Good Guidance Practices (GGPs)

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Key Words and Terms

GGPs = Good Guidance Practices policy (to provide transparency and consistency in policy development)

Docket = Division of Dockets Management is official repository for the administrative proceedings and rule-making documents for the FDA

NOA = Notice of availability, which announces a guidance and publishes in the FR

FR = *Federal Register*, our legal document of record. It publishes every working day of the year.

G^2 = Guidance on Guidance, a Center-only Web page, where employees can find all the information they need on guidance development and the GGP process, including templates, the style manual, and important links to other Web pages.

Why GGPs – Was There a Problem?

- Yes, a *big* problem! The FDA was using all kinds of methods to announce "policies."
  - Podium policy
  - "White Papers"
  - "Points to Consider" papers
  - "Information Sheets"
  - Phone and Fax
- Nobody was sure what our policy really was.

GGP Policy Was the Answer

- All centers worked together to develop a guidance policy.
- A 1997 notice announced Good Guidance Practices policy.
- Congress asked us to turn it into a regulation.
- We proposed new regulation 21 CFR 10.115.
- We finalized the regulation September 19, 2000: FDA's policies and procedures for developing, issuing, and using guidance documents.
- We hired editors (there are now 6) to help process guidances (and other documents) according to GGPs.

What Is a Guidance?

- It is the Agency's interpretation of, or policy on, a regulatory issue.
- A guidance represents the Agency's current thinking (no more podium policy, no more Faxes).
- Generally
  - prepared by FDA staff
  - for applicants, sponsors, and the public
- They are ***NOT*** binding.

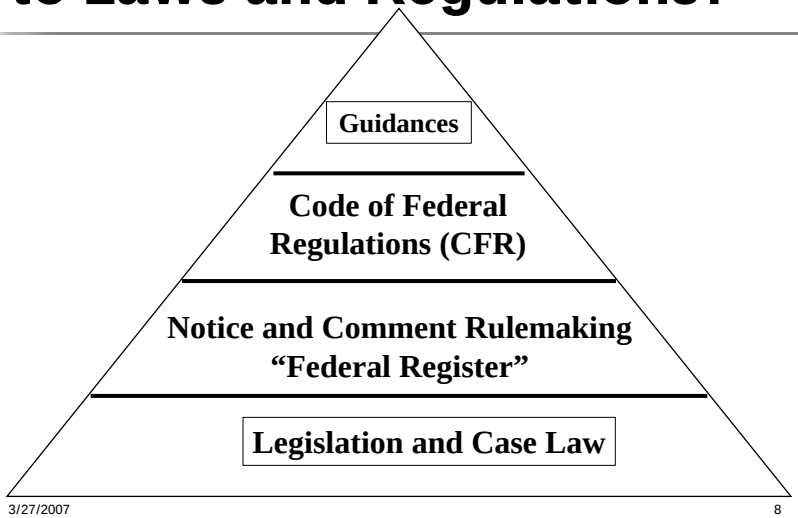
Guidances Do *NOT* Include:

- Internal FDA procedures
- Agency reports, articles, media interviews, press materials
- Warnings or letters, Memoranda of Understanding (MOUs)
- Speeches

What Are Some Examples?

- Documents that describe the
  - design, production, labeling, promotion, manufacturing, and testing of regulated products
  - processing, content, and evaluation or approval of submissions
  - inspection and enforcement policies

How Does Guidance Relate to Laws and Regulations?



What Is The Difference Between Level 1 and 2 Guidance?

- Level 1
  - Sets forth interpretations of statutory or regulatory requirements
  - Discusses changes in interpretation or policy that are more than of a minor nature
  - Includes complex scientific issues
  - Covers highly controversial issues
  - Must issue as a draft for comment
  - Cleared through high-level Agency staff

Level 2 Guidance

- Sets forth existing practices or minor changes in interpretation or policy (e.g., easy to figure out, not controversial)
- Includes all guidances that are not classified as a level 1
- Need not issue as a draft
- Clearance process is less extensive

How Many Guidances Issued Annually?

- Center for Drugs alone: 30 to 40 per year (e.g., ICH, draft, and final)
  - Rarely issue level 2 guidances

Guidance Requirements

- Must have the same format (created a guidance template)
- May not include mandatory language (e.g., “must,” “required”; they aren’t binding)
- Must include standard disclaimers (provided in the template)

What Should I Remember About GGP Process?

- It's transparent to all; equal public access
- Encourages broad public participation
- All guidances handled consistently, according to agreed to process
- FDA/industry should use guidance documents uniformly
- Guidances not binding

GGP Regulation Encourages Public Participation

- Public can review guidance agenda
  - List of guidances that the Agency is planning to develop (http://www.fda.gov/cder/guidance/index.htm)
- Public can submit suggestions and/or drafts to the Agency

Resources Provided

- GGP Regulation 21 CFR 10.115
- Guidance Template
- Copy of internal G2 page
- Standard Operating Procedures (MaPP 4000.2)
- Best Practices

Thank You