

March 12, 2007

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
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Email: fdadockets@oc.fda.gov

Re: FDA Public Docket Items 2004P-0349/PSA1, 2004P-0349/ANS 1 and 2004P-0349/RC1, and FDA Docket Item 2006P-0535/CP1

Dear Sirs:

Pursuant to:

1. FDA/OC's 21 December 2006 answer (see 2004P-049/ANS1) to the **CoMeD** 24 October 2006 petition for stay of action (see 2004P-0349/PSA1) and **CoMeD** Representative Paul G. King's unanswered 24 December 2006 response letter (see 2004P-0349/RC1), sent to the addressees and the FDA Division of Dockets Management (**see Attachments 1 and 2**),
2. **CoMeD** Representative Paul G. King's repeated calls to Nathaniel Geary (or his voice mail) (on 2 February 2007 and 2 March 2007) and, *on 2 March 2007*, to Dr. Jeffery Suren's office (handled by Mary Long), and
3. **21 CFR 10.30(g)**, governing the withdrawal of a citizen petition, which states:
"A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition,"

the undersigned respectfully request the FDA to immediately withdraw the citizen petition the agency filed in FDA Docket 2006P-0535 over the grounds-based objections of Paul G. King on behalf of **CoMeD** (see Attachment 2) and appropriately file written notice of the FDA's withdrawal of the "second citizen petition" in both FDA

Public Dockets (2004P-0349 and 2006P-0535) so that Paul G. King, Lisa K. Sykes, other individuals, and **CoMeD** may re-file their complaint with the Federal District Court for the District of Columbia as that Court directed in the Court's recent March 1, 2007 MEMORANDUM OPINION. [See: DC District Court Case: 1:06-CV-01357 EGS, Document 28, page 11, lines 5-7 (with underlining added for emphasis):

"Because plaintiffs can render the FDA Response a final agency action by simply withdrawing their second citizen petition, plaintiffs' amended complaint is **DISMISSED without prejudice**".

The preceding request, being made by CoMeD Representative Paul G. King, does not in any way constitute a waiver or release of any legal rights by the petitioners herein.

Let me thank you all in advance for your prompt attention to, acknowledgement of, and action to satisfy, this request that you withdraw the "second citizen petition," the one the FDA filed in FDA Public Docket 2006P-0535.

Respectfully,



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Collectively, Legal Advisers To **CoMeD**

Attachment 1

24 December 2006 Email

To: "Jennie Butler" <fdadockets@oc.fda.gov>
From: "Paul G. King" <drking@gti.net>
Subject: Response to Docket 2004P-0349 Re FDA/CBER 'DEC 21 2006' Letter
Cc: jeff.shuren@fda.hhs.gov, Nathaniel.geary@fda.hhs.gov,
"Cliff Shoemaker" <Cliff@attorneyaccess.net>
Bcc: <removed>
X-Attachments: C:\AD_Out\FDA21CFR10.35Filing\061224ResponseToFDAletterDate-
Stamped'DEC 21 2006'ReCoMeD's21CFR10_35PetitionForStayOfAction(PSA1)b.pdf;

Jennie Butler,
Division of Dockets Management

Since I am unaware of any mechanism by which the FDA can rescind a letter they have submitted to the public docket without that original letter's being posted to the public docket along with the objecting response letter posted to the public docket, if any, and a separate letter res[er]ving an original letter that the FDA/CBER has issued, please appropriately file the attached signed letter that is being submitted electronically to FDA public docket 2004P-0349 as CoMeD's 24 December 2006 response to the FedEx'ed FDA/CBER letter date-stamped "DEC 21 2006" which I received at about 15:00 on Friday, 22 December 2006.

As always, let me thank you in advance for your ongoing efforts to appropriately post all submissions to the FDA public docket as expeditiously as your limited resources permit.

*This transmission and any attachments are *
*confidential and may be protected by legal *
*privilege. If you are not the intended *
*recipient, be aware that any disclosure, *
*copying, distribution or use of this *
*transmission or any attachment is prohibited. *
*In such case, you should destroy this message *
*and kindly notify the sender by e-mail. *
* *
*NOTA BENE: The opinions, conclusions and the *
*other info, if any, in this message that do *
*not relate to the official activities of my *
*consultancy or CoMeD shall be understood as *
*neither given nor endorsed by either. *

Respectfully,

Dr. King
<http://www.dr-king.com>

Attachment 2

24 December 2006 Letter

December 24, 2006

Dr. Jeffery Shuren
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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 outweighed 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,

A handwritten signature in black ink, appearing to read "Paul King". The signature is written in a cursive, somewhat stylized font.

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