DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-277/S-001

Bayer Corporation
Attention: Robin Christoforides
Assistant Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Ms. Christoforides:

Please refer to your supplemental new drug application dated March 7, 2002, received March 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avelox® I.V. (moxifloxacin HCL in NaCl), 400 mg/250 mL 0.8% saline.

We acknowledge receipt of your submission dated April 5, 2002.

This supplemental new drug application provides for the following changes to the Avelox® I.V. overwrap and flexibag:

1. The established name was changed from "moxifloxacin HCl" to "moxifloxacin HCl in NaCl injection".

2. The expression of strength was revised to read "400 mg*/250 mL in 0.8% saline".

3. "(1.6 mg/mL)" was placed below the revised expression of strength.

4. "250 mL" that was located to the right of the established name on the overwrap only was deleted to provide room for the revised established name.

5. The following statement was added in bold print:

"**DO NOT REFRIGERATE-PRODUCT PRECIPITATES UPON REFRIGERATION"**

Please note that the expression of strength should be corrected to read "400 mg*/250 mL 0.8% saline". We had inadvertently recommended "in 0.8% saline." Please include this correction at the next convenient printing of the label.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted March 7, 2002).

Please 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 ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-277/S-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Robin Anderson, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Acting 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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