U.S. FOOD & DRUG ADMINISTRATION

Office of Orphan Products Development
Food and Drug Administration
WO32- 5295
10903 New Hampshire Avenue
Silver Spring, MD 20993

Scott M. Lassman
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Re: Docket No. FDA-2019-P-1679

Dear Mr. Lassman:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on April 5, 2019, and your supplements received on May 23, 2019, August 15, 2019, and August 22, 2019.

FDA is still considering your petition because it raises significant 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,

Janet W. Maynard, M.D., M.H.S
Director
Office of Orphan Products Development