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OTC Monograph Reform Legislation is Now Law – What Does It Do?

by David C. Spangler & Rachel Rathore

Introduction

Almost every American home has over-the-counter (OTC) products in their medicine cabinet. From ointments for minor cuts to headache relief, we rely on these household items to provide us with safe, effective, and affordable treatments. However, many Americans do not realize that due to outdated and cumbersome regulations, the system regulating a significant majority of OTC medicines has been stuck in the 1970s, making it difficult to bring innovative medicines to market. Fortunately, a new law requires the U.S. Food and Drug Administration (FDA) to take a fresh look at these regulations to help boost product development and give consumers more choice than ever before when walking down the pharmacy aisles of their local stores.

As passed by Congress and signed into law by the President on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act included a subtitle that will significantly alter the system that regulates most over-the-counter medicines—the OTC monograph system. Standalone bills on

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OTC monograph reform had previously passed the House in 2018 and again in January 2019 (H.R. 269 by a 401-17 vote), followed by passage in the Senate in December 2019 (S. 2740 by a 91-2 vote); however, since there were modest differences between the two bills, it had not been enacted into law.

While the OTC monograph system had been a sound regulatory framework that served the nation well for almost fifty years, Representatives Bob Latta (R-OH), Diana DeGette (D-CO), Brett Guthrie (R-KY), and Debbie Dingell (D-MI) and Senators Johnny Isakson (R-GA, now retired) and Bob Casey (D-PA) saw that the system needed to be modernized to reflect changes in science and regulatory processes and to incentivize innovation in OTC medicines. A range of public health and industry stakeholders have long supported these commonsense reforms, which will provide FDA with more resources and help increase the efficiency and responsiveness necessary to protect and promote consumer health.

About the Monograph System

The OTC monograph system began in 1972 as FDA's effort to assure that OTC medicines already on the market were Generally Recognized as Safe and Effective (GRAS/E). Many OTC medicines at the time had not been assessed by FDA for effectiveness, which was a requirement added to the Federal Food, Drug, and Cosmetic Act for drugs in 1962. The OTC monograph system, or OTC Review, was a mammoth regulatory undertaking by FDA, reviewing the safety and efficacy of OTC ingredients, doses, formulations, and labeling used in medicines available to consumers without a prescription for the over 100,000 products on the market prior to 1974. The heart of the monograph process is that it is rules-based. If a manufacturer follows FDA requirements—listing and registration, good manufacturing practices (GMP), etc.—and follows the conditions of use spelled out in one of the therapeutic category monographs, no pre-approval or individual application is needed. Today, the Consumer Healthcare Products Association (CHPA) estimates roughly two-thirds to three-quarters of OTC medicines are under the OTC monograph system. A minority of OTC medicines are subject to new drug applications (NDAs) or abbreviated new drug applications.

But the OTC Review monograph process was never completed. Over twenty percent of monographs remained unfinished. And as the decades marched by, the rulemaking process became slower, slower, and slower, leaving behind a broken system and years of backlog. In short, the monograph system had rusted shut, making it difficult for FDA to update product labels with new safety information based on new science and data, let alone finalize unfinished monographs. The cumbersome nature of the system also prevented the development of innovative products with existing ingredients to meet consumer needs. Seeing the challenges and limitations under the regulatory framework, Congress, FDA, public health stakeholders, and industry came together to fix the system to better serve American consumers.

Substantive Provisions of the CARES Act

Title 3's Subtitle F in the CARES Act is the change needed to clear the backlog of unfinished monographs, streamline the existing processes, and unlock the benefits of a novel OTC monograph system. The essence of these provisions can be boiled down to two essential elements: (1) the notice and comment rulemaking process of the OTC monograph system now shifts to an administrative order system within FDA (new drug application approvals are a type of administrative order today); and (2) it expands FDA resources to work on monograph-related issues through a user fee program authorized for five years.

Throughout the development of the new law, FDA publicly supported congressional efforts to modernize and reform the monograph framework during a House Committee on Energy and Commerce legislative hearing. FDA also transmitted a goals letter to Congress ahead of the passage of the Act. Now that this widely supported concept has been enacted into law, FDA is tasked with implementation. This law will deliver a regulatory structure that is modern, responsive, and more transparent than the prior system while continuing to ensure OTC medicines in the monograph system are safe for American families.

