DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-537/S-043

Bayer Corporation
Attention: Andrew Verderame
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

Dear Mr. Verderame:

Please refer to your supplemental new drug application dated January 17, 2002, received January 18, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cipro® (ciprofloxacin hydrochloride) Tablets.

We acknowledge receipt of your submission dated May 24, 2002.

Your submission of August 14, 2002 constituted a complete response to our May 17, 2002 action letter.

This supplemental new drug application provides for the following:

- A new packaging configuration, Cipro 500 mg Tablets in bottles of 30
- An alternate primary bottle label with revised wording from the currently available commercial drug product
- Five-year expiration dating for the 30 count bottle

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted August 14, 2002).

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jouhayna Saliba, Regulatory Project Manager, 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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