

April 6, 2007

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Re: Docket Numbers 2006P-0535/CP1 0349
and 2004P-0349/CP1

Dear Dr. Shuren:

This letter is being sent to you in response to your letter, date-stamped "MAR 28 2007," to "Paul G. King, Ph.D., and Other Representatives for CoMeD" concerning CoMeD's letters of December 24, 2006 and March 12, 2007 to the FDA.

These letters were sent in response to FDA's 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 to Docket 2004P-0349 by Dockets Management on 24 October 2006).

In this "Petition for Stay of Action," CoMeD only asked 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.

While the CoMeD does recognize the factual reality of the actions taken by the FDA, after carefully reviewing them, CoMeD contends:

- ❖ The FDA's actions are not supported by the clear language of the applicable petition regulations set forth in **21 C.F.R. Part 10**, and
- ❖ Since the CoMeD "Petition for Stay of Action" ONLY asked that the Commissioner's decision be stayed, your response has again continued to misrepresent the following facts concerning said "Petition for Stay of Action," namely that:
 - CoMeD filed said petition on 24 October 2006,
 - Dockets Management accepted said petition as CoMeD's "Petition for Stay of Action" (FDA Docket 2004P-0349/PSA1) on 24 October 2006 (FDA Docket 2004P-0349/ACK2)
 - Instead of promptly reviewing said PSA, as required by **21 C.F.R. 10.35(e)**, FDA's Dr. Shuren, apparently acting on behalf of the Commissioner, waited almost 2 months before sending CoMeD an answer (2004P-

0349/ANS1), dated December 21, 2006, that essentially denied **CoMeD**'s PSA by *wrongly* claiming, among other things:

- **CoMeD** filed the document to the wrong Docket, and
- The document **CoMeD** filed was not a “Petition for Stay of Action” simply because it contained new information and views, even though the PSA only asked that the FDA stay the “Commissioner’s” “SEP 26 2006” decision to deny the **CoMeD** citizen petition for an indefinite period of time because, *among other things*, Dr. King, Rev. Sykes, and **CoMeD** had, *prior to the Commissioner’s decision*, sued the FDA in the District Court for the District of Columbia on 1 August 2006,¹ seeking to have the Court compel the FDA to reply to the **CoMeD** citizen petition in a manner that fully complied with all applicable law.²
- Said PSA fully complies with the letter of the applicable administrative regulations set forth in **21 C.F.R. Part 10** governing petitions, notwithstanding the statements made previously or in the current FDA letter date-stamped “MAR 28 2007” and signed by Dr. Shuren.

On the pages that follow, **CoMeD** will fully explain the reason that **CoMeD** finds the FDA’s administrative decisions are not supported by the factual record and/or the clear language of the applicable regulations set forth in **21 C.F.R. Part 10**.

Finally, since **CoMeD** Representative King, who signed the **CoMeD** “Petition for Stay of Action” (PSA), declined to give his permission for the FDA to file the **CoMeD** “Petition for Stay of Action” as a “*citizen petition*,” it continues to appear to Dr. King that the FDA lacked the legal authority to ignore Dr. King’s denial because, *in doing so*, the FDA has obviously misappropriated Dr. King’s identity and signature and, technically, has taken actions that amount to the forgery of Dr. King’s name and the theft of **CoMeD**’s identity.

Respectfully,



Paul G. King, PhD,
Science Advisor and New Jersey Representative,
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¹ [King, et al. v. Leavitt, et al.](#), Civ. No. 06-1357 (D.D.C.)

² To date, notwithstanding the FDA’s protestations, the FDA has clearly failed to address the issues raised in the **CoMeD** citizen petition, filed as Docket 2004P-0349/CP1, in a manner that fully complies with the applicable law, which was the main issue raised by the **CoMeD** citizen petitioners.

In Depth Rebuttal To FDA's Letter, Date-stamped "MAR 28 2007"

To simplify this review, your comments on behalf of the FDA will be quoted in a "Times New Roman" font.

Then, **CoMeD**'s rebuttal remarks will be presented in indented text following each of your quoted remarks.

CoMeD's remarks will be in a "News Gothic MT" font except when **CoMeD** mentions or quotes a statute or regulation; these will be in a Lydian font.

When **CoMeD** quotes from statements made in your "MAR 28 2007" letter, an *italicized "Times New Roman"* font will be used.

When **CoMeD** quotes from other references, an "Arial" font will be used.

