



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

NDA 050731/S-008

**SUPPLEMENT APPROVAL**

West-ward Pharmaceuticals International Limited  
c/o Westward Pharmaceutical Corporation  
Attention: J. Kalis  
Sr. Director, Regulatory Affairs  
2 Esterbrook Lane, West-ward Pharmaceuticals Corp. C/o  
Cherry Hill, NJ 08003-4099

Dear Mr. Kalis:

Please refer to your Supplemental New Drug Application (sNDA) dated December 30, 2015, received December 30, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Daunorubicin Hydrochloride Injection.

We acknowledge receipt of your amendment dated November 2, 2017, which constituted a complete response to our March 30, 2016, action letter.

*We also refer to our approval letter dated January 2, 2018, which contained the following error:*

- *The letter did not include the approved carton and container labels and the content of labeling.*

*This replacement approval letter incorporates the correction of the error. The effective approval date will remain January 2, 2018, the date of the original approval letter.*

This Prior Approval supplemental new drug application provides for the transfer of drug product manufacturing as well as (b) (4) final product release and stability testing functions to Thymoorgan Pharmazie GmbH, Lower Saxony, Germany, (FEI 3002320821).

**APPROVAL & LABELING**

We have completed our review of this supplemental application. 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 prescribing information) 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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**

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 050731/S-008.**” Approval of this submission by FDA is not required before the labeling is used.

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 Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Chief, Branch I  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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