DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-404
NDA 21-405
NDA 21-061/S-010
NDA 21-062/S-011
NDA 21-061/S-016
NDA 21-062/S-017

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attention: Joan Fung-Tomc, Ph.D.
Director, Regulatory Science
5 Research Parkway
Wallingford, CT 06492-7660

Dear Dr. Fung-Tomc:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tequin® (gatifloxacin HCl) Tablets, 200 mg and 400 mg (NDAs 21-061 and 21-404) and for Tequin® (gatifloxacin HCl) Injection, 10 mg/mL (200 mg) 20 mL vials, 10 mg/mL (400 mg) 40 mL vials, 2 mg/mL (200 mg) 100 mL flexible container, and 2 mg/mL (400 mg) 200 mL flexible container (NDA 21-062 and 21-405).

1. NDA 21-404 and 21-405

NDAs 21-061 and 21-062, originally submitted on December 28, 1998, were approved on December 17, 1999 for community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, acute bacterial sinusitis, uncomplicated urinary tract infections, complicated urinary tract infections, pyelonephritis, and uncomplicated gonorrhea. The December 17, 1999 approval letter further stated that "we have concluded that the indication of uncomplicated skin and skin structure infections is approvable pending submission of post-marketing data confirming the safety of gatifloxacin and therefore demonstrating an acceptable risk/benefit profile." For our administrative purposes, we assigned NDA numbers 21-404 (Tequin Tablets) and 21-405 (Tequin Injection) for the indication of treatment of uncomplicated skin and skin structure infections. Your submissions of June 29, 2001 to these NDAs constituted a complete response to our December 17, 1999 approvable letter. A second approvable letter was issued for NDAs 21-404 and 21-405 on December 21, 2001. Your submissions of February 6, 2002 constituted a complete response to our December 21, 2001 approvable letter. A third approvable letter was issued for NDAs 21-404 and 21-405 on August 2, 2002.

Your submissions of August 23, 2002 constituted a complete response to our August 2, 2002 approvable letter.

We acknowledge receipt of your submissions dated August 9 and September 30, 2002.

NDAs 21-404 and 21-405 provide for the use of Tequin® Tablets and Tequin® Injection for the treatment of uncomplicated skin and skin structure infections.

2. NDA 21-061/S-010 and NDA 21-062/S-011

Please also refer to your supplemental new drug applications dated July 20, 2001, received July 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An approvable letter was issued for NDA 21-061/S-010 and NDA 21-062/S-011 on December 21, 2001. Your submissions of May 28, 2002 constituted a complete response to our December 21, 2001 approvable letter. A second approvable letter was issued for these supplements on August 2, 2002.

Your submissions of August 23, 2002 constituted a complete response to our August 2, 2002 approvable letter.

We acknowledge receipt of your submissions dated August 9 and September 30, 2002.

These supplemental new drug applications provide for revisions to the Tequin® package insert to add information regarding QTc prolongation.

3. NDA 21-061/S-016 and NDA 21-062/S-017

Please also refer to your supplemental new drug applications dated May 10, 2002, received May 13, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An approvable letter was issued for NDA 21-061/S-016 and NDA 21-062/S-017 on August 2, 2002.

Your submissions of August 23, 2002 constituted a complete response to our August 2, 2002 approvable letter.

We acknowledge receipt of your submissions dated July 29, August 9, and September 30, 2002.

These "Changes Being Effected" supplemental new drug applications provide updated information regarding disturbances in glucose homeostasis in the CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, ANIMAL PHARMACOLOGY, and Patient Package Insert sections of the package insert. These supplemental NDAs further provide for a change in the generic name from "gatifloxacin" to "gatifloxacin in 5% dextrose" and revisions to the labeling header and the DESCRIPTION, DOSAGE AND ADMINISTRATON, and HOW SUPPLIED sections of the package insert to reflect this change. In addition, these supplemental NDAs propose revisions to the artwork for both the primary bag and the overwrap for the Tequin® Injection minibags to reflect the change in generic name from "gatifloxacin" to "gatifloxacin in 5% dextrose."

We have completed the review of these applications (NDA 21-404, NDA 21-405, NDA 21-061/S-010, NDA 21-061/S-016, NDA 21-062/S-011, and NDA 21-062/S-017), as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container [primary bag and overwrap] submitted July 29, 2002).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL to each supplement as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, these submissions should be designated "**FPL for approved NDA 21-404, NDA 21-405, NDA 21-061/S-010, NDA 21-062/S-011, NDA 21-061/S-016, and NDA 21-062/S-017."** Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on the information submitted, we conclude the following:

For the use of Tequin® Tablets and Tequin® Injection for the treatment of uncomplicated skin and skin structure infections, we are deferring submission of pediatric studies for patients ages from birth through 16 years of age until January 2007.

In addition, we request that you submit three copies of the introductory promotional materials you propose to use for these products for the treatment of uncomplicated skin and skin structure infections. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Immunologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to NDAs 21-061 and 21-062 and a copy to the following address:

MEDWATCH, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). With the approval of administrative NDAs 21-404 and 21-405, these NDA numbers will be retired. All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDAs 21-061 and 21-062 for these drug products. In the future, please do not make submissions to NDAs 21-404 and 21-405 except for the final printed labeling requested above.

If you have any questions, call Diana Willard, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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