BLA 761105/S-009 & S-010

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Mary Konkowski
Director, Regulatory Strategy
1 N. Waukegan Road
Dept. PA72 Bldg. AP30-4
North Chicago, IL 60064

Dear Ms. Konkowski:

Please refer to your supplemental biologics license applications (sBLA) dated and received June 26 and July 27, 2020 respectively, and your amendments, submitted under section 351(a) of the Public Health Service Act for Skyrizi (risankizumab-rzaa) injection.

This Prior Approval supplemental biologics application provides for a change to a new 150 mg/mL formulation and product presentation (pre-filled syringe with needle stick prevention) in S-009. The purpose of the supplemental BLA (sBLA) S-010 is to propose a new autoinjector product presentation using the 150 mg/mL formulation.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on March 19, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761105/S-009 and S-010**." 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 (which includes new salts and new fixed combinations), 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.

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

1) For your AutoInjector, you state that the user needs to be able to determine if the dose was administered successfully, and therefore designed your combination product to indicate by auditory means to the user, that the injection process is complete. However, there is no specific acceptance criteria or related after-assembly release testing for this audible feedback (click sound volume, timing, correlation with dose delivery) function of your device to ensure that the quality of this attribute as designed is effectively and reliability maintained. Your intended user may solely rely on the audible feedback to indicate end of injection; therefore either,

    a) Implement and validate component inspection criteria specific to those design dimensions which are critical to maintain that the "hammers" of the control unit disengage at the stated fixed nominal distance relative to the end of the syringe barrel in order to achieve no more than (b) (4) mL at the time of the audible click. In addition, implement and validate component inspection criteria for those design dimensions which are responsible for the audible click volume.

Or

    b) Implement and provide verification testing of design input requirements and assembly release testing for your audible click volume (i.e., decibels) and timing (+/- seconds from end of injection) or residual volume after click (delivered volume remaining in device after audible click.

The timetable you submitted on April 21, 2021, states that you will conduct this study according to the following schedule:

Final Report Submission: 11/2021

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication,

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 Craig Johnson, Regulatory Project Manager, at 301-796-3921.

Sincerely,

{See appended electronic signature page}

Shari L. Targum, MD, MPH, FACP, FACC
Deputy Director
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SHARI L TARGUM
04/26/2021 05:34:15 PM