DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 4, 2019

Milon Roy
Director, Regulatory Affairs
Unichem Pharmaceuticals (USA), Inc.
777 Terrace Avenue, Ste. 102
Hasbrouch Heights, NJ 07604

Sent via email to: mroy@unichemusa.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration to determine whether one strength, 50 mg, of Sunovion Pharmaceuticals, Inc.'s ZONEGRAN (zonisamide) Capsules approved under NDA NO20789, has been discontinued from sale for safety or efficacy reasons was received by this office on 12/28/2018.

It was assigned docket number FDA-2019-P-0076. 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
Acting Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)