



NDA 21-085/S-026

NDA 21-277/S-022

Bayer Corporation
Pharmaceutical Division
Attention: Janet A. Herrington, Ph.D.
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Dr. Herrington:

Please refer to your supplemental new drug applications dated August 13, 2004, received August 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AVELOX® (moxifloxacin hydrochloride) Tablets and AVELOX® (moxifloxacin hydrochloride in NaCl injection) I.V.

We acknowledge receipt of your submissions dated:

October 21, 2004	February 2, 2005	April 19, 2005	May 21, 2005
November 8, 2004	March 2, 2005	April 20, 2005	June 1, 2005
December 9, 2004	March 11, 2005	April 28, 2005	June 6, 2005
December 30, 2004	March 18, 2005	April 29, 2005	June 10, 2005
January 4, 2005	April 11, 2005	May 11, 2005	

These supplemental new drug applications provide for the use of AVELOX® (moxifloxacin hydrochloride) Tablets and AVELOX® (moxifloxacin hydrochloride in NaCl injection) I.V. for the treatment of adults (≥ 18 years of age) with complicated skin and skin structure infections caused by methicillin susceptible *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae*.

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 submitted June 10, 2005. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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 is 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. For administrative purposes, these submissions should be designated “FPL for approved NDAs 21-085/S-026 and 21-277/S-022.” 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 are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. The Agency has not made a determination if a health benefit would be gained by studying AVELOX® (moxifloxacin hydrochloride) in pediatric patients for its approved indications. The agency held an internal meeting this month to discuss this matter and will inform you on or before October 10, 2006 whether pediatric studies are required under PREA. If FDA determines at that time that pediatric studies are necessary, we will also set a specified time at which you must submit the required assessments, which will be considered to be required postmarketing commitments. The status of any postmarketing study(ies) required under PREA shall be reported annually according to 21 CFR 314.81.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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(s) 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).

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If you have any questions, call Donovan F. Duggan, II, M.B.A., 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

Center for Drug Evaluation and Research

Enclosure

**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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