UNICHEM
PHARMACEUTICALS (USA), INC.

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV

Date: December 28, 2018 Ref#: CP/UNI/2018/002

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir/Madam,

The undersigned Unichem Pharmaceuticals (USA) Inc., the US Agent for Unichem Laboratories Limited hereby is submitting this Citizen Petition in pursuant to 21 C.F.R. §10.30, to request that the Commissioner of the Food and Drug Administration determine whether a listed drug has been discontinued for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner respectfully requests that the Commissioner of the Food and Drug Administration ("FDA") to determine whether one strength, 50 mg, of Sunovion Pharmaceuticals, Inc.'s ZONEGRAN (zonisamide) Capsules approved under NDA N020789, has been discontinued from sale for safety or efficacy reasons. The Marketing Status for the other two strengths 25 mg, and 100 mg are listed in the Orange book as "Prescription" whereas the 50 mg strength is listed as "Discontinued."

If the FDA determines that ZONEGRAN (zonisamide) 50 mg Capsules was not discontinued for safety or effectiveness reasons, the petitioner further requests that the FDA accepts ANDA's for all three strengths, 25 mg, 50 mg, and 100 mg of Zonisamide to be approved as generic equivalents to the designated ZONEGRAN (zonisamide) Capsules approved under NDA N020789 as the reference listed drug (RLD), on which an applicant can rely upon for submission of an abbreviated new drug application (ANDA).

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book"). ZONEGRAN (zonisamide) Capsules was approved under N020789 on Mar 27, 2000. Upon approval ZONEGRAN (zonisamide) 25 mg, 50 mg, and 100 mg capsules became the Reference Listed Drug (RLD) by its listing in the Orange Book against which generic equivalents can be developed and approved in an ANDA.

As verified on the Orange Book website the 50 mg strength is currently in "Discontinued" marketing status. See attached page from the Orange Book **(Attachment 1)**. Review of the labeling supplements for ZONEGRAN at drugs@fda shows that the RLD labeling included the 50 mg strength in the "How Supplied" section up until and including the package insert dated 11/2006 **(Attachment 2)** and has excluded it from the package insert dated 04/2009 **(Attachment 3)**.

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As stated above, approval of Sunovion Pharmaceuticals, Inc.' s ZONEGRAN (zonisamide) Capsules approved under NDA N020789 was listed in the Orange Book as the RLD for all three strengths 25 mg, 50 mg, and 100 mg. Currently, the 50 mg strength is in "Discontinued" status. Accordingly, Unichem Pharmaceuticals (USA) Inc. respectfully requests that FDA determine whether the ZONEGRAN (zonisamide) 50 mg capsules strength was discontinued for reasons of safety or effectiveness and if not, that FDA will accept ANDAs for all three strengths, 25 mg, 50 mg, and 100 mg.

C. Environmental Impact

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

D. Economic Impact

Pursuant to 21 C.F.R. § 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 petition, which is unfavorable to the petition.

Sincerely,

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