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September 17, 2020

**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 Warfarin Sodium Tablets USP 1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg and 10 mg.

## I. Action Requested

The Petitioner respectfully requests that the Commissioner designate RS status for Warfarin Sodium Tablets USP 10 mg, held by Taro Pharmaceutical Industries Ltd. (ANDA No. 040301).

## II. Statement of Grounds

Please note that as per FDA's Orange Book the RLD/RS is COUMADIN (warfarin sodium) Tablets NDA - N009218, of Bristol Myers Squibb Pharma Co. Quantities of the RLD/RS Product are required in order to conduct studies (In-Vivo Studies as per BE recommendation) to establish bioequivalence with the RLD/RS.

To obtain sufficient quantities of the present RLD/RS for the Product, diligent efforts were made but samples are not available in the market to conduct required studies.

Therefore, our client is requesting to designate RS status for Warfarin Sodium Tablets USP 10 mg, held by Taro Pharmaceutical Industries Ltd. (ANDA No. 040301).

Please note Warfarin Sodium Tablets USP 10 mg (A040301) manufactured by Taro Pharmaceutical Industries Ltd is available in market, Product details along with market share for Reference standard strength is mentioned below:

| Application Number | Strength | Manufacturer | Market Share* |
|---|---|---|---|
| ANDA040301 | 10 mg | Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761<br>Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532 | 33.22% |

| NDC wise Market Share* (wrt Total market share of 33.22%) | |
|---|---|
| Bottles of 100s: 51672-4035-1 | 87.86% |
| Bottles of 1000s: 51672-4035-3 | 12.14% |

*As per IMS health database Jun-2020

As per the Agency's published 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

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 unfavourable to the Petitioner.

Respectfully Submitted,

David L. Rosen, BS Pharm., JD