U.S. FOOD & DRUG ADMINISTRATION

October 5, 2022

[redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-0599

Dear [redacted]:

This is an interim response to the petition dated April 12, 2022, filed by the Food and Drug Administration (FDA) on April 15, 2022. In the petition, you requested FDA issue an Order regarding the practice of requiring neuropsychological testing prior to DBS surgery. More specifically, the Commissioner should specify that the use of such testing and the weighing of the perceived benefits and risks of DBS surgery, including that gleaned from any neuropsychological assessments, should be left to the patient to decide.

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

If you have any questions about this interim response, please contact Rachael Hunt at Rachael.Hunt@fda.hhs.gov.

Sincerely yours,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S Date: 2022.10.05 14:08:13 -04'00'

Ellen J. Flannery, JD
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