



NDA 21-085/S-045
NDA 21-277/S-039

SUPPLEMENTS APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Janet Herrington, Ph.D.
Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Herrington:

Please refer to your supplemental new drug applications dated and received on September 29, 2009 and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement Number	Drug Product
21-085	045	Avelox [®] (moxifloxacin) Tablets, 400 mg
21-277	039	Avelox [®] (moxifloxacin) I.V., 400 mg in 0.8% saline

These “Changes Being Effected” supplemental new drug applications propose revision of the **ADVERSE REACTIONS/Postmarketing Adverse Event Reports** subsection of the labeling for the package insert to include the possibility of the exacerbation of the symptoms of myasthenia gravis associated with the use of moxifloxacin.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on September 29, 2009.

The revision to the package insert was as follows (additions are noted with underline):

ADVERSE REACTIONS/Postmarketing Adverse Event Reports:

Additional adverse events have been reported from worldwide post-marketing experience with moxifloxacin. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events, some of them life-threatening, include anaphylactic reaction, anaphylactic shock, angioedema (including laryngeal edema),

hepatic failure, including fatal cases, hepatitis (predominantly cholestatic), photosensitivity/phototoxicity reaction (see **PRECAUTIONS**), psychotic reaction (very rarely culminating in self-endangering behavior), renal dysfunction or renal failure, Stevens-Johnson syndrome, tendon rupture, toxic epidermal necrolysis, and ventricular tachyarrhythmias (including in very rare cases cardiac arrest and torsade de pointes, and usually in patients with concurrent severe underlying proarrhythmic conditions). Cases of altered coordination and abnormal gait as well as exacerbation of myasthenia gravis have also been reported.

CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for these NDAs, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in these supplemental applications.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling for the package insert submitted on September 29, 2009 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21-085/S-045 and NDA 21-277/S-039.**" Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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

If you have questions, call Rebecca D. McKinnon, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21085	SUPPL-45	BAYER HEALTHCARE PHARMACEUTICA LS INC	AVELOX (MOXIFLOXACIN HCL)
NDA-21277	SUPPL-39	BAYER HEALTHCARE PHARMACEUTICA LS INC	AVELOX (MOXIFLOXACIN HCL) IV 400MG

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
11/24/2009