DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

**SUPPLEMENT APPROVAL**
**RELEASE REMS REQUIREMENT**

NDA 019537/S-079
NDA 019847/S-051
NDA 019857/S-058
NDA 020780/S-037
NDA 021473/S-032

Bayer Pharmaceuticals Corporation
Attention: Larry Winick
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, New Jersey 07045-1000

Dear Mr. Winick:

Please refer to your supplemental New Drug Applications (sNDAs), dated and received June 24, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CIPRO® (ciprofloxacin hydrochloride) 250 mg, 500 mg, and 750 mg Tablets (NDA 019537); CIPRO® (ciprofloxacin hydrochloride) 200 mg, 400 mg, and 1200 mg 1 % Solution in Vials (NDA 019847); CIPRO® (ciprofloxacin hydrochloride) 200 mg and 400 mg 0.2% Solution in 5% Dextrose (NDA 019857); CIPRO® (ciprofloxacin hydrochloride) 5% and 10% Oral Suspension (NDA 020780); and CIPRO® XR (ciprofloxacin hydrochloride) 500 mg and 1000 mg Extended Release Tablets (NDA 021473).

We also refer to your risk evaluation and mitigation strategy (REMS) assessment dated December 29, 2011.

These "Prior Approval" sNDAs provide for revisions to the Medication Guide.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

We request that the modifications approved today be available on your website within 10 days of receipt of this letter.

**RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT**

The REMS for CIPRO® (ciprofloxacin hydrochloride) Tablets, Extended Release Tablets, Vials, Injection, and Oral Suspension was originally approved on April 27, 2009, and the most recent REMS modification was approved on August 3, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of CIPRO® (ciprofloxacin hydrochloride) Tablets, Extended Release Tablets, Vials, Injection, and Oral Suspension outweigh its risks. We refer to the July 8, 2011 teleconference with Susmita Samanta, Safety Regulatory Project Manager, Division of Anti-Infective Products, where you agreed with this determination.

Therefore, a REMS for CIPRO® (ciprofloxacin hydrochloride) Tablets, Extended Release Tablets, Vials, Injection, and Oral Suspension is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

**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 any questions, call Susmita Samanta, MD, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Approved Medication Guide

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SUMATHI NAMBIAR
08/03/2011