Food and Drug Administration Silver Spring, MD 20993

June 11, 2015

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

Dear Petitioner,

Your petition to the Food and Drug Administration requesting that the FDA take the actions requested in the Petition with respect to the prescription drug tasimelteon (Hetlioz) was received by this office on 06/11/2015.

It was assigned docket number FDA-2015-P-2142, and it was filed on 06/11/2015. 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,

Dynna Bigby

Supervisory Administrative Proceedings Specialist

Division of Dockets Management

FDA/Office of the Executive Secretariat (OES)