That having been said, let us begin the review.

FDA DEPARTMENT OF HEALTH & HUMAN SERVICES
Logo

Public Health Service

Food and Drug Administration
Rockville, MD 20857

[MAR 28 2007]

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Paul G. King, Ph.D., and Other Representatives for CoMeD
Coalition for Mercury-Free Drugs
33A Hoffman Avenue, NJ 07034-1922

RE: Docket Numbers 2006P-0535/CP1 and
2004P-0349/CP1

Dr. King and Others:

We received your letter dated March 12, 2007, withdrawing your petition to modify the Commissioner's September 26, 2006, decision denying your citizen petition."

Factually, **CoMeD** did not submit any letter, dated March 12, 2007 or otherwise, asking the FDA to withdraw any **CoMeD**-filed petition to "*modify the Commissioner's September 26, 2006, decision denying*" **CoMeD**'s citizen petition (2004P-0349/CP1).

In **CoMeD**'s March 12, 2007 letter, **CoMeD** only asked that the FDA withdraw the "*citizen petition*" that the FDA had filed in Docket 2006P-0535.

That this is clearly the case can be seen by reading the opening statement in **CoMeD**'s March 12, 2007 letter, which states (with **bolding** added for emphasis):

"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 ...,

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.**"

Again, **CoMeD**'s March 12, 2007 letter plainly made no request to withdraw any petition that Dr. King or **CoMeD** had filed but, rather, only asked the FDA to withdraw the "*citizen petition*" that the FDA, not **CoMeD**, had filed (with **bolding** added for emphasis):

"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 ..."**

Therefore, the Agency's assertion, stated here as "*We received your letter dated March 12, 2007, withdrawing your petition to modify the Commissioner's September 26, 2006, decision denying your citizen petition,*" is clearly at odds with the "withdrawal" request **CoMeD** actually made in **CoMeD**'s March 12, 2007 letter.

"You had captioned your petition as a 'Petition for Stay of Action,' but for reasons in our letter dated December 21, 2006, and as further explained below, we deemed your petition to be a new citizen petition (hereinafter the "second citizen petition"), pursuant to 21 C.F.R. § 10.30(j), and gave it a new docket number, 2006P-0535/CP1, to reflect its correct status."

Based on another thorough review of the explicit language in all of the petition-applicable sections of **21 C.F.R. Part 10**, including those clearly articulated in **CoMeD**'s December 24, 2006 letter to the FDA (see Docket 2004P-0349/RC1), **CoMeD** finds that the Agency's actions are not consistent with the clear language set forth in **21 C.F.R. § 10.30**.

Further, **CoMeD** finds the FDA's assertions have ignored the explicit language set forth in **21 C.F.R. § 10.30(a)** (with underlining added for emphasis):

"This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter,"

which clearly indicates that the language set forth in **21 C.F.R. § 10.35**, one of the "**other sections of this chapter,**" supersedes the language set forth in **21 C.F.R. § 10.30(j)**

when one considers the following:

“...The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. ...”

That this is clearly the case is confirmed by **21 C.F.R. § 10.30(i)(7)**, which states (with underlining added for emphasis):

“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).”

Thus, based on **21 C.F.R. § 10.30(a)** and **21 C.F.R. § 10.30(i)(7)**, it is clear that, regardless of what action the FDA may take, the administrative record for a citizen petition is “the administrative record specified in ... §10.35(h)” whenever a petition for a stay of action is filed, such as the one **CoMeD** filed on October 24, 2006.

“In your March 12, 2007 letter, you expressed the belief that FDA, having opened a new docket for your second citizen petition, must be the party to withdraw that petition.”

Based on the clear “This section applies to any petition submitted by a person” language in **21 C.F.R. § 10.30(a)** (see quote on preceding page) and **21 CFR 10.30(g)**, which states (with underlining added for emphasis):

“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.”

and the undisputed fact that neither Dr. King nor **CoMeD** submitted a “*second citizen petition*” nor authorized the **CoMeD** “Petition for Stay of Action” to be filed as a “*second citizen petition*” (as your letter agrees), then, *notwithstanding any statements you make*, you and/or the FDA:

- Are the “person” who submitted the “*second citizen petition*” and, therefore, as the **CoMeD** March 12, 2007 letter states,
- Must be the “person” who withdraws the “*second citizen petition*” because you and/or the FDA, and not **CoMeD**, are the “person” who filed this “*second citizen petition*.”

