



NDA 22187/S-11  
NDA 22187/S-12  
NDA 22187/S-14

**SUPPLEMENT APPROVAL**

Janssen Research & Development, LLC  
Attention: Nancy V. Nair, PharmD, M.B.A.  
Associate Director, Global Regulatory Affairs  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560

Dear Dr. Nair:

Please refer to your Supplemental New Drug Applications (sNDAs) dated August 24, 2012 (supplement 11), August 29, 2012 (supplement 12) and December 17, 2012, (supplement 14), received August 27, 2012, August 29, 2012 and December 17, 2012 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Intelence® (etravirine) 200 mg, 100 mg, 25 mg tablets.

We acknowledge receipt of your amendments dated as follows

<u>sNDA 22187/S-11</u>	January 25, 2013	February 8, 2013
<u>sNDA 22187/S-12</u>	January 24, 2013	February 8, 2013
<u>sNDA 22187/S-14</u>	January 24, 2013	February 8, 2013

These Prior Approval supplemental new drug applications propose the following changes:

**sNDA 22187/S-11**

1. To update DRUG INTERACTIONS, Table 3 and CLINICAL PHARMACOLOGY, Table 5 and Table 6 with information regarding coadministration of etravirine with artemether/lumefantrine or telaprevir.
2. To update the patient package insert's "**What should I tell my doctor before taking INTELENCE®?**", section with information regarding artemether/lumefantrine .

**sNDA 22187-S-12**

3. To update ADVERSE REACTIONS, Clinical Trials Experience: Adults section of the package insert with information regarding the occurrence of rash in men versus women.

4. To update ADVERSE REACTIONS, Clinical Trials Experience: Pediatric Subjects (6 years to less than 18 years of age) section of the package insert with safety information regarding the occurrence of rash.

**sNDA 22187/S-14**

5. To update the WARNINGS AND PRECAUTIONS, Severe Skin and Hypersensitivity Reactions and ADVERSE REACTIONS, Postmarketing Experience sections of the package insert with information regarding Drug Rash with Eosinophilia and Systemic Symptoms (DRESS).

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 (text for the package insert and 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).

**PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

**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 Mammah Sia Borbor, M.S., M.B.A., Regulatory Project Manager, at (301) 796-7731 or (301) 796-1500.

Sincerely,

*{See appended electronic signature page}*

Kendall Marcus, M.D.  
Associate Director of Safety  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
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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KENDALL A MARCUS  
02/27/2013