



March 6, 2001

Sherman Frankel  
University of Pennsylvania  
School of Arts and Sciences  
Department of Physics and Astronomy  
David Rittenhouse Laboratory  
209 S. 33<sup>rd</sup> Street  
Philadelphia, Pennsylvania 20867

Dear Mr. Frankel:

Thank you for your letter of February 14, 2001, in regard to citizen petition 00P-1330/CP1. In your letter you state that the data sent to you in response to your citizen petition was flawed and request that it be re-reviewed taking into consideration the technical response you submitted.

In accordance with Title 21 Code of Federal Regulations (CFR), § 10.33, Administrative Reconsideration of Action, a petitioner may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR § 10.25, or can take the matter to court. If you decide to request reconsideration it must be submitted within 30 days after the date of the decision involved and must be submitted in accordance with 21 CFR §10.20.

Reconsiderations in the format requested, which I have attached, should be submitted to the following:

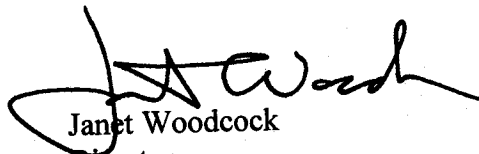
Dockets Management Branch  
Food and Drug Administration  
HFA-305, Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20857.

The letter you have written to me will be forwarded to the Dockets Management Branch as comments to your original citizen petition.

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Thank you for sharing your concerns with me. If I can be of any further assistance, please contact my office.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Woodcock". The signature is fluid and cursive, with a large initial "J" and "W".

Janet Woodcock  
Director

Center for Drug Evaluation and Research

Enclosure

[Code of Federal Regulations]  
[Title 21, Volume 1, Parts 1 to 99]  
[Revised as of April 1, 2000]  
From the U.S. Government Printing Office via GPO Access  
[CITE: 21CFR10.33]

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TITLE 21--FOOD AND DRUGS

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES--Table of Contents

Subpart B--General Administrative Procedures

Sec. 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under Sec. 10.25. Each request for reconsideration must be submitted in accordance with Sec. 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the Federal Register, the day of publication is the day of decision.

(Date) \_\_\_\_\_

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

Petition for Reconsideration

[Docket No.]

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. -----.

A. Decision involved

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. Action requested

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.

(No new information or views may be included in a petition for reconsideration.)

(Signature) \_\_\_\_\_

(Name of petitioner) \_\_\_\_\_  
(Mailing address) \_\_\_\_\_  
(Telephone number) \_\_\_\_\_

(c) A petition for reconsideration relating to a petition submitted under Sec. 10.25(a)(2) is subject to the requirements of Sec. 10.30 (c) and (d), except that it is filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

(2) The petitioner's position is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

(4) Reconsideration is not outweighed by public health or other public interests.

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision under Sec. 10.25(a).

(f) The decision on a petition for reconsideration is to be in writing and placed on public display as part of the docket file on the matter in the office of the Dockets Management Branch. A determination to grant reconsideration will be published in the Federal Register if the Commissioner's original decision was so published. Any other determination to grant or deny reconsideration may also be published in the Federal Register.

(g) The Commissioner may consider a petition for reconsideration only before the petitioner brings legal action in the courts to review the action, except that a petition may also be considered if the Commissioner has denied a petition for stay of action and the petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of review.

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A petition for reconsideration submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for reconsideration will be considered as submitted on the day it is received by the Dockets Management Branch.

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under Sec. 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under Sec. 10.25(a)(2) is subject to Sec. 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in Sec. 10.30(i).

(2) The petition for reconsideration, including all information on which it relies, filed by the Dockets Management Branch.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all information identified or filed by the Commissioner with the Dockets Management Branch as part of the record supporting the decision.

(5) Any Federal Register notices or other documents resulting from the petition.

(6) All documents filed with the Dockets Management Branch under Sec. 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in Sec. 10.30(i).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994]