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MEDIA MENTION

Ann Begley Discusses Delay in FDA's OTC Monograph User Fee Program Schedule

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Ann M. Begley, chair of Wiley's Food & Drug Practice, was quoted in a January 4 *HBW Insight* article about the withdrawal of the U.S. Food and Drug Administration's (FDA) fiscal year 2021 user fee schedule for manufacturers of over-the-counter (OTC) monograph drugs.

The article also cited Ms. Begley's recent Wiley alert regarding the FDA's December 29 notice of the first-ever fee rates under the OTC monograph drug user fee program (OMUFA). The FDA announcement followed last year's enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which significantly changed the way OTC monograph drugs would be regulated going forward.

The OTC monograph drug regulations will now be replaced by OTC monograph drug orders, and requests for changes in such orders or the addition of new orders will be the subject of OTC monograph order requests (OMORs). To fund this program and other FDA OTC drug activities, Congress legislated that manufacturers of OTC monograph drugs, and most OMOR applicants, will be subject to the new user fee program.

As reported by *HBW Insight*, the U.S. Department of Health and Human Services (HHS) announced on January 4 that the fee schedule was being withdrawn because it had been published without the HHS Secretary's signature. Yet an HHS memo published last fall raises questions about the agency's reasoning, according to the article.

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The memo – which apparently clarified procedures for agencies within its structure – stated that each rule must not only be approved by the Secretary but must have the Secretary's formal signature. While HHS has never formally released this memo, it did provide clarifying information in a Q&A document.

"There is a question of whether the congressionally mandated user fee notice amounts to a rule under this memo," Ms. Begley told HBW Insight. Traditionally, there has never been a notice and comment period associated with setting fees for other FDA user fee programs.

Ms. Begley added that it is "very clear" that the new HHS procedure applies to rules – but the memo also makes clear the policy does not apply to all HHS actions, for example, guidance documents, emergency use authorizations, and drug approvals are not impacted by this internal memo.

To read the article, click here (*subscription required*).