



BLA 125011/126

Glaxo Group Limited d/b/a GlaxoSmithKline
ATTENTION: Philip A. Witman, M.P.H.
P.O. Box 5089
1250 South Collegeville Road
Collegeville, PA 19426

**SUPPLEMENT BLA APPROVAL
RELEASE FROM POSTMARKETING
REQUIREMENT/COMMITMENT**

Dear Mr. Witman:

Please refer to your Supplemental Biologics License Application (sBLA) dated April 23, 2012, received April 23, 2012, submitted under section 351 of the Public Health Service Act for Bexxar (tositumomab and iodine I-131 tositumomab).

We acknowledge receipt of your amendments dated May 9 (2), May 15, June 4, June 25 and July 5, 2012.

This "Prior Approval" labeling supplement to your biologics license application proposes to revise the package insert by removing the indication for patients with relapsed or refractory, low grade, follicular or transformed CD20 positive non-Hodgkin's lymphoma who have not received Rituximab that was approved under the regulations at 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses under STN 125011/24 on December 22, 2004.

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.

We note that the following requirement to confirm clinical benefit was a condition of the accelerated approval:

PMC #1: To conduct an open-label efficacy trial of Rituximab versus the Bexxar therapeutic regimen in patients with lymphoma who have received at least one, and no more than two, prior chemotherapy regimens, and who are appropriate candidates for systemic therapy (Study CCBX001-049). The primary objective of this study was demonstration of a longer event-free survival in patients treated with the Bexxar therapeutic regimen as compared to those receiving Rituximab.

You are released from the above requirement as the postmarketing commitment is no longer applicable because the Rituxan-naïve indication has been withdrawn from the label.

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 Effected” (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>. For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 125011/126.**”

Also within 14 days, amend all pending supplemental applications 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.

The SPL will be accessible via publicly available labeling repositories.

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.

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
Division of Professional 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 Division of Professional Promotion, 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, call Vaishali Jarral, Regulatory Project Manager, at (301) 796-4248.

Sincerely,

{See appended electronic signature page}

Joseph Gootenberg, M.D.
Deputy Director
Division of Oncology Products 2
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/

JOSEPH E GOOTENBERG
08/15/2012