BLA 021765/S-013; S-014; S-044

SUPPLEMENT APPROVALS

EMD Serono, Inc.
Attention: Srinivas Patchala
Director, U.S. Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Mr. Patchala:

Please refer to your supplemental biologic license applications (sBLAs) dated and received July 1, 2011, March 15, 2012, and December 1, 2016, respectively, submitted as supplemental new drug applications (sNDAs) under section 505(b) of the Federal Food, Drug, and Cosmetic Act, and converted on March 23, 2020, to sBLAs under section 351(a) of the Public Health Service Act (PHS Act) for Gonal-f RFF (follitropin alfa for injection), and your amendments. Please also refer to our Notification of "Deemed" BLA letter dated March 23, 2020.

These applications provide for:

1. A Prior Approval supplement to comply with content and format of labeling for human prescription drug and biologic products with the Physician Labeling Rule (PLR) requirements.

2. A "Changes Being Effected" supplement to change the Post-Marketing Experiences section of the Prescribing Information (PI) to include updated safety information consisting of the addition of hypersensitivity and asthma.

3. A "Changes Being Effected" supplement to add thromboembolism under Post-marketing Experience section and update the WARNINGS section to state that thromboembolic events have been reported with Gonal-f products.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

Prescribing Information (PI):

- Correction of 'art' to 'ART'
- Deletion of ','

- Correction of ‘3’ to ‘1’
- Format spaces
- Revision of 7 to 12
- Addition of ‘.’
- Addition of a heading: **Lactation**

Patient labeling with Instructions for Use (IFU)

- Revision of 9 to 12
- Correction of ‘basic’ to ‘dibasic’
- Format spaces

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, Patient Package Insert, and Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effected” (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.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4).

[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.

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).

If you have any questions, call Kim Shiley, R.N., B.S.N., Regulatory Project Manager, at (301) 796-2117.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Director
Division of Urology, Obstetrics and Gynecology
Office of Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use