FDA Regulatory Policy Process and Current Trends

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Key Words

FDA Regulatory Process; FDA Trends; Congress Bills; Regulations

Abstract

The FDA issues regulations based on bills issued by the US Congress affecting food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs/medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal foods, and veterinary products.

SUMMARY

What federal agency is tasked with protecting and promoting the safety and quality of the food and drugs consumed in the United States? That would be the U.S. Food and Drug Administration (FDA), which is part of the United States Department of Health and Human Services. The Agency regulates food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs/medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary (animal) foods and medications.

So, what does regulation mean? After Congress passes a bill, the bill becomes a law. Then, this bill is given to experts at a federal agency, like the FDA, to create rules/regulations that must be followed. The FDA also releases guidance documents that help people understand and follow these regulations. While rules/regulations must be fol-

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lowed, guidance documents are not official laws—they are only the Agency's interpretation on how to comply with FDA Law. Good manufacturing practices should also abide with the Federal Code of Regulation (CFRs) which describe how companies can comply with FDA expectations.

Who is involved in the FDA approval process? Governmental stakeholders include federal advisory committees, the Health and Human Services Office of the Inspector General, the Government Accountability Office, special commissions, other groups, and U.S. citizens who can influence regulations. Why are U.S. citizens involved in the process? Well, whenever a regulation/revision is proposed, there is an announcement on the Federal Register. Public comments are allowed for usually 60 days after the proposal. Anyone can comment by going online to www.Regulations.gov, mail the Agency, or setting up an in-person appointment. The FDA takes all comments seriously and these comments can have a huge impact on decision making by the Agency.

What are some current FDA initiatives? The FDA's focus is on innovation, globalization, food safety, regulatory science, tobacco, transparency, medical countermeasures, and the Sentinel Initiative for transforming how FDA can best ensure public health and serves the American consumer.

New upcoming regulations to look forward to include but are not limited to:

- the blood initiative,
- the revocation of general safety tests in the biologics license application,
- new over-the counter prescriptions regulations,
- cold and topical antimicrobial regulations,
- electronic distribution of prescription information,
- regulations on fixed-dose combination,
- abbreviated new drug applications,
- pediatric study plan requirements, and
- Investigational new drug application annual reporting. □