

Critical assessment of an FDA letter concerning a Citizen Petition specifying actions against Thimerosal-containing drugs

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Abstract

The review that follows this introductory letter is a critical assessment of an FDA letter, date-stamped “SEP 26 2006,” to **CoMeD** regarding FDA Docket Number 2004P-0349/CP1, a Citizen Petition filed seeking to compel the FDA and the Secretary of Health and Human Services to take certain actions against Thimerosal-containing drugs until the federal government can prove the safety of such Thimerosal-containing drug products in a manner that complies with **21 CFR 610.15(a)** and **42 U.S.C. 300aa-27(a)(2)**. **CoMeD** and the petition signers received the *complete* letter, which is being reviewed, at some time on 28 September 2006.

In general, to clearly differentiate between the assessment comments and those of the letter **CoMeD received**, when the letter’s printed statements are quoted, they are quoted in an *italicized “Times New Roman”* font followed by the reviewers, remarks in indented text written in a “**News Gothic MT**” font. Quotes from general reference articles and documents will, in general, be presented in an “**Arial**” font; federal laws, statutes and court decisions will be quoted in a “**Lydian**” font.

Overall, this critical assessment established that the FDA letter failed to address the issues raised in the **CoMeD** Citizen Petition and, instead, addressed issues *not* raised in the **CoMeD** Citizen Petition—issues that the FDA created.

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