NDA 220149

NDA APPROVAL

Janssen Biotech, Inc.
Attention: Jenna Giacchi, MS
Associate Director, Global Regulatory Affairs, Immunology
Welsh and McKean Roads, P.O. Box 776
Spring House, PA 19477

Dear Jenna Giacchi:

Please refer to your new drug application (NDA) received July 18, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Icotyde (icotrokinra) tablets.

This NDA provides for the use of Icotyde (icotrokinra) tablets for treatment of moderate-to-severe plaque psoriasis (PsO) in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. 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.

[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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on December 23, 2025, March 13, 2026, and March 16, 2026 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 *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 220149**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Icotyde (icotrokinra) tablets shall be 24 months from the date of manufacture when stored at 20 °C to 25 °C (68 °F to 77 °F).

ADVISORY COMMITTEE

Your application for Icotyde was not referred to an FDA advisory committee because outside expertise was not necessary; there were no issues that would benefit from advisory committee discussion.

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages 0 to <4 years because necessary studies are impossible or highly impracticable. This is because the number of such pediatric patients is so small or geographically dispersed and treatment algorithm recommends topical treatments as first line therapy.

We are deferring submission of your pediatric study for ages 4 to less than 12 years for this application because this product is ready for approval for use in adults and pediatric patients 12 years of age and older.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this/these postmarketing study(ies) must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act/FDCA. This required study is listed below.

4964-1 Conduct a trial to evaluate the safety and pharmacokinetics of icotrokinra in pediatric subjects 4 years to less than 12 years of age with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy. Evaluate a sufficient number of subjects exposed to icotrokinra at the highest proposed dosage for a minimum of 26 weeks to evaluate for safety and pharmacokinetics of icotrokinra in pediatric subjects 4 years to less than 12 years of age with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy.

Draft Protocol Submission:	10/2026
Final Protocol Submission:	03/2027
Study Completion:	03/2030
Final Report Submission:	09/2030

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 156446, with a cross-reference letter to this NDA. Reports of this required pediatric postmarketing study must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify an unexpected serious risk in subjects who are pregnant or lactating.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess this serious risk.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

4964-2 Conduct a worldwide, as applicable, descriptive study that collects prospective and retrospective data in women exposed to Icotyde (icotrokinra) during pregnancy to assess risk of pregnancy and maternal complications, and adverse effects on the developing fetus, neonate, and infant. Assess infant outcomes up to the first year of life. The minimum number of patients will be specified in the protocol.

The timetable you submitted on March 10, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	12/2026
Final Protocol Submission:	06/2027
Study Completion:	03/2037
Final Report Submission:	09/2037

4964-3 Perform a lactation study in lactating women who have received icotrokinra to measure concentrations of icotrokinra in breast milk using a validated assay. Assess the effects on the breastfed infant, if available, based on study population.

The timetable you submitted on March 10, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	09/2026
Final Protocol Submission:	03/2027
Study Completion:	03/2029
Final Report Submission:	09/2029

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[4]

Submit clinical protocol(s) to your IND 156446 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o), REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o), REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o).**

Submission of the protocol(s) for required postmarketing observational studies to your IND is for purposes of administrative tracking only. These studies do not constitute

[4] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

clinical investigations pursuant to 21 CFR 312.3(b) and therefore are not subject to the IND requirements under 21 CFR part 312.

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

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.*[5]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[6] Information and Instructions for completing the form can be found at FDA.gov.[7]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[5] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[7] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

REQUESTED ENHANCED PHARMACOVIGILANCE (EPV)

We request that for Icotyde you submit all serious and non-serious domestic and/or foreign cases of gastrointestinal (GI) bleeding (including, but not limited to, upper GI hemorrhage, lower GI hemorrhage, GI perforation, and GI ulceration) and related adverse events as 15-day "Alert reports" (described under 21 CFR 314.80(c)(1)) through the 5th year following initial U.S. approval date.

As described in 21 CFR 314.80(c)(1)(ii), we request that you promptly investigate all 15-day Alert reports of GI bleeding and related adverse events within 15 calendar days of receipt of new information.

We also request that you provide a narrative summary including analysis of GI bleeding and related adverse events as part of your required periodic safety reports [e.g., periodic adverse drug experience report (PADER) required under 21 CFR 314.80(c)(2)], quarterly during the first 3 years post-approval and annually thereafter, through the 5th year following initial U.S. approval date.

Your analysis should include interval and cumulative data relative to the date of approval of Icotyde. Your analysis should provide an assessment of causality. Include documentation of indication, temporal association, dosage and duration of Icotyde therapy, concomitant medications (including dosage, duration, and indication when available) and other potential confounders, associated signs and symptoms, underlying risk factors, social history (e.g., tobacco use, alcohol use), patient characteristics (such as age, sex, race), treatment given for the event, outcome, and dechallenge/rechallenge. We also request you include interval and cumulative drug utilization information.

To identify cases of GI bleeding, we request that you use the following search strategy, including, but not limited to, the Medical Dictionary for Medical Activities (MedDRA) Preferred Terms (PTs) within the following Standardised MedDRA Queries (SMQs):

Broad SMQ *Gastrointestinal hemorrhage*
Broad SMQ *Gastrointestinal perforation*
Broad SMQ *Gastrointestinal ulceration*

POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[8].

If you have any questions, contact Tina Whang, Regulatory Project Manager, at tina.whang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nikolay Nikolov, MD
Office Director
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

[8] https://www.uspnf.com/

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/

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