Since the preceding is the factual case, **CoMeD** finds your “*you expressed the belief*” language to be, *at best*, disingenuous.

“Because you submitted that petition, however, it remains your petition.”

Were the preceding true, then, contrary to what transpired, the FDA would have honored **CoMeD**’s refusal of the Agency’s “*courtesy*” offer to authorize filing the **CoMeD** “Petition for a Stay” as a “*second citizen petition*.”

Since, at best, you and/or the FDA ignored **CoMeD**’s grounds-based objections to the FDA’s proposal to file **CoMeD**’s “Petition for Stay of Action” as a “*citizen petition*,” it is clear that this “*second citizen petition*,” as you label it, is the fruit of your and/or the FDA’s unilateral misappropriation of a document properly filed elsewhere by **CoMeD**.

Thus, the “*second citizen petition*,” an artful phrase that the FDA created, is clearly not a **CoMeD** “*citizen petition*.”

“Consequently, your letter dated March 12, 2007, was sufficient to legally withdraw your second citizen petition. Accordingly, that petition is now fully withdrawn and we have closed that docket.”

While **CoMeD** is heartened that you and the FDA have withdrawn the “*second citizen petition*” and “*have closed that docket*” (Docket 2006P-0535), **CoMeD** again asserts that you/the FDA are the “*person*” who filed the “*second citizen petition*” of which you speak, and not **CoMeD**.

“In addition, we have closed the docket to your original citizen petition.”

Here, **CoMeD** finds your response somewhat misleading.

This is the case because, *based on your letter of December 21, 2006, filed as Docket 2004P-0349/ANS1 with the Document Management’s remark, “Closed 12/27/2006,”* your answer (ANS1) closed Docket 2004P-0349 in December of 2006 – essentially, three months before the date stamped on your current letter.

Moreover, *even though, as an attorney, you are an officer of the Court,* you have apparently failed to notify the Court,¹ or have the Department of Justice notify the Court, that Docket 2004P-0349 was closed on “12/27/2006” and withdraw their motion to dismiss the Court case¹, as you/they should have done.

Thus, it appears to **CoMeD** that you may be guilty of obstruction of justice by knowingly withholding or conspiring to withhold a material fact from the Court because the closing of Docket 2004P-0349 on “12/27/2006” clearly settled all administrative issues and eviscerated the government’s basis for their motion to have the Court dismiss said Court case.¹

“The entire administrative record for your original citizen petition is the record that was submitted to the Court and served on your counsel on December 22, 2006, in King, et al. v. Leavitt, et al., Civ. No. 06-1357 (D.D.C.). That record, as provided in 21 C.F.R. § 10.30(j), does not include the material you submitted with your now withdrawn second citizen petition.”

Factually, given **21 C.F.R. § 10.30(a)** and **21 C.F.R. § 10.30(i)(7)**, you/the FDA failed to submit the “*entire administrative record*” for Docket 2004P-0349, as it existed on December 19, 2006, the date of your certification statement, as you are claiming here.

This is the case, because, *contrary to your views*, **CoMeD** finds that the **CoMeD** “Petition for Stay of Action” is a valid, fully compliant “**§ 10.35 Administrative stay of action**” petition within the clear petition language set forth in **21 C.F.R. Part 10**.

All that the **CoMeD** “Petition for Stay of Action” did was request that an action (the Commissioner’s decision) be stayed for an indefinite period of time (until any one of three alternative conditions were met).

The **CoMeD** “Petition for Stay of Action” did seek to “*modify the Commissioner’s September 26, 2006, decision denying your citizen petition*” by simply asking the Commissioner to stay his action (his decision to deny the **CoMeD** citizen petition).

Since the preceding are the facts, the administrative record that should have been “*submitted to the Court and served on your counsel on December 22, 2006, in King, et al. v. Leavitt, et al., Civ. No. 06-1357 (D.D.C.)*” is the applicable parts of the administrative record set forth in **21 C.F.R. 10.35(h)** (with underlining added to the applicable subsections):

“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).”

