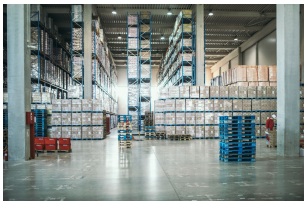

FDA Reverses Exemption of Seven Class I Gloves from 510(k) Premarket Notification Process

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On April 16, 2021, the Federal Drug Administration (FDA) issued two notices in reaction to the January 15, 2021 Department of Health and Human Services' (HHS) "Notice about making permanent regulatory flexibilities during COVID-19 related to certain medical devices" (January Notice) exempting seven Class I gloves and proposing the exemption of an additional 84 Class II devices. Our full analysis of the January Notice can be found here.

Suppliers, distributors, and customers should ensure that all medical gloves either have 510(k) approval or meet the requirements of the FDA's Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency.

In "Medical Devices; Class I Surgeon's and Patient Examination Gloves" (April Notice), the FDA recommended reinstating the 510(k) premarket approval process for seven types of Class I gloves previously exempted in the January Notice. Additionally, the FDA rescinded the proposal to exempt an additional 84 Class II medical devices in "Making Permanent Regulatory Flexibilities Provided During the Covid-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Withdrawal of Proposed Exemptions."

The April Notice criticized HHS' January Notice, stating that HHS' determination that these Class I devices do not pose a significant risk was flawed based on several factors, including:

- HHS relied solely on Manufacture and User Facility Device Experience (MAUDE) database adverse events.
- HHS did not consult with the FDA before issuing the January Notice and therefore did not address the FDA's decision to *not* exempt these seven types of Class I gloves in previous years.

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Use of MAUDE Data

The FDA and HHS determined that the sole use of MAUDE data to exempt Class I gloves was ill-informed. According to the April Notice,

> The incidence or prevalence of an event cannot be determined from adverse event reports alone, due to underreporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Adverse event data is not adequate on its own for assessing safety, let alone whether to determine a device to be exempt from 510(k).

Additionally, HHS' January Notice assumed that the temporary Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency skewed the MAUDE data to demonstrate safety and effectiveness without 510(k) approval. However, the January Notice does not explain the basis for this assumption nor provide data to support this assumption.

FDA's Previous Decision to Not Exempt Class I Gloves

In the April Notice, the FDA points to several reasons to reverse the exemption of the seven types of Class I gloves, including gloves' vital role in preventing contamination and gloves' role in preventing occupational exposure to chemotherapy drugs. The April Notice holds that, "[b]ecause of their importance in preventing impairment of human health, FDA has long considered these seven types of gloves to meet the reserved criteria under Section 510(*l*) of the FD&C Act and to be subject to the 510(k) requirement." The FDA evaluated the seven types of Class I gloves most recently in 2017 during its determination of the necessity of the 510(k) premarket approval process for all Class I reserved devices.

Not only did the FDA recommend that the January Notice be reversed, but the April Notice specified that the FDA will increase

surveillance of the seven types of Class I gloves to ensure that all gloves on the market meet FDA's regulatory standards. The FDA will focus these efforts on imported gloves and will inspect the gloves at the time of import.

The April Notice provides a comment period until May 17, after which it is expected that the FDA will issue a final rule requiring the 510(k) premarket approval process for the seven previously exempted Class I gloves. If you are a manufacturer, importer, or distributor of Class I gloves, you should ensure that your gloves are compliant with the Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency and/or are 510(k) cleared.

If you have any questions about FDA medical device compliance or the FDA's April Notice, please contact Maureen Bickley (mbickley@fbtlaw.com) or Kaitlyn Hawkins-Yokley (khawkinsyokley@fbtlaw.com).

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