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April 22, 2021

VIA EMAIL:
CBERDCMRecommendations@fda.hhs.gov

Ms. Mary A. Malarkey
Director, Office of Compliance and Biologics Quality
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue, Bldg. 71
Silver Spring, MD 20993

Re: Response to FDA's March 23, 2021 Letter to Curex, Inc.

Dear Ms. Malarkey:

I am writing to you on behalf of our client, Curex, Inc. ("Curex") in response to your letter of March 23, 2021, concerning Curex's website, www.getcurex.com. In your letter, you refer to statements that appeared on the company's website concerning allergenic extracts intended for sublingual immunotherapy (SLIT), and you note that the marketing of a drug that is a biological product requires a valid biologics license application to be in effect pursuant to 42 U.S.C. 262(a).

Please be assured that Curex takes very seriously the concerns in your letter and has implemented corrective actions to address them. Curex has removed the statements identified in your letter and other similar statements promoting unlicensed products.

Curex's website now consists of "help-seeking" promotional material. It describes allergies and allergy therapy generally and instructs the viewer to contact a clinician to discuss appropriate allergy treatments. Launched during the COVID-19 pandemic, Curex provides patients with access to licensed allergy clinicians via its telehealth platform. The revised website can be found at www.getcurex.com.

On behalf of Curex, I trust that this adequately responds to the concerns described in your letter. If you have any further questions, please feel free to contact me at (202) 672-5430 or via email at drosen@foley.com.

Sincerely,

David L. Rosen, BS Pharm., JD

Cc: Mr. Gene Kakaulin
Curex, Inc.