CoMeD
Coalition for Mercury-Free Drugs
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December 24, 2006

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Re: Docket Number CP3004P-0349

Dear Sirs:

This letter is being sent to you in response to your letter date-stamped "DEC 21 2006" to "Paul G. King, Ph.D., and Other Representatives for CoMeD" concerning **CoMeD**'s new petition filed under **21 CFR § 10.35** (which is dated October 21, 2006 and was filed electronically by Dr. King and assigned by Dockets Management to 2004P-0349 on 24 October 2006) in which **CoMeD** requested the Secretary of Health and Human Services (DHHS) and the then Acting Commissioner of the Food and Drug Administration (FDA) to stay the FDA's September 26, 2006 decision denying **CoMeD**'s July 30, 2004 citizen petition.

First, **CoMeD** agrees that **CoMeD** captioned its request as a "Petition for Stay of Action" pursuant to **21 CFR § 10.35**, since that is the course of action that **CoMeD** elected to pursue.

Second, with respect to **21 CFR § 10.30(j)**, "A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section," we note that, *since this directive does not state "a new **citizen** petition,"* **CoMeD**'s filing of a "Petition for Stay of Action," a new petition, was and is consistent with the directive you cited in your letter.

Third, **CoMeD** notes that **21 CFR § 10.30(i)(7)** (with underlining added for emphasis):

> "(i) The record of the administrative proceeding consists of the following:
>
> …
>
> (7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in §10.33(k) or §10.35(h)."

clearly indicates that the operative "administrative record" for a petition filed under "§10.35" differs from the "administrative record" considered at the time the then Acting Commissioner issued his decision.

Since:

- A "Petition for Stay of Action" under **21 CFR Sec. 10.35** is "a new petition," and

- *Unlike **21 CFR § 10.33**, which restricts responses to the preexisting "administrative record,"* **21 CFR § 10.35** (with underlining added for emphasis) states:

"**§ 10.35 Administrative stay of action.** (a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with §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 date of decision.

(Date)

Petition for Stay of Action

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision involved

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. Action requested

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) _____ (Name of petitioner) (Mailing address) (Telephone number)

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

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under §10.30 or a petition for reconsideration under §10.33 or a request for an advisory opinion under §10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

(1) The petitioner will otherwise suffer irreparable injury.

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

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

(4) The delay resulting from the stay is not outweighted by public health or other public interests.

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

(g) A petition for a stay of action 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 a stay of action is considered submitted on the day it is received by the Division of Dockets Management.

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

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all information on which it relies, filed by the Division of Dockets Management.

(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 (e) of this section, including all information identified or filed by the Commissioner with the Division of Dockets Management 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 Division of Dockets Management under §10.65(h)."

Thus, the "**record of the administrative proceeding**" for a **21 CFR § 10.35** petition is clearly *not* restricted to the "**record of the proceeding to which the petition for stay of action is directed**" (**§ 10.35(h)(1)**) but it also explicitly extends to include "**The petition for stay of action, including all information on which it relies, filed by the Division of Dockets Management**" (**§ 10.35(h)(2)**) and more. (**§§ 10.35(h)(3) – (h)(6)**).

Thus, your decision to convert the **CoMeD** "Petition for Stay of Action" under **21 CFR § 10.35** into a "new *citizen* petition" filed to a "new docket" is clearly contrary to the regulations set forth in **§ 10.35 Administrative stay of action** for a "**Petition for Stay of Action**."

This is the case because the **CoMeD** "Petition for Stay of Action" filed under **21 CFR § 10.35** is explicitly "**a new petition**" that was properly

- Submitted,
- Filed, and
- Listed as 2004P-0349/PAS1.

Moreover, we note that your letter fails to indicate that, *by its nature*, our "**Petition for Stay of Action**" has, *in general*, exhausted the administrative remedies available to **CoMeD** for

FDA Public Docket "CP2004P-0349," regardless of the action the FDA subsequently decides to take concerning this citizen petition.

Consequently, since:

- A petition under **21 CFR § 10.35** is "a new petition," and
- **21 CFR § 10.35(c)** clearly states:

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

the petitioners:

- ❖ Correctly oppose your attempt to:
  - Change the nature of **CoMeD**'s "Petition for Stay of Action" (PSA) into something it is *not*, "a new citizen petition" and
  - Assign **CoMeD**'s PSA "its own docket number," and
- ❖ Note that this attempt to raise these issues comes effectively two months after the FDA properly listed the petitioners' **21 CFR §10.35 petition** as a "Petition For a Stay of Action ("PSA1") and, *based on the Division of Dockets Management's understanding of the regulations at* ***§10.35(c)***, correctly posted it to the current FDA public docket, 2004P-0349, as 2004P-0349/PSA1.

Moreover, *for the reasons stated*, we strongly oppose any attempt to recast this **21 CFR § 10.35** "Petition for Stay Of Action" as "a citizen petition."

Based on the preceding realities, we also see no valid reason to give our "Petition for Stay of Action" a new docket number.

Hopefully, the preceding narrative has:

- Established that the **CoMeD** "Petition for Stay of Action" was correctly filed under the applicable regulations set forth in **21 CFR §§ 10.30** and **10.35,**
- Adequately addressed the issues you raised in your letter, and
- Provided the regulatory grounds for opposing the course of action you proposed.

Should you find any other cogent regulatory compliance issue with the **CoMeD** "Petition for Stay of Action" *per se*, please let us know.

Respectfully,

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