DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Erin Monaco, Executive Director
Regulatory Advertising & Promotion
Bausch Health Companies Inc.
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807

RE: NDA 203567
JUBLIA® (efinaconazole) topical solution, 10% for topical use
MA 852

Dear Erin Monaco:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement (JUB.0058.USA.24)(TV ad) for JUBLIA® (efinaconazole) topical solution, 10% for topical use (Jublia) submitted by Bausch Health Companies Inc. (Bausch) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Jublia and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes claims and representations that misrepresent the efficacy of Jublia. The TV ad begins when a yoga instructor draws attention to and identifies a male participant's condition as a "contagious nail fungus" while a female student quickly moves away from him. The man's infected toenail is then portrayed as a large, hairy, discolored, attention-grabbing Bigfoot foot, startling him. The yoga instructor responds to his reaction with the claim, "don't fear the fungus." This portrayal of onychomycosis as a Bigfoot foot is depicted again and the claim, "don't fear the fungus" is repeated throughout the ad in the voiceover and as on-screen supers or in branded side panels.

The TV ad is misleading because it creates a misleading impression that all patients, once treated with Jublia, can expect a complete cure, when this has not been demonstrated. Specifically, the man is shown applying Jublia and then confidently returns to yoga class, lacking any signs of his previously portrayed Bigfoot foot. He is shown touching his uninfected bare feet, while sitting amongst other participants who are no longer moving away to avoid him; thus, creating the impression that his onychomycosis is completely cured. However, according to the CLINICAL STUDIES section of the FDA-approved Prescribing Information (PI) for Jublia, the two clinical trials demonstrated a 17.8% and 15.2% Complete Cure rate with Jublia treatment compared to 3.3% and 5.5% with vehicle solution, respectively. Mycologic Cure was observed in 55.2% and 53.4% of Jublia patients compared to 16.8% and 16.9% of those in the vehicle solution groups, respectively. Furthermore, the

claim, “don’t fear the fungus” minimizes the condition of onychomycosis by creating an implication that it is easily treated and cured with Jublia and the condition should not be feared by patients. However, per the results stated above, treatment with Jublia does not guarantee a complete cure for onychomycosis in all patients, and claims and representations that suggest such, are unsupported and misleading.

Additionally, the TV ad is misleading because it creates the impression that Jublia can offer immediate results treating onychomycosis, when this has not been demonstrated. Specifically, the TV ad depicts the resolution of onychomycosis after a single application of Jublia as the man returns to yoga class with his foot looking normal shortly after doing yoga alone. He confidently smiles and states, “don’t’ fear the fungus.” However, according to the CLINICAL STUDIES section of the PI, the efficacy endpoints of Complete Cure, Complete or Almost Complete Cure, and Mycologic Cure, were not assessed until week 52 (4 weeks after completion of 48 weeks of treatment). Furthermore, according to the DOSAGE AND ADMINISTRATION section of the PI, the recommended course of treatment with Jublia consists of application to the affected toenails once daily for 48 weeks. Thus, the impression that Jublia can offer immediate results for the treatment of onychomycosis is misleading.

We acknowledge the disclaimer, “Apply to affected toenails for 48 weeks. Individual results may vary.” appears as an onscreen super 15 seconds into the TV ad. However, this super precedes the representations of Jublia’s application and resulting efficacy. The lag time and lack of comparative emphasis placed on this information undermines its communication. Therefore, the disclaimer does not correct or mitigate the overall misleading impression created by the TV ad regarding the timeframe or scope of Jublia’s efficacy for treatment of onychomycosis.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Jublia 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 Bausch 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 Jublia that contain representations like those described above, and explaining your plan for the timely discontinuation of such communications, or for ceasing distribution of Jublia.

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 852 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 5296 under NDA 203567. 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}

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 05:12:26 PM
On behalf of George Tidmarsh, M.D., Ph.D