

MEMORANDUM

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

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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-0278

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Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission.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 Arnall Golden Gregory LLP on April 20, 2006.

On September 8, 2015, the Food and Drug Administration sent a letter via certified mail to Arnall Golden Gregory LLP 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of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

In response to our September 8, 2015 letter, Arnall Golden Gregory LLP submitted an email communication to the Food and Drug Administration indicating that the petitioner clients are no longer interested in pursuing the petition. In light of the above, we consider the citizen petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.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 email 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

Alan G. Minsk  
David Hoffman  
Arnall Golden Gregory LLP  
171 17<sup>th</sup> Street, NW  
Suite 2100  
Atlanta, GA 30363-1031

Docket No. FDA-2006-P-0278

Dear Mr. Minsk and Mr. Hoffman:

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.<sup>1</sup>

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 Arnall Golden Gregory LLP 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](http://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-0278 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

<sup>1</sup> This petition was originally assigned docket number 2006P-0167/CP1 and 2006P-0167/CP2. The number changed to FDA-2006-P-0278 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

If you have any questions, please contact Maarika Kimbrell of my staff at (240)402-5924.  
Thank you for your attention to this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'Kristin Davis', written in a cursive style.

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

## **Kimbrell, Maarika**

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**From:** Minsk, Alan G. <Alan.Minsk@AGG.com>  
**Sent:** Monday, September 14, 2015 5:42 PM  
**Subject:** Long lost Suitability Petition -- Docket No. FDA-2006-P-0278  
**Attachments:** 0382\_001.pdf; 0383\_001.pdf

Maarika and Kristin, I have checked with our client, and they are no longer in pursuing this Petition.

Alan

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**Note:**  
This message and any attachments from the law firm Arnall Golden Gregory LLP may contain CONFIDENTIAL and legally protected information. If you are not the addressee and an intended recipient, please do not read, copy, use or disclose this communication to others; also, please notify the sender by replying to this message, and then delete it from your system. Thank you.

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