



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 *The Dan Le Batard Show with Stugotz* on March 31, 2025 and can also be accessed through *LeBatardShow'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:

- “Kenan’s here because he’s teamed up with Phathom Pharmaceuticals to raise awareness about GERD...” (Host AVO)
- “...it stands for gastroesophageal reflux disease...but I personally was suffering with acid reflux and was prescribed Voquezna...” (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 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

¹ This video is available on the internet at <https://www.youtube.com/watch?v=Gji2jNhaZI> (last accessed date September 8, 2025)

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 05:11:48 PM
On behalf of George Tidmarsh, M.D., Ph.D