

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

MAY 4 1998

Food and Drug Administration  
Rockville MD 20857

Charles J. Raubicheck, Esq.  
Skadden, Arps, Slate, Meagher & Flom  
919 Third Ave.  
New York, NY 10022-3897

Re: Docket No. 92P-0262/CP1

Dear Mr. Raubicheck:

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.

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will be filed in Docket No. 92P-0262/CP1 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Dave Read 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

92P-0262

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