DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-537/S-073
NDA 20-780/S-030

PRIOR APPROVAL SUPPLEMENTS

Bayer Pharmaceuticals Corporation
Attention: Janet Herrington, Ph.D.
Deputy Director, Regulatory Affairs
P.O. Box 1000
Montville, New Jersey 07045-1000

Dear Dr. Herrington:

Please refer to your supplemental new drug applications dated and received on March 4, 2009 and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA	Supplement Number	Drug Product Name
19-537	S-073	CIPRO® (ciprofloxacin hydrochloride) Tablets, 250 mg, 500 mg, 750 mg
20-780	S-030	CIPRO® (ciprofloxacin hydrochloride) Oral Suspension 5% and 10%

These supplemental applications provide for clarification of the directions in the package insert and on the carton label regarding inappropriate administration of the oral suspension through feeding and nasogastric tubes.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. These supplemental new drug applications provide for the following changes to the content of labeling for the package insert and carton (additions are noted with double underline and deletions noted with strikethrough):

1. The **Instructions To The Pharmacist For Use/Handling of CIPRO Oral Suspension/Preparation of Suspension** section of the package insert was modified as follows:

   CIPRO Oral Suspension should not be administered through feeding or NG (nasogastric) tubes due to its physical characteristics.

2. The text on the carton was modified as follows:

   Should not be administered through feeding or NG (nasogastric) tubes.

CONTENT OF LABELING

As soon as possible, but no later than one month from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "**SPL for approved supplements NDA 19-537/S-073 and NDA 20-780/S-030**."

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in SPL format to include the changes approved in these applications. Marketing the product with final printed labeling that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We request that the revised labeling for the package inserts approved today be available on your website within 10 days of receipt of this letter and that the revised labeling be reflected in the next printing of the labeling. While you may use labeling already printed as of the date of this letter until July 1, 2009, after that date we request that the revised labeling accompany any newly shipped product.

Failure to make these changes promptly could make your product misbranded under Sections 201(n) and 502(a) of the FDCA.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Food and Drug Administration
Suite 12B05
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 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

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

/s/

Ozlem Belen

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Signing for Dr. Renata Albrecht, Division Director, DSPTP