NDA 021057/S-014
NDA 021057/S-017
NDA 021057/S-019
NDA 021057/S-021

SUPPLEMENT APPROVAL

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

Dear Sandra Cron:

Please refer to your supplemental new drug applications (sNDAs) dated and received August 31, 2015; May 29, 2018; February 12, 2019; and November 16, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ganirelix Acetate (ganirelix acetate) Injection.

These sNDAs provide for the following:

S-014: Revisions to Pregnancy subsection of Precautions and Congenital Anomalies subsection of Adverse Reactions

S-017: Revisions to Contraindications, General subsection of Precautions, and How Supplied to include dry natural rubber/latex

S-019: Revisions to Contraindications, General subsection of Precautions to address potential latex allergy

S-021: Revisions to Directions for Using Ganirelix Acetate Injection, under Dosage and Administration regarding air bubbles

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 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 FDA.gov.[1] 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

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 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 NDA (21 CFR 314.80 and 314.81).

[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.

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

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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
08/14/2023 11:19:52 AM