FDA U.S. FOOD & DRUG ADMINISTRATION

Vincent Canzanese
Summit Health Pharmacy Inc.
3400 Edgmont Ave.
Brookhaven, PA 19014

Re: Docket No. FDA-2019-P-2088

OCT 25 2019

Dear Mr. Canzanese:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 30, 2019. Your petition requests that the Agency add oxitriptan, also known as 5-hydroxytryptophan (5-HTP), to the list of bulk drug substances that can be used in compounding under section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) (the 503A Bulks List) and "allow continued compounding of oxitriptan for the treatment of tetrahydrobiopterin deficiency diseases in the interim."

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.[1]

Sincerely,

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

[1] In July 2019, FDA issued guidance for industry titled "Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency" concerning the conditions under which the Agency does not generally intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician using the bulk drug substance oxitriptan to compound oral drug products for patients with BH4 deficiency. The guidance also states that in light of new information provided to the Agency regarding use of oral oxitriptan to treat BH4 deficiency, FDA is considering whether to reevaluate the exclusion of oxitriptan from the 503A Bulks List. The guidance is available at https://www.fda.gov/media/128603/download. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

U.S. Food & Drug Administration
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