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INSIGHT

FDA Regulation of Tampons

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An August 2024 study led by researchers at Columbia University evaluated the concentration of 16 different metals in multiple brands of tampons and reported detecting measurable concentrations of all 16 metals. The authors concluded that using tampons may be a potential source of metal exposure, although the study did not evaluate if the metals were released by the product or absorbed by the user. Research in this area is limited.

In response, FDA has announced that it is undertaking a review of metals in tampons to help support its regulation of these products. Specifically, FDA plans to commission an independent literature review to learn more about data available regarding to what extent chemicals may be present in tampons, in addition to possible health effects. The agency also plans a laboratory study of tampons in typical use situations, to try to determine the extent to which metal may be released during normal use.

These findings have focused attention on FDA's oversight of tampons, which are regulated as devices by the agency. Specifically, questions have been raised about the sufficiency of labeling requirements for these products (i.e., transparency around intentionally added ingredients in the product), as well as the adequacy of premarket testing requirements for potential contaminants and elimination of those contaminants. This Insight provides an overview of FDA's current regulation of tampons.

FDA Regulation

FDA regulates medical devices generally by the risk they pose to the consumer and what is known about the device type, and therefore what is known about measures that may be taken to mitigate risk. The agency classifies low-risk devices as Class I, moderate-risk devices as Class II, and high-risk devices as Class III. Regulatory control increases by class, and for devices, regulatory control must be sufficient to provide a "reasonable assurance of safety and effectiveness." This is partially determined by an analysis of the benefit of using the device as compared with the risk of using the device.

FDA regulates tampons as Class II medical devices, subject to general regulatory controls, including 510(k) premarket notification, and special controls, specifically, performance standards. General controls include, for example, Quality System regulation (device good-manufacturing practices), establishment registration and device listing, Medical Device Reporting (MDR, device adverse event reporting), labeling, recall authority, and premarket notification. To meet the 510(k) premarket notification requirement, the device manufacturer provides to FDA a submission demonstrating that its device is "substantially equivalent" to a legally marketed predicate device, and receives clearance to market the

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device if the device is found to be so. Substantial equivalence is defined in statute to mean having the same intended use and the same technological characteristics as a predicate device, or different technological characteristics that do not raise different questions of safety or effectiveness. In addition, tampons are required to undergo specific testing for absorbency and to bear certain labeling related to absorbency and toxic shock syndrome (TSS).

510(k) Premarket Notification

FDA has more than one type of 510(k) submission pathway available to manufacturers, including the Abbreviated 510(k) Program, which allows submission of a "summary report" in lieu of detailed information about testing of the device in cases where guidance, special controls, or voluntary consensus standards exist for that type of device. The summary report includes, for example, "device description, the manufacturer's device design requirements, risk management information, and a description of test methods used to address performance characteristics." In addition, the manufacturer must submit certain information that is required for any 510(k) submission; these requirements are listed in regulation (21 C.F.R. §807.87, §807.92) and include, for example, the device's intended use and proposed labeling.

2005 Guidance Document

In 2005, FDA published a device-specific guidance document for industry related to 510(k) premarket submissions for tampons, *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)*, that presents "the risks to health identified by FDA and describe[s] measures that will generally address the risks … and lead to a timely review and clearance." The manufacturer may use the 2005 guidance document to develop the summary report required as part of the Abbreviated 510(k) submission, which FDA maintains "provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a device-specific guidance document."

The 2005 guidance document provides recommendations for the information that should be included in the summary report. This includes (1) device description and discussion of the intended use of the device; (2) a risk analysis to describe approaches to mitigate the health risks identified by FDA, as well as to identify any additional risks the specific device might pose; and (3) a description of the device's *performance aspects*. Performance aspects include certain "performance characteristics," specifically the absorbency range and chemical residues. FDA recommends the summary report include a summary of testing for absorbency as required by the tampon labeling regulation. Additionally, the agency recommends tampons be free of certain chemicals, including dioxin, pesticides, and herbicides, and that the summary report include a summary of testing demonstrating this absence, or else the level of the chemical present. With respect to device description, FDA recommends including information about component materials (including additives) present in the device, specifically chemical identity and quantity for components and any fragrances. Finally, FDA recommends including a summary of testing to assess toxicology (biocompatibility) and microbiology, as well as a summary of any clinical studies, if needed.

Labeling

The 2005 guidance provides recommendations for proposed device labeling so that the requirements specific to the 510(k) submission (21 C.F.R. §807.87(e)), as well as those found in general labeling requirements for devices (21 C.F.R. Part 801), are satisfied. The agency recommends labeling that includes information about how to use the device safely, as well as a description of the materials in the device and certain instructions related to reducing risk for TSS.

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