



BLA 103705/S-5458

## **SUPPLEMENT APPROVAL**

Genentech, Inc.  
Attention: Gigi Lee  
Regulatory Program Management  
1 DNA Way  
South San Francisco, CA 94080-4990

Dear Ms. Lee:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received October 30, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for Rituxan (rituximab).

This “Changes Being Effected” supplemental biologics license application provides for the introduction of a new packaging configuration of 10 vials per carton for the 100 mg/10 mL vial presentation. The Applicant also updated the one count carton as follows: “single-use” changed to “single-dose”, updated storage statement, alphabetizing the inactive ingredients, and adding strength per total volume in the “Contents” listing.

### **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 agreed-upon labeling text enclosed.

### **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 prescribing information) 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>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 103705/S-5458.**” Approval of this submission by FDA is not required before the labeling is used.

### **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 BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Kelly Ballard, Senior Regulatory Business Process Manager, at (301) 348 - 3054.

Sincerely,

*{See appended electronic signature page}*

Kathleen A. Clouse, Ph.D.  
Director  
Division of Biotechnology Review and Research I  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Prescribing Information  
Carton and Container Labeling



Kathleen  
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel  
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