March 23, 2021

UPS EXPRESS MAIL

Mr. Gene Kakaulin
Chief Executive Officer
Curex, Inc.
95 Fifth Avenue
Floor 4
New York, NY 10003

Dear Mr. Kakaulin:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research of the United States Food and Drug Administration (FDA) has reviewed your firm's Internet website www.getcurex.com.

Based on our review, you and your firm market mixtures of allergenic extracts intended for sublingual immunotherapy (SLIT), which you refer to on your website as "allergy drops" and "drop compounds". For example, your website states:

- "Curex treats people who suffer from all types of allergies . . . ."
- "Curex allergy drops (also known as sublingual immunotherapy) is an equally effective, much less invasive way to treat allergies from home."
- "We use FDA-approved extracts in a clinically proven practice that, when done diligently with proper medical care, can significantly reduce your allergy symptoms."
- "You take sublingual immunotherapy by putting a daily drop of the compound under your tongue . . . ."
- "Our doctors will assist you at the different stages of your allergy care journey. They will help you start drops and will monitor your treatment to see if drop compounds and/or dosages need to be adjusted."

- "Our doctors formulate a unique treatment for you that may include multiple allergies, including pets, dust mites, grasses, pollens, molds and fungi, and many more."

- "The therapy is a formulation of specific allergens that helps reduce allergy symptoms and the need for allergy medications (i.e., antihistamines) over time. Each compound is customized to the individual patient based on their medical profile, test results, and lifestyle needs."

The "allergy drops" and "drop compounds" marketed on your website are drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)].

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 application (IND) in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312; 21 CFR Part 601.21].

Licensed biological products may not be combined with other licensed biological products, either therapeutic, prophylactic, or diagnostic, except as a license is obtained for the combined product [21 CFR 610.17]. Accordingly, to be lawfully marketed, a mixture of licensed allergenic extracts must be the subject of an approved biologics license application (BLA).

Your products are not the subject of an approved BLA nor is there an IND in effect for any of your products. Therefore, the marketing and distribution of such products appears to violate the FD&C Act and the PHS Act.

Please be advised that biological products subject to licensure under section 351 of the PHS Act are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FD&C Act. For additional information, we recommend that you review FDA's Guidance for Industry, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approve Biologics License Application (January 2018), available at https://www.fda.gov/files/drugs/published/Mixing--Diluting--or-RepackagingBiological-Products-Outside-the-Scope-of-an-Approved-Biologics-LicenseApplication.pdf.

This letter is not intended to be an all-inclusive review. You and your firm are responsible for ensuring that all your products fully comply with the FD&C Act, PHS Act, and all applicable regulations. We request a written response within 30 days of your receipt of this letter. 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. In addition, you may also submit an electronic copy of your response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER 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