DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Michelle Folz, MS
Director, Regulatory Advertising & Promotion
Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg 337
East Hanover, NJ 07936-1080

RE: NDA 218276
FABHALTA® (iptacopan) capsules, for oral use
MA 637

Dear Michelle Folz:

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 (DTC) broadcast advertisement (FA-11370984) (TV ad) for FABHALTA® (iptacopan) capsules, for oral use (Fabhalta) submitted by Novartis Pharmaceuticals Corporation (Novartis) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Fabhalta and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The major statement is presented from frames 18 through 33, during which the TV ad introduces a romantic story arc where “Lewis is selecting produce” and “brush[es] hands accidently” with a woman and ends up “really hitting it off” with her before the woman leaves the store. This all occurs while the boxed warning risk of serious and life-threatening infections associated with Fabhalta is disclosed. The TV ad then includes multiple scene changes away from the romantic story arc before eventually returning back to “Lewis . . . at a wedding and heading to the dance floor” where it is revealed that “[t]he woman from the grocery story is Lewis’ date!” The TV ad is misleading because this compelling and attention-grabbing presentation, combined with multiple scene changes and background music during the presentation of the major statement, interferes with comprehension of the major statement.

Frame 17 of the TV ad includes the claim, “It’s a twice-daily pill that substantially improved hemoglobin levels compared to SOLIRIS® or ULTOMIRIS® infusions” in the voiceover. The bottom of frames 16 and 17 include a SUPER that qualifies this claim, which states:

> 82% of adults who switched to FABHALTA vs 0% who remained on SOLIRIS® or ULTOMIRIS® had an increase in Hb ≥2g/dL, and 68% of adults who switched to FABHALTA vs 0% who remained on SOLIRIS® or ULTOMIRIS® had Hb levels ≥12g/dL without a need for red blood cell transfusions in a 24-week study. ULTOMIRIS® (ravulizumab-cwvz) and SOLIRIS® (eculizumab) are registered trademarks of Alexion Pharmaceuticals, Inc.

However, the presentation of the SUPER is undermined by multiple, competing presentational aspects that distract the viewer from material information about the benefits of Fabhalta and, therefore, creates a misleading impression about the drug's efficacy. Specifically, the presentational aspects of the TV ad undermine the communication of material information regarding the hemoglobin improvement data in the SUPER, which is needed to qualify the "substantially improved" hemoglobin levels in patients who switched to Fabhalta compared to patients who remained on SOLIRIS® or ULTOMIRIS®.

The SUPER that includes the material information for the "substantially improved" hemoglobin level claim in the ad presents 65 words in approximately 9 seconds, which translates to a reading speed of 433 words per minute (wpm). A review and meta-analysis found that the average silent reading rate for adults in English is 238 wpm for uninterrupted non-fiction reading, with most adults falling in a range of 175 to 300 wpm.[1]

Moreover, during the 9-second period that the SUPER appears, there are multiple, competing audio and visual presentations. The audio states, "It's a twice-daily pill that substantially improved hemoglobin levels compared to SOLIRIS® or ULTOMIRIS® infusions" while the music plays in the background. Simultaneously, a graphic with the claim "IMPROVED HEMOGLOBIN LEVELS COMPARED TO SOLIRIS® OR ULTOMIRIS® INFUSIONS" appears with the words flying onto the screen with stylistic transitions in a larger type size and more central location on the screen than the SUPER with the material information describing the results of the clinical study.

Overall, by presenting compelling and attention-grabbing visual information as well as information in other competing modalities during the presentation of the SUPER, which itself is presented in a manner that would not allow most viewers to read, process, and comprehend the material information it presents, the TV ad misleadingly undermines the communication of material information about the drug's efficacy.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Fabhalta and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Novartis 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 Fabhalta that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Fabhalta.

[1] Brysbaert, Marc. (2019). How many words do we read per minute? A review and meta-analysis of reading rate. 10.31234/osf.io/xynwg.

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 637 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 6638 under NDA 218276. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Melissa Khashei, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

{See appended electronic signature page}

Jina Kwak, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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/

MELISSA KHASHEI
09/23/2025 03:19:24 PM

JINA KWAK
09/23/2025 03:21:28 PM