DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050718/S-048

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Janssen Products, LP
c/o Janssen Research & Development, LCC
Attention: Matthew Scurato
Associate Director, Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869

Dear Mr. Scurato

Please refer to your Supplemental New Drug Application (sNDA) dated November 4, 2015, received November 4, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DOXIL® (doxorubicin HCl liposome injection), 20 mg/10 mL and 50 mg/25 mL.

We acknowledge receipt of your amendments dated February 4, and March 10 and 25, 2015.

This "Prior Approval" supplemental new drug application provides updates to the CLINICAL STUDIES section of the United States Prescribing Information based on the final study report for DOXIL Study MMY-3001 entitled "*A Randomized Controlled Study of DOXIL/CAELYX (doxorubicin HCL liposome injection) and VELCADE (bortezomib) or VELCADE Monotherapy for the Treatment of Relapsed Multiple Myeloma*." In addition, the DOSAGE AND ADMINISTRATION and HOW SUPPLIED sections of the label revised to reflect the current language for handling cytotoxic agents.

APPROVAL & LABELING

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(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), 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).

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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated November 4, 2014, containing the final report for the following postmarketing commitment listed in the May 17, 2007, approval letter.

We have reviewed your submission and conclude that the above commitment was fulfilled.

PMC 261-1 To continue follow-up of safety and efficacy on clinical study MMY-3001 and to submit the final survival data and analysis as well as an updated clinical study report after at least 80% of events have occurred.

Protocol submission:	August 13, 2004
Study start:	December 20, 2004
Final Report Submission:	December 2011

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our May 17, 2007, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, please call Kimberly Scott, Regulatory Project Manager, at (240) 402-4560.

Sincerely,
{See appended electronic signature page}

Robert C. Kane, MD
Deputy Director for Safety
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/

ROBERT C KANE
04/16/2015