MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

01 AUG -9 A9:34

DATE: JUL 31 2001

FROM: Dave Read (HFD-7)

SUBJECT: Docket No. 96P-0001/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-7) dated March 19, 2001, and the attached letter of mine dated Dec. 10, 1997.

By the terms of Ms. Axelrad's letter, if the petitioner (Washington Legal Foundation) wished to keep this petition active, within 30 days the WLF was to submit a written response to the docket; if the WLF submitted no reponse within that time, the petition would be considered to have been voluntarily withdrawn.

No response from the WLF has been received as of the date of this memo.

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

Attachments

96P-0001

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 19 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Daniel J. Popeo
Paul D. Kamenar
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036

Re: Docket No. 96P-0001/CP1

Dear Messrs. Popeo and Kamenar:

According to the records of FDA's Dockets Management Branch, 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 has reviewed the unresolved citizen petitions assigned to it for action. One goal of this review is to identify citizen petitions submitted more than five 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 Agency'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 been given a low priority, and it is unlikely that the Agency will have the resources to respond to them in the foreseeable future.

Your petition was submitted more than five years ago, and a review of the docket indicates 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. In a December 10, 1997, letter to Ryan McInstry of the Washington Legal Foundation (on which Mr. Kamenar was copied), Dave Read of my staff explained that FDA's regulations at 21 CFR 312.7(a) do not, as the petition asserts, operate as a bar to disclosure of study results relating to investigational new drugs in reports with the SEC and in press releases, and public companies make such disclosures on a routine basis.

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. 96P-0001/CP1 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

Docket No. 96P-0001/CP1

If you have any questions, please contact Dave Read at 301-594-2041. Thank you for your attention to this matter.

Sincerely,

Jane A. Axelrad

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

Enclosures