December 10, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

Alpha Cognition USA Inc., the US Agent for Alpha Cognition, Inc. (439 Helmcken St., Vancouver BC, Canada) hereby submits this petition pursuant to the Federal Food, Drug and Cosmetics Act ("FD&C Act") and in accordance with 21 CFR 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to designate an additional reference standard (RS) for Galantamine Oral Tablet in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) since the current Reference Listed Drug (RLD) and the RS in not available in the market.

A. Action Requested

The petitioner respectfully requests the Commissioner of the Food and Drug Administration to designate an additional reference standard (RS) for Galantamine Hydrobromide Oral Tablets in the active section of the Orange Book for conducting BE studies.

B. Statement of Grounds

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the Food and Drug Administration (FDA or the Agency) a New Drug Application that relies in part on FDA's finding of safety and/or efficacy for a listed drug. In order to rely on data for a listed drug product, the applicant will need to establish a bridge-demonstrating that reliance is scientifically justified, using comparative bioavailability data between the proposed drug product and the listed drug upon which the applicant relies. The Reference Standard selected by FDA is the specific drug product that the applicant must use in conducting any in vivo bioequivalence testing required to establish a scientific bridge. All the approved drug products by the FDA are listed in the Orange Book.

In accordance with Section III.C.2 of FDA's Guidance for Industry, 'Referencing Approved Drug Products in ANDA Submissions', "FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in

distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard has not been withdrawn from sale). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the RLD and is the market leader based on commercial data."

Section II.C.3 of the guidance document also states, "There are circumstances in which a potential ANDA applicant may ask FDA to select a refence standard. These circumstances include, for example, if FDA has not selected a reference standard, if a reference standard is moved to the Discontinued Section and FDA has not selected a new reference standard for the same drug product, if a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, or if the quantity of reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing. A potential ANDA applicant may submit controlled correspondence to FDA to ask FDA to select a reference standard for a drug product."

Currently, the designated reference standard for Galantamine Hydrobromide Oral Tablets, 4 mg is Janssen NDA #021169 and shown as active in the electronic Orange Book (**Table 1 and Attachment 1 Electronic Orange Book search results**) but the product is not available in the market. Alpha Cognition has been informed that Janssen has discontinued their product and the last batch for distribution was in April 2019 (**Table 2**).

Table 1

RX	GALANTAMINE HYDROBROMIDE	RAZADYNE	N021169	TABLET	ORAL	EQ 4MG BASE	AB	RLD	RS	JANSSEN PHARMACEUTICALS INC
RX	GALANTAMINE HYDROBROMIDE	RAZADYNE	N021169	TABLET	ORAL	EQ 8MG BASE	AB	RLD		JANSSEN PHARMACEUTICALS INC
RX	GALANTAMINE HYDROBROMIDE	RAZADYNE	N021169	TABLET	ORAL	EQ 12MG BASE	AB	RLD		JANSSEN PHARMACEUTICALS INC

Table 2

Janssen Pharmaceuticals (*New 10/29/2018*)

Company Contact Information:
800-526-7736

Presentation	Posting Date	Related Information
4 mg tablets (NDCs 50458-396-60 and 10147-0881-6)	10/29/2018	The last batches will be distributed April 2019.
8 mg tablets (NDCs 50458-397-60 and 10147-0882-6)	10/29/2018	The last batches will be distributed April 2019.
12 mg tablets (NDCs 50458-398-60 and 10147-0883-6)	10/29/2018	The last batches will be distributed April 2019.

The lack of availability of the current reference standard is preventing bioequivalence study in support of Alpha Cognition's New Drug Application. Therefore, the petitioner respectfully requests the Commissioner to designate a marketed, approved generic drug product to be designated as the reference standard to enable establishment of a scientific bridge to allow reliance on FDA's finding of safety and efficacy for the listed drug, Razadyne Oral Tablets, 4mg.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the Agency.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views, on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

If you have any questions regarding the information provided in this submission or require additional information, please contact me by telephone at 910-512-1482 or by email at cjohns@alphacognition.com.

Sincerely,

Colleen M. Johns

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Attachment 1: Screenshot of the electronic Orange Book search results for Galantamine Oral Tablet.