

A Commentary on the FDA Draft Guidance on CAM Products

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On February 27, 2007, the Food and Drug Administration (FDA) announced in the *Federal Register* the availability of a draft guidance document entitled *Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration*. The FDA comment period closes on April 30, 2007. Document identifiers and web locations are provided at the end of this article.

The draft guidance document has been responded to with alarm by some members of the CAM community. The concern seems to center on the notions that the guidance document dictates new or stricter regulations of CAM products. These are mistaken notions. The draft guidance document does not break any new ground, and does not promulgate any new and binding regulations. It does provide a concise summary of standing FDA definitions for drug, new drug, device, food, food additive, dietary supplement, cosmetic, and biological product. It also supplies the sharp reminder that CAM products occupy this standard regulatory playing field.

The draft guidance document reiterates the FDA's current stance on context of use, and applies it to CAM products. Context of use defines a product's regulatory category. For example: A metal bracelet provided as a treatment for arthritis is thereby considered a medical device due to its context of use, and falls under FDA medical device regulations. The same metal bracelet provided as a piece of jewelry is just jewelry and not considered a medical device at all due to its context of use. It is not even under FDA jurisdiction. The lesson here is obvious: Be very careful with respect to what you claim for products.

It would be prudent to heed the draft guidance document as a foreshadowing of future compliance actions. If CAM entities are out of FDA compliance, they would be well advised to promptly come into compliance.

I do not believe there is any need to respond to the FDA with comments on this draft guidance document. However, I would have expected national CAM professional associations to have brought this document to the attention of their members in a timely way. Some associations responded late in the comment period, and others have not broached the matter to date. The draft guidance contains information that does pertain to all CAM professionals. Coverage of national regulatory affairs is a vital function. Failure to competently perform it may put CAM professionals at risk.

Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration

Docket No. 2006D-0480. Pages 8756-8757 [FR Doc. E7-3259]

Federal Register notice of Feb 27, 2007:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-3259.pdf>

The Draft Guidance document:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0480-gld0001.pdf>

To submit comments electronically: <http://www.fda.gov/ohrms/dockets/default.htm>

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