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: Maarika Kimbrell
Acting Deputy Director, Division of Policy Development
Office of Generic Drugs
Center for Drug Evaluation and Research

RE: Docket No. FDA-2006-P-0211

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Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission.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 QPharma, LLC on March 15, 2006.

On September 8, 2015, the Food and Drug Administration sent a letter via certified mail to QPharma, LLC 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of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.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 QPharma, LLC on September 17, 2015. To date, the Agency has not received a response from QPharma, LLC. In light of the above, we consider the citizen petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.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

Ranga Namburi, Ph. D.
QPharma, LLC
2572 Brunswick Pike
Lawrenceville, New Jersey 08648

Docket No. FDA-2006-P-0211

Dear Dr. Namburi:

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 QPharma, LLC 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-0211 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Maarika Kimbrell of my staff at (240)402-5924.

[1] This petition was originally assigned docket number 2006-p-0117/CP1. The number changed to FDA-2006-P-0211 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

Thank you 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

USPS Tracking®

Tracking Number: 70141200000039802436

Updated Delivery Day: Thursday, September 17, 2015

Product & Tracking Information

Postal Product:

Features:
Certified Mail™

Available Actions

DATE & TIME	STATUS OF ITEM	LOCATION
September 17, 2015 , 10:43 am	**Delivered**	**BELTSVILLE, MD 20705**
Your item was delivered at 10:43 am on September 17, 2015 in BELTSVILLE, MD 20705.		
September 17, 2015 , 8:47 am	Out for Delivery	BELTSVILLE, MD 20705
September 17, 2015 , 8:37 am	Sorting Complete	BELTSVILLE, MD 20705
September 17, 2015 , 7:05 am	Arrived at Unit	BELTSVILLE, MD 20705
September 17, 2015 , 1:09 am	Departed USPS Facility	CAPITOL HEIGHTS, MD 20790
September 16, 2015 , 12:21 pm	Arrived at USPS Facility	CAPITOL HEIGHTS, MD 20790
September 15, 2015 , 11:26 pm	Departed USPS Facility	TETERBORO, NJ 07699
September 14, 2015 , 2:29 am	Arrived at USPS Facility	TETERBORO, NJ 07699
September 12, 2015 , 5:33 pm	Moved, Left no Address	TRENTON, NJ 08638
September 10, 2015 , 1:46 pm	Undeliverable as Addressed	LAWRENCE TOWNSHIP, NJ 08648
September 10, 2015 , 7:27 am	Out for Delivery	TRENTON, NJ 08638
September 10, 2015 , 7:17 am	Sorting Complete	TRENTON, NJ 08638
September 10, 2015 , 7:09 am	Arrived at Unit	TRENTON, NJ 08638
September 9, 2015 , 5:18 pm	Departed USPS Facility	TRENTON, NJ 08650

DATE & TIME	STATUS OF ITEM	LOCATION

Track Another Package

Tracking (or receipt) number

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