Date: July 29, 2022

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

Suitability Petition Amendment
(FDA-2022-P-0151)
Information Request

Reference:

- ***ANDA Suitability Petition for Solriamfetol Tablets, 37.5 mg***
- ***Response to Suitability Petition (FDA-2022-P-0151) Information Request Dated July 25, 2022***

Dear Sir/Madam,

Alkem Laboratories hereby submit the response to Information Request for Suitability Petition (FDA-2022-P-0151) dated July 25, 2022 received from the agency.

Agency's Comment:

Reference is made to your suitability petition FDA-2022-P-0151, received on February 9, 2022, seeking permission to file an ANDA for Solriamfetol Tablets, 37.5 mg. We ask that you submit the following information as an amendment to the aforementioned petition to the Division of Dockets Management, in order for the Agency to complete the review of this petition:

1. Pursuant to 21 CFR 314.93(d), provide the proposed drug product labeling.

Response:

We note the agency's comment.

As per the agency's recommendation and pursuant to 21 CFR 314.93(d) following proposed drug product labeling are provided in this response to file an ANDA for Solriamfetol Tablets, 37.5 mg strength in addition to Solriamfetol Tablets, 75 mg and 150 mg strengths.

1. Proposed Prescribing Information with medication guide (PDF & Word) for Solriamfetol Tablets, 37.5 mg, 75 mg and 150 mg.
2. Side-by-side comparison between RLD and proposed generic Prescribing Information (PDF & Word) Solriamfetol Tablets, 37.5 mg, 75 mg and 150 mg.

3. Specimen proposed draft container labels for Solriamfetol Tablets, 37.5 mg, 75 mg and 150 mg.

Yours truly,
Hindy Schiff,
Ascend Laboratories, LLC.,
(Subsidiary of Alkem Laboratories Limited)

Address: 339 Jefferson Road,
Parsippany, New Jersey 07054
Phone: 201-326-9010
Fax: 201-256-3927
Email: HSchiff@ascendlaboratories.com