



NDA 218764/S-002

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
COMMITMENT**

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Lorraine Sachs, M.S., RAC
Director, Regulatory Affairs
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877

Dear Lorraine Sachs:

Please refer to your supplemental new drug application (sNDA) dated March 16, 2026, received March 16, 2026, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Jascayd (nerandomilast) tablets.

This Prior Approval sNDA provides for revisions to the DOSAGE AND ADMINISTRATION, DRUG INTERACTIONS, and CLINICAL PHARMACOLOGY sections of the Prescribing Information based on two drug-drug interaction (DDI) clinical trials, Trial 1305-0113 and Trial 1305-0119 supporting PMC 4912-02.

APPROVAL & LABELING

We have completed our review of this application. 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, Patient Package Insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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).

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.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated March 16, 2026, containing the final reports for the following postmarketing commitment listed in the October 7, 2025, approval letter.

- 4912-2 Conduct DDI clinical trials to assess the magnitude of change in nerandomilast exposure with repeat doses of a moderate CYP3A inducer and a strong CYP3A inducer to determine appropriate dosing recommendations with CYP3A inducers. Conduct the trials in accordance with the FDA Guidance for Industry entitled "M12 Drug Interaction Studies."

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there is a postmarketing commitment listed in the October 7, 2025, approval letter that is still open.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

If you have any questions, contact Julianne Lee, Senior Regulatory Project Manager, at 240-402-5130 or Julianne.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Miya Paterniti, MD
Deputy Director for Safety
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

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/

MIYA O PATERNITI
08/14/2026 11:39:27 AM