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

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, on behalf of Rubicon Research Private Limited ("Rubicon"), 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 Diclofenac Sodium, delayed release tablet, 75 mg.

A. Action Requested

We respectfully request that the Commissioner designate RS status for Diclofenac Sodium, delayed release tablet, 75 mg, held by Unique Pharmaceutical Laboratories a division of J.B. Chemicals and Pharmaceuticals Ltd. (ANDA No. 077863).

B. Statement of Grounds

Rubicon is planning to submit an Abbreviated New Drug Application (ANDA) for Diclofenac Sodium, delayed release tablet, 75 mg (the "Product"). As such, quantities of the RS of the Product are required in order to conduct studies to establish bioequivalence with the RS. The present RS for Diclofenac Sodium, delayed release tablet, 75 mg is held by CASI Pharms, Inc. ("CASI") (ANDA No. 074394).

Despite diligent efforts to obtain sufficient quantities of the present RS for the Product, Rubicon has concluded that it is not available on the market. *See* **Rubicon Declaration**, submitted herewith as Attachment 1 (detailing attempts to obtain RS).

Notably, CASI, the current RS holder, has prioritized the drug market in China, not the United States, and appears intent on directing its drug supply even further away from the U.S. market. According to a press release announcing CASI's purchase of 25 ANDA products from Sandoz, Inc., including the ANDA for the RS at issue, Ken Ren, Ph.D., CASI's chief executive officer commented, "The acquisition of the Sandoz ANDAs enhances our strategic focus to build a robust pipeline and commercialize quality drug candidates in China . . .." *See* **Barry Declaration, Ex. A**,[1] *also available at* https://www.casipharmaceuticals.com/investor-relations/news/casi-pharmaceticals-aquires-anda-portfolio-from-sandoz-inc (last accessed May 15, 2019). Indeed, CASI has expressly stated that its purpose in purchasing the ANDAs was "[t]o address the demand by patients in China for high-quality, affordable pharmaceuticals" and seems poised to transfer manufacturing operations to China, if it has not already done so. *See* **Barry Declaration, Ex. B**, *also available at* https://www.casipharmaceuticals.com/product-pipeline/us-fda-approved-andas/ (last accessed May 15, 2019).

Due to unavailability of the present RS for the Products and the likelihood that the unavailability will persist, indefinitely, due to CASI's prioritizing the China market, Rubicon is hereby requesting the Commissioner assign Reference Standard (RS) status to an alternative product, specifically for Diclofenac Sodium, delayed release tablet, 75 mg, held by Unique Pharmaceutical Laboratories a division of J.B. Chemicals and Pharmaceuticals Ltd. (ANDA No. 077863), which appears to lead the U.S. market in terms of number of tablets sold as per IMS data, and should therefore be more readily accessible and more appropriate for RS designation. See **Rubicon Declaration** (providing market data).

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."

[1] The Declaration of George J. Barry III in support of this Citizen Petition, with exhibits, is being submitted herewith as Attachment 2.

Accordingly, the undersigned, on behalf of Rubicon, respectfully requests the Commissioner of Food and Drug Administration to designate Diclofenac Sodium, delayed release tablet, 75 mg, held by Unique Pharmaceutical Laboratories a division of J.B. Chemicals and Pharmaceuticals Ltd. (ANDA No. 077863), as an alternative reference standard in the Orange Book.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR § 25.31.

D. Economic Impact

Pursuant to 21 CFR § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

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 that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,

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Attachment 1: Declaration of Rubicon
Attachment 2: Declaration of George J. Barry III