DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Paul Kowalczyk
Director Regulatory Advertising & Promotion
Phathom Pharmaceuticals, Inc.
100 Campus Drive, Suite 102
Florham Park, NJ 07932

RE: NDA 215151
VOQUEZNA (vonoprazan) tablets, for oral use
MA 185

Dear Mr. Kowalczyk:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer video of an interview (video) featuring Kenan Thompson, a spokesperson for Phathom Pharmaceuticals, Inc. (Phathom) for VOQUEZNA (vonoprazan) tablets, for oral use (Voquezna). The video originally appeared on *Rolling Out* on April 4, 2025 and can also be accessed through *Rolling Out*'s YouTube page.[1] FDA has determined that the video is false or misleading. Thus, the video misbrands Voquezna and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The video is misleading because it presents efficacy claims for Voquezna but fails to communicate **any** risk information. For example, the video includes the following claims:

- "…I personally have dealt with acid reflux. This is like my first time like openly kind of talking about it because I ended up partnering with Phathom Pharmaceuticals because I was prescribed Voquezna and it actually worked for me…" (Spokesperson AVO)
- "So, in my case the tool I needed was Voquezna and now I'm out here on a much better journey." (Spokesperson AVO)
- "I'm spreading the word and you need the website is GERDisnojoke.com - it's got a lot of information there if you're dealing with those kinds of symptoms and stuff like that, and if you get the Voquezna, I hope it works for you like it did for me." (Spokesperson AVO)

The video, however, entirely omits all risk information. By omitting the risks associated with Voquezna, the video fails to provide material information about the consequences that may

[1] This video is available on the internet at https://www.youtube.com/watch?v=rAqCK23H07s (last accessed date September 8, 2025)

result from the use of Voquezna and creates a misleading impression about the drug's safety.

Conclusion and Requested Action

For the reasons discussed above, the video misbrands Voquezna and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Phathom take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Voquezna that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Voquezna.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 185 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 5183 under NDA 215151. Questions related to the submission of your response letter should be emailed to the OPDP RPM at CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research

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.

/s/

CARTER M BEACH
09/09/2025 05:12:12 PM
On behalf of George Tidmarsh, M.D., Ph.D