

Comment from Public Member Erika Lietzan
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This regulation – on “good guidance practices” (which was required by statute) – says that guidance documents aren’t binding on anyone, including FDA, and yet ... staff are somewhat bound. (FDA lawyers use this language to force “review” of decisions that deviate, and in my experience agency staff take it seriously.)

<https://www.law.cornell.edu/cfr/text/21/10.115>

(d) Are you or FDA required to follow a guidance document? (1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

(2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.

(3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

The more I think about this, the more I think this is a very elegant approach. FDA has managed to effectively bind its *staff* without binding *the agency itself*. It has created a modest amount of certainty (predictability) for regulated parties, and a mechanism for accountability (and “justification”) within the agency, *without* binding itself in a way that could lead to judicial review. It’s quite clever, if you think about it.

That said, the FDCA mandates this. Section 701(h) of the FDCA, 21 USC 371(h), requires FDA to promulgate good guidance practice regulations. And 701(h)(1)(B) says, “Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.”

The history here is a little unusual, though. The agency received a petition in the mid-1990s asking it to develop good guidance practices. It responded by publishing a guidance document (announced in 62 Fed. Reg. 8961 (Feb. 27, 1997)). The FR announcement noted, “Although guidance documents cannot legally bind FDA or the public, the agency recognizes the value of guidance documents in providing consistency and predictability. A company wants assurance that if it chooses to follow a guidance document, FDA generally will find it to be in compliance with the statute and regulations. Moreover, FDA issues guidance to its staff so that they will apply the statute and regulations in a consistent manner. With these principles in mind, FDA's

decisionmakers will take steps to ensure that their staff do not deviate from guidance documents without appropriate justification and without first obtaining concurrence from a supervisor. This practice will provide assurance to companies that choose to follow a guidance, yet will not legally bind the agency or its decisionmakers to a guidance document.” I can’t easily find the 1997 guidance, but I expect it said something similar to what the statute (enacted in the fall 1997) says and what the regulation now says. In other words, although the FDCA contains this language, I believe FDA developed it first.