



NDA 020411/S-027

**SUPPLEMENT APPROVAL**

Forest Laboratories, Inc.  
Attention: Maricarmen Raposo  
Senior Associate, Regulatory Affairs  
Harborside Financial Center, Plaza V Suite 1900  
Jersey City, NJ 07311

Dear Ms. Raposo:

Please refer to your Supplemental New Drug Application (sNDA) dated October 24, 2008, received October 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cervidil<sup>®</sup> (dinoprostone) Vaginal Insert 10 mg.

We acknowledge receipt of your submissions dated January 29, and May 3, 2010.

This "Prior Approval" supplemental new drug application provides for changes to the package insert to include: (1) addition of information regarding disseminated intravascular coagulation 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 and (3) changes to the REFERENCES section of the label.

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

We note that your May 3, 2010 submission includes final printed labeling (FPL) for your packet insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for package insert) and include the labeling changes

proposed in any pending “Changes Being Effectuated” (CBE) supplements. 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 from publicly available labeling repositories.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
5600 Fishers Lane  
Rockville, MD 20857

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

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):  
Content of Labeling

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-20411

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SUPPL-27

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CONTROLLED  
THERAPEUTICS  
(SCOTLAND) LTD

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CERVIDIL

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

05/26/2010