



NDA 20-701/S-014

Columbia Laboratories, Inc.
Attention: Susan Withan
Vice President, Regulatory Affairs
354 Eisenhower Parkway
Plaza 1, Second Floor
Livingston, NJ 07039

Dear Ms. Withan:

Please refer to your supplemental new drug applications dated September 22, 2004, received September 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crinone®/ Prochieve® (progesterone gel) 4% and 8%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for editorial changes to the labeling

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-701/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 George Lyght, R.Ph., Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Division Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Daniel A. Shames
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