DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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October 22, 2013

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

Dear Mr. Sabo:

Your petition to the Food and Drug Administration requesting the Agency to determine that a tablet dosage form may be submitted as an ANDA versus the RLD capsule dosage form for DIAMOX® SEQUELS® (Acetazolamide Extended-Release Capsules), was received by this office on 10/4/2013. It was assigned docket number FDA-2013-P-1296/CP1, and it was filed on 10/22/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)