



NDA 021529/S-019
NDA 021529/S-020

SUPPLEMENT APPROVAL

Organon USA Inc., a subsidiary of Merck & Co., Inc
Attention: Shawn Moylan, Director
Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Mr. Moylan:

Please refer to your supplemental new drug applications (sNDAs) dated and received, October 7, and October 31, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexplanon (etonogestrel implant) 68 mg.

This “Changes Being Effected” supplemental new drug application (S-019) and Prior Approval supplemental new drug application (S-020) provide for the following:

- Addition of language to the Post Marketing section, 6.2, of the Prescribing Information (PI) reflecting the results of the Nexplanon Observational Risk Assessment (NORA) study.
- The addition of “cough” and “hemoptysis” to section 6.2, “Postmarketing Experience” and to section 5.1, “Complications of Insertion and Removal” in the PI.
- Updates to section 2, “Dosage and Administration” in the PI.
- The addition of cough and/or the coughing up of blood or blood-stained mucus and a minor editorial update to the Patient Package Insert (PPI).

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 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, Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (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.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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).

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>.

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If you have any questions, call Charlene Williamson, Senior Regulatory Project Manager, at 301-796-1025.

Sincerely,

{See appended electronic signature page}

Christine Nguyen, M.D.
Director (Acting)
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

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/

CHRISTINE P NGUYEN
09/24/2020 02:34:03 PM