



NDA 21-085/S-024
NDA 21-277/S-019

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

Dear Ms. Christoforides:

Please refer to your supplemental new drug applications dated April 7, 2004, received April 9, 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.

These "Changes Being Effected" supplemental new drug applications provide for the addition of quinolone class labeling as requested in our supplement request letter dated November 26, 2003 and in our facsimile dated March 10, 2004. The following revisions have been made to the package insert under the **WARNINGS** section (additions are double underlined and deletions are ~~strikethrough~~):

Peripheral neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

Tendon Effects: Ruptures of the shoulder, hand, Achilles and other tendon ruptures—tendon or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including with quinolones, including moxifloxacin. Post-marketing surveillance reports indicate that ~~the~~ this risk may be increased in patients receiving concomitant corticosteroids, especially ~~in~~ the elderly. Moxifloxacin should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been excluded. Tendon rupture can occur during or after therapy with quinolones, including moxifloxacin.

We completed our review of these supplemental new drug applications. They are approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 7, 2004.

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 Robin Anderson, R.N., M.B.A., Labeling Reviewer 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

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/s/

Renata Albrecht
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