



NDA 017735/S-104  
NDA 017919/S-086  
NDA 018985/S-050  
NDA 019653/S-046  
NDA 019697/S-042  
NDA 020301/S-025

**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):

<b>NDA Number</b>	<b>Supplement Number</b>	<b>Product Name</b>	<b>Date of Submission</b>	<b>Date of Receipt</b>
017735	104	MODICON (norethindrone/ethinyl estradiol)	May 24, 2012	May 25, 2012
017919	086	ORTHO NOVUM (norethindrone/ethinyl estradiol)	May 24, 2012	May 25, 2012
018985	050	ORTHO NOVUM (norethindrone/ethinyl estradiol)	May 24, 2012	May 25, 2012
019653	046	ORTHO-CYCLEN (norgestimate/ethinyl estradiol)	May 24, 2012	May 25, 2012
019697	042	ORTHO TRI-CYCLEN (norgestimate/ethinyl estradiol)	May 24, 2012	May 25, 2012
020301	025	ORTHO-CEPT (desogestrel/ethinyl estradiol)	May 30, 2012	May 30, 2012

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

These amendments constitute a complete response to our action letters below:

<b>NDA Number</b>	<b>Supplement Number</b>	<b>Date of Complete Response Letter</b>
NDA 017735	104	May 6, 2008
NDA 017919	086	May 6, 2008
NDA 018985	050	May 6, 2008
NDA 019653	046	June 6, 2008
NDA 019697	042	June 6, 2008
NDA 020301	025	May 14, 2008

### **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 in the enclosed, agreed-upon labeling text.

### **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, 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.

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### **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

Enclosures:  
Content of Labeling

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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  
10/03/2013