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

ANDA Suitability Petition for Solriamfetol Tablets, 37.5 mg

Dear Sir /Madam,

Alkem Laboratories submits this ANDA suitability petition pursuant to section 505(j)(2)(c) of the Federal Food Drugs & Cosmetic Act and in accordance with 21 CFR parts 10.25, 10.30 requesting the Commissioner of the Food and Drug Administration to provide a determination if Solriamfetol Tablets, 37.5 mg is suitable for ANDA submission.

A. Action Requested

The petitioner requests that, FDA determines that the proposed Solriamfetol Tablets, 37.5 mg is suitable for ANDA submission. This suitability petition pursuant to section 505(j)(2)(c) of FD&C Act and 21 CFR § 314.93 is the appropriate mechanism to secure FDA's authorization to submit an ANDA for a drug product that differs in strength from the Reference Listed Drug (RLD).

B. Statement of Grounds

The FD&C Act permits the submission of an ANDA for a drug product that differs in tablet strength from the RLD after FDA has approved a petition seeking permission to file such an application.

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products. *SUNOSI (solriamfetol) tablets 75 mg and 150 mg* of *JAZZ*

PHARMACEUTICALS IRELAND LTD, was approved by the FDA on June 17, 2019 (Refer Attachment-1).

The RLD is indicated for the treatment of to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). The dosage and administration also includes administration of 37.5 mg dose by splitting the 75 mg tablet which has a functional scoreline (Refer Attachment-2).

The following text is reflected in the Dosage and Administration section of RLD package insert (Refer Attachment-2):

2 DOSAGE AND ADMINISTRATION

2.1 Important Considerations Prior to Initiating Treatment

Prior to initiating treatment with SUNOSI, ensure blood pressure is adequately controlled [see Warnings and Precautions (5.1)].

2.2 General Administration Instructions

Administer SUNOSI orally upon awakening with or without food. Avoid taking SUNOSI within 9 hours of planned bedtime because of the potential to interfere with sleep if taken too late in the day.

SUNOSI 75 mg tablets are functionally scored tablets that can be split in half (37.5 mg) at the score line.

2.3 Dosage in Narcolepsy

Initiate SUNOSI at 75 mg once daily in adults with narcolepsy. The recommended dose range for SUNOSI is 75 mg to 150 mg once daily. Based on efficacy and tolerability, the dosage of SUNOSI may be doubled at intervals of at least 3 days. The maximum recommended dose is 150 mg once daily. Dosages above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions [see Warnings and Precautions (5.1)].

2.4 Dosage in OSA

Initiate SUNOSI at 37.5 mg once daily in adults with OSA. The recommended dosage range for SUNOSI is 37.5 mg to 150 mg once daily. Based on efficacy and tolerability, the dosage of SUNOSI may be doubled at intervals of at least 3 days. The maximum recommended dosage is 150 mg once daily. Dosages above 150 mg daily do not confer increased

effectiveness sufficient to outweigh dose-related adverse reactions [see Warnings and Precautions (5.1)].

2.5 Dosage Recommendations in Patients with Renal Impairment

Moderate renal impairment (eGFR 30-59 mL/min/1.73 m2): Initiate dosing at 37.5 mg once daily. Based on efficacy and tolerability, dose may be increased to a maximum of 75 mg once daily after at least 7 days [see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)].

Severe renal impairment (eGFR 15-29 mL/min/1.73 m2): Administer 37.5 mg once daily. The maximum recommended daily dose is 37.5 mg [see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)].

End Stage Renal Disease (eGFR <15 mL/min/1.73 m2): SUNOSI is not recommended for use in patients with ESRD [see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)].

Based on the above information and considering the patient compliance with medication regimens, Alkem intends to submit an additional strength of 37.5 mg for ANDA submission of Solriamfetol Tablets.

C. Environmental Impact

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

D. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

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 includes representative data and information known to the petitioner, which is unfavorable to the petition.

Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Version, accessed February 07, 2022.
2. SUNOSI® (solriamfetol) tablets 75 mg and 150 mg of JAZZ PHARMACEUTICALS IRELAND LTD approved labeling (RLD Labeling).

Yours truly,
Ascend Laboratories, LLC

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