



BLA 125019/213
BLA 125019/210

SUPPLEMENT APPROVAL

Spectrum Pharmaceuticals, Inc.
Attention: Anil K. Hiteshi, RAC
Vice President, Global Regulatory Affairs
157 Technology Drive
Irvine, CA 92618

Dear Mr. Hiteshi:

Please refer to your Supplemental Biologics License Application (sBLA), dated February 28, 2013, received March 1, 2013, submitted under section 351(a) of the Public Health Service Act for Zevalin[®] (irbritumomab tiuxetan).

We acknowledge receipt of your amendments dated August 1 and 16, 2013.

This Prior Approval supplemental biologics application provides for updates to the prescribing information (PI) based on the safety data presented in the final postmarketing commitment report for trial SAG 304820/307722.

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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT and COMMITMENT

We have received your submissions dated August 14, 2012 and February 28, 2013 containing the final reports for the following postmarketing requirement and commitment listed in the September 3, 2009 approval letter for BLA 125019/156.

PMR 125019/156-1

Continue the long-term monitoring of subjects enrolled in the SAG 304820 clinical trial to determine the incidence of myelodysplastic syndrome (MDS), acute myelogenous leukemia (AML) and other secondary cancers. We acknowledge your August 18, 2008, submission to STN BL 125019/151 which contained pre-BLA meeting briefing material, including the final protocol for SAG 304820. The timetable you submitted on May 5, 2009, states that you will conduct this trial according to the following timetable:

| | |
|--------------------------|--------------------------------|
| Interim Report: | By August 15, 2009, 2010, 2011 |
| Final Report Submission: | By August 15, 2012 |

PMC 125019/156-2

Submit the results of the final analysis of overall survival (OS) from trial SAG 304820, entitled "Efficacy and safety of subsequent treatment with 90-ibritumomab triuxetan versus no further treatment in patients with stage III or IV follicular NHL having achieved a partial or complete remission after first-line chemotherapy. A prospective, multicenter, randomized, phase III clinical trial." The report will include both the analysis results and the primary datasets used to generate the final analysis in electronic, SAS-compatible format. The timetable you submitted on May 5, 2009, states that you will conduct this trial according to the following timetable:

| | |
|-------------------|----------------------|
| Trial Completion: | By February 28, 2012 |
| Final Report: | By February 28, 2013 |

We have reviewed your submission and conclude that the above requirement and commitment were fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our September 3, 2009, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see 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 BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, please contact Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-8493.

Sincerely,

{See appended electronic signature page}

Robert C. Kane, M.D.
Deputy Director for Safety
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

ROBERT C KANE
08/30/2013