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-0535

DATE: November 27, 2015

The citizen petition in the above-referenced docket has been voluntarily withdrawn without prejudice to resubmission. The petition was submitted by Olsson, Frank and Weeda, P.C. on October 26, 2006.

On September 8, 2015, the Food and Drug Administration sent a letter via certified mail to Olsson, Frank and Weeda, P.C. requesting that the petitioner respond to our request if the petitioner wished to keep the petition active. Due to a delivery issue, a copy of the letter was emailed to the petitioner on November 10, 2015.

On November 11, 2015, the petitioner responded and requested that the citizen petition be withdrawn without prejudice to future resubmission. Therefore, we request closure of this docket.

The letter and withdrawal request 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

Arthur Y. Tsien
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, NW
Suite 400
Washington, D.C. 20036-2220

Docket No. FDA-2006-P-0535

Dear Mr. Tsien:

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 Olsson, Frank and Weeda, P.C. 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-0535 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

[1] This petition was originally assigned docket number 2006P-0438/CP1. The number changed to FDA-2006-P-0535 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

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

Ciurca, Lauren

From: Arthur Tsien <atsien@ofwlaw.com>
Sent: Wednesday, November 11, 2015 10:14 AM
To: Ciurca, Lauren
Cc: Arthur Tsien
Subject: FW: September 8, 2015 Letter re: Docket No. FDA-2006-P-0535
Attachments: 2015_09_08 Letter to Olsson Frank and Weeda PC re FDA-2006-P-0535.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms. Ciurca:

I hereby withdraw my citizen petition without prejudice to future resubmission.

By the way, I noticed that the docket at regulations.gov is incomplete. Some comments were filed in early 2007, including a reply comment I submitted dated 3/28/2007. These comments do not appear in the regulations.gov docket. The agency may want to correct this apparent docketing error so that anyone who finds the petition in the future is aware of its history.

Thank you for your attention to this matter.

Best regards, AYT

Arthur Y. Tsien, Esq.
OFW Law

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