



NDA 19268/S-039

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

Dear Mr. Diaz:

Please refer to your supplemental new drug application dated May 20, 2002, received May 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytotec[®] (misoprostol) Tablets.

We acknowledge receipt of your submission dated February 10, 2003. Your submission of February 10, 2003 constituted a complete response to our September 28, 2000 action letter.

This supplemental new drug application provides for revising the bottle labels to be consistent with the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling text (bottle labels and unit dose carton submitted February 10, 2003 and the unit dose blister submitted May 20, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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, R.N., MSN, 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

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/s/

Robert Justice
8/13/03 10:33:08 AM