Lannett

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October 2, 2013

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

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned submits this petition under Sections 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA, or the "Act") and 21 CFR § 314.93 to request that the Commissioner of Food and Drugs determine that an Abbreviated New Drug Application (ANDA) for Acetazolamide Extended-Release Tablets may be submitted based on the Reference Listed Drug (RLD) DIAMOX® SEQUELS® (Acetazolamide Extended-Release Capsules).

A. **Action Requested**

The petitioner seeks a determination from the Commissioner of Food and Drugs that a tablet dosage form may be submitted as an ANDA versus the RLD capsule dosage form for DIAMOX® SEQUELS® (Acetazolamide Extended-Release Capsules). **Attachment 1** contains a copy of the pertinent pages from the electronic version of the "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" which lists the approved RLD referenced in this petition.

B. **Statement of Grounds**

This petition requests a change in the dosage form from the RLD. Both the RLD and the proposed drug product are solid oral dosage forms with the same route of administration. The proposed drug product is expected to have the same therapeutic effect as the RLD when administered to patients under the same conditions of use.

The package insert for the RLD is provided in **Attachment 2**. The proposed package insert for the Lannett product is provided in **Attachment 3**.

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A Pediatric Research Equity Act (PREA)Waiver Request is provided in **Attachment 4.**

For all the reasons mentioned above, the Commissioner should approve this petition no later than 90 days after this petition is submitted and authorize the submission of an ANDA for the proposed drug product.

C. **Environmental Impact**

The actions requested herein are subject to categorical exclusion under 21 CFR §25.31(a).

D. **Economic Impact**

An economic impact statement will be submitted upon request should the Commissioner determine such assessment is necessary in evaluating this petition.

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.

Please direct any questions or comments regarding this submission to my attention via phone at (215) 333-9000, ext. 2277, e-mail at esabo@lannett.com or facsimile at (215) 624-2126.

Sincerely,

Ernest J. Sabo

Ernest J. Sabo
Vice President, Regulatory & Chief Compliance Officer
Lannett Company, Inc.
13200 Townsend Road
Philadelphia, PA 19154

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