In more detail, the law makes a number of significant changes in how OTC monograph medicines are regulated:

Conditions of use (i.e., labeling) for active ingredients that FDA had found GRAS/E in unfinished monographs at the proposed rule stage (Tentative Final Monographs) are now deemed final.

Active ingredients that FDA categorized as needing more data (termed Category 3 in OTC Review parlance) before a final GRAS/E determination could be made may remain on the market, with their future status dealt with through administrative orders.

Administrative orders replace rulemaking. This will be true for existing Monograph regulations in Title 21 of the Code of Federal Regulations (which will transfer to an FDA website as orders) and for future requirements under OTC monographs. FDA will issue a proposed

administrative order, including a notice of its availability in the Federal Register similar to a notice about an FDA guidance today, receive and review public comments, and issue a final administrative order that has the force of law. Because notice and rulemaking are bypassed, the law includes a dispute resolution and hearing process to assure due process.

An expedited order process may be used for safety labeling under a heightened standard. Under the expedited process, an interim final order takes the place of a proposed order. FDA would still be required to finalize the administrative order after a comment period.

An OTC monograph drug sponsor may file a requestor-initiated order request (also called an OTC monograph order request, or OMOR) to establish or change conditions for an OTC drug. After a filing determination, FDA will proceed under the ordinary administrative order process. Adding an existing active ingredient that is from another country or currently under an NDA to a monograph, adding a new indication to a monograph ingredient, adding a new combination, or introducing a truly novel dosage form to a monograph would all be examples of what is possible through an OMOR. If the requestor's OMOR is supported by new human data studies essential to the approval of the change (including clinical trials of safety or effectiveness, actual use, pharmacokinetics, or bioavailability) or if it adds an active ingredient to a monograph, then the change or addition will be effective only for the requestor of the change for eighteen months from the effective date of the order and beginning on the date the requestor may market the drug.

A minor changes provision would cover changes in dosage forms that fall short of a truly novel dosage form requiring an OMOR, but are beyond the normal dosage form changes we frequently see today (such as changing from a tablet to a capsule). Under that provision, FDA is directed to issue administrative orders and guidance to provide requirements and standards for determining whether a change will affect safety or effectiveness.

FDA is directed to annually post a dashboard to preview upcoming monograph work, or more formally list administrative orders in development with FDA's current expectations for issuance over a three-year period.

While GRAS/E determinations by definition require the underlying information to be public, closed meetings with FDA are now permitted for OTC monograph products for the first time. This will be important for companies considering filing an OMOR to be able to have a meeting with FDA on their proprietary development plans.

The Sunscreen Innovation Act (SIA) has been amended to allow pending sunscreen ingredients under time and extent applications to elect to shift to the new OTC monograph system or to remain under the SIA (with modifications to allow for private meetings and for the possibility of exclusivity). The SIA sunsets at the end of fiscal year 2022.

User Fee Authorization

For the first time, the law authorizes user fees for OTC monograph products through facility fees. The additional resources will allow FDA to increase its staffing capacity to support OTC-related work and build a necessary information technology platform to efficiently submit and review monograph information. As with other FDA user fees authorizations, user fees are authorized for a five-year program (FY2021-FY2025). Fees are due *ahead* of a fiscal year, with a May 2020 target for FDA to set the first year's facility fee. While no single provision sets the annual fee total, before inflation adjustments or operating reserve adjustments, target fee collections from facility fees are $22 million for FY2021, $22 million for FY2022, $25 million for FY2023, $31 million for FY2024, and $34 million for FY2025.

As with other FDA user fee programs, an FDA goals or commitment letter was sent to Congress outlining FDA's performance and procedural goals and other commitments for the five years of the authorization. FDA is also directed to annually submit a performance report and a fiscal report to the authorizing committees in Congress.

Conclusion

The reformed OTC monograph system provides FDA with additional resources and makes the system more nimble, more transparent, more certain, and more conducive to innovation. Ultimately, and most importantly, the added flexibility and updates to the monograph framework will benefit consumers by protecting public health and increasing self-care choices. In fact, this law will reach far beyond the OTC market and benefit the entirety of the health care system. OTC medicines provide Americans with safe, at-home treatment options for minor ailments, which reduce doctor office visits and keep overall health care costs low. The implementation of this law will only further support and encourage the creation of new uses for OTC ingredients and dosage forms, resulting in the expansion and availability of consumer health care products.

The overhauled OTC monograph system has finally moved into the 21st century and will help meet American families' needs while ensuring these medicines continue to be safe and effective.