



NDA 019781/S-022

APPROVAL LETTER

Virtus Pharmaceuticals, LLC
Attention: Timothy E. Wheeler
Vice President, Quality Assurance and Regulatory Affairs
2050 Cabot Blvd. West
Suite 200
Langhorne, PA 19047

Dear Timothy E. Wheeler:

Please refer to your Supplemental New Drug Application (sNDA) dated May 31, 2020, received June 1, 2020, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PROMETRIUM (progesterone, USP).

This “Changes Being Effected in 30 days” supplemental new drug application provides for:

Introduction of a 30-count bottled presentation for PROMETRIUM (progesterone, USP) 100 mg and 200 mg capsules.

- The 30-count presentation for 100 mg PROMETRIUM capsules will be filled into 90-cc HDPE bottles closed with a 38-mm (b) (4) closure (b) (4) (b) (4). This presentation will be labeled with a 36 month expiry.
- The 30-count presentation for 200 mg PROMETRIUM capsules will be filled into 120-cc HDPE bottles closed with a 38-mm (b) (4) closure (b) (4) (b) (4). This presentation will be labeled with a 36 month expiry.

APPROVAL & LABELING

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.

CONTENT OF LABELING

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 prescribing information, and 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 CONTAINER LABELS

Submit final printed carton and container labels that are identical to carton and container labels submitted on August 7, 2020, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 019781/S-022.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jacquelyn Truffer, Regulatory Business Process Manager, at (301) 796 - 4164.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling



David
Lewis

Digitally signed by David Lewis
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