



NDA 19-268/S-041

**APPROVAL LETTER**

G.D. Searle LLC  
Attention: Clara Arroccain, M.D.  
Associate Director, WW Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Dr. Arroccain:

Please refer to your supplemental new drug application dated and received March 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytotec® (misoprostol) Tablets.

We acknowledge receipt of your submissions dated June 3, 2009, July 30, 2009, and September 1, 2009. We also reference our emails to you on May 26, 2009, July 15, 2009, and August 18, 2009.

This "Changes Being Effected" supplemental new drug application provides for changes to the PRECAUTIONS and ADVERSE REACTIONS sections of the Package Insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to labeling enclosed and submitted to us September 1, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 19-268."

**PROMOTIONAL MATERIALS**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**LETTERS TO HEALTH CARE PROFESSIONALS**

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  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

**REPORTING REQUIREMENTS**

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D.  
Deputy Director, Safety  
Division of Gastroenterology Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19268	SUPPL-41	GD SEARLE LLC	CYTOTEC (MISOPROSTOL) TABS

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

/s/

JOYCE A KORVICK  
09/11/2009