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Head of Regulatory Affairs, U.S. Advertising and Promotion  
AbbVie, Inc.  
1 N. Waukegan Road, Dept. PA95, Bldg. ABV1  
North Chicago, IL 60064

**RE: NDA 211765**  
UBRELVY (ubrogepant) tablets, for oral use  
MA 934

Dear Dr. Hill:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television advertisement (TV ad), titled “Serena TV :30” (US-UBR-230259) for UBRELVY (ubrogepant) tablets, for oral use (Ubrovelvy) submitted by AbbVie, Inc., under cover of Form FDA 2253.<sup>1</sup> The TV ad makes false or misleading representations and suggestions about the efficacy of Ubrovelvy. Thus, the TV ad misbrands Ubrovelvy within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act) and makes its distribution violative. 21 U.S.C. 352(n); 321(n); 331(a). 21 CFR 202.1(e)(5). These violations are concerning from a public health perspective because the TV ad, featuring Serena Williams, misleadingly suggests that Ubrovelvy will provide a greater treatment benefit to patients suffering from migraine headache than has been demonstrated. Migraine headache is one of the most common debilitating neurologic conditions in the US, with millions of Americans (one out of six Americans) experiencing a migraine within any 3-month period.<sup>2</sup> Healthcare providers, patients, and caregivers should not be misled regarding the benefits that can be expected from acute migraine headache treatments. Moreover, the use of a celebrity athlete in this TV ad amplifies the misleading representations and suggestions made and increases the potential for audiences to find the misleading promotional communication more believable due to the perceived credibility of the source.<sup>3</sup>

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<sup>1</sup> The Form FDA 2253 submission included the final produced TV ad video as well as a storyboard annotated with frame numbers. We have referred to those frame numbers in this letter to facilitate communication of our concerns. The TV ad is also available at <https://www.ispot.tv/ad/567Q/ubrovelvy-when-migraine-strikes-featuring-serena-williams> (last accessed August 27, 2024).

<sup>2</sup> Burch R, Rizzoli P, and Loder E, 2018, The Prevalence and Impact of Migraine and Severe Headache in the United States: Figures and Trends From Government Health Studies, *Headache*, 58(4):496-505.

<sup>3</sup> See, e.g., Bergkvist L and Zhou KQ, 2016, Celebrity endorsements: a literature review and research agenda, *Int J Advert*, 35(4):642-663.; Rollins B, Huh J, Bhutada N, and Perri M, 2021, Effects of endorser type and testimonials in direct-to-consumer prescription drug advertising (DTCA), *Int J Pharm Healthc Mark*, 15(1):1-17.; Atkin C and Block M, 1983, Effectiveness of celebrity endorsers, *J Advert Res*, 23(2):57-61.; Friedman HH and Friedman L, 1979, Endorser effectiveness by product type, *J Advert Res*, 19(5):63-71.; Ohanian R, 1991. The impact of celebrity spokespersons' perceived image on consumers' intention to purchase. *J Advert Res*, 31(1): 46-54.

## Background

Below are the indication and summary of the most serious and most common risks associated with the use of Ubrelvy.<sup>4</sup> According to the INDICATIONS AND USAGE section of the FDA-approved prescribing information (PI):

Ubrelvy is indicated for the acute treatment of migraine with or without aura in adults.

### Limitations of Use

Ubrelvy is not indicated for the preventive treatment of migraine.

Ubrelvy is contraindicated with concomitant use of strong CYP3A4 inhibitors and in patients with a history of serious hypersensitivity to ubrogepant or any component of Ubrelvy. The PI contains a warning and precaution regarding hypersensitivity reactions. The most common adverse reactions are nausea and somnolence.

### Prior Communications

OPDP notes that our advisory comments dated March 10, 2020, to Allergan, Inc.<sup>5</sup> addressed

(b) (4)

While Allergan, Inc. is no longer the application holder, OPDP is concerned that AbbVie, Inc. appears to be promoting Ubrelvy using similar claims and presentations in a misleading manner.

## False or Misleading Benefit Presentation

Prescription drug advertisements and labeling (promotional communications) misbrand a drug if they are false or misleading with respect to benefits. The determination of whether a promotional communication is misleading includes, among other things, not only representations made or suggested in the promotional communication, but also the extent to which the promotional communication fails to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the

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<sup>4</sup> This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional communication(s) cited in this letter.

<sup>5</sup> We note that at the time of the advisory comments, Allergan, Inc., was the holder of NDA 211765. On March 23, 2023, FDA acknowledged AbbVie's correspondence notifying FDA that ownership of NDA 211765 was transferred to AbbVie Inc. following acquisition of Allergan Sales LLC (Sequence No. 0083).

drug as recommended or suggested in the promotional communication.

The TV ad includes the following claims and presentations (in pertinent part, emphasis original):

- Frames one to four:
  - Serena Williams is in a talk show dressing room when she closes her eyes and puts her hand to her head, appearing to experience migraine pain. With her hand to her head, she takes a deep breath and starts walking. Serena Williams looks down a hallway with glaring lights. She holds up her hand and recoils from the light, appearing to shield her eyes.
  - Serena Williams voiceover (VO): “When migraine strikes, you’re faced with a choice. Ride it out with the tradeoffs of treating? Or push through the pain and symptoms?”
- Frames five to seven:
  - The Ubrelvy logo appears in the backstage hallway and a soft blue path appears down the hallway. Serena Williams begins walking down the blue path with her face relaxed and arms at her sides, no longer touching her head or shielding her eyes from light. She then holds up a single 100 mg dose packet of Ubrelvy.
  - Serena Williams VO: “With Ubrelvy, there’s another option. One dose works fast to eliminate migraine pain.”
  - SUPER: “**UBRELVY® QUICKLY ELIMINATES MIGRAINE PAIN**”
- Frames 8 to 14:
  - Serena Williams is sitting in her dressing room in front of a lighted stage mirror talking with another person. She is now seen laughing and smiling. Then the blue path appears as she excitedly walks on the blue path through the stage curtains and waves to an audience. Serena Williams continues walking on the blue path onto a brightly lit talk show stage, smiling and waving to the studio audience as they applaud.
  - Serena Williams VO: “Migraine pain relief starts with U. Ask about Ubrelvy.”

