BLA 125504/S-084

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Ashley Brower
Global Program Regulatory Director
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Brower:

Please refer to your supplemental biologics license application (sBLA) dated and received September 25, 2024, submitted under section 351(a) of the Public Health Service Act for Cosentyx (secukinumab) injection.

This "Changes Being Effected" sBLA provides for changes in Section 2 [Dosage and Administration (2.11)] of the Prescribing Information to revise the storage instructions for the 125 mg/5 mL single-dose vial and the diluted solution once removed from refrigerated storage conditions and to revise instructions for the flushing volume when administration is complete.

APPROVAL & LABELING

We have completed our review of this sBLA. 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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.

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}

Ashutosh Rao, Ph.D.
Director
Division of Product Quality Assessment XIV
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Content of Labeling

Ashutosh Rao

Digitally signed by Ashutosh Rao
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