DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-847/S-046
NDA 19-857/S-053

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Bradley Jones, RAC
Associate Director, Global Regulatory Affairs
P.O. Box 1000
Montville, New Jersey 07045-1000

Dear Mr. Jones:

Please refer to your supplemental New Drug Applications (sNDAs), dated November 30, 2010, received November 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA # / Supplement	**Drug Name**
NDA 19-847/S-046	Cipro (ciprofloxacin) For Intravenous Infusion-Vial
NDA 19-857/S-053	Cipro (ciprofloxacin) For Intravenous Infusion- Flexible Container

We acknowledge receipt of your amendment(s) dated December 22, 2010, and November 10, 2011.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

1. In the Medication Guide, under #1 "**Tendon rupture or swelling of the tendon (tendinitis)" bullet 1,** add a space between CIPRO and Tendons as indicated below.

   Tendon problems can happen in people of all ages who take CIPRO. Tendons are tough cords of tissue that connect muscles to bones.

2. In the Medication Guide under "Tell your healthcare provider about all the medicines you take":
   - Bullet 5, bold the sentence "What are the possible side effects of CIPRO?"as indicated below.

Glyburide (Micronase®, Glynase®, Diabeta®, Glucovance®). See "**What are the possible side effects of CIPRO?"**

- Bullet 6, correct the spelling of Penytoin after the word Prompt as indicated below.

  Phenytoin (Fosphenytoin Sodium®, Cerebyx®, Dilantin-125®, Dilantin®, Extended Phenytoin Sodium®, Prompt Phenytoin Sodium®, Phenytek®).

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 package insert, text for the patient package insert, 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.

Also within 14 days, amend all pending supplemental applications for this NDA, including 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Fariba Izadi, Pharm.D, Regulatory Project Manager, at (301) 796-0563.

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

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

/s/

SUMATHI NAMBIAR
11/15/2011