DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22393/S-006

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Celgene Corporation
Attention: Jean Nichols, Ph.D.
Corporate VP, Global Leadership - Romidepsin
86 Morris Avenue
Summit, NJ 07901

Dear Dr. Nichols:

Please refer to your Supplemental New Drug Application (sNDA) dated March 31, 2011, received March 31, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Istodax® (romidepsin) for Injection.

We acknowledge receipt of your amendments dated June 30, and August 18, and September 20 and 28, 2011.

This Prior Approval supplemental new drug application proposes revisions to labeling and patient package insert that incorporates information related to postmarketing requirements (PMR 1556-1 and PMR 1556-8).

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, 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 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).

POSTMARKETING REQUIREMENTS:

We have received your submission dated March 31, 2011 containing the final reports for the following postmarketing requirements listed in the November 5, 2009 approval letter

PMR 1556-1: Conduct a GLP embryo-fetal developmental reproductive toxicology study in rats to assess the embryo-fetal toxicity of romidepsin. The results from the rat study will determine if a study in a second species is warranted.

The timetable you submitted on October 14, 2009, states that you will conduct this study according to the following timetable:

Final Protocol Submission:	July 31, 2010
Study Completion Date:	November 30, 2010
Final Report Submission:	June 30, 2011

PMR 1556-8: Perform trial GPI-06-0005 with adequate number of subjects to determine the potential of ISTODAX to prolong QT. The final analysis plan for the previously submitted protocol GPI-06-0005 will be provided. Exposure-response, central tendency and outlier analyses will be included in the final report.

The timetable you submitted on October 27, 2009, states that you will conduct this trial according to the following timetable:

Final Analysis Plan Submission:	February 28, 2010
Trial Completion Date:	August 31, 2010
Final Report Submission:	March 31, 2011

We have reviewed your submission and conclude that the above requirements were fulfilled. We remind you that there are postmarketing requirements and postmarketing commitments listed in the June 16, 2011 and November 05, 2009 approval letters that are still open.

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications (DDMAC), 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 Marcus Cato, Regulatory Project Manager, at (301) 796-3903.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S): 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/

ANN T FARRELL
09/30/2011