



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 16, 2020

Colleen M. Johns
Head of Regulatory Affairs
Alpha Cognition USA, Inc
1645 Palm Beach Lakes Blvd., Suite 1200
West Palm Beach, FL 33401

Sent via email to: cjohns@alphacognition.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to designate an additional reference standard (RS) for Galantamine Hydrobromide Oral Tablets in the active section of the Orange Book for conducting BE studies was received by this office on 12/16/2020.

It was assigned docket number FDA-2020-P-2301. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)