OPPORTUNITIES FOR INPUT INTO GUIDANCE DEVELOPMENT

Background

Guidances are documents prepared for FDA staff, the regulated industry, and/or the public that describe the Agency's interpretation of, or policy on, a regulatory issue. Unlike statutes and regulations, guidances themselves cannot generally create legally binding requirements.

There are two types of guidances: Level 1 guidance and Level 2 guidance. Level 1 guidances are those that: (1) set forth initial interpretations of statutory or regulatory requirements, (2) set forth changes in interpretation or policy that are of more than a minor nature, (3) include complex scientific issues, or (4) cover highly controversial issues. In contrast, Level 2 guidances set forth existing practices or minor changes in interpretation or policy.

FDA issues a significant number of guidances each year and devotes substantial resources to the guidance process. For example, in FY 2009, the Agency issued approximately 124 guidances. Since that time, its issuance of guidances has been trending upward, with the Agency issuing approximately 133 guidances in FY 2010 and approximately 144 guidances in FY 2011.

Opportunities for Input

FDA's Good Guidance Practices (GGP) regulation (21 C.F.R. § 10.115) governs the development and issuance of guidances, and it gives interested persons a number of opportunities to provide input into the guidance development process.

(1) Comments on Draft Level 1 Guidance

Generally, FDA solicits public input on Level 1 guidances prior to implementation. The Agency posts draft Level 1 guidances on its website, and it publicizes them by issuing a Notice of Availability (NOA) of the draft guidance in the *Federal Register*.

Generally, the public has 60 days to provide comments to FDA on draft guidances. In some instances, FDA may also hold public meetings or workshops on draft Level 1 guidances to solicit additional comments, or present the draft Level 1 guidance to an advisory committee for review. Once the comment period has closed, the Agency reviews and considers the comments it has received, as it prepares the final guidance. The Agency also posts final Level 1 guidances on its website and publicizes them by publishing an NOA in the *Federal Register.*

Interested persons may also comment on final guidances at any time after they have been issued.

(2) Comments on Level 2 Guidance and Level 1 Guidance "For Immediate Implementation"

Generally, FDA does not solicit public input on Level 2 guidances or on Level 1 guidances "for immediate implementation" (*i.e.*, Level 1 guidances for which "prior public participation is not feasible or appropriate," (21 C.F.R. § 10.115(g)(2)), prior to implementing the guidance.

However, FDA publishes an NOA in the *Federal Register* for Level I guidance "for immediate implementation" and posts both types of guidance on its website. Interested persons may comment on them at any time after they have been issued. FDA will review the comments and revise the guidances, as appropriate. This streamlined approach permits FDA to issue Level 1 guidances "for immediate implementation" and Level 2 guidances more expeditiously than other Level 1 guidances, while still providing stakeholders an opportunity to comment.

Importantly, the additional administrative steps required for typical Level 1 guidances, which are *not* issued "for immediate implementation" (*i.e.*, issuing a draft guidance, providing a comment period, and issuing a final guidance), generally make the issuance of such Level 1 guidances a longer process.

(3) Comments on Guidance Topics/Proposed Draft Guidance

In addition to the opportunity to comment on guidances themselves, interested persons have an opportunity to provide input to FDA on topics for guidances.

First, FDA publishes an annual guidance agenda listing possible topics for future guidance development or revision during the next year. FDA's most recent guidance agenda may be found in the *Federal Register* at http://edocket.access.gpo.gov/2010/pdf/2010-30623.pdf. Interested persons may submit comments on the topics on the list or suggestions for additional topics for guidance.

Interested persons also may identify issues in Citizen Petitions that the Agency may decide to address by issuing a guidance. (The procedures for filing citizen petitions are in FDA's regulations at § 10.30).

Requests for guidances also come to FDA informally. Frequently, interested persons identify issues that would benefit from guidance at advisory committee meetings, industry meetings, roundtables, and listening sessions, or by contacting the appropriate FDA office.

Finally, interested persons sometimes submit a proposed draft guidance document to FDA. Submitting proposed draft guidance documents, rather than guidance topics, enables FDA to approach a guidance topic with a better understanding of the issues that interest the stakeholder. This may expedite the guidance development process,

particularly if the topic involves novel scientific issues. FDA solicits proposed draft guidance at a variety of different venues, such as trade association meetings and on the FDA website. Interested persons may submit proposed draft guidance documents on unsolicited topics, as well.

All guidance topic suggestions and proposed draft guidance documents are taken under consideration, but resource limitations may prevent the Agency from responding to each suggestion. In addition, resource limitations may prevent the Agency from taking action on the suggestions, as may legal constraints and policy considerations.

Please submit any questions you have regarding commenting on guidance or guidance topics, or submitting proposed draft guidance, to the mailbox appropriate for your topic on *FDA Basics for Industry*, Submit Questions and Comments, http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm261194.htm.

More Information About Guidances

Guidance Development Process – In December 2011, as part of FDA's Transparency Initiative, FDA issued the Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency (GGP Report), to the public to make the Agency's processes regarding guidance development and issuance more transparent and to solicit public comment on the report and recommendations. For more information about the guidance development process, interested parties may access the report at http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm284740.htm

Guidance List (Existing Guidances) – *FDA Basics For Industry*: Guidances, http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm

FDA's Good Guidance Practices Regulation – 21 C.F.R. § 10.115, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

Coming Soon

Recently Withdrawn Guidances – As part of the Transparency Initiative, FDA released the Phase III Transparency Report, which states that FDA will provide a centralized webpage with links to lists of guidances that have been withdrawn in the past year. This list is under development, and it will be posted on *FDA Basics for Industry*. A partial list may now be found at http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm