BLA 103792/S-5349

SUPPLEMENT APPROVAL

Genentech Inc
Attention: Lorraine Gorrey, Ph.D.
Assistant Director
1 DNA Way
South San Francisco, CA 94080-4900

Dear Dr. Gorrey:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received April 1, 2020, submitted under section 351(a) of the Public Health Service Act for Herceptin (trastuzumab) for injection.

This "Changes Being Effected" supplemental biologics license application provides for the addition of a 10-count carton packaging configuration for the 150 mg/vial strength presentation.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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 (instructions for use) 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

We acknowledge your April 1, 2020, submission containing final printed carton and container labels.

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 Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Wendy Weinberg, Ph.D. for
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

Enclosure(s):
Carton Labeling

Wendy Weinberg

Digitally signed by Wendy Weinberg
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