



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 25, 2013

FILE COPY

Allen Waxman
Senior Vice President and General Counsel
Law & Government Affairs
Eisai Inc.
100 Tice Boulevard
Woodcliff Lake, NJ 07677

Dear Mr. Waxman:

Your petition to the Food and Drug Administration requesting the following actions be taken as it pertains to BELVIQ® to determine that the date of approvals that starts the five-year NCE and respond to the petition before FYCOMPA™'s CSA scheduling is finalized, was received by this office on 07/25/2013. It was assigned docket number FDA-2013-P-0884/CP1, and it was filed on 07/25/2013. 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
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0884

ACK