

## FDA LAW, REGULATION, and POLICY

What is a law? A law is enacted by Congress and enforced through the agencies of the executive branch. Our main law, or statute, is the Federal Food, Drug & Cosmetic Act, which originated in 1906 and has been amended many times since.

What is a regulation? It is a standard or requirement of conduct set by a government agency under the statutory authority granted to it by Congress. In effect, Congress leaves the task of preparing implementing details for a piece of legislation to the agency.

For example, consider Good Manufacturing Practices (GMP's) for devices. Enacting a law setting forth the GMP's in detail would have required tremendous expertise and research. Updating such law would have been cumbersome since it would require Congressional passage of an amendment. Rather than give up the concept of GMP's as legislatively impractical, Congress simply delegated this authority to the FDA (Section 520(f)). The agency is qualified to handle this responsibility because it has individuals with expertise in the area of concern. Regulations promulgated by the agency in accordance with these sections have the force of law.

In a lawsuit, the agency may prove a violation of the law by proving a violation of the regulation itself. Thus, proof of a violation of a device GMP requirement in the regulations promulgated under 520(f) is the equivalent of adulteration under 502(h). An adulterated device can be seized under 304(a)(2), or the person or company causing the violation can be restrained under 302 or subject to criminal penalty under 303(a) or (b).

What are guidance documents? Guidance documents represent FDA's current thinking on matters under the agency's jurisdiction. For example, guidance documents intended for industry provide assurance that if organizations choose to follow the guidance, FDA generally will find them to be in compliance with the laws and regulations relating to that particular matter.

The specific purpose of guidance documents is dependent on their intended audience. Some are intended to provide assistance to the regulated industry by clarifying requirements imposed by Congress or issued in regulations by FDA. Others provide specific review and enforcement approaches to help ensure that FDA employees implement the agency's mandate in an effective, fair, and consistent manner.

Guidance documents are **not** binding on the agency or the public. They do not create or confer any rights for or onto any person. This must be communicated clearly and emphatically to FDA staff and the public. It is extremely important that guidance documents are not being applied as binding requirements because, unlike regulations, guidance documents do NOT have the force and effect of law.

Although guidance documents are non-binding, it is important to realize that FDA employees must not deviate from such guidance without appropriate justification and supervisory concurrence.

## Alternatives

Inspected firms can use an alternate approach to any particular agency guidance so long as the approach satisfies the requirements of the applicable statute, regulations, or both. FDA encourages industry or other interested persons to discuss alternate approaches to complying with the applicable statutes and regulations with the agency prior to implementation. The goal is to determine if the alternative approach will result in compliance.

When no formal regulation exists, the government can not rely on the existence of a guidance document, but has the burden of proving that a violation has occurred on a case by case basis. An example is the US v. Bioclinical Systems Inc. case. The case involves proving a GMP violation relating to an FDA guidance which addressed assurance levels for plated culture media.

## WHAT ARE REGULATIONS?

What is a regulation? It is a written rule or guidance information issued by a government agency. A regulation that is a rule that has the force of law may be a standard or requirement of conduct which is set by a government agency under the statutory authority granted to it by Congress. In effect, Congress leaves the task of preparing implementing details for a piece of legislation to the agency. A guidance regulation that does not have the force of law may simply be recommendations as to how to prepare a submission to the FDA though it may not intend to be the sole method for preparing the submission to the Agency.

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