Moreover, when the FDA closed Docket 2004P-0349 on December 27, 2006, the administrative record should have been amended and Docket 2004P-0349/ANS1 should have been “*submitted to the Court and served on your counsel on December 22, 2006, in King, et al. v. Leavitt, et al., Civ. No. 06-1357 (D.D.C.)*” because, based on **21 C.F.R. 10.35(h)(4)**, Docket 2004P-0349/ANS1 is 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.*”

Further, **CoMeD** finds that your/the FDA’s assertion, claiming:

“*That record, as provided in 21 C.F.R. § 10.30(j), does not include the material you submitted with your now withdrawn second citizen petition,*”

is, at best, misleading, because the material **CoMeD** submitted was submitted with **CoMeD**’s properly filed “Petition for Stay of Action.”

Finally, as we have repeatedly stated and as the facts clearly support:

- ❖ **CoMeD** has, to date, filed no “*second citizen petition,*” and
- ❖ The only petition that **CoMeD** has asked the FDA to withdraw is the non-valid “*second citizen petition*” the FDA filed in Docket 2006P-0535 over **CoMeD**’s grounds-based objections and without both Dr. King’s and **CoMeD**’s consent.

“With your letter of March 12, 2007, you attached your letter of December 24, 2006, in which you objected to the FDA’s deeming your ‘Petition for Say of Action’ to be a new citizen petition and to the FDA’s opening a new docket for your second citizen petition.”

CoMeD agrees that with CoMeD’s letter of March 12, 2007, Dr. King attached CoMeD’s letter of December 24, 2006, in which CoMeD had objected to:

- ❖ The FDA’s deeming CoMeD’s “Petition for Say of Action” (“PSA”) to be a “*citizen petition*”
- ❖ The FDA’s opening a new docket (2006P-0535) and improperly filing CoMeD’s PSA to that docket as “*citizen petition*” (Docket 2006P-0535/CP1),
- ❖ The FDA’s repeatedly:
 - Mischaracterizing CoMeD’s PSA as a “CoMeD citizen petition” by retitling it (*without the signing author’s and the submitting organization’s written consent*) and
 - Misusing the language “*your second citizen petition*” to characterize the document the FDA generated (*using a document that CoMeD filed as the basis for their fabrication*)

when, *in fact*, CoMeD’s PSA does not conform to the format required by law for a “*citizen petition*,” and

- ❖ The FDA’s *knowingly* filing a document the Agency fabricated as a “*second citizen petition*” when the document the FDA created fails to conform to the legal requirement minimums for a valid “*citizen petition*” as set forth in **21 C.F.R. § 10.30(b)**.

“Below is a fuller explanation of FDA’s basis for that administrative decision.”

CoMeD only notes that, *as unanimously affirmed by the US Supreme Court in Berkovitz v. USA (1988)*,³ the FDA’s administrative discretion is limited by the legally binding laws and statutes, including the administrative regulations set forth in **21 C.F.R. Part 10**.

Thus, *as a rule*, any “*administrative decision*” the FDA makes pursuant to **21 C.F.R. Part 10** must first conform to the letter of the regulations set forth therein.

“Page 2 – Coalition for Mercury-Free Drugs

Subsection 10.30(j) states:

The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner’s decision. The record of administrative proceedings closes on the date of the Commissioner’s decision unless some other date is specified. Thereafter, any interested person may submit a petition for reconsideration under § 10.33 or a petition

³ Kevan Berkovitz, a Minor by his Parents and Natural Guardians Arthur Berkovitz, et ux., et al., Petitioners, v. United States of America. [108 S.Ct. 1954 100 L.Ed.2d 531, 56 USL W 4549 (Cite as: 486 U.S. 531, 108 S.Ct. 1954)].

for stay of action under §10.35. 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.

(Emphasis added).”

CoMeD agrees that **21 CFR 10.30(j)** has been quoted correctly.

“This subsection makes several things clear. First it defines the administrative record for the citizen petition.”

CoMeD agrees that the first sentence in “*Subsection 10.30(j)*” states:

“The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner’s decision,”

and defines the record for the Commissioner’s decision(s) subject to the additions allowed under **21 C.F.R. 10.30(a)** and required by **21 C.F.R. 10.35(h)** because **21 C.F.R. 10.35(e)** clearly requires another decision by the Commissioner.

“Second, it provides when a petition for stay of action or a petition for reconsideration may be filed.”

CoMeD notes that, in addition to stating when “*a petition for stay of action ... may be filed,*” subsection 10.30(j) states that “..., any interested person may submit ... a petition for stay of action under §10.35.”

“Immediately following this reference to petitions for stay and petitions for reconsideration, the subsection makes clear that anyone submitting new information or views must file a new petition in accordance with “this section,” 21 C.F.R. § 10.30 (which governs citizen petitions).”

