Fact Sheet: FDA Good Guidance Practices

FDA guidances are documents that explain the agency's interpretation of, or policy on, a regulatory issue. The FDA prepares guidances primarily for industry, but also for other stakeholders and its own staff, and uses them to address such matters as the design, manufacturing, and testing of regulated products; scientific issues; content and evaluation of applications for product approvals; and inspection and enforcement policies.

Although guidances are not legally binding, they show stakeholders one way to reach their regulatory goal. However, stakeholders are free to use other approaches that satisfy the relevant law and regulations. Recently, FDA published a report on how to improve the processes that make these important documents available.

Guidance Development

FDA issues more than 100 guidances each year. In fiscal year (FY) 2009, for example, FDA issued approximately 124 draft and final guidance documents; in FY 2010, the total was approximately 133, and in FY 2011, it was approximately 144. FDA develops two types of guidance documents - Level 1 and Level 2. In general:

- Level 1 guidances set forth the agency's initial interpretations of new significant regulatory requirements; describe substantial changes in FDA's earlier interpretation or policy; and deal with complex scientific or highly controversial issues.
- Level 2 guidances usually address existing practices or minor changes in FDA's interpretation or policy.
- Industry, consumers and other stakeholders play a significant role in the agency's guidance development processes. FDA welcomes individuals' and stakeholders' suggestions of topics for guidances, and in certain instances solicits draft proposals. Draft proposals can help the agency better understand stakeholder positions, particularly if the subject involved deals with novel scientific issues.
- The agency also invites the public to comment on its draft Level 1 guidances and reviews and considers the submitted comments in preparing the final documents. In some instances, FDA may hold public meetings or workshops on draft Level 1 guidance to solicit additional comments, or it may present draft Level 1 guidance to an advisory committee for review.
- Although Level 2 guidances and Level 1 guidances "for immediate implementation" are implemented without prior public comment, all FDA guidances are posted on the agency's Web, and anyone can submit comments on any guidances after they are implemented. FDA reviews those comments and revises the guidances, if necessary.

A Blueprint for Improvement

As part of the Transparency Initiative, Dr. Margaret A. Hamburg, the Commissioner of Food and Drugs, called for a cross-Agency working group to prepare a report identifying FDA's "best practices" for making the agency's guidance development processes more transparent and efficient.

The working group, under the leadership of the Office of Policy in the Office of the Commissioner, prepared a report, entitled the "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency" (GGP Report). This report may be found at http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf, and it is open for comment by interested parties.