These claims and presentations misleadingly suggest that Ubrelvy provides greater benefits to patients with acute migraine headache than has been demonstrated. Serena Williams is

presented in frames one through four preparing to appear on a talk show while experiencing pain and photophobia from a migraine headache. Immediately after this presentation, a blue lit path with the Ubrelvy logo appears in frame five. In frame six, Serena Williams is shown walking down the blue lit path, appearing relaxed and no longer holding her head or shielding her eyes from the lights that continue to shine overhead. The presentation in frame six is in conjunction with Serena Williams's VO claim that, "One dose works fast to eliminate migraine pain" and the accompanying prominent graphic "UBRELVY QUICKLY ELIMINATES MIGRAINE PAIN." This compelling before-and-after presentation in conjunction with claims such as, "One dose works fast to eliminate migraine pain" and "UBRELVY QUICKLY ELIMINATES MIGRAINE PAIN" (emphasis added) misleadingly suggests that Ubrelvy eliminates migraine pain and symptoms more quickly than was demonstrated in the clinical trials. According to the CLINICAL STUDIES section of the Ubrelvy PI, the efficacy of Ubrelvy for the acute treatment of migraine was established in two clinical trials based on two endpoints: 1) effect on pain freedom at two hours post-dose (defined as a reduction of moderate or severe headache pain to no pain) and 2) effect on most bothersome symptom (MBS) (i.e., photophobia, phonophobia, nausea) freedom at two hours post-dose (defined as the absence of the self-identified MBS), compared to placebo. In Study 1, 19.2%, 21.2%, and 11.8% of patients achieved pain freedom at 2 hours in the Ubrelvy 50 mg, Ubrelvy 100 mg, and placebo groups, respectively (7.4%-9.4% difference from placebo); 38.6%, 37.7%, and 27.8% of patients achieved freedom from MBS in the Ubrelvy 50 mg, Ubrelvy 100 mg, and placebo groups, respectively (9.9%-10.8% difference from placebo). In Study 2, 21.8% and 14.3% of patients achieved pain freedom at 2 hours in the Ubrelvy 50 mg and placebo groups, respectively (7.5% difference from placebo); and 38.9% and 27.4% of patients achieved freedom from MBS in the Ubrelvy 50 mg and placebo groups, respectively (11.5% difference from placebo). We acknowledge that the claim, "Some people had pain freedom within 2 hours" appears in a small SUPER on frame six. However, the SUPER is not sufficient to mitigate this misleading suggestion that Ubrelvy can eliminate migraine pain and symptoms more quickly than has been demonstrated.<sup>6</sup>

In addition, the claim in frame six of the TV ad that "One dose works fast to eliminate migraine pain," (emphasis added) misleadingly suggests that all patients who take Ubrelvy can expect their migraine pain to be eliminated after a single dose of Ubrelvy, when this has not been demonstrated. As described above, according to the CLINICAL STUDIES section of the Ubrelvy PI, approximately 19% to 22% of patients achieved pain freedom at two hours after receiving one dose of Ubrelvy. Conversely, approximately 78% to 81% of patients did not achieve pain freedom after receiving one dose of Ubrelvy. In addition, according to the DOSAGE AND ADMINISTRATION section of the PI, in pertinent part, "If needed, a second dose [of Ubrelvy] may be taken at least 2 hours after the initial dose" (emphasis added). We

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<sup>6</sup> We note that the storyboard submitted with the TV ad on FDA Form 2253 states in frame one, "Open in the afternoon to Serena in a talk show dressing room . . . ." and in frame eight, "In the evening, Serena does a final check in the mirror . . . ."; however, the audience viewing the TV ad is not privy to this information and the TV ad in the public domain does not portray the passing of time in a manner that is consistent with the description in the storyboard.

acknowledge that the claim, “Some people had pain freedom within 2 hours” appears in a small SUPER on frame six. However, this does not mitigate the misleading suggestion that “one dose eliminate[s] migraine pain.” Therefore, the claim that “one dose eliminate[s] migraine pain” is misleading.

### **Conclusion and Requested Action**

For the reasons discussed above, the TV ad misbrands Ubrelvy within the meaning of the FD&C Act and makes its distribution violative. 21 U.S.C. 352(n); 321(n); 331(a). 21 CFR 202.1(e)(5).

This letter notifies you of our concerns and provides you with an opportunity to address them. OPDP requests that AbbVie cease any violations of the FD&C Act. 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 Ubrelvy that contain representations like those described above, and explaining your plan for the timely discontinuation of such communications, or for ceasing distribution of Ubrelvy.

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 undersigned at 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 934 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 3465 under NDA 211765.

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}

Lindsay McCann, PharmD, BCCCP  
Regulatory Review Officer  
Division of Advertising & Promotion Review 1  
Office of Prescription Drug Promotion

{See appended electronic signature page}

Susannah O'Donnell, MPH, RAC  
Team Leader  
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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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LINDSAY M MCCANN  
08/29/2024 11:17:59 AM

SUSANNAH O'DONNELL  
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