



NDA 21-085/S-023

NDA 21-277/S-018

Bayer Pharmaceuticals Corporation  
Attention: Robin M. Christoforides  
400 Morgan Lane  
West Haven, CT 06516

Dear Ms. Christoforides:

Please refer to your supplemental new drug applications dated February 5, 2004, received February 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AVELOX<sup>®</sup> (moxifloxacin hydrochloride) Tablets and I.V.

These “Changes Being Effected” supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled “**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use**” (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003.

These “Changes Being Effected” supplemental new drug applications provide for the following additions to the package insert:

Location	Text
At the beginning of the label, under “ <b>PRODUCT NAME</b> ”	To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVELOX and other antibacterial drugs, AVELOX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
<b>INDICATIONS AND USAGE</b>	To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVELOX and other antibacterial drugs, AVELOX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
<b>PRECAUTIONS</b> section, under “General” subsection	Prescribing AVELOX in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.”
<b>PRECAUTIONS</b> section, under “Information for Patients”	Patients should be counseled that antibacterial drugs including AVELOX should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When AVELOX is prescribed to treat a bacterial infection, patient should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as

	directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacterial will develop resistance and will not be treatable by AVELOX or other antibacterial drugs in the future.
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We completed our review of these applications and they are approved effective on the date of this letter.

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, HFD-410  
FDA  
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 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

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/s/

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Renata Albrecht  
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