NDA 022417/S-027
NDA 209512/S-010

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Katie Kocyan
Manager, Global Regulatory Strategy
1 N. Waukegan Road
Dept. PA72/Bldg. AP30
North Chicago, IL 60064

Dear Katie Kocyan:

Please refer to your supplemental new drug applications (sNDAs) dated and received February 13, 2026, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norvir (ritonavir) tablets and Norvir (ritonavir) oral powder.

These Prior Approval sNDAs provides for the following revisions to the Prescribing Information (PI) and Patient Package Insert (PPI):

- Addition of contraindication for suzetrigine (PI, Section 4, Contraindications)
- Addition of suzetrigine to the list of established and other potentially significant drug interactions (PI, Section 7, Drug Interactions)
- Removal of drug presentation: tablet debossed with the “a” logo and code NK providing 100 mg ritonavir (PI, Sections 3, Dosage Forms and Strengths, and 16, How Supplied/Storage and Handling)
- Removal of information pertaining to Norvir (ritonavir) oral solution and capsule throughout the PI and PPI
- Updated lactation information (PPI), for consistency with other HIV-1 products
- Editorial revisions throughout, including addition of command language to Section 2, Dosage and Administration, and Section 4, Contraindications

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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.

- Updated with approval month and year in Highlights of Prescribing Information (Recent Major Changes and revision date) and Patient Package Insert (revision date)

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, and Instructions for Use), 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).

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 applications, you are exempt from this requirement.

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[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.

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 Kevin Allen, Regulatory Project Manager, at 301-837-7467 or kevin.allen@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Prabha Viswanathan, MD
Director (Acting)
Division of Antivirals
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use (Version previously approved September 29, 2017)

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/

POONAM MISHRA
07/23/2026 10:50:57 AM
on behalf of the Division Director