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22 Feb. 2022

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

Re: SUITABILITY PETITION – Vigabatrin for oral solution 25 g/bottle

Dear Sir/Madam:

Upadhye Tang LLP, submits this Suitability Petition, on behalf of an unnamed client ("Petitioner") as authorized attorney for the person under 21 C.F.R. §10.20(b). Pursuant to Section 355 (j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance to 21 C.F.R. §§314.93(b); and 10.30 Petitioner requests the Commissioner of the Food and Drug Administration (FDA) to provide a determination whether the drug product Vigabatrin for oral solution (Sabril) 500 mg/packet can be submitted as Vigabatrin for oral solution, 25 g/bottle (Change of Strength) are suitable for submission in an Abbreviated New Drug Application (ANDA).

Action Requested

Petitioner requests that the Commissioner determine whether Vigabatrin for oral solution, 25 g/bottle is suitable for submission in an ANDA. The Reference Listed Drug (RLD) upon which this petition is based is Vigabatrin for oral solution (Sabril) 500 mg/packet held by LUNDBECK PHARMACEUTICALS LLC NDA #022006. Therefore, Petitioner is seeking a change in strength (total drug content per container).

Statement of Grounds

21 U.S.C. §355(j)(2)(A) permits the submission of an ANDA for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition submitted pursuant to §355(j)(2)(C) that proposed submitting such an application.

The RLD is Vigabatrin for oral solution (Sabril) 500 mg/packet. We attach for reference a copy of the listing in the current electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1) and the current RLD labeling (Attachment

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2). Petitioner's proposed drug product in a 25 g/bottle is a multi-dose drug in a bottle represents a change in strength (total drug content).

Per 21 C.F.R. §314.93(d), the active ingredients of the ANDA supplement are the same as the reference listed drug. Because both products are oral solutions of the same active ingredient, the proposed drug product is expected to have the same therapeutic effect as the reference listed drug. Per §314.93(e), Petitioner believes that no new investigations must be conducted to show the safety and efficacy of the proposed supplement. Further, the proposed changes to the supplemental product will not jeopardize the safe and effective use so as to necessitate significant labeling changes to address any newly introduced safety or effectiveness problem. The Reference Listed Drug as not been withdrawn for any safety or efficacy concerns.

Pursuant to 21 U.S.C. §355(j)(2)(A), the abbreviated new drug application (ANDA) for a proposed drug product is not obligated to use the same container closure system or strength as the one used by the applicant of the reference-listed drug. However, the ANDA is required to provide appropriate information to ensure that the proposed drug product has the same conditions of use and the same labeling as the RLD pursuant to Section §355(j)(2)(A)(v) of the FD&C Act except for the changes allowed in change of strength & packaging.

Please note that the changes proposed by Petitioner in strength and container size do not affect dosing, administrations and conditions of use. The indications, warnings and directions for use will remain the same as that of the RLD. According to the Dosage and Administration in the currently approved RLD package insert the dose is "for oral solution".

The 25 g/bottle fill sizes would provide an appropriate multi-dose presentations when these volumes of drug product are required in different clinical settings. This availability will help minimize the unused portions waste.

Petitioner's draft labeling for the proposed product is included in Attachment 3, and the RLD's current labeling (from DailyMed) is provided in Attachment 2. No changes from the RLD are proposed in labeling for 25 g/bottle fill sizes with the exception of the obvious changes in strength (total drug content) sought in this petition, administrative information and container closure size.

Therefore, the Petitioner requests that the FDA grant this suitability petition within the time limit specified in 21 C.F.R. §314.93(e).

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Environmental Impact

In accordance with the requirements set forth in 21 C.F.R. §25.31, the Petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

Economic Impact

Pursuant to 21 C.F.R. §10.30(b)(3) an economic impact analysis will be provided upon request.

Certification

Petitioner certifies that to the best knowledge and belief of the undersigned, this Suitability Petition includes all information and views on which the Petition relies, and includes representative data and information known to the petitioner, which is unfavorable to the Petition.

Should you have any questions, please feel free to contact the undersigned.

Regards,

Shashank Upadhye
Attorney for Petitioner
Upadhye Tang LLP