



NDA 20-411/S-023

Forest Laboratories, Inc.
U.S. Agent for: Controlled Therapeutics (Scotland) Ltd.
Attn: Amjad Iqbal, PharmD.
Sr. Manager, Regulatory Affairs
Harborside Financial Center
Plaza 3, Suite 602
Jersey City, NJ 07311

Dear Dr. Iqbal:

Please refer to your supplemental new drug application dated May 26, 2006, received May 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cervidil® (dinoprostone) 10 mg vaginal insert.

This "Changes Being Effected" supplemental new drug application provides for revisions to the "DESCRIPTION" and "DOSAGE and ADMINISTRATION" sections of the package insert.

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 May 26, 2006.

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

We request that you submit a copy of the May 25, 2006, Dear Health Care Provider letter to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 796-0997.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic 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/

Scott Monroe
11/28/2006 11:09:47 AM