CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-277

CORRESPONDENCE

NDA 21-277

Bayer Corporation Pharmaceutical Division
Attention: Andrew Verderame
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Verderame:

Please refer to your new drug application (NDA) dated and received November 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avelox ® I.V. Solution (moxifloxacin hydrochloride injection), 400 mg.

We are reviewing your application and have the following comments regarding the Chemistry, Manufacturing, and Control that need to be addressed in order to continue our evaluation of your NDA application.

1. Please note that the currently available stability data for the drug product, packaged in the container/closure system Proposed for market, do not support the proposed 36-month expiration dating. Please revise the expiration dating from the requested 36 months to 30 months for this product.

2. Please revise your current stability protocol (document T.04.22-01 provided in the July 3, 2001, amendment) to include 9- and 18-month testing at both [redacted] conditions for the production batches 837465A, 837470L, and 837473B manufactured at the Leverkusen facility.

If you have any questions, call Yoon J. Kong, Pharm.D., Regulatory Project Manager, at (301) 827-2127.

November 29, 2001

Renata Albrecht, MD, Acting Director
Division of Special Pathogens and Immunologic Drug Products
Office of Drug Evaluation IV (HFD-590)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Re: NDA 21-277
AVELOX® (moxifloxacin hydrochloride) I.V. Solution
General Correspondence

Dear Dr. Albrecht,

Reference is made to the Avelox (moxifloxacin hydrochloride) I.V. NDA, 21-277. Reference is also made to the teleconference on November 29, 2001 with representatives from the Division.

Bayer Corporation agrees to the following Phase IV commitments:

1. Bayer will provide a summary (safety and efficacy) of ongoing intravenous studies to the Division on March 1, 2002, June 1, 2002, September 1, 2002 and December 1, 2002. Final reports of ongoing studies will be submitted to the Division.

2. Bayer will provide expedited (15 day) reporting of certain post-marketing serious adverse events in intravenously-treated geriatric patients (age ≥ 65 years and patients where age is unknown) until December 1, 2002.

3. Bayer will conduct a blinded comparative trial in elderly patients with a clinical diagnosis of pneumonia and will report the results to the Division by June 1, 2004.

If there are any questions or concerns, please do not hesitate to contact me at (203) 812-5172.

Sincerely,

Andrew S. Verderame
Deputy Director, Regulatory Affairs

Desk copy: Yoon Kong, PharmD, Project Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-277

Bayer Corporation
Pharmaceutical Division
Attention: Andrew Verderame
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Verderame:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Avelox® (moxifloxacin hydrochloride) I.V. Solution

Review Priority Classification: Standard (S)

Date of Application: November 2, 2000

Date of Receipt: November 2, 2000

Our Reference Number: NDA 21-277

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on January 3, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be September 2, 2001 and the secondary user fee goal date will be November 2, 2001.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will make a determination whether to grant or deny a request for a waiver of pediatric studies during the review of the application. In no case, however, will the determination be made later than the date action is taken on the

application. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Valerie Jensen, R.Ph., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research