

August 13, 2026

Jessica Lee, M.D.
Director, Division of Gastroenterology
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Response to PREA Non-Compliance Letter

Re: NDA 216457; SN0078
APONVIE® (Aprepitant) Injectable Emulsion, for Intravenous Use
Response to Pediatric Research Equity Act Non-Compliance Letter for
Postmarketing Requirement 4292-1

Attn: Mary Chung, PharmD, Senior Regulatory Project Manager, DRO-II

Dear Dr. Lee:

Reference is made to New Drug Application (NDA) 216457 for APONVIE® (aprepitant) injectable emulsion, for intravenous use for the prevention of postoperative nausea and vomiting (PONV) in adults approved on September 16, 2022.

Further reference is made to the FDA Notification of Non-compliance with Pediatric Research Equity Act (PREA) letter dated July 1, 2026 (Reference ID: [5827091](#)) regarding the pediatric assessment not yet submitted for the following PREA Postmarketing Requirement (PMR):

PMR 4292-1

A randomized, double-blind, active-controlled, dose-ranging trial to evaluate the efficacy, safety, and pharmacokinetics of Aponvie (aprepitant) injectable emulsion as prophylaxis for postoperative nausea and vomiting in children ≥ 12 years to ≤ 17 years of age.

Final Protocol Submission: 08/2023

Study/Trial Completion: 08/2025

Final Report Submission: 02/2026

The purpose of this submission is to provide the Division with a [Response to the Non-Compliance Letter](#) including a PREA PMR [Deferral Extension Request](#) for PMR 4292-1 (Module 1, Section 1.17.2).

If you have any questions regarding this submission, please contact me at ngetz@herontx.com or by telephone at (984) 208-8328.

Sincerely,

{See appended electronic signature page}

Natasha Getz
Director, Regulatory Affairs
Heron Therapeutics, Inc.

This submission was scanned using Symantec Endpoint Protection (version 12.1.6) and is confirmed to be virus free.

Signature Page for VV-REG-016551 v1.0

Approval Task	Natasha Getz Regulatory 13-Aug-2026 14:59:23 GMT+0000
---------------	---

Signature Page for VV-REG-016551 v1.0