DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nikkolette Hill, PharmD
Head of Regulatory Affairs, U.S. Advertising and Promotion
AbbVie, Inc.
1 N. Waukegan Road, Dept. PA95, Bldg. ABV1
North Chicago, IL 60064

RE: BLA 761105; 761262
SKYRIZI® (risankizumab-rzaa) injection, for subcutaneous or intravenous use
MA 2876; 1060

Dear Dr. Hill:

The Food and Drug Administration has completed evaluation of your response to our Untitled Letter dated September 9, 2025. After the review of the actions taken by AbbVie, Inc. (AbbVie) upon receipt of the Untitled Letter, along with the information submitted by AbbVie, OPDP believes that the concerns cited in our Untitled Letter dated September 9, 2025 have been addressed.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during subsequent surveillance or through other means.

If you have any questions or comments, please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 2876 and MA 1060 in addition to the BLA numbers in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format.

All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 7979 under BLA 761105 and eCTD Sequence 5979 under BLA 761262. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Quynh-Nhu Capasso, PharmD
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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/

QUYNH-NHU D CAPASSO
02/13/2026 11:05:37 AM