



NDA 21-061/S-022
NDA 21-062/S-023

Bristol-Myers Squibb Company
Attention: Joan Fung-Tomc, Ph.D.
c/o: Amy Jennings, Ph.D.
5 Research Parkway, Dept. 718
Signature 91 Building
Wallingford, CT 06492

Dear Dr. Fung-Tomc:

Please refer to your supplemental new drug applications dated December 30, 2003, received December 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement Number
TEQUIN® (gatifloxacin) Tablets	21-061	S-022
TEQUIN® (gatifloxacin) Injection and TEQUIN® (gatifloxacin in 5% Dextrose) Injection	21-062	S-023

We acknowledge receipt of your submissions dated:

February 20, 2004 (2)	March 16, 2004	June 28, 2004
March 12, 2004	May 11, 2004	June 29, 2004

These supplemental new drug applications provide for the treatment of Community Acquired Pneumonia caused by multi-drug resistant *Streptococcus pneumoniae*.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text with the following agreed upon additional minor change: the footnote about MDRSP in the "Clinical Studies" section will be placed at the end of this section (immediately preceding the tables).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted June 29, 2004) with the agreed upon change noted above.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be

submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

All applications for new active ingredients, new dosage forms, new indications, significant modifications of existing indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for Community Acquired Pneumonia caused by MDRSP in pediatric patients ages 0 months to 18 years until June 30, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of Community Acquired Pneumonia caused by multi-drug resistant *Streptococcus pneumoniae* in pediatric patients ages 0 months to 18 years.

Final Report Submission: June 30, 2009

Submit final study reports to these NDAs. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated “**Required Pediatric Study Commitments.**”

In addition, submit three copies of the introductory promotional materials that you propose to use for the modification of the indication for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts 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 these NDAs and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you should have any questions, please call Anne Marie Homonnay-Weikel, 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

Enclosure (labeling)

**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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