Life Sciences and FDA COVID-19 Update: A Special Edition of HB Health Law Vitals.

By Bill Morrison, Suzie Trigg, Jennifer S. Kreick, Kayla J. Cristales | March 24, 2020

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FDA: SARS-CoV-2 (COVID-19) Is Not a Food Safety Threat

By: Suzie Trigg, Joanna Pearce, and Sally Dahlstrom

As many Americans begin weeks of unwanted shut ins, the food industry is heading to work or working from home, with the goal of keeping a strong, safe, and abundant food supply. As recognized in guidance recently issued by the Department of Homeland Security, food producers and many of the businesses that support them are essential. Still, amidst the crisis, fears about the safety of food – and the ability of food and food packaging to transmit the novel coronavirus – have spread quickly. But the FDA has sought to reassure Americans that food is safe, providing a dedicated page for COVID-19 and stating that "[c]urrently there is no evidence of food or food packaging being associated with transmission of COVID-19." The FDA's remarks during a March 18th stakeholder briefing were similar.Read the full article here.

FDA Issues Guidance for Conducting Clinical Trials During COVID-19.

By: Phil Kim, Suzie Trigg, Jennifer Kreick, and Kayla Cristales

The FDA issued Guidance for Industry, investigators, and institutional review boards (IRBs) conducting clinical trials during the COVID-19 pandemic. The FDA recognized that certain challenges may arise in connection with COVID-19 that may create difficulty for clinical trials, such as quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected. Protocol modifications may be required, and there may be unavoidable protocol deviations. In its guidance, the FDA outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practices (GCPs), and minimizing risks to trial integrity. Noted considerations include, among others, the following: Read the full article here.

FDA Demonstrates Regulatory Flexibility and Relaxes Policies on Hand Sanitizer Amid COVID-19

By: Suzie Trigg, Kayla Cristales, and Sally Dahlstrom

The rapid spread of Coronavirus Disease 2019 (COVID-19) has sparked public fear and panic-induced stockpiling of alcohol-based sanitizing gels, leaving retailers and consumers without access to hand sanitizer. In response, the FDA has issued two new guidance documents on the preparation of certain alcohol-based hand sanitizer products by compounding pharmacies or by other manufacturing firms that register as over-the-counter (OTC) drug establishments to prepare alcohol-based hand sanitizers. In addition, the Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued guidance that permits distilleries to produce hand sanitizer for the duration of the current

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emergency. These measures demonstrate the willingness of regulatory agencies to allow for flexible, practical approaches to meeting consumer and Industry needs. Read the full article here.

Quick Shots

FDA Scales Back Domestic Inspections Amid COVID-19 Pandemic. The FDA announced that it has temporarily postponed all domestic routine surveillance facility inspections. Read the full article here.

FDA Issues Temporary Guidance on Food Supplier Verification Audit Requirement. To help prevent disruptions in the food supply-chain during the COVID-19 pandemic, on March 17, 2020, the FDA issued a temporary policy for Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements. Read the full article here.

FDA Revised Guidance on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic. The FDA revised its guidance on postmarket adverse event reporting for medical products and dietary supplements during a pandemic to apply the guidance to the ongoing COVID-19 pandemic. Read the full article here.

FDA Issues "Immediately in Effect" Guidance to Accelerate Availability of COVID-19 Diagnostic Tests. The FDA issued immediately-in-effect guidance to accelerate the development of certain laboratory tests for the urgent need caused by SARS-CoV-2. Read the full article here.

HHS Extends PREP Act Immunity to COVID-19 Countermeasures. The U.S. Department of Health and Human Services issued a declaration (the "Declaration") under the Public Readiness and Emergency Preparedness Act (the "PREP Act") to protect "Covered Persons" from liability in relation to the manufacture, distribution, or administration of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product" (or "Covered Countermeasures"). Read the full article here.

FDA Takes Action to Increase U.S. Supplies in Response to COVID-19. The FDA took action to increase U.S. supplies to support the U.S. response to COVID-19 by providing instructions to manufacturers importing personal protective equipment and other devices. Read the full article here.

FDA Warns Consumers About Unauthorized Fraudulent COVID-19 Products. The FDA issued a Consumer Update advising consumers to be beware of fraudulent coronavirus tests, vaccines and treatments. The FDA has seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. Read the full article here.

FDA announces process for FDA guidance documents related to COVID-19. The FDA has announced procedures, which operate within the FDA's established good guidance practices regulations, for making available FDA guidance documents related to COVID-19. Read the full article here.

Haynes Boone has a COVID-19 task force in place and continues to monitor the global impact of COVID-19 on various industries. For questions on the FDA's evolving COVID-19 policies or food

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safety during the COVID-19 crisis, please contact Suzie Trigg or any member of the Healthcare and Life Sciences Group.

Read the entire newsletter here.

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