

BLA 020604/S-104

SUPPLEMENT APPROVAL

EMD Serono, Inc.
Attention: Marina Carbonari
Associate Director, Global Regulatory Affairs US
200 Pier 4 Blvd., Suite 300
Boston, MA 02210

Dear Marina Carbonari:

Please refer to your supplemental biologics license application (sBLA) received September 23, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Serostim (somatropin) for injection.

This Prior Approval sBLA provides for revised product labeling for Serostim in response to the Notification of "Deemed" BLA letter issued on March 23, 2020, so that the product labeling conforms to labeling requirements for biological products regulated under section 351 of the PHS Act. In addition, this supplement provides for conversion to Pregnancy and Lactation Labeling Rule (PLLR) format.

APPROVAL & LABELING

We have completed our review of this 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,¹ that is identical to the enclosed labeling (text for the Prescribing Information) and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 “**Final Printed Carton and Container Labeling for approved BLA 020604/S-104.**” Approval of this submission by FDA is not required before the labeling is used.

For information on FDA’s compliance policy for requirements related to BLA-specific labeling revisions, see guidance for industry, *The “Deemed to be a License” Provision of the BPCI Act: Questions and Answers*.³

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 supplemental application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

³ Available at: <https://www.fda.gov/media/119274/download>. For the most recent version of a guidance, check the FDA Guidance Documents Database at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, contact Elisabeth Hanan, Chief, Project Management Staff, at 240-402-0350 or Elisabeth.Hanan@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Marina Zemskova, MD
Deputy Director
Division of General Endocrinology
Office of Cardiology, Hematology, Endocrinology,
and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARINA ZEMSKOVA
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