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

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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-0013

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Please consider the citizen petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission.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 Lupin Pharmaceuticals, Inc. on June 22, 2006.

On September 8, 2015, the Food and Drug Administration sent a letter via certified mail to Lupin 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of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.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 Lupin Pharmaceuticals, Inc. on September 14, 2015. To date, the Agency has not received a response from Lupin Pharmaceuticals, Inc. In light of the above, we consider the citizen petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.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

Vinita Gupta
Lupin Pharmaceuticals, Inc.
Harborplace Tower
111 South Calvert Street, 21st Fl.
Baltimore, Maryland 21202

Docket No. FDA-2006-P-0013

Dear Ms. Gupta:

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 Lupin 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-0013 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-0265/CP1. The number changed to FDA-2006-P-0013 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,

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:** 70141200000039802399

**Updated Delivery Day:** Saturday, September 12, 2015

## Product & Tracking Information

**Postal Product:**

**Features:**
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| DATE & TIME | STATUS OF ITEM | LOCATION |
|---|---|---|
| **September 14, 2015 , 2:28 pm** | **Delivered** | **BALTIMORE, MD 21202** |
| Your item was delivered at 2:28 pm on September 14, 2015 in BALTIMORE, MD 21202. | | |
| September 12, 2015 , 8:21 am | Out for Delivery | BALTIMORE, MD 21202 |
| September 12, 2015 , 8:11 am | Sorting Complete | BALTIMORE, MD 21202 |
| September 11, 2015 , 2:05 pm | Arrived at Unit | BALTIMORE, MD 21202 |
| September 9, 2015 , 5:42 pm | Departed USPS Facility | BALTIMORE, MD 21233 |
| September 9, 2015 , 11:18 am | Arrived at USPS Facility | BALTIMORE, MD 21233 |
| September 8, 2015 , 10:57 pm | Arrived at USPS Facility | GAITHERSBURG, MD 20898 |

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