



BLA 021211/S-027
BLA 021211/S-036
BLA 021211/S-042

SUPPLEMENT APPROVAL

Organon USA Inc., a subsidiary of Merck & Co., Inc.
Attention: Sandra V. Cron
Assoc Principal Scientist, Regulatory Liaison
30 Hudson Street, 33rd Floor
Jersey City, NJ 07302

Dear Ms. Cron:

Please refer to your supplemental biologics license application (sBLA) dated and received December 20, 2018, submitted as a supplemental new drug application (sNDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act, and administratively converted on March 23, 2020, to an sBLA under section 351(a) of the Public Health Service Act (PHS Act) for Follistim AQ Cartridge (follitropin beta) for injection, and your amendments. Please also refer to our Notification of "Deemed" BLA letter dated March 23, 2020.

We also refer to your supplemental biologics license applications (sBLAs) dated and received April 30, 2020, and September 24, 2021, submitted under section 351(a) of the Public Health Service Act for Follistim AQ Cartridge (follitropin beta) for injection.

These Prior Approval supplemental biologics applications provide for:

S-027: Revisions to the Prescribing Information (PI) to comply with the Pregnancy and Lactation Labeling Rule requirements

S-036: Revisions to the carton and container labeling and PI to comply with the FDA Guidance "Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single Dose, and Single-Patient-Use Containers for Human Use"

S-042: Revisions to the carton and container labeling and PI to conform to the labeling requirements for biological products regulated under section 351 of the Public Health Service Act

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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, Patient Package Insert, and Instructions for Use) 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.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (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 021211/S-027**,”

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>.

BLA 021211/S-036 BLA 021211/S-042.” Approval of this submission by FDA is not required before the labeling is used.

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 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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

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If you have any questions, call Samantha Bell, Regulatory Project Manager, at (301) 796-9687.

Sincerely,

{See appended electronic signature page}

Catherine Pilgrim-Grayson, M.D., M.P.H.
Deputy Director for Safety
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
- 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/

CATHERINE A PILGRIM-GRAYSON
03/21/2023 10:13:02 AM