DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-085/S-022
NDA 21-277/S-017

Bayer Pharmaceuticals Corporation
Attention: Robin Christoforides
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

Dear Ms. Christoforides:

Please refer to your supplemental new drug applications dated December 23, 2003, received February 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AVELOX® (moxifloxacin hydrochloride) Tablets and AVELOX® I.V. (moxifloxacin hydrochloride in sodium chloride injection), 400 mg.

We acknowledge receipt of your submissions dated:

March 8, 2004	April 5, 2004	April 26, 2004	May 5, 2004 (2)
March 12, 2004	April 6, 2004	April 28, 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted May 5, 2004).

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 as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-085/S-022 and NDA 21-277/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, 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 ages 0 months to 18 years until March 12, 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. These commitments are 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: March 12, 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

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

If you have any questions, call Susan Peacock, 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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