DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017735/S-114
NDA 017919/S-096
NDA 018985/S-060
NDA 019653/S-054
NDA 019697/S-050
NDA 020301/S-034

**SUPPLEMENT APPROVAL**

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

Dear Dr. Nemeth:

Please refer to the following Supplemental New Drug Applications (sNDAs), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA):

| NDA Number | Supplement Number | Product Name | Date of Submission | Date of Receipt |
|---|---|---|---|---|
| 017735 | 114 | MODICON (norethindrone/ethinyl estradiol) | October 26, 2011 | October 26, 2011 |
| 017919 | 096 | ORTHO NOVUM (norethindrone/ethinyl estradiol) | October 26, 2011 | October 26, 2011 |
| 018985 | 060 | ORTHO NOVUM (norethindrone/ethinyl estradiol) | October 26, 2011 | October 26, 2011 |
| 019653 | 054 | ORTHO-CYCLEN (norgestimate/ethinyl estradiol) | October 25, 2011 | October 25, 2011 |
| 019697 | 050 | ORTHO TRI-CYCLEN (norgestimate/ethinyl estradiol) | October 25, 2011 | October 25, 2011 |
| 020301 | 034 | ORTHO-CEPT (desogestrel/ethinyl estradiol) | October 21, 2011 | October 21, 2011 |

We acknowledge receipt of your amendments dated October 2, 2013.

These "Prior Approval" supplemental new drug applications propose changes to the Boxed Warning, WARNINGS section and PRECAUTIONS: Drug Interactions subsection. The changes update these sections to be consistent with labeling of ORTHO EVRA.

## APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended.

## 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 agreed upon labeling, 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 numbers and annual report dates.

## 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 applications, 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 Pamela Lucarelli, Regulatory Health Project Manager, at (301) 796-3961.

Sincerely,

*{See appended electronic signature page}*

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

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

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/s/

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AUDREY L GASSMAN
10/02/2013