



NDA 211801/S-002

SUPPLEMENT APPROVAL

Ardelyx, Inc.
Attention: Robert Blanks
Chief Regulatory and Quality Officer
34175 Ardenwood Blvd., Suite 100
Fremont, CA 94555

Dear Mr. Blanks:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 9, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for lbsrela (tenapanor) tablets.

This “Changes Being Effected” supplemental new drug application provides for revised container label with a new product logo for the commercial product and for the professional sample

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 211801/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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

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, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



David
Lewis

Digitally signed by David Lewis
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