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Food and Drug Administration
Office of Policy and Planning
5600 Fishers Lane
Rockville, MD 20857-43

April 12, 2007

S. Elizabeth Clay
3470 Olney Laytonsville Road # 187
Olney, MD 20832

Dear Ms. Clay,

This responds to your request, dated March 16, 2007, for an extension of the comment period for the draft guidance titled, "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration." You identified yourself as a private citizen with significant interest in the issue and experience in both the government and private sector, and you sought an extension of at least 60 days or preferably 90 days.

Your reasons for an extension were that:

- FDA had taken more than 60 days to publish the document, and the guidance document "was not yet (almost 3 weeks into the Federal Register release) posted on the 2006 or 2007 Dockets page itself." You also said that members of the general public and small non-profit entities "do not typically review the Federal Register each day" and that the "first actual notification...came through an email newsletter posting by the National Center for Complementary and Alternative Medicine on March 13, more than 2 weeks after the Federal Register notice, thus shortening the response time to 45 days."
- The issues in the guidance are complex, so more time is needed to "give the community, including the patient population time to be informed and to conduct an adequate review and develop a response."
- "Trade associations will need adequate time to review the issue, develop a response and receive input from membership."

We are denying your request. In brief:

- The procedures used in announcing the availability of the guidance document are the same as those used for *all* other FDA guidance documents.

2006D-0480

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- The guidance document, contrary to your assertion, was available electronically through Dockets on February 27, 2007; the link to the guidance appeared immediately below the corresponding entry for the notice on the daily entry for February 27, 2007. We have reproduced the relevant entry from the website page below:

NOTICES-DRAFT GUIDANCES

Docket No. 2006D-0480, OC 2006139. Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration; Availability. Pages 8756-8757 [FR Doc. E7-3259] [TXT] [PDF] [PRE-PUB] **Comments due April 30, 2007**

The Draft Guidance

- The information sent by the National Center for Complementary and Alternative Medicine, as well as the timing of that information, does not alter the fact that FDA provided notice about the guidance document, using standard procedures and through the publication (the *Federal Register*) used by Federal agencies to provide such notice, and provided a standard comment period for the guidance.
- You do not identify a reason why you cannot prepare your comment within the comment period.
- Similarly, an argument that trade associations may need more time to formulate comments has no apparent bearing on your ability to submit comments because you do not claim to represent any trade association.

For the reasons given above, we deny your request for an extension.

Sincerely,



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