DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

NDA 20-013/S-015

Pfizer, Inc.
Attention: Mr. Robert Clark
Vice President, U.S. Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Gamper:

Please refer to your supplemental new drug application dated April 9, 2004, received April 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MAXAQUIN® (lomefloxacin hydrochloride) Tablets, 400 mg.

Your submission of February 4, 2005 constituted a complete response to our October 8, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert (additions are double underlined and deletions are in ~~strikethrough~~):

1. WARNINGS

- The following paragraph was added for peripheral neuropathy:

> **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, including lomefloxacin. Lomefloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and /or weakness, or is found to have deficits in light touch, pain, temperature, position sense, vibratory sensation, and/or motor strength in order to prevent the development of an irreversible condition.

- The tendon rupture paragraph was revised to read:

> ~~Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with lomefloxacin. Lomefloxacin 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 confidently excluded. Tendon rupture can occur at any time during or after therapy with lomefloxacin.~~
>
> **Tendon Effects:** Ruptures of the shoulder, hand, Achilles tendon or other tendons that require surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including lomefloxacin. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids,

especially the elderly. Lomefloxacin should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until diagnosis of tendonitis or tendon rupture had been excluded. Tendon rupture can occur during or after therapy with quinolones, including lomefloxacin.

2. PRECAUTIONS

- A peripheral neuropathy bullet was added under **Information for Patients** as follows;

  - that peripheral neuropathies have been associated with lomefloxacin use. If symptoms of peripheral neuropathy including pain, burning, tingling, numbness and/or weakness develop, they should discontinue treatment and contact their physicians.

3. ADVERSE REACTIONS

- The header **"~~Quinolone class adverse events~~"** was deleted and replaced with the header **"Post-Marketing Adverse Events".**

- Peripheral neuropathy and torsades de pointes were added to the *Quinolone-class adverse events* subsection to read:

  Quinolone-class adverse events: Additional quinolone-class adverse events include: Peripheral neuropathy, torsades de pointes, erythema nodosum, hepatic necrosis, possible exacerbation of myasthenia gravis, dysphasia, nystagmus, intestinal perforation, manic reaction, renal calculi, acidosis and hiccough.

We have completed the review of this supplemental new drug 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 (enclosed). Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (text for the package insert submitted February 4, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submission in Electronic Format – NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission as "**FPL for approved supplement NDA 20-013/S-015**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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, 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

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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