DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-701/S-011
NDA 20-756/S-012

Columbia Laboratories
Attention: Susan Witham
Vice President Regulatory Affairs
220 S. Orange Avenue
Livingston, NJ 07029

Dear Ms. Witham:

Please refer to your supplemental new drug applications dated November 18, 2002, received November 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crinone® (progesterone gel) 4% and 8%.

These "Changes Being Effected" supplemental new drug applications provide for changes in Serono's address, a change from "distributed by" to "manufactured for", and an update to the pictures to reflect the appearance of the new applicator.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 18, 2002.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-701/S-012 and NDA 20-756/S-011." Approval of these submissions 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 Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
(HFD-580)
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/

Daniel A. Shames
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