



ANDA 071484/S-042

**SUPPLEMENT APPROVAL**

Hospira, Inc.  
275 North Field Drive  
Lake Forest, IL 60045

Attention: Felice Sommerfield  
Sr. Associate, Global Regulatory Affairs

Dear Ms. Sommerfield:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated and received January 28, 2014, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vincristine Sulfate Injection USP, 1 mg/mL and 2 mg/2 mL vials.

This “Changes Being Effected” sANDA provides for revision of the insert labeling to align with the request made in the Agency’s correspondence dated May 7, 2013 in the approval letter for S-041.

We have completed the review of this supplemental application and it is approved, effective on the date of this letter.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files. If you have any questions, contact Surjit Basi, Regulatory Project Manager, at (240) 402-8892 or [surjit.basi@fda.hhs.gov](mailto:surjit.basi@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Koung Lee, RPh, MSHS  
Acting Director  
Division of Labeling Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

Attachment: 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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08/05/2014  
for Koung Lee