



NDA 020229/S-034

SUPPLEMENT APPROVAL

Janssen Products, LP
Attention: Melissa L. Gannon
Director, Global Regulatory Affairs
920 U.S. Highway 202
P.O. Box 300
Raritan NJ 08869-0602

Dear Ms. Gannon:

Please refer to your Supplemental New Drug Application (sNDA) dated February 24, 2012, received February 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Leustatin[®] (cladribine) Injection, 1.0 mg/mL.

We acknowledge receipt of your amendments dated June 1, 2012, and July 17, 2012. The February 24, 2012, submission constituted a complete response to our April 8, 2011, action letter.

This “Prior Approval” supplemental new drug application provides for revisions to the Package Insert to ensure consistency with the data in COBPLP’s global safety database, which includes updates to the Adverse Reactions, Pregnancy Category & Impairment of Fertility, Warnings, Postmarketing Experience, and Dosage & Administration sections.

We have completed our review of this supplemental application, as amended. It is 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(1)] 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), 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 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).

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 Theresa Ferrara, Regulatory Project Manager, at (301) 796-2848.

Sincerely,

{See appended electronic signature page}

Edvardas Kaminskas, MD
Deputy Division Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

EDVARDAS KAMINSKAS
08/02/2012