U.S. FOOD & DRUG ADMINISTRATION

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

Re: Docket No. FDA-2019-P-0076

JUN 28 2019

Dear Ms. Roy:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on December 28, 2018. Your petition requests that the Agency determine whether Zonegran (zonisamide) capsules, 50 milligram, approved under new drug application 020789 held by Sunovion Pharmaceuticals Inc. has been discontinued for safety or effectiveness reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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