U.S. FOOD & DRUG ADMINISTRATION

Diane Kramer
2217 Concord Drive
State College, PA 16801

October 1, 2020

Re: Docket No. FDA-2019-P-5440

Dear Ms. Kramer:

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 November 18, 2019. Your petition requests that the Agency "issue an indication for the drug modafinil (Provigil) [to] be used in the management of multiple sclerosis related fatigue." Specifically, you ask that the labeling for this product be amended to add "multiple sclerosis related fatigue" to the Indications and Usage section, as well as a recommended dosage for multiple sclerosis related fatigue of 200 mg per day to the Dosage and Administration section.

FDA has been unable to reach a decision on your petition due to other Agency priorities. 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 Bennett -S

Digitally signed by Carol Bennett -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

bcc:

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