



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 18, 2019

Diane Kramer

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to issue an indication for the drug modafinil (Provigil) be used in the management of multiple sclerosis related fatigue was received by this office on 11/18/2019.

It was assigned docket number FDA-2019-P-5440. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard
Director
Dockets Management Staff
OC/OO/OEMS/DIG