

NDA 021197/S-029

**APPROVAL LETTER**

EMD Serono, Inc.  
Attention: Ruchi Khanna  
Regulatory Lead, Fertility Products, US  
One Technology Place  
Rockland, MA 02370

Dear Ruchi Khanna:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 6, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cetrotide (cetorelix acetate for injection).

This “Changes Being Effected” supplemental new drug application provides for removal of the pH value from the diluent label (1ml prefilled water for injection) and from the US Package Insert (USPI) for Cetrotide

**APPROVAL & LABELING**

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

We note that your June 6, 2023, submission includes final printed labeling (FPL) for your prescribing information. 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 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) 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>.

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/Drugs/GuidanceComplianceRegulatoryInformation/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**

We acknowledge your June 6, 2023, submission containing final printed carton and container labeling.

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 Stephanie Ngan, Regulatory Business Process Manager, at (240) 402 - 5932.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure(s):

Content of Labeling

Carton and Container Labeling

**INSTRUCTIONS FOR ENCLOSURES:**

- **CONTENT OF LABELING (INCLUDING PATIENT LABELING (PPI), MEDGUIDE, & INSTRUCTIONS FOR USE, IF APPLICABLE) – REQUIRED TO BE ATTACHED**
- **CONTAINER & CARTON LABELING – ASSURE THAT C&C ATTACHMENTS ARE CONSISTENT WITH C&C STATEMENTS IN THE LETTER, IF AVAILABLE**



David  
Lewis

Digitally signed by David Lewis

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