DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Morgan Loh, PharmD, Senior Manager
Advertising and Promotional Compliance
Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard
Boston, MA 02110

RE: BLA 761108
ULTOMIRIS® (ravulizumab-cwvz) injection, for intravenous use
MA 972

Dear Dr. Loh:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television (DTC) advertisement (TV ad), titled "ULTOMIRIS gMG DTC TV Spot – 2025 2_(v1.0)" (US/ULT-g/0744) for ULTOMIRIS® (ravulizumab-cwvz) injection, for intravenous use (Ultomiris) submitted by Alexion Pharmaceuticals, Inc. (Alexion) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Ultomiris and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

- **VO/SUPER**: "Ultomiris **IS** continuous symptom control"
- **VO**: "With improvement in activities of daily living"
- **SUPER**: "**IS** more than **2x improvement** in activities of daily living (MG-ADL)"

These claims and presentations misleadingly suggest that Ultomiris provides treatment benefits beyond what has been demonstrated. According to the CLINICAL STUDIES section of the FDA-approved prescribing information (PI), over 80% of patients were receiving acetylcholinesterase inhibitors, 70% were receiving corticosteroids, and 68% were receiving non-steroidal immunosuppressants at study entry. Patients on concomitant medications to treat generalized myasthenia gravis (gMG) were permitted to continue on therapy throughout the course of the study. The primary efficacy endpoint was a comparison of the change from baseline between treatment groups in the MG-ADL total score at Week 26. The improvement in MG-ADL scores in the clinical study does not correlate with continuous symptom control as claimed in the TV ad. FDA acknowledges that treatment with Ultomiris demonstrated a statistically significant change in the MG-ADL from baseline at Week 26 compared to placebo. However, as described above, the trial allowed concomitant gMG treatments and the MG-ADL was not assessed on a daily basis. MG-ADL also assesses only a certain aspect of daily activities and not the entire spectrum of a typical patient. We acknowledge that the TV ad includes the SUPER, "Based on the MG-ADL, a scale that measures the

impact of 8 gMG symptoms on daily functions." However, this statement does not mitigate the misleading impression that patients can expect continuous symptom control when taking Ultomiris.

The TV ad is misleading because the attention-grabbing visuals (e.g., the camera following the male character as he walks through multiple different scenes with bright backgrounds while performing various activities such as taking a waffle from a plate his wife is holding and eating it, interacting with his wife and grandson at a party, getting into a car with his wife and preparing to drive off) and frequent scene changes during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

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

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 972 in addition to the BLA 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 1295 under BLA 761108.
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 05:18:02 PM
On behalf of George Tidmarsh, M.D., Ph.D