

Sessions Ends Use of Agency Guidance Documents for Civil Enforcement

February 5, 2018 Suzie Trigg

PRACTICES Procurement and Supply Chain Management, FDA Regulatory and Compliance, Franchise and Distribution

FDA-regulated companies have long relied upon the FDA's Guidance for Industry (GFI) documents to predict the FDA's interpretation of the applicable Code of Federal Regulation (CFR). Despite the GFI documents disclaimers that they are nonbinding, there are company-concerns that the FDA is using the GFI documents to circumvent notice-and-comment rulemaking.

On November 16, 2017, Attorney General Jeff Sessions issued a [memorandum](#) prohibiting Executive Branch agencies from enforcing issued guidance documents as de facto regulations on third-party entities reasoning that the Department of Justice and other agencies have blurred the distinction between regulations and guidance documents. Then on January 25, 2018, the Attorney General's office issued a [follow-up memorandum](#) terminating all pending and future affirmative civil enforcement brought by the Department of Justice on behalf of the United States to, among other things, impose penalties for violating of Federal health and safety guidance documents.

Pursuant to the Administrative Procedure Act (APA), an Executive Branch agency must provide a public opportunity for notice-and-comment rulemaking to create a right or obligation binding members of the public or the agency. Many such *regulations* that bind or obligate the U.S. Food and Drug Administration (FDA) and the public are found in Title 21 of the CFR. Despite Title 21 of the CFR having been promulgated through notice-and-comment rulemaking, the FDA provides interpretations of the CFR in its GFI documents. Each GFI document, whether in draft or final, is presents the FDA's "current thinking" on specific topics; generally the CFR—the FDA's own codified rules—and not an existing *legislative* rule or statute. Because the FDA applies the GFI to interpreting its own codified rules, it is entitled to almost carte blanche authority as long as the GFI are not the reason for imposing penalties. Because the FDA cites either the CFR or the Food, Drug and Cosmetic Act (FDCA) but not GFI documents, the Attorney General's memorandum reaffirming the Executive Branch's commitment to the APA should not significantly impact the FDA's actions and enforcement.

Implications of the Attorney General's Memorandum

The November 16 memorandum pulls back erroneously enacted and enforced "regulations" that were created by an agency without following the APA. By contrast, the FDA relies on and cites to its CFR or the FDCA when imposing penalties on a company. For instance, an active pharmaceutical ingredient (API) manufacturer may be cited for current Good Manufacturing Practice (cGMP) violations. The FDA is careful, however, to cite the violation to *drug adulteration* within the purview of the FDCA rather than the [guidance on cGMP for APIs](#).¹ Likewise, a drug product manufacturer that acts contrary to the [guidance on cGMP for finished drug products](#) will be cited for violating Title 21 of the CFR instead of the [Guidance for Industry – Quality Systems Approach to Pharmaceutical CGMP Regulations](#). In sum, the FDA's GFI documents are not enacted through the formal rulemaking process and therefore do not carry the full force and effect of the law. If a company is violating the codified regulations of Title 21, it is failing to adhere to the FDA's pertinent GFI. By

contrast, a company that fails to follow the FDA's pertinent GFI may still be in compliance with Title 21 of the CFR. Simply put, the FDA may find conflicts between a company's activities and the GFI but will find a corresponding CFR to cite against the company.

Conclusion

The Attorney General's memorandum may have large and lasting effects on many of the Executive Branch's agencies but not the FDA. The FDA provides its GFI library as merely interpretations of its codified regulations and accordingly, imposes penalties based on violations of its regulations.

¹ The FDA does not have a regulation for cGMPs of APIs. The International Conference of Harmonization Q7 (ICH Q7) is the guidance that represents the FDA's current thinking on cGMPs for API but there is no regulation. The FDA even provides explicitly that it considers a company in compliance with ICH Q7 to be in compliance with Section 501(a)(2)(B) of the FDCA. See [FDA Compliance Trends, February 24, 2017](#).