DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

DEC 7 2015

Elizabeth Barbehenn, PhD
Public Citizen
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. FDA-2015-P-2142

Dear Dr. Barbehenn:

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 June 11, 2015. Your petition asks FDA to:

- Require changes to the approved labeling for Hetlioz (tasimelteon) 20 milligram oral capsules (NDA 205677), narrowing the approved indication and adding certain risk information,
- Require distribution of a medication guide with each prescription of Hetlioz informing patients of the changes to the labeling requested in your petition,
- Require the holder of NDA 205667 to send a "Dear Doctor" letter notifying physicians and health care providers of the narrower indication, and
- Require the holder of NDA 205667 to conduct a postmarketing clinical trial intended to collect safety information.

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.

Sincerely,

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