July 25, 2024

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

SUITABILITY PETITION

Dear Sir or Madam:

The undersigned petitioner submits this petition, on behalf of a client, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30 requesting the Commissioner of the Food and Drug Administration ("FDA") to declare that the proposed drug product Sertraline Capsules, 25 mg, 50 mg, and 100 mg is suitable for consideration in an Abbreviated New Drug Application ("ANDA").

I. ACTION REQUESTED

The petitioner requests that the Commissioner of the FDA declare that the proposed drug product, Sertraline Capsules, 25 mg, 50 mg and 100 mg is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Sertraline Capsules, 150 mg and 200 mg by Almatica Pharma, LLC., NDA #215133.

The petitioner hereby seeks approval of a change in strength to 25 mg, 50 mg and 100 mg capsules compared to the approved 150 mg and 200 mg capsules of the RLD.

II. STATEMENT OF GROUNDS

The FD&C Act § 505(j)(2)(C) provides for the submission of an ANDA for a drug product that differs in strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

Sertraline Hydrochloride (HCl) Capsules are indicated for the treatment of Major Depressive Disorder (MDD) in adults and Obsessive-Compulsive Disorder (OCD) in adults and pediatric patients 6 years and older.

Dosing and administration recommendations for NDA 215133 include the following information in Section 2.1 Dosage in Patients with MDD and OCD:

> Do not initiate treatment with Sertraline HCL Capsules because the only available dose strengths are 150 mg and 200 mg. Use another sertraline HCl product for initial dosage, titration, and dosages below 150 mg once daily. Refer to Prescribing Information of the other sertraline HCl products for the recommended dosage for those products.
>
> Sertraline HCl Capsules can be initiated in patients receiving 100 mg or 125 mg of sertraline HCl for at least one week. The recommended dosage of Sertraline HCl Capsule is 150 mg or 200 mg once daily. The maximum dosage recommended is 200 mg once daily.

Maintenance Therapy and Initial Titration

Current dosing recommendations for NDA 215133 clearly contemplate administration of 100 mg and 125 mg doses for patients where these doses are currently unattainable via existing capsule products since the 150 mg and 200 mg capsule products that are approved cannot be opened, crushed, or chewed. Thus, patients initiating therapy must obtain the appropriate starting dose and titrate with an alternate dosage form where the options are either tablets or oral concentrate. For patients that prefer a capsule dosage form for ease of swallowing, the unavailability of sertraline HCl capsules in lower strengths means that the patient must initiate therapy and titrate their dose with an alternate dosage form that may be less preferred by the patient and then later switch to the capsule dosage form.

It is clear from the approved labeling of Almatica's NDA 215133 for Sertraline HCl Capsules 150 mg and 200 mg that additional strengths of the capsule dosage form would be useful for initiation of patient therapy at 100 mg (single proposed 100 mg capsule) and 125 mg (single proposed 100 mg capsule with single proposed 25 mg capsule) as well as when clinicians are titrating patients to the lowest effective dose. When titrating patients, both the proposed 25 mg and 50 mg capsules can be combined with the 100 mg capsule until the patient has been titrated to the appropriate maintenance dose. The proposed 50 mg capsule could also be used during titration where therapy is initiated at 100 mg (2 X 50 mg capsules), titrated to 150 mg (3 X 50 mg capsules), and further titrated to 200 mg (4 X 50 mg capsules) all with a single Sertraline HCl Capsule, 50 mg product which would result in less out of pocket expense to the patient as they would pay a single prescription copay if titrated in this manner. After titration, the patient could then be converted to the single daily Sertraline HCl Capsule, 150 mg or 200 mg product that was appropriate to meet their clinical needs.

Discontinuation of Therapy with Sertraline

Lack of availability of strengths of Sertraline HCl Capsules that are less than 150 mg also represents a challenge for patients that are discontinuing treatment with sertraline. Section 2.5 of the approved labeling for NDA 215133 includes the following information:

> Adverse reactions may occur upon discontinuation of Sertraline HCl Capsules [see Warnings and Precautions (5.5)]. Gradually reduce the dosage rather than stopping Sertraline HCL Capsules abruptly whenever possible. Given that dosage strengths lower than 150 mg of Sertraline HCl Capsules are not available, gradual reduction will require the use of another sertraline HCl product.

Availability of Sertraline HCL Capsules in 25 mg, 50 mg and 100 mg strength would perhaps offer the greatest benefit when tapering patients off sertraline therapy as the availability of these three proposed strengths would offer clinicians maximum flexibility in gradually reducing the patient's dosage consistent with recommendations in FDA approved labeling. Clinicians would be able to effectively taper down patients being treated for MDD or OCD without worrying about changing those patients to an alternate dosage form, as recommended in the approved labeling for NDA 215133, that is unfamiliar to the patient or any other variability associated with the change during the critical tapering phase of treatment.

Petitioner also notes that FDA has previously approved a Suitability Petition for Sertraline Capsules, 25 mg, 50 mg and 100. FDA approved Suitability Petition FDA-2000-P-0214 on July 3, 2002, where this Suitability Petition cited Zoloft® Tablets approved NDA 19839 as the RLD upon which a change in dosage form from tablets to capsules was approved by FDA.

III. Inapplicability of the Pediatric Research Equity Act ("PREA")

PREA, which is codified at FD&C Act§ 505B, does not apply to a new strength such as the one proposed in this petition. As such, PREA should not serve as an impediment to the Agency's granting of this petition.

IV. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

V. Economic Impact

The petitioner will submit information on economic impact upon request by the agency if applicable.

VI. 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.

Sincerely,

Martin Shimer Digitally signed by Martin Shimer Date: 2024.07.25 10:17:48 -04'00'

Martin Shimer
Executive Director, Regulatory Services
Lachman Consulting Services, Inc.

Please contact me at m.shimer@lachmanconsultants.com if you have any questions related to this petition.

Attachments accompanying this petition:

- Attachment 1: Copy of the relevant excerpt from the current electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) –
- Attachment 2: Current Package Insert for SERTRALINE HCL CAPSULES , NDA #215133 Revision 8/2023; source: Drugs@FDA
- Attachment 3: Draft Package Insert Proposed for Sertraline HCl Capsules, 25 mg, 50 mg and 100 mg