Factually, **CoMeD** finds that you and the Agency have mischaracterized what the final statement in **21 C.F.R. § 10.30(j)** states.

The last statement in subsection 10.30(j) actually states:

“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.”

Since a petition for stay of action, governed by **21 C.F.R. § 10.35**, is “a new petition” and one that clearly seeks a modification of a “decision” – *namely a stay of that decision* – it is clear to **CoMeD** that a PSA may/must submit and rely on information not in the pre-existing administrative record because:

- ❖ **21 C.F.R. § 10.35** does not prohibit the submission of information or views not included in the administrative record at the time of the Commissioner’s decision and
- ❖ Information not in the pre-existing administrative record prior to the filing of a PSA must be submitted (e.g., in a PSA asking for a “n”-day stay of Commissioner’s decision to require a labeling change by some date, the filing party must submit information not in the existing administrative record that firmly establishes why the requested stay is justified),

Moreover, the language in subsections 10.30(a), 10.30(i)(7), and 10.35(h) clearly supports **CoMeD**'s views.

“In other words, those who rely on information or views not included in the administrative record of the citizen petition must file a new citizen petition.

Based on the preceding factual realities established by **CoMeD**, while the filing of a new petition is clearly required, subsection 10.30(j) does not and, *based on the on-point example cited for a petition for a stay of a labeling change, cannot* require any interested party to “*file a new citizen petition*” as you assert.

“It is this subsection that governed the situation presented by your ‘petition for stay of action’ filed on October 24, 2006.”

Contrary to the claims you have asserted and are again asserting, petitions for a stay of action are governed by the strictures set forth in **21 C.F.R. § 10.35** and not by the strictures set forth in **21 C.F.R. § 10.30** and, *based on 21 C.F.R. § 10.30(a)*, “This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter” and **21 C.F.R. § 10.30(i)(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),” it is plain that **21 C.F.R. § 10.30** recognizes **21 C.F.R. § 10.35** adds information and views not in the pre-existing administrative record since **21 C.F.R. § 10.35(h)** not only allows the submitter of a PSA to add to the administrative record but also permits *unrestricted* commenters to add whatever comments they wish to the administrative record (subsection 10.35(h)(3), “The record of the administrative proceeding consists of the following: ... (3) All comments received on the petition, including all information submitted as a part of the comments. ...”).

Based on the preceding realities, **CoMeD** finds that your views are not supported by the clear language governing PSA filings as set forth in **21 CFR Part 10**.

“You affirmed in your ‘Petition for Stay of Action’ that you had submitted information and views not included in the administrative record as of the date of the Commissioner’s decision.^{FDA 1} Consequently, under subsection 10.30(j), you were required to file your new views and information as new citizen petition under section 10.30.”

Based on an analysis of all of the applicable regulations governing petitions set forth in **21 CFR Part 10**, **CoMeD** reiterates that your myopic focus on subsection 10.30(j) is clearly not only misplaced but also contrary to the clear language set forth in subsections 10.30(a), 10.30(i)(7), 10.35(b), and, *most of all*, 10.35(h).

^{FDA 1} The document index in the filing listed in the Docket as PSA0001-02-index confirms this fact. Specifically, in that index, you listed 18 references which you described as “Referenced documents not in petition and/or not referenced by FDA in their ‘SEP 26 2006’ ‘decision’ letter to CoMeD date-stamped ‘SEP 26 2006.’” Clearly, you intended to supplement the administrative record with new evidence. Except for references 5.8 and 5.18 (which was previously referenced and which are already in the record), the addition of these materials would supplement the administrative record after FDA’s decision on the matter by including new evidence.

Therefore, **CoMeD** must reject your views because they are at odds with the clear language governing petitions, in general, and petitions for a stay of action, in specific.

“You also contend that subsection 10.33(e) expressly prohibits extra-record information in petitions for reconsideration while section 10.35, on stay petitions, does not.”

CoMeD notes that you do not deny “*subsection 10.33(e) expressly prohibits extra-record information in petitions for reconsideration while section 10.35, on stay petitions does not.*”

Second, as **CoMeD** has established, a PSA must add to and rely on supporting information that is not in the pre-existing administrative record if any “interested person may request the Commissioner to stay the effective date of any administrative action” (**21 C.F.R. § 10.35(b)**).

