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MEETING

Public Meeting on the Reauthorization of the Over-the-Counter Monograph Drug User Fee Program (OMUFA)

SEPTEMBER 28, 2023

Good morning. My name is Lisa Parks, and I am the Senior Vice President of Regulatory and Scientific Affairs at the Consumer Healthcare Products Association (CHPA). On behalf of CHPA, I would like to extend our appreciation for this opportunity to address you today.

CHPA represents manufacturers and marketers of Over the Counter (OTC) medicines. Our mission is to empower self-care by preserving and expanding choice and availability of trusted consumer healthcare products. One way we achieve that mission is working closely with the Food and Drug Administration (FDA) for the efficient and effective implementation of monograph reform.

The OTC Monograph User Fee Act (OMUFA) stands at the core of our collective success in implementing monograph reform. A well-structured OMUFA program provides the FDA with resources for efficient OTC monograph review, while guiding and supporting industry and stakeholders via guidance and feedback.

We commend the FDA for the steps it has already undertaken in the pursuit of monograph reform and the fulfillment of its OMUFA I commitments. Specifically:

- We appreciate the issuance of draft guidance on vital topics. These guidance documents serve as invaluable resources for the industry.
- CHPA also appreciates that FDA has fulfilled its obligation to issue deemed final orders for drugs that were previously classified as Category I drugs under final monographs and tentative final monographs. This is an important first step that will allow FDA to focus on label changes and reviewing new OMOR submissions in the coming years.
- We applaud the FDA's efforts in establishing new OTC IT infrastructure and meeting its OMUFA hiring goals.

As we approach the reauthorization of OMUFA II, CHPA would like to underscore five critical points that we believe are pivotal in building upon these achievements and ensuring the success of the Program.

1. **Maintaining the GRASE Standard:** The existing regulations dictate that GRASE determinations should primarily rely on published studies, potentially supplemented by unpublished research, data, and significant market experience. The OTC monograph reform law was very intentional in leaving the substantive standard for GRAS/E determinations in place. This legislative intent is underscored by statements from the primary sponsor of the bill in the House of Representatives on the very day the new law was enacted.

   The FDA itself acknowledged this in its June 2023 draft guidance on Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders, where it confirmed that "general recognition of safety and effectiveness" requires, among other things, the information demonstrating that a drug is safe and effective for its intended use to be published so that such information is generally available to qualified experts. It is imperative for the FDA to base its review and guidance on this standard, with a specific emphasis on affirming that GRASE determinations should principally rely on reports from relevant studies in published literature. Moreover, it is crucial for the FDA to recognize the valuable role that real-world evidence can play in supporting GRASE conclusions, including evidence indicating the absence of safety concerns for drugs with a long-standing market presence. This standard must remain intact and be adhered to by FDA to ensure the viability and sustainability of the overall Program for the American public.

2. **GRAS/E determinations distinct from NDA-Style Submissions:** GRAS/E determination should not be dependent on New Drug Application (NDA) style submissions and review. The focus should be on assessing the safety and efficacy of active ingredients for conditions specified in the applicable monograph. This evaluation does not involve a review of inactive ingredients, which may vary among products authorized under a single monograph, as long as those inactive ingredients meet the applicable regulatory standards for safety and suitability.

   Similarly, while monograph drugs must be produced in compliance with FDA's drug CGMPs, GRASE determinations do not involve a review of the manufacturing process for each drug marketed under a monograph. Thus, sponsors are not required to submit the same CMC data to support an OTC GRASE determination that they would be expected to submit under an NDA.

In the assessment of OMOR submissions for drug previously examined by an advisory panel, such as Category III under a TFM or Category I under an ANPR, the FDA should not aim to re-evaluate all the data already considered by the panel. Instead, the law specifies that the FDA should outline the general types of data it believes are necessary to establish general recognition. The FDA should identify gaps that need to be addressed based on prior agency findings, rather than initiating a completely new review. This approach maintains robust review standards while allowing for efficiencies in either the OMOR process or FDA initiated GRASE determinations for Category III ingredient uses.

3. **Encouraging FDA to Initiate Orders:** Both the FDA and the industry have pathways to initiate the administrative order process. We encourage the FDA to initiate orders where it possesses sufficient data to support GRASE determinations or changes to Monographs. This will streamline the OTC monograph process and allocate industry resources effectively.

4. **Enhancing OMUFA Meeting Efficiency:** Timely and comprehensive advice during OMUFA meetings is essential. Industry stakeholders require clear and concise guidance from the FDA, particularly concerning the data needed to support OMOR submissions since this is a new and less familiar procedure. CHPA has some concerns about how the FDA has been handling OMUFA meetings. For instance, some stakeholders have experienced delays in scheduling meetings, and scheduling in-person meetings. Although its understandable that FDA would have been less inclined for in-person meetings, delayed in responding to meeting requests during the pandemic, and during the staffing up phase of implementation, but response delays and hesitation toward scheduling in-person meetings persist. The FDA should work to streamline meeting processes, ensuring timely responses, maximizing in-person engagement, offering comprehensive advice based on legal principles, and considering the full record, including any relevant OTC panel reviews.

5. **Prioritizing Administrative Orders and Guidances for Minor Changes:** The new law establishes a pathway for sponsors to make minor changes in dosage forms without needing an OMOR. They must maintain specific records supporting the change, and, on request, sponsors must provide these records to the FDA.

This pathway enables the industry to introduce important innovations in the OTC drug market more efficiently, addressing a significant hurdle in the previous monograph system. Ultimately, this aims to offer consumers easier access to improved and convenient dosage forms of safe and effective products.

We know that the first of these order-guidance pairs on solid oral dosage forms has a goal of next year, and we look forward to working with the Agency.

Going forward, we request the FDA prioritize the development of administrative orders and companion guidance's that permit minor changes in dosage forms without the need for submission and approval of OMORs.

In closing, CHPA would like to express our appreciation to the FDA for convening this meeting and providing us with this opportunity to share these insights. We anticipate collaborating closely with the FDA and other stakeholders throughout the OMUFA reauthorization process, as we jointly strive to ensure the continued success of the Program.