



10 May 2023

NDA 211,801
SequenceNo.: 0152

Jessica J. Lee, MD
Director, Division of Gastroenterology
Center for Drug Evaluation and Research
Food and Drug Administration
Building 22, Suite 4177
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: NDA 211,801 Sequence No. 0152
IBSRELA® (tenapanor)
RESPONSE TO PREA NON-COMPLIANCE LETTER
PEDIATRIC DEFERRAL EXTENSION REQUESTED

Dear Dr. Lee,

Reference is made to the original NDA application (Sequence 0001, submitted 12 September 2018) for IBSRELA (tenapanor) for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults. Reference is also made to the NDA Approval Letter received on the 12th of September 2019 ([Reference ID: 4490626](#)).

The Sponsor received a General Advice letter from the Agency on 20 January 2023 ([Reference ID:5112918](#)) recommending that we request a deferral for two of our post-marketing requirements (PMRs) for NDA 211,801; PMR 3583-2 “*A randomized, double-blind, controlled, dose-ranging study to assess the safety and efficacy of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C) in pediatric patients 6 to less than 12 years of age*” and PMR 3583-3 “*A 12-week, randomized, controlled study to assess the safety and efficacy of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C) in pediatric patients 12 to less than 18 years of age*”.

Subsequently, the Sponsor received a Notification of Non-Compliance with PREA letter for PMR 3583-2 from the Agency on 19 April 2023 ([Reference ID: 5160843](#)).

This submission contains the Sponsor's request for a deferral extension of PMRs 3583-2 and 3583-3 as well as the response to the Notification of Non-Compliance with PREA letter with respect to PMR 3583-2 (See [Module 1.9.2](#)). This information has been cross-referenced to IND 108,732 to which the protocol has been submitted.

This submission is being sent in eCTD format via FDA Electronic Submissions Gateway. The size of this submission is less than 100 MB. The file is certified as virus free using Symantec Endpoint Protection, version 12.1.6608.6300 with the most recent virus definitions available at the time of submission. For questions related to information technology and electronic formatting issues, contact Michelle Cheung, Regulatory Publishing Sr. Manager via telephone (510) 456-7716 or via e-mail at mcheung@ardelyx.com.

If you require further information concerning this submission, please do not hesitate to contact me by telephone (510) 745-1702, cell (617) 513-4943, facsimile (510) 745-1727, or by e-mail rblanks@ardelyx.com.

Sincerely,

DocuSigned by:

Robert C. Blanks



Signer Name: Robert C. Blanks
Signing Reason: I approve this document
Signing Time: 08-May-2023 | 09:05 PDT

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Robert C. Blanks, MS, RAC
Chief Regulatory & Quality Officer
Ardelyx, Inc.

