DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 19-617/S-010

Pfizer Global Pharmaceuticals
Attention: Clara Arrocain
Associate Director
235 East 42nd Street 605/5/14
New York, NY 10017

Dear Ms. Arrocain:

Please refer to your supplemental new drug application dated and received on July 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prepidil® (dinoprostone) Cervical Gel.

We acknowledge receipt of your submissions dated January 15 and February 18, 2009.

This "Changes Being Effected" supplemental new drug application provides for the following changes in the package insert: (1) addition of information regarding disseminated intravascular coagulation (DIC) in the **WARNINGS** section and in the Post-marketing Surveillance subsection of the **ADVERSE REACTIONS** section and (2) addition of information regarding anaphylactoid syndrome of pregnancy in the **WARNINGS** section.

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

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(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. 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 19-617/S-010**." The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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 Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director of Safety
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19617	SUPPL-10	PHARMACIA AND UPJOHN CO	PREPIDIL

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

/s/

AUDREY L GASSMAN
02/12/2010