U.S. FOOD & DRUG ADMINISTRATION

October 11, 2018

VIA UPS EXPRESS MAIL AND FASCIMILE

To the Registrant of www.ollereg.com
c/o Dr. Dat Tran
(b) (6)

Dear Dr. Tran:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your Internet websites: http://www.ollereg.com, and http://www.innovativeallergy.com. Your websites market OLLEREG™ Oral Immunotherapy treatment product(s) to adults and children for food, respiratory and environmental allergies.

Specifically, your websites state:

- ". . . [OLLEREG is] a painless, convenient and effective treatment for food and environmental allergies[.]"
- "We offer OLLEREG, an innovative oral immunotherapy as an alternative to allergy shot for the treatment of environmental allergies."
- "OLLEREG is a painless & fun treatment. Why endure the anxiety, pain and inconvenience of the needle from allergy shots when you can have a fun treatment with OLLEREG? One spray into the mouth twice daily, anytime, anywhere. Now that's COOL!"
- "Convenient Oral Allergy Treatment. OLLEREG is perfect for adults and kids without disrupting your busy schedule. Just one simple spray in the morning before you step out the door and a second one in the evening."
- "OLLEREG is also perfect for environmental allergies without the inconvenience of side effects from medications, frequent doctor visits or painful injections from allergy shots."
- "OLLEREG is unique in its adjuvant and delivery system for allergen desensitization."
- "OLLEREG contains FDA-approved allergens used off label for oral immunotherapy."

Based on these statements, it appears that your product is intended to treat and/or prevent allergies in adults or 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 involving your product. Based on this information, your actions violate the FFD&C Act and the PHS Act.

This letter is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that you and your products comply with all applicable laws and regulations.

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, Office of Compliance and Biologics Quality at (240) 402-9155. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Please be advised that only written communications are considered official.

Sincerely,

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

cc: Innovative Allergy Clinic
ATTN: Dr. Dat Tran
4110 Bellaire Blvd Ste 202
Houston, TX 77025