DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020701/S-020
NDA 020701/S-021
NDA 020701/S-023

**SUPPLEMENT APPROVAL**

Watson Laboratories, Inc.
Attention: Wendy DeSpain, B.S., M.B.A., R.A.C.
Associate Director, Regulatory Affairs
577 Chipeta Way
Salt Lake City, UT 84108

Dear Ms. DeSpain:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 12, 2007, October 16, 2007 and May 28, 2009, received October 15, 2007, October 17, 2007 and May 29, 2009 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Crinone® (progesterone gel) 4% and 8%.

We acknowledge receipt of your amendments dated April 9, April 10, October 23, October 27, 2008; October 13, 2009; and June 15 and June 16, 2011.

We have completed our review of these supplemental applications, as amended. They are 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 16, 2011, submission containing final printed carton and container labels.

## REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## 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 Kim Shiley, R.N., B.S.N., Regulatory Health Project Manager, at (301) 796-2117.

Sincerely,

*{See appended electronic signature page}*

Christine Nguyen, M.D.
Acting Deputy Director for Safety
Office of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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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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CHRISTINE P NGUYEN
12/08/2011