“However, there is a fundamental difference between a petition for reconsideration and a petition for stay. A petition for reconsideration relates to the merits of an action, while a proper petition for stay under section 10.35 seeks only to delay implementation of an action. See, e.g., 42 Fed. Reg. 4680, 4687 (Jan. 25, 1977).”

First, **CoMeD** does not challenge your characterization that there is a “*difference between a petition for reconsideration and a petition for stay.*”

However, **CoMeD** only agrees that a “*petition for stay under 10.35*” asks the Commissioner to “*stay the effective date of any administrative action.*”

Thus, contrary to your “*delay the implementation of an action*” view, the plain language of subsection 10.35(b) states that an interested person “*may request the Commissioner to stay the effective date of any administrative action,*” including *inter alia* a decision to deny a petition.

Therefore, based on the plain language in **21 C.F.R. 10.35(b)**, **CoMeD** acted properly when it filed a petition for stay of the Commissioner’s decision because the Commissioner’s decision denying the **CoMeD** citizen petition clearly falls within the “any administrative action” provision set forth in subsection 10.35(b).

Moreover, since **21 C.F.R. § 10.35** was not added to **21 CFR Part 10** until April of 1979 [see 44 FR 22323, Apr. 13, 1979], **CoMeD** is ignoring your example citation, “42 Fed. Reg. 4680, 4687 (Jan. 25, 1977),” because that citation predates the current controlling regulations set forth in subsection 10.35 by more than two (2) years.

“Consequently, section 10.35 needs no express prohibition because extra-record information going to the merits of the action is not included in proper stay petitions.”

CoMeD finds the specious argument made by you here to have no bearing in the issue of whether, or not, additional information and views may be included in a petition for stay.

Moreover, **CoMeD** has clearly established that any complete analysis of the regulations governing petitions set forth in **21 CFR Part 10** plainly supports the reality that additional information and views may be added to any petition for a stay of action.

“In contrast, your ‘stay’ petition was based on new information and views that went to the merits of the underlying decision.

Since:

- ❖ In the applicable regulations (not the FDA’s stated views thereof), there are no prohibitions of, or restrictions on, any new information and views that an interested person may file in support of the grounds upon which the request for stay is based, and
- ❖ The new information and views that **CoMeD** filed were expressed in support of the grounds⁴ **CoMeD** raised in requesting the Commissioner to stay his decision to deny the **CoMeD** citizen petition,

CoMeD must reject your stated views because they are clearly contrary to the clear regulations governing petitions set forth in **21 C.F.R. Part 10**.

“Indeed, the relief you sought through your second citizen petition is identical to the relief you sought through your original citizen.”

Factually, as set forth in the “**II. Actions Requested**” section of the **CoMeD** “**PETITION FOR STAY OF ACTION**,” the only relief that **CoMeD** sought was to stay the Commissioner’s decision to deny the **CoMeD** citizen petition,⁵ and nothing else!

In contrast, as set forth in the “**I. Actions Requested**” section of the **CoMeD** “**CITIZEN PETITION**,” the relief sought in **CoMeD**’s 2004 citizen petition was stated as:

“Petitioners request:

1. *Until the federal government can **prove** that any and all Thimerosal-containing products have a **10X** safety margin with respect to the risk of causing any level of*

⁴ **CoMeD**’s October 21, 2006 “**PETITION FOR STAY OF ACTION**,” “**IV. Statement of Grounds For Stay of Decision**” : “The sections which follow contain an in-depth review of said FDA letter that clearly supports the grounds that **CoMeD** has asserted” (bottom of page **S-2**).

⁵ **CoMeD**’s October 21, 2006 “**PETITION FOR STAY OF ACTION**,” “**II. Actions Requested**”:

“Petitioners request the aforementioned decision be stayed until:

1. The Federal government, in general, and the Secretary of HHS and the FDA, in specific, address the issues in this petition in a manner that complies with all applicable policies, laws and statutes governing the proof of safety in vaccines and other drugs, **or**
2. The courts determine that the Federal government, in general, and the Secretary of Health and Human Services and the Food and Drug Administration have acted in a manner that adheres to all court decisions, policies, laws and statutes governing its actions or the permissible actions of any vaccine or other drug product manufacturer pursuant to any requirement to prove the safety and/or effectiveness of any vaccine or other drug product, including any indirect mandate to reduce the risk of adverse effects of childhood vaccines, **or**
3. The use of Thimerosal or any other mercury –based compound is banned from all of medicine and all Thimerosal-containing vaccines and other drug products that contain any amount of Thimerosal or any other mercury-based compound are withdrawn from the market and destroyed.” (Pages S-1— S-2)

neurological damage in newborns and children under 36 months of age,^{1, 2} we request, under **42 U.S.C. Section 300aa-27**, the **Secretary** of the Department of Health and Human Services or the **Acting Commissioner** of the Food and Drug Administration to **immediately issue an order** proscribing the use of disease-preventive Thimerosal-containing vaccines or other similarly preserved medical products in newborns, children under the age of 36 months, and pregnant women unless: ...

