DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Alar Pharmaceuticals Inc.
(b) (4)

RE: (b) (4)
ALA-3000 (ketamine pamoate) injection
MA 1

Dear (b) (4):

As part of its monitoring and surveillance program, the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed Alar Pharmaceuticals Inc.'s (Alar) exhibit booth display and brochure that discuss the investigational new drug ALA-3000 (ketamine pamoate) injection (ALA-3000), which is the subject of the above-referenced investigational new drug application (IND). You are receiving this letter as the authorized representative for Alar, the sponsor of ALA-3000. The exhibit booth display and brochure were presented in the exhibit hall at the American Psychiatric Association (APA) 2026 Annual Meeting[1] and viewed by an OPDP representative. FDA has determined that the exhibit booth display and brochure represent, in a promotional context, that ALA-3000, an investigational new drug, is safe and effective for the purposes for which it is being investigated or otherwise promote the drug. As a result, ALA-3000 is misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and is in violation of section 301(a) of the FD&C Act. The claims on the exhibit booth display and in the brochure are particularly concerning from a public health perspective because ketamine, the active ingredient of ALA-3000, is a Schedule III (CIII) controlled substance associated with a number of serious risks, including sedation, dissociation, respiratory depression, hemodynamic instability (including increase in blood pressure), and abuse and misuse. The exhibit booth display and the brochure make conclusory representations in a promotional context regarding the safety and efficacy of ALA-3000, an investigational new drug that has not been approved by FDA and whose safety and efficacy have not been established.

Under section 502(f)(1) of the FD&C Act, a drug shall be deemed to be misbranded unless its labeling bears adequate directions for use. Under FDA regulations, adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. 21 CFR 201.5. Your exhibit booth display and brochure describe the use of ALA-3000 for treating treatment-resistant depression (TRD). This use is one for which a

[1] The American Psychiatric Association Annual Meeting took place May 16-20, 2026, in San Francisco, CA.

prescription would be needed because it requires the supervision of a physician and, therefore, for which adequate directions for lay use cannot be written.

Although 21 CFR 201.115(b) provides an exemption from the adequate directions for use requirement in section 502(f)(1) of the FD&C Act if a new drug "complies with section 505(i)...and regulations thereunder," your investigational drug fails to do so.[2] Among the requirements for this exemption for investigational drugs, 21 CFR 312.7(a) provides that, "[a] sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution."

The exhibit booth display and brochure include claims that promote ALA-3000 as safe and effective for the purposes for which it is being investigated or otherwise promote the drug, including the following examples (emphasis original):

- "**ALA-3000 Breaks Key Barriers in Ketamine Therapy for TRD**" (brochure)
- "Sustained-release profile for weeks without pronounced initial burst or dose dumping effect" (brochure)
- "No overall sedative, dissociative, psychosis-like side effects" (exhibit booth display)
- "No sedation, dissociation, psychosis-like effects, or commonly ketamine-reported AEs (e.g., blood pressure elevation, urinary toxicity)" (brochure)
- "No abuse signals" (brochure)
- "Potentially eliminates the mandatory ≥2-hour post-dose on-site monitoring required with ketamine therapies." (brochure)

The above claims make numerous conclusory statements that represent that ALA-3000 is safe and effective for the treatment of TRD. However, ALA-3000 is an investigational new drug, which the brochure appears to indicate has only been studied in Phase 1 clinical trials. The claims are extremely concerning given the lack of adequate safety and efficacy data for ALA-3000. The exhibit booth display and brochure claims also represent in a promotional context that ALA-3000 is different from or superior to approved therapies for treating TRD. In particular, the representation that ALA-3000 is safe and has none of the concerns associated with other ketamine products is especially concerning given the known serious risks

[2] 21 CFR 201.100 offers another exemption from the requirement for adequate directions for use for prescription drugs provided certain requirements are met; however, ALA-3000 does not fall within that exemption because it is an investigational new drug for which there is no marketing authorization in the United States. Because ALA-3000 is an investigational new drug its indication(s), warnings, precautions, adverse reactions, and dosage and administration have not been established.

associated with ketamine (e.g., sedation, dissociation, respiratory depression, hemodynamic instability, and abuse and misuse) and its CIII controlled substance status.

Additionally, we note that the exhibit booth display did not include any information to indicate that ALA-3000 is an investigational new drug that has not been approved for commercial distribution in the United States, and that the ALA-3000 booth appeared in the exhibit hall at APA near booths for approved products.

In summary, the above cited claims on the exhibit booth display and in the brochure represent ALA-3000 as treating TRD, when the drug has not been proven safe and effective within the meaning of the FD&C Act and has not been approved as a drug under that authority for any use.

Conclusion and Requested Action

For the reasons discussed above, the exhibit booth display and brochure misbrand ALA-3000 under section 502(f)(1) of the FD&C Act and in violation of section 301(a) of the FD&C Act. The claims in the exhibit booth display and brochure are particularly concerning because ketamine, the active ingredient of ALA-3000, is a Schedule III controlled substance associated with a number of serious risks, including sedation, dissociation, respiratory depression, hemodynamic instability, and abuse and misuse. The claims make representations in a promotional context regarding the safety and efficacy of an investigational new drug that has not been approved or authorized by the FDA.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Alar take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that misbrand the drug 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 for ALA-3000 that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of ALA-3000.

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 1 in addition to the IND 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. 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}

Emily Foltz, PharmD, RPh
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Taylor Burnett Mmagu, PharmD, RAC
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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.

/s/

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08/21/2026 02:32:46 PM

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