BLA 017692/S-028
BLA 017692/S-036
BLA 017692/S-043

**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 June 23, 2017, 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 Pregnyl (chorionic gonadotropin) 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 Pregnyl (chorionic gonadotropin) for injection.

These Prior Approval supplemental biologics applications provide for:

S-028: Revisions to the Contraindications, Warning, Precaution, and Adverse Events sections of the Prescribing Information (PI)

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-043: 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 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 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.

## 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 this 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 017692/S-028, BLA 017692/S-036, and BLA 017692/S-043**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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 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).

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
Carton and Container Labeling

[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.

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**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.**

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/s/

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CATHERINE A PILGRIM-GRAYSON
03/02/2023 09:05:01 AM