DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

NOV 1 0 2016

VIA UPS

Dr. David Erstein, CEO
c/o Assured Bites, Inc.
137-49 70th Road
Flushing, NY 11367

Dear Mr. Erstein:

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.hello-peanut.com. Your website offers for sale three products: Hello-Peanut! ™ Introduction kit, Maintenance Kit, and Combination Kit. Hello, Peanut! ™, made of an all-natural United States Department of Agriculture (USDA) certified organic blend of peanut and sprouted oats.

Specifically, your website states:

- Hello, Peanut!™ offers parents a way to introduce babies to peanuts early, and allows for continued consumption which is recommended by scientific studies and the American Academy of Pediatrics.

- Hello, Peanut!™ is an innovative food product that offers parents peace of mind when it comes to babies and peanut introduction.

- "Our product is modeled after validated scientific studies. Studies have recommended early introduction of peanut and continued consumption of peanut, a few times weekly, to help prevent a child from developing a peanut allergy."

- Hello, Peanut!™ is a new and effective system designed to gradually introduce peanuts to infants as early as 5 months old.

- Hello, Peanut! ™ is a system modeled after scientifically designed food challenge and desensitization protocols used in allergists' offices and academic institutions nationwide.

Based on these statements, 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 the 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,

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

cc: Isaac Gottlieb
Assured Bites, Inc.
137-49 70th Road
Flushing, New York 11367