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Alert | Health Care & FDA Practice

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Key FDA Drug and Device Updates

Over the past month, there have been a significant number of developments affecting FDA-regulated companies. This GT Alert provides an update on key FDA personnel changes; on final regulations governing software that are exempt from FDA-regulation as a result of the 21st Century Cures Act (Pub. L. 114-255); and on a new FDA policy related to drug facility inspections. In addition, there are other announcements regarding medical devices and the regulation of certain personal protection equipment (PPE).

Personnel at FDA

Dr. Patrizia Cavazzoni appointed director of the Center for Drug Evaluation and Research (CDER).

On April 12, Patrizia Cavazzoni, MD, was named the permanent director of CDER, after serving as acting CDER director since spring 2020. Dr. Cavazzoni had moved into the acting director role when Janet Woodcock, MD, left the position for her current role of acting FDA commissioner.

Dr. Cavazzoni joined FDA in 2018 as CDER's deputy director for operations. She previously served for almost 20 years in various roles in the pharmaceutical industry and before that was an assistant professor at the University of Ottawa.

Drug and Biologics

FDA issues guidance on "remote interactive evaluations" during COVID-19.

On April 14, FDA issued a guidance document on how it will request and conduct voluntary remote interactive evaluations of drug facilities (including biologics facilities) for the duration of the COVID-19 public health emergency.

In the early weeks of the COVID-19 pandemic, FDA stopped conducting facility inspections entirely. Eventually FDA began conducting some domestic inspections and "mission-critical" foreign inspections. Nevertheless, FDA is still conducting far fewer inspections – domestic and foreign – than it did before the COVID-19 pandemic, and in January and March 2021 the U.S. Government Accountability Office expressed concern about FDA's growing inspection backlog.

The new FDA guidance document clarifies that FDA will use remote interactive evaluations in a variety of contexts, including pre-approval and pre-license inspections, post-approval inspections, surveillance inspections, follow-up and compliance inspections, and bioresearch monitoring inspections.

FDA also notes in the guidance that remote interactive evaluations are voluntary and are not the same as a remote records request under the authority and requirements of section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For remote interactive evaluations, FDA will not issue a Form 482, Notice of Inspection, Form 483, or an Inspectional Observations form. Otherwise, however, a remote interactive evaluation generally resembles an inspection. FDA, via video teleconference, will request to examine the parts of the facility and documents that it would normally request to examine during a physical inspection. FDA will also notify the facility of any deficiencies it observes during the inspection and will expect a response with 15 business days. If a company refuses a remote interactive evaluation request, FDA could potentially follow up with a remote records request or in-person inspection notice under FD&C Act section 704, refusal of which is a Prohibited Act and can prevent a foreign drug firm from exporting drug products to the United States.

Medical Devices

FDA issues a final rule amending certain device classification rules to reflect changes made by the 21st Century Cures Act (Cures Act).

On April 19, FDA issued a final rule amending certain device classification regulations to reflect changes to the FD&C Act made by the Cures Act, which had, in pertinent part, amended the definition of a medical device to exclude certain software functions.

The software functions excluded from the definition of a medical device by the Cures Act include those functions intended to transfer, store, convert formats, or display clinical laboratory test or other device data, results, and findings; that do not interpret or analyze such clinical laboratory test or other device data, results, and findings.

In the final rule, FDA revises the device classification regulations for the following eight types of devices to remove provisions that described transfer, storage, conversion, and/or display functions no longer regulated by FDA: Calculator/Data Processing Module for Clinical Use (21 CFR 862.2100), Continuous Glucose Monitor Secondary Display (21 CFR 862.1350), Automated Indirect Immunofluorescence Microscope and Software-Assisted System (21 CFR 866.4750), Medical Device Data System (21 CFR 880.6310), Home Uterine Activity Monitor (21 CFR 884.2730), Medical Image Storage Device (21 CFR

892.2010), Medical Image Communications Device (21 CFR 892.2020), and Picture Archiving and Communications System (892.2050).

FDA reverses the previous presidential administration's two decisions relating to 510(k) exemptions.

On April 16, 2021, FDA reversed two decisions the prior administration implemented as to whether certain devices should require 510(k) clearance by FDA to be marketed in the United States.

On Jan. 15, 2021, the Department of Health and Human Services (HHS) issued a notice in the Federal Register that examination gloves and surgical gloves (which are reserved class I devices) would be exempted from 510(k) requirements, and HHS also proposed to exempt 83 class II devices and one unclassified device from 510(k) requirements.

On April 16, 2021, HHS and FDA published a Federal Register notice reversing the Jan. 15 determination to exempt examination and surgical gloves from 510(k) requirements, stating that the Jan. 15 determination had been legally flawed for various reasons. Although the April 16 notice indicates that FDA still believes 510(k) clearance is justified for examination and surgical gloves, FDA is accepting public comments on the issue until May 17, 2021.

In a separate Federal Register announcement on April 16, HHS and FDA withdrew the previous administration's Jan. 15 proposal to exempt 83 class II devices and one unclassified device from 510(k) clearance requirements. These devices had ranged from surgical gowns to burst suppression detection software for electroencephalographs, and had been identified by HHS primarily based on its conclusion that these devices had been subject to few adverse event reports. When FDA withdrew the proposal on April 16, FDA remarked that the Jan. 15 determination had been legally flawed for various reasons, including an undue reliance by HHS on reports of adverse events and because FDA had not been consulted.

While the FDA is still focused on treatments, diagnostics, and other critical issues relating to COVID-19, there are other areas where the FDA is focused on releasing rules and updating guidance.

Authors

This GT Alert was prepared by:

- Nancy E. Taylor | +1 202.331.3133 | taylorn@gtlaw.com
- Tyler M. Scandalios | +1 202.530.8573 | scandaliost@gtlaw.com