How to Comment on FDA Guidance Documents

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AMDM 2017 IVD Focus Meeting

Importance of Guidance

- Guidances are non-binding policy statements from the Agency
- Intended to clarify FDA's position on a particular topic
- However, they can sometimes become *de facto* rules, especially in the premarket space
- Can create new requirements that can be burdensome to industry

How to Find out About New Guidance

- Federal Register
  - Receive Table of Contents Daily – sign up at https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new
- FDA's website
  - https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm
- Blogs
  - FDA Law Blog http://www.fdalawblog.net/
  - FDA Voice Blog (Official FDA Blog) https://blogs.fda.gov/FDAvoice/index.php
- Trade Press

Agency Procedure

- Guidance is easier procedurally than rule making
- For this reason, we see a great deal more guidance issued than rules
  - In 2016, CDRH issued 19 draft guidances, and over two dozen final guidances
  - Brief lull at the start of this administration.
  - However, since August we have started to see both draft and final guidances coming from CDRH again

Agency Procedure

- In a formal rule making, FDA has to publish a proposed rule, allow time for comment, and then respond to the comments in a preamble to the final rule when the final rule is issued
  - Also, additional administrative steps are required, including an economic impact assessment
- No such requirement to respond to guidance comments
- Nonetheless, **comments on draft guidances matter**!

Why Should I Comment?

- FDA may not necessarily be the expert and providing comments offers an opportunity to educate the Agency
- The practical effects of a guidance may be unduly burdensome
  - E.g., 510(k) Changes Guidance
- What may appear to be a simple process may be far more complex and require additional clarification
  - E.g., UDI
- Changing rules or creating binding requirements should be done through rule making
  - E.g., LDT Guidance, RUO Guidance
- Support FDA taking a certain action
  - E.g., adoption of a new consensus standard on a topic

Guidance Considerations

- Does the guidance change any current practice?
- Does the guidance create any new (non-binding) requirements?
- What are the benefits / burdens of the new or changed (non-binding) requirements?
- Are there any unclear or ambiguous statements?

Ways to Submit

- Under your own name
- Anonymously through a third party (e.g., attorney or consultant)
- Create a small group coalition with other similarly situated companies
  - Often attorneys or consultants are willing to create such groups
- Trade association

Form of Comments

- No requirement as to form
- Include docket number and name of guidance
- Introduction / Background
- Why this guidance is of importance to your company
- Key points and explanations
- Conclusion

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BY ELECTRONIC SUBMISSION

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061, HFA-305
Rockville, Maryland 20852

RE: Docket No. FDA-2011-D-0360, Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), and FDA-2011-D-0357, Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs).

Dear Sir or Madam:

On October 3, 2014, the U.S. Food and Drug Administration ("FDA") issued the above-referenced Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) ("Draft Framework Guidance") and Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests ("Draft Notification Guidance") (collectively, "Draft Guidances"). Hyman, Phelps & McNamara, P.C. ("HPM") is submitting these comments on behalf of a group of innovative laboratories that offer Laboratory-Developed Tests ("LDTs") that would be adversely affected by the adoption of the Draft Guidances.

HPM is pleased to submit comments in response to the Draft Guidances on this important issue on behalf of these laboratories. They collectively offer a wide range of LDTs, such as tests that help parents to have healthy children, cardiac tests that reduce risks to patients, tests for infectious disease, immune response tests, and tests for genetic variants.

How to Submit

- Instructions in Federal Register notice announcing the guidance
- Federal eRulemaking Portal: https://www.regulations.gov.
  - Comments submitted electronically will be posted to the docket unchanged.
  - **Do Not Include Confidential or Proprietary Information**
- If comments include confidential information comments can be submitted in paper
  - Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
  - Full comments (including attachments) will be posted to regulations.gov with the exception of information expressly marked as confidential
  - Submit 2 copies – one full and one redacted

Questions & Discussion

Contact Information

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