Lupin Inc.
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202
Attn: Venkata S. Devarakonda

Sent via email to: VenkataDevarakonda@lupin.com

Docket No. FDA-2024-P-0526

Dear Venkata S. Devarakonda:

This is in response to your petition received on January 26, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Apixaban Oral Suspension, 1.25 mg/mL. The listed drug product to which you refer in your petition is Eliquis (Apixaban) Tablets, 2.5 mg and 5 mg approved under NDA 202155 and held by Bristol-Myers Squibb.

Your request involves a change in strength and dosage form from that of the listed drug product (i.e., from 2.5 mg and 5 mg tablets to 1.25 mg/mL oral suspension). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, for the reasons explained below, the Agency denies your request.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, that investigations must be conducted to show the safety and effectiveness of the drug product or of any of its active ingredients, its route of administration, dosage form or strength which differs from the reference listed drugs. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i).

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement,

the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)]."). Because you are seeking a change in dosage form, this proposed product triggers PREA.

The Agency has determined that clinical trials are required under PREA. The reference listed drug is indicated (among other uses) for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and to reduce the risk of recurrent DVT and PE following initial therapy, which are conditions that affect pediatric patients. The proposed drug product could represent a meaningful therapeutic benefit over existing therapies for pediatric patients.

Therefore, this petition is being denied because clinical trials are required under PREA for the approval of the requested change to the drug product. The request for a waiver of the pediatric study requirements under PREA has been denied. Please contact the Division of Cardiology and Nephrology in the Office of Cardiology, Hematology, Endocrinology and Nephrology, Office of New Drugs at (301) 796 - 2240 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Ilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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William Chong

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