DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017735/S-108
NDA 017919/S-090
NDA 018985/S-054
NDA 019653/S-049
NDA 019697/S-045
NDA 020301/S-028

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	108	MODICON (norethindrone/ethinyl estradiol)	April 17, 2009	April 17, 2009
017919	090	ORTHO NOVUM (norethindrone/ethinyl estradiol)	April 17, 2009	April 17, 2009
018985	054	ORTHO NOVUM (norethindrone/ethinyl estradiol)	April 17, 2009	April 17, 2009
019653	049	ORTHO-CYCLEN (norgestimate/ethinyl estradiol)	April 17, 2009	April 17, 2009
019697	045	ORTHO TRI-CYCLEN (norgestimate/ethinyl estradiol)	April 17, 2009	April 17, 2009
020301	028	ORTHO-CEPT (desogestrel/ethinyl estradiol)	May 11, 2009	May 11, 2009

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

These "Prior Approval" supplemental new drug applications propose changes to the CONTRAINDICATIONS and WARNINGS: Elevated Blood Pressure, subsection. The changes reflect additional specification regarding use of the product in women with hypertension.

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

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
10/02/2013