Phathom PHARMACEUTICALS

2150 East Lake Cook Road, Suite 800
Buffalo Grove, IL 60089

25 June 2026

Matthew Kowalik, MD, Acting Director
Division of Gastroenterology
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attn: Maureen Dewey, Senior Regulatory Health Project Manager

Re: **NDA 215151**
Sequence No. 0109
VOQUEZNA® (vonoprazan) tablets, 10 mg and 20 mg

RESPONSE TO PREA NON-COMPLIANCE LETTER FOR PMR 4367-7 (AGE-APPROPRIATE FORMULATION)

Dear Dr. Kowalik:

Phathom Pharmaceuticals, Inc. (Phathom) herein provides a response to the NOTIFICATION OF NON-COMPLIANCE WITH PREA received on 11 June 2026 for the following Postmarketing Requirement (PMR):

4367-7	Develop an age-appropriate formulation for pediatric patients 1 month to <6 months of age.	
	Final report submission date:	01/2025

Note, a request to be released from this PMR was submitted to NDA 215151 (Sequence 0106) on 29 May 2026 due to the inability to develop an age-appropriate formulation for pediatric subjects <6 years of age.

A complete response is provided in Module 1.9.6.

This submission is provided in full compliance with ICH and FDA regulatory guidelines. The undersigned certifies that this submission was checked for the presence of computer viruses by CrowdStrike Falcon Sensor Antivirus Software. If you should have any questions regarding this submission, please do not hesitate to contact me.

Nancianne Knipfer

Digitally signed by Nancianne Knipfer
Date: 2026.06.24 09:34:34 -05'00'

Sincerely,
Nancianne Knipfer, PhD, RAC
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