January 22, 2021

VIA E-MAIL & UPS EXPRESS MAIL

William Chatoff, R.Ph., BCNP
Founder & CEO
Edge Pharma, LLC
856 Hercules Drive
Colchester, VT 05446

Dear Mr. Chatoff:

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 https://allergy.edgepharma.com, as well as other information available to FDA.

Based on the materials reviewed, you and your firm market mixtures of allergenic extracts for allergy treatment (immunotherapy), which your firm's website refers to as "custom mix allergy immunotherapy vials." It appears that these products are not prepared for individual patients; your firm's website has previously referred to the products as "bulk vials without . . . patient names." Additionally, based on the materials reviewed, you and your firm market mixtures of allergenic extracts for patient specific allergy treatment, some of which are intended for sublingual immunotherapy (SLIT). Your firm's website refers to these mixtures as "patient specific immunotherapy vials."

This letter focuses on your "patient specific immunotherapy vials" intended for SLIT and your "custom mix allergy immunotherapy vials" (hereafter, referred to collectively as "your products").[1] Your products 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)].

[1] Although not the focus of this letter, we also note that certain of your firm's materials refer to "LDA" products. Please be advised that, as a general matter, Low Dose Antigen (LDA) products intended for the treatment of allergies and consisting of mixtures of licensed allergenic extracts at dosages lower than described in the approval labeling for those extracts are regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act and are subject to premarket review and approval requirements.

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].

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.

We also note that your firm's website refers to Edge Pharma as a "registered 503B outsourcing facility." 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 Approved Biologics License Application (January 2018), available at https://www.fda.gov/files/drugs/published/Mixing--Diluting--or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.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. 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

Cc: James Baker, MD
Founder & President
Xtract Solutions
9954 SW Arctic Dr.
Beaverton, OR 97005

Luke Barratt
Chief Executive Officer
Xtract Solutions
9954 SW Arctic Dr.
Beaverton, OR 97005