Crash Course Compliance: Top 5 Things Every Company Should Know About U.S. Drug and Device Regulation

Related Attorneys

Jolie N. Havens

Related Industries

Manufacturing

Retail and Consumer Products

CLIENT ALERT | 9.9.2020

In response to the COVID-19 pandemic, many companies have recently expanded or transitioned into the manufacture and distribution of products regulated by the U.S. Food and Drug Administration (FDA), including face masks, personal protective equipment (PPE), and hand sanitizer. While many companies entered this space knowingly, others did not and remain unaware of the compliance obligations associated with, among other things, providing these products to their own employees. To be clear, if you are manufacturing, importing, exporting, selling, distributing, or otherwise providing these products to your employees, you likely have FDA compliance obligations.

While the compliance burden associated with these products to date has been eased by certain temporary waivers and authorizations, some compliance requirements still remain even under this framework. Further, these relaxed requirements will terminate with the end of the federally declared Public Health Emergency (PHE), at which point full FDA compliance will again be required. Set forth below are five key points every company should understand in preparing for the next stage of compliance, with a particular focus on gauging and minimizing legal risk.

> *5. Criminal penalties are authorized for (among other things) the distribution of "adulterated" and "misbranded" drugs and devices, which you may already be doing.*

Generally, a product is unlawful to distribute under the federal Food, Drug and Cosmetic Act (FD&C Act) if it is deemed to be "adulterated" and/or "misbranded." These terms capture a wide range of more specific regulatory issues, from non-compliance with Quality System or Current Good Manufacturing Practice (cGMP) regulations (rendering a product "adulterated") to failure to obtain required premarket clearance or provide proper labeling (rendering a product "misbranded"). Importantly, the same criminal[1] penalties (including fines of up to $1,000 and/or imprisonment for up to one year) are effectively authorized for nearly any violation. Although the FDA's jurisdiction is technically limited to products that have traveled in "interstate

commerce," practically, almost any product in the modern economy would meet this threshold as the courts have interpreted it.

4. FDA has broad discretion in enforcing regulatory requirements.

In part because of the penalty structure described above, the FDA has significant discretion in determining how or even whether to address a particular regulatory violation. Frequently, an enforcement action will begin with a "warning" or "untitled" letter outlining any issues FDA has identified and seeking corrective action, but the agency's response in each instance will depend on its assessment of the associated public health risk. Notably, the fact that a product does not in and of itself create a significant risk of harm may not be enough to avoid scrutiny if consumers using the product would be less likely to seek out approved products or treatments.

3. There is no private cause of action under the FD&C Act – but plaintiffs may have other avenues for recourse.

Although private plaintiffs are not entitled to bring suit to enforce the requirements of the FD&C Act, they may be able to successfully assert related claims under various state laws. For example, a plaintiff might use allegations of misbranding in an FDA warning letter to help establish that a company defrauded consumers, or point to non-compliance with FDA regulatory requirements as evidence of negligence. Particularly in states such as California, where provisions of the FD&C Act are substantively incorporated into the state code, defenses based on federal preemption may be ineffective, and class actions may result in large awards against a company even where individuals suffered only inconsequential injury (e.g., the cost of purchasing the product).

2. The intended use of a product determines how it is regulated.

The FD&C Act defines regulated products such as drugs and medical devices by reference to their "intended use," which the FDA evaluates by examining a product's labeling and advertising. As a result, making certain claims about a product (including on a company's website or social media accounts) may literally change the product's regulatory status, significantly expanding the associated compliance burden and regulatory risk. The FDA also shares jurisdiction over the advertising of drugs and devices with the Federal Trade Commission (FTC), which (unlike the FDA[2]) has independent authority to bring suit to address violations.

1. The effectiveness of your Emergency Use Authorization lasts only as long as the federally declared PHE.

As noted above, the effectiveness of various waivers and policies designed to facilitate the national response to COVID-19 is tied to the federal PHE declaration. This declaration was most recently renewed through October 23, 2020, and its further extension – particularly in such close proximity to the presidential election – is likely to carry significant political weight. Because the Department of Health and Human Services (HHS) may not conclusively indicate whether the PHE declaration will be renewed until the days immediately leading up to its expiration, we recommend proactively taking steps to ensure that your company is prepared for full compliance.

For a more detailed discussion of what you can do to best position your business going forward, join us for a complimentary webinar on September 29. To register, click here.

If you have any questions about how the U.S. Drug & Device regulations apply to your company, please contact Jolie Havens, Mairi Mull or your Vorys attorney.

--

Vorys COVID-19 Task Force

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at vorys.com/coronavirus.

_____

[1] Civil penalties are also authorized for certain types of non-compliance – for example, each violation related to medical devices may result in a civil penalty of up to $15,000.

[2] The FDA may initiate judicial proceedings only in cooperation with the Department of Justice (DOJ).