DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring MD 20993

NOV 16 2016

VIA UPS

Clarence Friedman
Chief Executive Officer
Antera Therapeutics
21 Hews Street, No. 3
Cambridge, MA 02139

Dear Mr. Friedman:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States (U.S.) Food and Drug Administration (FDA) has reviewed your Internet website: http://www.aralyte.com. Your website offers for sale "Aralyte Starter Kit, an all-natural formula that makes giving peanut protein to your child safe and easy. Each liquid dose contains clinically supported amounts of peanut protein."

Specifically, your website states:

- "Aralyte…is strictly a preventive measure intended to reduce the risk of allergy development in children who are not allergic."
- "Your child should begin Aralyte between 4 and 11 months of age, as this is an important time in the development of your baby's immune system and when your baby is able to ingest more foods."
- "Aralyte is designed to help the body process the peanut allergen in the most safe and effective way."
- "The Aralyte daily regimen was crafted to be a precise amount of exposure to the allergen, keeping your baby safe."
- "Aralyte's formula, manufacturing, packaging, and storage have been developed to be maximally **effective in allergy prevention** and with your family's safety in mind." **(emphasis added)**
- "Studies show that early, controlled exposure to allergens tolerizes the immune system. Aralyte... provides this in an easy regimen"

Based on these claims, it appears that your product is intended to prevent a peanut allergy from developing in children, and therefore appears to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man [21 U.S.C. 321(g)]. Additionally, your product appears to be a biological product as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)] because it is an allergenic product applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Please be advised that in order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations (21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312). Your product is not the subject of an approved biologics license application (BLA) nor is there an IND in effect for the use of this product. Based on this information, we have determined that your actions have violated the FFD&C Act and PHS Act.

We request that you notify this office, in writing, of the steps you have taken or will take to address the violations noted above and to prevent their recurrence. Your response should be sent to the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 71, Silver Spring, MD 20993.

If you have any questions regarding this matter, you may contact the Division of Case Management at (240) 402-9155. Please be advised that only written communications are considered official.

Sincerely,

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Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research