FDA U.S. FOOD & DRUG ADMINISTRATION

Alan Dumoff
30 Windbrooke Circle
Gaithersburg, MD 208792

SEP 16 2019

Re: Docket No. FDA-2019-P-1351

Dear Mr. Dumoff:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on March 20, 2019. Your petition requests that the Agency, among other things, revise the final rule issued February 19, 2019 to establish criteria for and identify an initial list of bulk drug substances that can be used in compounding under section 503A of the Federal Food, Drug, and Cosmetic Act, although those substances are not the subject of an applicable United States Pharmacopeia or National Formulary monograph or components of FDA-approved drug products.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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