2. *Until the federal government can **establish** that any and all Thimerosal-containing products have no less than a **10X** safety margin with respect to the risk of causing any level of neurological damage to developing fetuses, newborns, children and adolescents*, we request that the Commissioner of the Food and Drug Administration move to withdraw the approval (under **21 U.S.C. 355(e)**) of any FDA-approved drug product (e.g., ophthalmic products) and revoke the license (under **42 U.S.C. 262(a)(2)(A)**) of any FDA-licensed biological product (e.g., vaccines and other preserved serological preparations) that uses Thimerosal, *or any other mercury-based neurotoxic compound*, as a “preservative” or “adjuvant” unless the federal government and/or the manufacturer of said medical product can **prove, at its maximum level, its safety and efficacy as a preservative or adjuvant** in scientifically sound animal model studies using appropriate susceptible animal strains as the test subjects. ...
3. Issue:
 - a. *Pursuant to the statutory authority set forth in **42 U.S.C. 262(d)(1)** and the procedures set forth in **21 C.F.R. Section 7**, governing recalls*, an immediate Class I, or Class II, recall¹ and destruction of all batches of multi-dose vaccines and other mercury-containing drug products: **i)** containing a mercury level of more than 0.5 microgram per dose or 0.0001 % (1 part per million [ppm]; 1 µg per milliliter [mL] or 1 µg per gram [g]), *whichever is higher*, **and ii)** having approved alternatives that are **not more than** 0.0002% mercury, **and**
 - b. *If the “Class II recall” option is chosen*, an open letter to all physicians advising them that they should destroy any of the drug products recalled in **Point 3.a.** ...
4. *Until medical products containing Thimerosal and other mercury-based preservatives can be removed from the market and be replaced by a suitable non-neurotoxic alternative, or, reformulated to contain not more than 0.5 microgram of mercury per dose of vaccine or, for other drugs, not more than 1.0 microgram of mercury per milliliter or gram, or said current products can be proven to have not less than a **10X** safety margin for **susceptible individuals***, we request that the Commissioner of the Food and Drug Administration issue orders requiring:
 - a. All such medical products, *including all OTC products*, to contain a clear “Black Box” warning of the potential risk for neurological damage to **susceptible** fetuses, newborns, and children on all of said medical product’s labeling,
 - b. *For prescription medical products, including vaccines, preserved with mercury-based compounds that are administered to newborns, children, and all women of child bearing age*, informed written consent be obtained, as appropriate, from all such patients or their guardians before any such medical product is administered to any covered patient and that said consent forms: **i)** clearly state the possibility of neurological injury **and ii)** permit patients or their guardians, as appropriate, to postpone, *for any reason*, or decline, *for religious or other stated health reasons*, the administration of said medication, **and**
 - c. All vaccines remaining in commerce after 1 January 2006 that contain more than 0.5 micrograms of mercury per dose of drug product and all other drugs containing more than 1.0 microgram of mercury per milliliter or gram to be recalled and destroyed.

5. Finally, *on the grounds that the manufacturer must prove safety for whomever may be treated with each drug product*, we request that the Commissioner of the Food and Drug Administration issue a policy that requires any preservative or other component of a vaccine, RhoD injection, flu shot, or other FDA-regulated product administered to humans or animals must be a substance that **either**:
 - a. Is not mercury based, **or**
 - b. *When the manufacturer of such medical products **provides proof** that said preservative or other component must be mercury-based*, the level of mercury-based preservative or other mercury-containing component in the formulation must be proven (in scientifically sound repetitive acute and/or intermediate-term chronic-toxicity studies using “susceptible” animals [e.g., SJL/J mice]) to be non-neurotoxic: ...” (pages P-1 – P-6).

