DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19268-S051

SUPPLEMENT APPROVAL

G.D. Searle LLC
A subsidiary of Pfizer Inc.
Attention: Karen Baker
Director, Pfizer Essential Health
Global Regulatory Affairs Brands
235 East 42nd Street
New York, NY 10017-7555

Dear Ms. Baker:

Please refer to your Supplemental New Drug Application (sNDA) dated February 15, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cytotec (misoprostol).

We also refer to our letter dated January 18, 2018 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Cytotec (misoprostol). This information pertains to the risk of high fevers accompanied by autonomic and central nervous system effects in postpartum hemorrhagic patients managed with Cytotec (misoprostol).

This supplemental new drug application provides for revisions to the labeling for Cytotec (misoprostol), consistent with our January 18, 2018 Safety Labeling Change Notification letter.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions indicated, the enclosed labeling for the package insert with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Benjamin Vali, Regulatory Project Manager, at (301) 796-4261.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Prescribing Information

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
02/28/2018