



Vidya Vepuri, Director
AVANTHI, INC.
110 Terry Drive, Suite 100
Newtown, PA 18940

RE: ANDA 203495
LOMAIRA™ (phentermine hydrochloride USP) tablets, CIV
MA 47

WARNING LETTER

Dear Ms. Vepuri:

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 AVANTHI, INC.'s (Avanthi) panel for LOMAIRA™ (phentermine hydrochloride USP) tablets, CIV (Lomaira) that appeared in the main exhibit hall at the Endocrine Society's 99th Annual Meeting and Expo¹ and the American College of Cardiology's 66th Annual Scientific Session and Expo.² This panel makes false or misleading claims and/or representations about the risks associated with Lomaira and omits material facts. Thus, the panel misbrands Lomaira within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act), and makes its distribution violative. 21 U.S.C. 352(a); 321(n), 331(a). Cf. 21 CFR 202.1(e)(3)(ii); (e)(5). These violations are concerning from a public health perspective because they create a misleading impression about the safety and approved indication for Lomaira.

Background

Below are the indication and summary of the most serious and most common risks associated with the use of Lomaira.³ According to the FDA-approved product labeling (PI):

LOMAIRA™ tablets are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial body mass index greater than or equal to 30 kg/m², or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). . . .

¹ The Endocrine Society's 99th Annual Meeting and Expo took place from April 1st to 4th, 2017.

² The American College of Cardiology's 66th Annual Scientific Session and Expo took place from March 17th to 19th, 2017.

³ This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

The limited usefulness of agents of this class, including phentermine, should be measured against possible risk factors inherent in their use

Lomaira is contraindicated in patients with a history of cardiovascular disease; during or within 14 days following the administration of monoamine oxidase inhibitors; in patients with hyperthyroidism, glaucoma, agitated states, or history of drug abuse; in pregnant or nursing patients; and in patients with a known hypersensitivity, or idiosyncrasy to the sympathomimetic amines. The PI for Lomaira contains warnings regarding coadministration with other drug products for weight loss, primary pulmonary hypertension, valvular heart disease, development of tolerance and discontinuation, effect on the ability to engage in potentially hazardous tasks, risk of abuse and dependence, usage with alcohol, use in patients with hypertension, and use in patients on insulin or oral hypoglycemic medications for diabetes mellitus. Adverse events have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems.

False or Misleading Risk Presentation

Promotional materials misbrand a drug if they are false or misleading with respect to risk. The determination of whether promotional materials are misleading includes, among other things, not only representations made or suggested in promotional materials, but also failure to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials.

The panel makes representations and/or suggestions about the benefits of Lomaira; however, it fails to communicate **any** risk information. By omitting the risks associated with Lomaira, including serious and potentially fatal risks, the panel fails to provide material information about the consequences that may result from the use of the drug and creates a misleading impression about the drug's safety.

Omission of Material Facts

The panel makes several representations and/or suggestions about the benefits of Lomaira such as the following (emphasis original):

- **“THE POWER OF THREE”**
“Diet” “Exercise” “Lomaira”TM,”
- **“Consider adding LomairaTM to your patients’ weight-management plan”**

However, the panel is misleading because it fails to communicate material information regarding the FDA-approved indication for Lomaira. Specifically, it omits the following material information from the INDICATIONS AND USAGE section of the PI (underlined emphasis added):

LOMAIRATM tablets are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial body mass index

greater than or equal to 30 kg/m², or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).

The limited usefulness of agents of this class, including phentermine, should be measured against possible risk factors inherent in their use

By omitting this information, the panel creates a misleading impression about the FDA-approved indication for Lomaira. These omissions are particularly concerning from a public health perspective due to the serious health risks associated with Lomaira.

Conclusion and Requested Action

For the reasons discussed above, the panel misbrands Lomaira within the meaning of the FD&C Act and makes its distribution violative. 21 U.S.C. 352(a); 321(n), 331(a). Cf. 21 CFR 202.1(e)(3)(ii); (e)(5).

OPDP requests that Avanthi immediately cease misbranding Lomaira and/or cease introducing the misbranded drug into interstate commerce. Please submit a written response to this letter on or before January 4, 2018, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Lomaira that contain statements such as those described above, and explaining your plan for discontinuing use of such materials, or, in the alternative, for ceasing distribution of Lomaira. Because the violations described above are serious we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials. In order to clearly identify the violative promotional piece(s) and/or activity and focus on the corrective message(s), OPDP recommends that corrective piece(s) include a description of the violative promotional piece(s) and/or activity, include a summary of the violative message(s), provide information to correct each of the violative message(s), and be free of promotional claims and presentations. To the extent possible, corrective messaging should be distributed using the same media, and generally for the same duration of time and with the same frequency that the violative promotional material was disseminated.

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. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 47 in addition to the ANDA 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 Warning Letter. OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Lomaira comply with each applicable requirement of the FD&C Act and FDA implementing regulations. Failure to

correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

{See appended electronic signature page}

Robert Dean
Director
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

cc: Anthony Tabasso, President and CEO
KVK-TECH, INC. [US Agent for AVANTHI, INC.]
110 Terry Drive, Suite 200
Newtown, PA 18940

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT T DEAN
12/19/2017