



NDA 215152/S-012  
NDA 215153/S-012

**SUPPLEMENT APPROVAL  
FULFILLMENT OF POSTMARKETING REQUIREMENT**

Phathom Pharmaceuticals, Inc.  
Attention: Nancianne Knipfer, PhD, RAC  
Vice President, Regulatory Affairs and Medical Writing  
2150 East Lake Cook Road, Suite 800  
Buffalo Grove, IL 60089

Dear Dr. Knipfer:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 18, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 215152: Voquezna Triple Pak (vonoprazan tablets; amoxicillin capsules; clarithromycin tablets) 20 mg, 500 mg, 500 mg, co-packaged  
NDA 215153: Voquezna Dual Pak (vonoprazan tablets; amoxicillin capsules) 20 mg, 500 mg, co-packaged

These Prior Approval sNDAs provide for changes to the prescribing information (PI) of Voquezna Triple Pak and Voquezna Dual Pak. The changes made were primarily to update the Pregnancy and Lactation subsections of the PI along with other changes as follows:

1. Addition of Drug-Induced Enterocolitis Syndrome (DIES) to the **ADVERSE REACTIONS (6)** section and **Postmarketing Experience with Components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK (6.2)** subsection, and addition of linear IgA bullous dermatosis to the **Postmarketing Experience with Components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK (6.2)** subsection to align with NDA 215152/S-015 and NDA 215153/S-014, approved on June 12, 2025.
2. Addition of the Pregnancy Exposure Registry language to the **USE IN SPECIFIC POPULATIONS (8)** section, **Pregnancy (8.1)** subsection, and revision of the existing language in the **USE IN SPECIFIC POPULATIONS (8)** section, **Lactation (8.2)** subsection, and the **PATIENT COUNSELING INFORMATION (17)** section to all align with the FDA guidance for industry *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format* (July 2020).

3. Revision of the **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection to update the information regarding CYP2D6 and CYP2C19 metabolizer status.

In addition, minor editorial changes were made throughout the PI.

## **APPROVAL & LABELING**

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

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these sNDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **FULFILLMENT OF POSTMARKETING REQUIREMENT**

We have received your submission dated March 18, 2025, containing the final report for the following postmarketing requirement listed in the May 03, 2022, approval letter.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

4270-3 Conduct a lactation study (milk only) in lactating women who have received vonoprazan-containing products to assess concentrations of vonoprazan in breast milk using a validated assay. A mother-infant pair study may be required in the future depending on the results of this milk-only study.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the May 03, 2022, approval letter that are still open.

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

### **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, contact Eva Zuffova Regulatory Project Manager, at 301-796-0697 or [eva.zuffova@fda.hhs.gov](mailto:eva.zuffova@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infectives  
Office of Infectious Diseases  
Office of New Drugs  
Center for Drug Evaluation and Research

NDA 215152/S-012

NDA 215153/S-012

Page 4

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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