DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

MEMORANDUM

TO: Division of Dockets Management, HFA-305

FROM: Maarika Kimbrell
Acting Director, Division of Legal and Regulatory Support
Office of Generic Drug Policy
Office of Generic Drugs
Center for Drug Evaluation and Research

Office of Generic Drugs, Center for Drug Evaluation and Research

RE: Docket No. 2006-P-0012 (Old Legacy No. 2006-P-0131)

DATE: August 18, 2016

Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission. The suitability petition is dated March 24, 2006, and was submitted by AAC Consulting Group.

On September 8, 2015, the Food and Drug Administration sent a letter to the petitioner's last known address 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of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

The agency could not confirm delivery of the letter, postmarked September 8, 2015. The petitioner did not submit an alternative address to the petition docket.

In light of the above, we are considering the petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.

The letter is 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

Salvatore J. Pinella
AAC Consulting Group
7361 Calhoun Place, Suite 500
Rockville, Maryland 20855-2765

Docket No. FDA-2006-P-0012

Dear Mr. Pinella:

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 AAC Consulting Group 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-0012 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 2006/0131/CP1. The number changed to FDA-2006-P-0012 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