DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JAN 21 2014

Allen Waxman
Eisai Inc.
100 Tice Boulevard
Woodcliff Lake, NJ 07677

Re: Docket No. FDA-2013-P-0884

Dear Mr. Waxman:

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 July 25, 2013. Your petition requests that the Agency take the following actions: (1) determine that the date of approval that starts the five-year new chemical entity (NCE) exclusivity period for Belviq (lorcaserin hydrochloride) is June 7, 2013, the date that Eisai could commercially market Belviq in interstate commerce, (2) determine that the date of approval that starts the five-year NCE exclusivity period for Fycompa (perampanel) is the date that Eisai can commercially market the product in interstate commerce, and (3) provide a substantive response to this petition before Fycompa's Controlled Substances Act (CSA) scheduling is finalized, or within five months from the date this petition is submitted to FDA, whichever date is earliest.

FDA has been unable to reach a decision on your petition because it raises significant and 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,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research