



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 27 2004

0219 104 JUL 20 11:13

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Richard S. Morey, Esq.
Kleinfeld, Kaplan and Becker
1140 19th Street, N.W.
Washington, D.C. 20036

Re: Docket No. 95P-0382/CP1

Dear Mr. Morey:

According to the records of the Food and Drug Administration's Division of Dockets Management, the petition referenced above has not been resolved.

As part of the Agency's efforts to reduce the backlog of unresolved citizen petitions, the Center for Drug Evaluation and Research (CDER) has reviewed the unresolved petitions assigned to it for action. One goal of this review is to identify citizen petitions submitted more than 5 years ago that, as a result of subsequent events, no longer appear to raise significant and current public health issues. CDER believes that having to respond to these old petitions diminishes the Center's capacity to address in a timely fashion petitions that raise more significant and current public health issues, as well as its capacity to perform its many other duties. Therefore, these petitions have a low priority and it is unlikely that the Center will have the resources to respond to them soon.

Your petition was submitted more than 5 years ago, and a review of the docket shows that it has been inactive for many years. CDER believes that this petition does not raise a significant and current public health issue that merits a formal Agency response.

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. If we do not receive a written response from you within 30 days, a copy of this letter will be filed in Docket No. 95P-0382/CP1 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Brian Pendleton of my staff at 301-594-2041. Thank you for your attention to this matter.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

Enclosure

95P-0382

LET 2

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

RICHARD S. MOREY, ESQ.
KLEINFELD, KAPLAN AND BECKER
1140 19TH STREET, N.W.
WASHINGTON, D.C. 20036

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) B. Date of Delivery

C. Signature *R. Morey* 6/1
 Agent
 Addressee

D. Is delivery address different from item 1? Yes
If YES, enter delivery address below: No

3. Service Type
 Certified Mail Express Mail
 Registered Return Receipt for Merchandise
 Insured Mail C.O.D.

4. Restricted Delivery? (Extra Fee) Yes

2. Article Number (Copy from service label)
7002 0510 0003 5474 1351

(95P-0382) *CP*
1



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

MEMORANDUM

DATE: July 19, 2004

FROM: Brian Pendleton (HFD-7) *BLP*

SUBJECT: Docket No. 95P-0382/CP1

TO: Dockets Management Branch (HFA-305)

In the docket indicated above, please file this memo as well as the attached letter from Jane Axelrad (HFD-5) dated May 27, 2004, and the attached copy of the return receipt for the letter.

The return receipt indicates that the petitioner received the May 27 letter on June 1, 2004. By the terms of the May 27 letter, the petition would be considered to have been voluntarily withdrawn if the petitioner failed to respond within 30 days. We have received no response from the petitioner as of the date of this memo. Therefore, the petitioner has acquiesced to the withdrawal of the petition.

This docket can be closed; no further action is needed. Thanks.

Attachments