DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 016954/S-106

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869

Dear Dr. Nemeth:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 21, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MICRONOR (norethindrone) Tablets.

This Prior Approval supplemental new drug application provides for addition of the following text to the ADVERSE REACTIONS section of the label:

> The following adverse reactions were also reported in clinical trials or during post-marketing experience: Gastrointestinal Disorders: vomiting, abdominal pain; General Disorders and Administration Site Conditions: fatigue, edema; Psychiatric Disorders: depression, nervousness; Musculoskeletal and Connective Tissue Disorders: pain in extremity; Reproductive System and Breast Disorders: genital discharge; breast pain, menstruation delayed, suppressed lactation, vaginal hemorrhage, menorrhagia, withdrawal bleed when product is stopped; Immune System Disorders: anaphylactic/anaphylactoid reaction, hypersensitivity; Hepatobiliary Disorders: hepatitis, jaundice cholestatic; Skin and Subcutaneous Tissue Disorders: alopecia, rash, rash pruritic.

Corresponding language was also added to the patient labeling.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in your submission dated March 21, 2013.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), 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 titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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, 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 NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jennifer Mercier, Chief, Project Management Staff, at (301) 796-0957.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

AUDREY L GASSMAN
06/18/2014