGORY/INDICATION: antimigraine
dOSAGE FORM: tablets
STRENGTHS: 1.0, 2.5 mg
ROUTE OF ADMINISTRATION: oral
DISPENSED: XX Rx _ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA: structure above right.
IUPAC name: N-methyl-3-(1-methyl-4-piperidinyl)-1H-indole-5-ethanesulfonamide monohydrochloride
CAS name: N-methyl-3-(1-methyl-4-piperidyl)indole-5-ethanesulfonamide monohydrochloride
C_{17}H_{25}N_{2}O_{2}S \cdot HCl  Mol. Weight: 371.93  CAS #: 143388-64-1 (salt), 121679-13-8 (base)

CONCLUSIONS & RECOMMENDATIONS: See Reviews #1, 2. This review: amendments and correspondence on/after 17OCT97. May be approved for chemistry.

cc: Orig. NDA
HFD-120/Division File
HFD-120/DJBates/20JAN98
HFD-120/LChen
HFD-120/MGuzewska/Init: No 1.26.98
HFD-810/JSimmons/Init:
HFD-810/CHoiberg/Init:

Doris J. Bates, Ph.D., Review Chemist
Filename: nararev.003
DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA#: 20-763

CHEMISTRY REVIEW: # 2  
DATE REVIEWED: 11SEP97

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C_{17}H_{23}N_{2}O_{3}S • HCl  Mol. Weight: 371.93  CAS #: 143388-64-1 (salt), 121579-13-8 (base)

CONCLUSIONS & RECOMMENDATIONS: See Review #1. Methods validation requested, firm has been contacted by labs, validation pending. EER acceptable for all sites as of 11JUN97. First amendment listed above includes stability update for drug substance and drug product. First product stability update is superseded by second amendment which includes cumulative update for product alone, plus answers to questions in FDA letter of 09JUL97. First General Correspondence proposes trade name; acceptable (Nomenclature Committee, 02SEP97.) Second General Correspondence includes electronic version of CMC update. Stability data, responses satisfactory; acceptable validation results anticipated: APPROVE for CMC.

cc: Orig. NDA

HFD-120/Division File
HFD-120/DBates/11SEP97
HFD-120/LChen
HFD-120/MGuzewaska/Init: 9-9-97
HFD-810/JSimmons/Init: Cholberg/Init:  

Dori J. Bates, Ph.D., Review Chemist  
Filename: nararev.002