



NDA 021991/S-008

**SUPPLEMENT APPROVAL**

Merck Sharp and Dohme Corp  
Attention: Daria Flynn  
Associate Director, Global Regulatory Affairs  
351 North Sumneytown Pike  
PO Box 1000, UG2C 50  
North Wales, PA 194541099

Dear Ms. Flynn:

Please refer to your Supplemental New Drug Application (sNDA) dated June 19, 2015, received June 19, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZOLINZA<sup>®</sup> (Vorinostat) capsule, 100 mg.

This “Prior Approval” supplemental new drug application provides for a revised Patient Package Insert (PPI) with revised text aimed at improving patient comprehension and formatting revisions to the prescribing information (PI).

**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 and with minor editorial revisions.

Per the Physician’s Labeling Rule Guidance, the word “see” in cross references should be lower case. “The preferred presentation of cross-references in Highlights is the numerical identifier in parentheses following the summarized labeling information (e.g., (5.1)). **The preferred presentation of cross-references in the FPI is the section heading followed by the numerical identifier (e.g., [see Warnings and Precautions (5.1)].**”

All instances of the word “see” in the cross-references have been changed back to lower case throughout the label.

**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, text for the patient 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 none of these criteria apply to your application, you are exempt from this requirement.

### **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 Janet G. Higgins, Regulatory Project Manager, at (240) 402-0330.

Sincerely,

*{See appended electronic signature page}*

Ann T. Farrell, MD  
Director  
Division of Hematology Products  
Office of Hematology Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
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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ANN T FARRELL  
12/17/2015