

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  
Lake Hiawatha, NJ 07034-1922

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

Dear 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. You had captioned your petition as a "Petition for Stay of Action," but for the 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.

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. Because you submitted the petition, however, it remains your 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 Accordingly, that petition is now fully withdrawn and we have closed that docket.

In addition, we have closed the docket for your original citizen petition. 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 That record, as provided in 21 C.F.R. § 10.30(j), does not include the material you submitted with your now-withdrawn second citizen petition.

With your letter of March 12, 2007, you attached your letter of December 24, 2006, in which you objected to FDA's deeming your "Petition for Stay of Action" to be a new citizen petition and to FDA's opening a new docket for your second citizen petition. Below is a fuller explanation of FDA's basis for that administrative decision.

2004P-0349

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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 the administrative proceeding 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 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).

This subsection makes several things clear. First, it defines the administrative record for the citizen petition. Second, it provides when a petition for stay of action or a petition for reconsideration may be filed. 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). 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. It is this subsection that governed the situation presented by your "petition for stay" filed on October 24, 2006.

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.<sup>1</sup> Consequently, under subsection 10.30(j), you were required to file your new views and information as a new citizen petition under section 10.30.

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

In contrast, your "stay" petition was based on new information and views that went to the merits of the underlying decision. Indeed, the relief you sought through your second citizen petition is identical to the relief that you sought through your original citizen

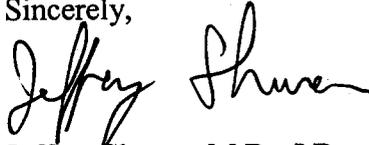
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<sup>1</sup> The document index in the filing listed in the Docket as PSA0001-02-index confirms this fact. Specifically, in that index, you listed 18 references which you described as "Referenced documents not in petition and/or not referenced by FDA 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 were 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.

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

For those reasons, we declined to accept your objections to our letter of December 21, 2006. As a courtesy to you, we deemed your petition, which was inaccurately captioned as a petition for stay, to be a new citizen petition under section 10.30, as of the date that you filed it. Your letter dated March 12, 2007, as we explained above, fully withdrew that new citizen petition.

Sincerely,

A handwritten signature in black ink that reads "Jeffrey Shuren". The signature is written in a cursive style with a large, prominent "J" and "S".

Jeffrey Shuren, M.D., J.D.

Assistant Commissioner for Policy

cc: Division of Dockets Management (HFA-305)

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