



NDA 50467/S-073

**SUPPLEMENT APPROVAL**

Pharmacia & Upjohn Company  
Attention: Tricia Racanelli  
Director  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Dr. Racanelli:

Please refer to your Supplemental New Drug Application (sNDA) dated June 28, 2012, received June 28, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for "Doxorubicin Hydrochloride for Injection, 10 mg, 20 mg, 50 mg, or 150 mg."

We acknowledge receipt of your amendments dated July 3 and October 12, 2012, and March 7, April 30, May 10, June 25, July 3, July 23, July 31, August 7, October 11, October 22, October 25, October 28, and October 30, 2013.

This "Prior Approval" supplemental new drug application provides for revisions to the package insert to conform to the requirements of content and format of labeling as described at 21 CFR 201.56 and 201.57 and to include new clinical pharmacology information on drug interactions in product 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 (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).

### **CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your amendment dated July 23, 2013, in which you confirmed that Doxorubicin Hydrochloride for Injection has not been marketed since 2003. As stated in your October 11, 2013 amendment, if you decide to reintroduce Doxorubicin Hydrochloride for Injection to the U.S. market, you will submit a supplement containing updated carton and container labeling as well as data that support the specified expiry dating period for this product at least 60 days prior to the planned reintroduction. The proposed carton and container labeling are to include modifications consistent with that for carton and container labeling approved under your NDA 50629 for Doxorubicin Hydrochloride Injection.

### **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 application, you are exempt from this requirement.

### **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/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. 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, call Mona Patel, Regulatory Project Manager, at (301) 796-4236.

Sincerely,

*{See appended electronic signature page}*

Patricia Keegan, M.D.  
Director  
Division of Oncology Products 2  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
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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PATRICIA KEEGAN  
10/31/2013