Compounding Quality Center of Excellence Annual Conference

FDA Guidance and Opportunities to Comment

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Rechelle Buford, JD
Regulatory Counsel
Division of Compounding Policy and Outreach
Office of Compounding Quality and Compliance
Office of Compliance, CDER, FDA

Objectives

- Definition and types of guidance documents
- Guidance development
- How to comment
- References

What is a Guidance?

- Guidance documents are prepared for FDA staff, the regulated industry, and/or the public and describe the Agency's interpretation of or policy on a regulatory issue (§ 10.115(b)).
- Unlike statutes and regulations, guidance documents do not establish legally enforceable rights or responsibilities (§ 10.115(d)). Firms may employ alternative approaches.

What is Not a Guidance?

These documents are **NOT** guidance documents, but may be publicly available and mistaken for guidance:

- Documents relating solely to internal FDA procedures
- FDA reports
- General information documents provided to consumers or health professionals
- Speeches, journal articles, editorials, media interviews, or press materials
- Warning letters
- Memoranda of understanding
- Other communications or actions taken by individual staff at FDA that are directed to individual persons or firms

21 CFR § 10.115(b)(3)

Types of Guidance

- Level 1 (§ 10.115(c)(1)):
  - Includes:
    - First interpretations of statutory or regulatory requirements
    - Changes in interpretation or policy (not minor in nature)
    - Complex scientific or highly controversial issues

- Level 2 (§ 10.115(c)(2)):
  - Includes:
    - Existing practices or minor changes in interpretation or policy
    - All guidance documents that are not level 1

Guidance Development Process (1 of 3)

Level 1 guidances:

- After preparing a draft of a Level 1 guidance document, FDA will:
  - Publish a notice in the *Federal Register* announcing that the draft guidance is available;
  - Post the draft guidance document on the Internet and make it available in hard copy; and
  - Provide an opportunity for public comment.
- After providing an opportunity for public comment, FDA will:
  - Review any comments; and prepare the final version of the guidance
  - Incorporating suggested changes, when appropriate;
  - Publish a notice in the *Federal Register* announcing that the final guidance is available
  - Post the draft guidance document on the Internet and make it available in hard copy; and
  - Implement the guidance

Guidance Development Process (2 of 3)

Level 1 guidances:

FDA may decide, after reviewing comments, that it should issue another draft of the guidance document. In that case, FDA will again follow the above steps.

- Alternatively, FDA may determine that public participation before implementation of a Level 1 guidance is not feasible or appropriate. In which case, FDA will publish a notice in the Federal Register, post the guidance on the internet and make it available in hard copy, immediately implement the guidance, and provide an opportunity for public comment. If FDA receives comments on the guidance document, FDA will review those comments and revise the guidance document when appropriate.

Guidance Development Process (3 of 3)

Level 2 guidances:

- After preparing the Level 2 guidance document, FDA will:
  - Post the guidance document on the Internet and make it available in hard copy
  - Immediately implement the guidance document, unless FDA indicates otherwise when the document is made available; and
  - Invite your comment when it issues or publishes the guidance document.
  - FDA reviews any comments and revises guidances, as appropriate.

FDA publishes a Guidance Agenda (§ 10.115(f)(5)) annually in both the *Federal Register* and on internet: https://www.fda.gov/media/134778/download. You can comment on the list and make recommendations on the topics that FDA is considering.

How to Comment (1 of 2)

- Serves as an opportunity for public to provide input into the guidance development process
- FDA must ensure public participation prior to implementation of guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues unless we determine that such prior public participation is not feasible or appropriate (Section 701(h)(1)(C) of the FD&C Act and 21 CFR § 10.115(g)(2)).
- FDA solicits public input on Level 1 guidance documents by posting guidance on our website and by issuing a Notice of Availability (NOA) of the guidance in the *Federal Register* (21 CFR § 10.115(g)(1)(ii)).

How to Comment (2 of 2)

- Comments on guidance documents:
  - Can be received at any time per § 10.115(g)(5) (even on final guidance), but it's advised to submit comments before closing date of the comment period specified in the NOA
  - May be Submitted electronically through Regulations.gov

Guidance Document Posting

- All human drug guidance for industry (GFI) can be retrieved at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
  - For Compounding GFI, filter your search by selecting Product as “Drugs”, FDA Organization as “Center for Drug Evaluation and Research”, topic as “Compounding” and Document Type as “Guidance Document”
- All agency guidances are also posted at: https://www.hhs.gov/guidance/

References

- FDA Report on Good Guidance Practices (December 2011)
- FDA Good Guidance Practices Fact Sheet

Questions?