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September 26, 2019

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

The undersigned submits this Citizen Petition pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR § 10.25(a) and 10.30, to request the Commissioner of Food and Drug Administration to designate a suitable additional Reference Standard ("RS") for purposes of submitting an abbreviated new drug application ("ANDA") for Propranolol Hydrochloride Tablets USP 10 mg, 20 mg, 40 mg, 60 mg and 80 mg.

I. Action Requested

The Petitioner respectfully requests that the Commissioner designate RS status for Propranolol Hydrochloride Tablets USP 80 mg, held by Watson Laboratories Inc. (ANDA No. 070178)

II. Statement of Grounds

Please note that the FDA's Orange Book identifies the RLD (N016418-Inderal) as Discontinued. As such, quantities of the RS Product are required in order to conduct studies (BCS or In-Vivo Studies as per BE recommendation) to establish bioequivalence with the RS in absence of RLD which is discontinued. The present RS for Propranolol

Hydrochloride Tablets USP 80 mg is held by Impax Laboratories INC (ANDA No. 071976).

Despite diligent efforts to obtain sufficient quantities of the present RS for the Product, samples are not available in the market to conduct required studies.

Please note Propranolol Hydrochloride Tablets USP 80 mg manufactured by Watson Laboratories INC's, A070178 and distributed by Amneal Pharmaceuticals LLC are available in market. Amneal Pharmaceuticals LLC is using the same labeler code as of Impax Laboratories INC that is **(0115)** [DailyMed Label attached for reference]. Further as per information available in public domain and Impax Laboratories website (https://www.impaxlabs.com/) there is business merger of Impax Laboratories and Amneal Pharmaceuticals LLC.

ANDA Number	**Strengths**	**NDC**	**Remarks**
A070178	80 mg	0115-1662-01 (100's) 0115-1662-02 (500's)	Manufactured by Watson Laboratories INC's Distributed by Amneal Pharmaceuticals LLC

The market share of reference standard strength *i.e.*, 80 mg of Watson Laboratories Inc.'s is tabulated below for Agency's ready reference as per IMS health database.

NDC Number	**Market Share***	**Application Number**	**Manufacturer**
0115-1662-01	28.45%	ANDA070178	WATSON LABORATORIES INC
0115-1662-02	28.25%	ANDA070178	WATSON LABORATORIES INC

* Based on IMS Health Database as on July, 2019.

Per the Agency's published Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions (Jan. 2017), "If there is a reference standard in the 'Active Section' of the Orange Book for a drug product the applicant intends to duplicate but there are limited or no quantities in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition

under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

Conclusion

For the above stated reasons, this Citizen Petition should be granted.

III. Environmental Impact

The Petitioner believes that this petition does not require an environmental impact analysis report under 21 C.F.R. § 25.1(g).

IV. Economic Impact

An economic impact report is required only when requested by the Administration and such report has not been requested under 21 C.F.R. § 10.30(b).

V. Certification

The Petitioner certifies that, to the best of its knowledge and belief, this Petition includes all of the 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 Petitioner.

Respectfully submitted,

David L. Rosen, BS Pharm., JD
Foley & Lardner LLP

Attachment