DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-268/S-040

Pharmacia Corporation
Attention: Rubin Diaz
4901 Searle Parkway
Skokie, IL 60077

Dear Mr. Diaz:

Please refer to your supplemental new drug application dated March 19, 20003, received March 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytotec (misoprostol) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revising the PRECAUTIONS and ADVERSE REACTIONS section of the package insert to add information on cardiovascular events.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 19, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alice Kacuba, MSN, RN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Robert Justice
8/13/03 10:35:38 AM