DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED VIA FACSIMILE

Martina Ziska, M.D., Ph.D.
Deputy Director, Regulatory Affairs
Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

RE: NDA #21-085
Avelox (moxifloxacin HCL)
MACMIS ID # 10160

Dear Dr. Ziska:

This letter concerns violative promotional activities by the Bayer Corporation Pharmaceutical Division (Bayer). As a part of the Division of Drug Marketing, Advertising, and Communications' (DDMAC) routine surveillance, we have identified statements made by a Bayer sales representative about Avelox (moxifloxacin HCL) in the commercial exhibit hall of the American Society of Health-System Pharmacists' (ASHP) annual meeting in June, 2001 that are in violation of the Federal Food, Drug, and Cosmetic Act and its applicable regulations. Specifically, we object to the following:

Promotion of Unapproved Use

Bayer engaged in promotional activities that state or suggest that Avelox is safe or effective for the treatment of penicillin-resistant *Streptococcus pneumoniae* (PRSP) infections. At the ASHP annual meeting, a Bayer sales representative stated, "Avelox can be used to treat penicillin-resistant *Streptococcus pneumoniae* infections," while promoting the antibiotic coverage of Avelox to visitors at the commercial exhibit booth. This statement promotes Avelox for an unapproved use.

Avelox is indicated for the treatment of adults (≥18 years of age) with infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

- **Acute Bacterial Sinusitis** caused by *Streptococcus pneumoniae, Haemophilus influenza, or Moraxella catarrhalis.*
- **Acute Bacterial Exacerbation of Chronic Bronchitis** caused by *Streptococcus pneumoniae, Haemophilus influenza, Haemophilus parainfluenza, Klebsiella pneumoniae, Staphylococcus aureus, or Moraxella catarrhalis.*
- **Community Acquired Pneumonia** (of mild to moderate severity) caused by *Streptococcus pneumoniae, Haemophilus influenza, Mycoplasma pneumoniae, Chlamydia pneumoniae, or Moraxella catarrhalis.*

The approved product labeling (PI) for Avelox clearly states that Moxifloxacin exhibits *in vitro* minimum inhibitory concentrations (MICs) of 2 micrograms per milliliter or less against most (≥ 90%) strains of *Streptococcus pneumoniae* (penicillin-resistant strains); however, the safety and effectiveness of moxifloxacin in treating clinical infections due to this microorganism has not been established in adequate and well-controlled clinical trials. Therefore, promotion of Avelox for the treatment of PRSP infections is violative and is evidence of Bayer's intent to promote Avelox for unapproved uses.

Requested Action

We request that Bayer representatives immediately cease making such false or misleading statements. We request that you submit a written response by July 12, 2001 describing your intent and plans to comply with the above. Your response should include your method of ceasing such oral statements.

You should direct your response to the undersigned by facsimile at (301) 594-6771, or in writing to the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 10160 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

James R. Rogers, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

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

/s/

James Rogers
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