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OTC Drug Regulatory Paradigm Open to Stakeholder Feedback Until July 10

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Continuing a discussion that began in 2014, on June 10, 2016 FDA hosted a **public meeting** on the potential development of a user fee program for OTC (over-the-counter, or nonprescription) drug products marketed pursuant to the Agency's monograph system. Agency leader Dr. Janet Woodcock **wrote last week** in *Health Affairs* that FDA's "current system of OTC review is simply too sluggish to promote OTC modernization." Many of the OTC monograph reviews initiated in the 1970's are far from complete, and there is little expectation that FDA will be finalizing anything soon, in light of the minimal funding and support the OTC program receives in comparison to other parts of the Agency.

User fee programs currently exist to help fund the Agency's review and policy-development activities for prescription drugs, biologics, medical devices, generic drugs, and even some aspects of food inspectional programs. Will the OTC drug industry become subject to user fees and, if so, what will they look like? Although certainly no one is expecting a $2.5 million application fee like what is required for a new prescription drug, it will be a difficult balance for regulators to meet all of the Agency's stated goals - to ensure stable revenue from year to year; to have fees paid by industry members who benefit from the OTC monograph program and to have them pay only a "fair share"; and to have sufficient fees collected to cover the intended services, without the program costs becoming unreasonable.

A webcast of the June 10th meeting, along with FDA's presentations and other background information, can be accessed through the meeting page **here**. Interested stakeholders can respond to the Agency's specific questions or submit more general comments on the OTC drug monograph development process to Docket FDA-2016-N-0192 before it closes on July 10th.

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Joanne S. Hawana counsels global Mintz clients on regulatory and distribution-related considerations for new FDA-regulated products. She also advises clients on the business impacts of new federal and state actions on food, drugs, cosmetics, electronic nicotine systems, and medical devices.