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RESEARCH**

APPLICATION NUMBER:

21-678

MICROBIOLOGY REVIEW(S)

MICROBIOLOGY REVIEW
DIVISION OF SPECIAL PATHOGEN AND IMMUNOLOGIC DRUG PRODUCTS
(HFD-590)

NDA #: 21-678

REVIEWER: Peter A. Dionne
CORRESPONDENCE DATE: 27-OCT-03
CDER DATE: 28-OCT-03
REVIEW ASSIGN DATE: 30-OCT-03
REVIEW COMPLETE DATE: 15-JAN-04

SPONSOR: Bristol-Myers Squibb Pharmaceutical Research Institute
Five Research Parkway
Wallingford, CT 06492-7660

CONTACT PERSON: Joan C. Fung-Tomc, Ph.D.
Director, Regulatory Science
Phone Number: (203) 677-6370

SUBMISSION REVIEWED: Original New Drug Application for Gatifloxacin powder for Oral Suspension—
in Adults for use

DRUG CATEGORY: Antimicrobial: Fluoroquinolone

INDICATIONS: ABECB, Acute Sinusitis, Community Acquired Pneumonia, Urinary Tract Infections and Gonorrhea in adults

DOSAGE FORM: 40mg/mL (1g/25mL, 2g/50mL, 3g/75mL, 4g/100mL)

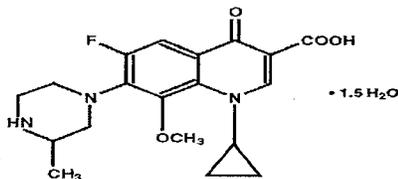
DRUG PRODUCT NAME

PROPRIETARY: TEQUIN®

NONPROPRIETARY/USAN: Gatifloxacin

CHEMICAL NAME: (±)-1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(3-methyl-1-piperazinyl)-4-oxo-3-quinolone carboxylic acid sesquihydrate

STRUCTURAL FORMULA:



Molecular Formula: C₁₉H₂₂FN₃O₄•1½ H₂O

Molecular Weight: 402.42

NDA #21-678
Bristol-Myers Squibb
Gatifloxacin Powder for Oral Suspension

Page 2 of 25

SUPPORTING DOCUMENTS: NDA 21-061—Gatifloxacin Tablets (approved 12/1999)
NDA 21-062—Gatifloxacin IV solution (approved 12/1999)
IND 57,672—Gatifloxacin for oral suspension

BACKGROUND:

The data in this application are submitted to support the use of gatifloxacin oral suspension

Data are also included for the use of gatifloxacin oral suspension in adults for the same indications as the currently approved tablets.

The data supporting the use of gatifloxacin oral suspension in adults are based on two Phase I studies: a bioequivalence study and a food effect/drug interaction study.

CONCLUSIONS & RECOMMENDATIONS:

This application should be approved from the microbiological viewpoint under section 505 (b) of the Act.

23 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling

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/s/

Peter Dionne
2/13/04 08:35:43 AM
MICROBIOLOGIST

Shukal signed 1/16/04--Steve signed 2/11/04

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2/13/04 08:40:21 AM
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