



NDA 220446

TENTATIVE APPROVAL

Lupin Inc.
Attention: Kalpana Vanam, MBA
Senior Vice President, Regulatory Affairs
400 Campus Drive
Somerset, NJ 08873

Dear Kalpana Vanam:

Please refer to your new drug application (NDA) dated November 26, 2025, received November 26, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Apixaban oral suspension.

This NDA proposes the use of Apixaban oral suspension for



We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information, (b) (4) and container labeling). This tentative approval determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired. Pursuant to section 505(b)(2)(A)(iii) of the FD&C Act and 21 CFR 314.50(i)(1)(i)(A)(3), you provided a paragraph III certification to U.S. Patent

No. 6,967,208 listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for Eliquis (apixaban) tablets (NDA 202155). Note that a pediatric extension has been granted to that patent. Refer to the Orange Book for more information.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **“REQUEST FOR FINAL APPROVAL”**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*, guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products*, and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)^{1,2}

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.

¹ 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>.

² <https://www.fda.gov/media/151712/download>

We note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, contact Bridget Kane, Regulatory Project Manager, at (240) 402-2170 or bridget.kane@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Selena DeConti, PharmD, MPH
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology,
& Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES: (tentatively approved)

- Content of Labeling
 - Prescribing Information
 - Medication Guide
 - Instructions for Use
 - Carton and Container Labeling

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/

SELENA D DECONTI
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