

BLA 125319/S-110

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Jake Myhill, PharmD, MBA
Senior Global Program Regulatory Manager
Regulatory Affairs, Immunology
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Myhill:

Please refer to your supplemental biologics license application (sBLA), dated and received September 18, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Ilaris (canakinumab).

We also refer to our letter dated July 26, 2024, notifying you, under Section 505(o)(4) of the Food Drug and Cosmetic Act (FDCA), of new safety information that we have determined should be included in the labeling for Ilaris (canakinumab). This information pertains to the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) with Ilaris (canakinumab).

This supplemental biologics license application provides for revisions to the labeling for Ilaris (canakinumab). The agreed upon changes to the language included in our July 26, 2024, safety labeling change notification letter are as follows (additions are noted by underline and deletion are noted by ~~striketrough~~).

WARNINGS AND PRECAUTIONS

In the WARNINGS AND PRECAUTIONS section, revise 5.3 Hypersensitivity subsection title and language as follows:

Hypersensitivity Reactions

Hypersensitivity reactions have been reported with ILARIS. During clinical trials, no anaphylactic reactions attributable to treatment with canakinumab have been reported. It should be recognized that symptoms of the underlying disease being treated may be similar to symptoms of hypersensitivity [see *Adverse Reactions (6.1)*]. ^{(b) (4)} Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), characterized by serious skin eruptions, has been reported in patients with autoinflammatory conditions treated with ILARIS. If a severe hypersensitivity reaction occurs, immediately discontinue ILARIS; treat promptly and monitor until signs and symptoms resolve.

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 and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

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.

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 supplement application, you are exempt from this requirement.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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>.

PROMOTIONAL MATERIALS

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.³ Information and Instructions for completing the form can be found at FDA.gov.⁴

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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, contact June Germain, Senior Regulatory Project Manager, at june.germain@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Hyon Kwon, Pharm.D., M.P.H.
Deputy Director for Safety
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
 - Prescribing Information
 - Medication Guide

³ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁴ <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/

HYON J KWON
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