NDA 218860/S-003

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
REQUIREMENT AND COMMITMENT

Ipsen Biopharmaceuticals, Inc.
Attention: Mukta Ullah
Director, Global Regulatory Affairs
One Main Street, 7th Floor
Cambridge, MA 02142

Dear Mukta Ullah:

Please refer to your supplemental new drug application (sNDA) dated and received February 6, 2026, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Iqirvo (elafibranor) tablets.

This Prior Approval sNDA provides for changes to the prescribing information for Iqirvo (elafibranor) based on data from study CLIN-60190-468 titled, *An Open-label, Phase I Study to Evaluate the Effects of Steady-state Levels of Elafibranor on the Pharmacokinetics of Combined Oral Contraceptives in Healthy Female Participants*, conducted to address postmarketing requirement (PMR) 4629-4 cited in the Accelerated Approval letter dated June 10, 2024.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

1. Addition of “5.3” in the HL/ Recent Major Changes

2. Addition of corresponding vertical line on the left margin in the FPI/W&P subsections

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

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Prescribing Information and Medication Guide), 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]

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).

FULFILLMENT OF POSTMARKETING REQUIREMENT AND COMMITMENT

We have received your submissions dated April 18, 2025, and February 6, 2026, containing the final reports for the following postmarketing requirement and commitment listed in the June 10, 2024, approval letter.

4629-4 Conduct a clinical drug-drug interaction study to evaluate the effect of elafibranor on the pharmacokinetics of combined oral contraceptives.

4629-6 Conduct an in vitro phenotyping study (or studies) to assess the contribution of cytochrome P450 (CYP) and UDP-glucuronosyltransferase (UGT) enzymes to the metabolism of GFT1007. The findings from in vitro studies should be followed up with in vivo drug-drug interaction studies if warranted.

We have reviewed your submissions and conclude that the above requirement and commitment were fulfilled.

We remind you that there are postmarketing requirements and a postmarketing commitment listed in the June 10, 2024, approval letter that are still open.

We remind you that accelerated approval PMR 4629-8 listed in the October 24, 2024, New Postmarketing Requirement letter is still open. Pursuant to 21 CFR 314.510 (Subpart H), continued approval of the drug is contingent upon verification and description of clinical benefit and completion of the clinical trial for PMR 4629-8.

[2] https://www.fda.gov/media/71211/download.

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 Terry Tsui, Regulatory Project Manager, at terry.tsui@fda.hhs.gov or at 240-402-1941.

Sincerely,

{See appended electronic signature page}

Mary Andrews, MD
Deputy Director for Safety
Division of Hepatology and Nutrition
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

MARY A ANDREWS
08/07/2026 12:03:51 PM