



DEC 21 2006

749 6 1027 2128

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 Number CP2004P-0349

Dear Dr. King and Others:

This letter is in response to your letter dated October 21, 2006, in which you requested the Secretary of Health and Human Services and the Commissioner of the Food and Drug Administration (FDA) to stay FDA's September 26, 2006 decision denying your July 30, 2004 citizen petition. In your letter, you captioned your request as a Petition for Stay of Action pursuant to 21 CFR 10.35. However, in your October 21, 2006 letter, you relied on information and views not included in the administrative record, contrary to FDA regulations. Specifically, 21 CFR 10.30(j) states that "[a] person who wishes to rely on information and 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." Consequently, your petition, by law, is a new citizen petition, which must follow the provisions set forth in 21 CFR 10.30.

To save you the burden, time, and expense of re-filing your petition as a new citizen petition, FDA has decided, as a courtesy to you, to deem your October 21, 2006 letter to be a new citizen petition, with its own docket number. The new citizen petition is deemed filed on October 24, 2006, the original filing date, and requests the Commissioner to modify FDA's September 26, 2006 decision.

If you object to any of the above, please let us know, and provide the grounds for your objection.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Assistant Commissioner for Policy

2006P-0535

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cc: Division of Dockets Management (HFA-305)

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