M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

TO: Division of Dockets Management, HFA-305

FROM: Lauren Ciurca
Regulatory Counsel, Division of Legal and Regulatory Support
Office of Generic Drug Policy
Office of Generic Drugs
Center for Drug Evaluation and Research

RE: Docket No. FDA-2006-P-0077

DATE: November 27, 2015

Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission. The petition was submitted by Sicor Pharmaceuticals, Inc. on December 11, 2006.

On September 8, 2015, the Food and Drug Administration sent a letter via certified mail to Sicor Pharmaceuticals, Inc. requesting that the petitioner respond to our request if the petitioner wished to keep the petition active. The letter stated that if we do not receive a written response within 30 days, a copy of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

Our September 8, 2015 letter was delivered by the US Postal Service to Sicor Pharmaceuticals, Inc. on September 15, 2015. To date, the Agency has not received a response from Sicor Pharmaceuticals, Inc. In light of the above, we consider the citizen petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.

The letter and US Postal service tracking information are attached to this memorandum.

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 8, 2015

Rosalie A. Lowe
Sicor Pharmaceuticals, Inc.
19 Hughes
Irvine, California 92618-1902

Docket No. FDA-2006-P-0077

Dear Ms. Lowe:

According to the records of the U.S. Food and Drug Administration's (FDA or Agency) Division of Dockets Management, the petition referenced above has not been resolved.[1]

As part of the Agency's efforts to reduce the backlog of unresolved citizen petitions, the Center for Drug Evaluation and Research (CDER or Center) has reviewed the unresolved petitions assigned to it for action. One goal of this review is to identify petitions submitted more than 5 years ago that petitioners may believe are no longer timely. CDER believes that having to respond to these old petitions diminishes the Center's capacity to address in a timely fashion pressing public health issues. Therefore, these petitions have a lower priority, and it is unlikely the Center will have the resources to respond to them soon.

This petition referenced above was submitted more than 5 years ago by Sicor Pharmaceuticals, Inc. and a review of the docket shows that the petition has been inactive for many years. CDER believes that this petition does not raise a significant and current public health issue, and given the length of time since the petition was submitted, we are uncertain as to whether the views expressed in the petition reflect the current views of the petitioner.

Accordingly, we have enclosed a copy of the petition and would appreciate it if you would review it and respond to the docket number listed above if you wish to keep this petition active. Your response should reference the docket number and may be sent to the Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockville, MD 20852; or submitted electronically at www.regulations.gov. If we do not receive a written response from you within 30 days from the date of this letter, a copy of this letter will be filed in Docket No. FDA-2006-P-0077 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Lauren Ciurca of my staff at 301-796-8771. Thank you

[1] This petition was originally assigned docket number 2006P-0507/CP1. The number changed to FDA-2006-P-0077 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

for your attention to this matter.

Sincerely yours,

Kristin Davis, J.D.
Acting Director
Division of Legal and Regulatory Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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Product & Tracking Information

Postal Product:

Features:
Certified Mail™

DATE & TIME	STATUS OF ITEM	LOCATION
September 15, 2015 , 10:18 am	**Delivered**	**IRVINE, CA 92618**
Your item was delivered at 10:18 am on September 15, 2015 in IRVINE, CA 92618.		
September 13, 2015 , 6:43 pm	Departed USPS Facility	SANTA ANA, CA 92799
September 11, 2015 , 6:46 pm	Arrived at USPS Facility	SANTA ANA, CA 92799
September 9, 2015 , 5:07 pm	Departed USPS Facility	GAITHERSBURG, MD 20898
September 8, 2015 , 10:57 pm	Arrived at USPS Facility	GAITHERSBURG, MD 20898

Available Actions

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Tracking (or receipt) number

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