Thus, your statement:

“Indeed, the relief you sought through your second citizen petition is identical to the relief you sought through your original citizen petition,”

is obviously incorrect.

“Page 3 – Coalition for Mercury-Free Drugs”

“... Therefore, your petition was not a petition for stay, but rather, a petition to modify the Commissioner’s decision.”

Clearly, **CoMeD** has established that your understanding of:

- ❖ The regulations governing petitions,
- ❖ The single (1) action that **CoMeD** requested in **CoMeD**’s October 21, 2006 “Petition of Stay of Action” (to stay the Commissioner’s September 26, 2006 decision to deny **CoMeD**’s citizen petition),
- ❖ The five (5) actions that **CoMeD** requested in **CoMeD**’s July 30, 2004 “Citizen Petition” (see the preceding **CoMeD** response), and
- ❖ The difference between the single “stay” action in **CoMeD**’s October 21, 2006 “Petition of Stay of Action” and the five (5) actions in **CoMeD**’s July 30, 2004 “Citizen Petition”

is, or appears to be, at odds with factual reality.

Since all petitions for a stay request the Commissioner to modify the time aspect of the Commissioner’s decision, all petitions for a stay of action are petitions to *“modify the Commissioner’s decision.”*

Thus, the FDA’s statement:

“Therefore, your petition was not a petition for stay, but rather, a petition to modify the Commissioner’s decision”

is an unsuccessful attempt to fabricate a petition “type” that not only does not exist (“*a petition to modify ...*”) but also is not one of the two petitions (a petition for reconsideration [see section 10.33] and a petition for a stay of action [see section 10.35]) that may be filed after a Commissioner’s decision on a citizen petition.

“For these reasons, we declined to accept your objections to our letter of December 21, 2006.”

Since **CoMeD** has established:

- ❖ The “reasons” you have outlined are not valid and
- ❖ **CoMeD**’s “Petition for Stay of Action” complied with the explicit strictures set forth for all of the applicable petition regulations in **21 CFR Part 10**,

CoMeD respectfully requests that you and the Agency:

- ❖ Reconsider the obviously specious arguments you have advanced and
- ❖ Correct the record by:
 - Simply denying **CoMeD**’s “Petition for Stay of Action” because the FDA’s “December 21, 2006” letter effectively denied **CoMeD**’s petition for a stay,
 - Properly correcting the administrative record filed in Docket 2004P-0349 to comply with clear requirements set forth in subsection 10.35(h), and
 - Notifying the Court that the government’s motion, filed on December 22, 2006, to dismiss in King, et al. v. Leavitt, et al., Civ. No. 06-1357 (D.D.C.), was fatally flawed because the FDA’s letter dated December 21, 2006:
 - Was final agency action with respect to the citizen petition **CoMeD** filed in Docket 2004P-0349 and,
 - As such, exhausted all administrative remedies available to Dr. King and **CoMeD**.

“As a courtesy to you, we deemed your petition to be a new citizen petition under section 10.30, as of the date you filed it.”

Contrary to your “(a)s a courtesy to you” remark, your ignoring **CoMeD**’s valid grounds-based objections to your suggested course of action clearly establishes the actions the FDA actually took were, *at best*, discourteous to both Dr. King and **CoMeD**.

“Your letter dated March 12, 2007, as we explained above, fully withdrew that new citizen petition.”

As **CoMeD** has shown, **CoMeD**’s “*letter dated March 12, 2006*” only asked the FDA to withdraw the unwarranted “*citizen petition*” the FDA created from a valid signed **CoMeD** “Petition for Stay of Action” submission without obtaining the written consent of Dr. King for the use of his signature and of **CoMeD** to use the **CoMeD** “Petition for Stay of Action” documents.

However, **CoMeD** is pleased that the FDA has withdrawn the “*citizen petition*” filed to Docket 2006P-0535 and “closed” that Docket.

“Sincerely,
<signature of Jeffery Shuren>
Jeffery Shuren, M.D., J.D.

Assistant Commissioner for
Policy”

Hopefully, after you carefully study this review of:

- ❖ Your letter date-stamped “MAR 28 2007,”
- ❖ All the applicable regulations governing petitions as set forth in 21 CFR Part 10, and
- ❖ The findings in Berkovitz v. USA³ that clearly limit your administrative discretion in cases where there are laws that regulate the Agency’s and its employees’ administrative discretion,

you and the Agency will take the corrective actions suggested by **CoMeD** on the previous page.

Respectfully,



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