



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-158/S-002

Parexel International
Attention: Gail Glifort
Senior Regulatory Associate
2520 Meridian Parkway, Suite 200
Durham, NC 27713

Dear Ms. Glifort:

Please refer to your supplemental new drug application dated February 5, 2004, received February 9, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FACTIVE[®] (gemifloxacin mesylate) Tablets, 320mg.

This "Changes Being Effected" supplemental new drug application provides 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.

We acknowledge receipt of your submission dated February 13, 2004.

This "Changes Being Effected" supplemental new drug application provides for the following additions to the package insert:

Location	Text
At the beginning of the label, under "PRODUCT NAME"	To reduce the development of drug-resistant bacteria and maintain the effectiveness of FACTIVE and other antibacterial drugs, FACTIVE should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
INDICATIONS AND USAGE	To reduce the development of drug-resistant bacteria and maintain the effectiveness of FACTIVE and other antibacterial drugs, FACTIVE 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.
PRECAUTIONS section, under "General" subsection	Prescribing FACTIVE 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."
PRECAUTIONS section, under "Information for	Patients should be counseled that antibacterial drugs including FACTIVE should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When FACTIVE is prescribed to treat a

Patients”	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 FACTIVE or other antibacterial drugs in the future.
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We completed our review of this application and it is 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

**This is a representation of an electronic record that was signed electronically and
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/s/

Renata Albrecht
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