



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription NDA Drug Products Subgroup

November 12, 2025 | 4:00 pm-5:00 pm

Virtual Format

MEETING PURPOSE

To continue discussions as part of the ongoing PDUFA VIII negotiation process on nonprescription drug products. In this meeting, CHPA is to provide examples on cases with potential for PMC use for labeling (proposal #3). FDA will continue asking clarifying questions.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Karen Murry	CDER
Kate Greenwood	OCC
Nana Adjeiwaa-Manu	CDER
Sara Abdollahi	CDER

INDUSTRY

Marcia Howard	CHPA
Glen Murphy	CHPA (Kenvue)
Erin Oliver	CHPA (Haleon)
David Spangler	CHPA
Carolyn Herrmann	CHPA
Annetta Beauregard	BIO
Lucy Vereshchagina	PhRMA
Ryan Kaat	PhRMA

MEETING SUMMARY

In the previous meeting, three proposals were presented by CHPA 1) to establish a pathway for special protocol assessment (SPA) eligibility of over-the-counter drug (OTC) relevant data, 2) to implement a representative labeling approach that consists of a stepwise labeling submission for OTC New Drug Applications (NDAs), and 3) to use post-market commitments (PMCs) for labeling OTC NDAs for some cases.

This meeting focused on three CHPA proposals aimed at improving regulatory efficiency for over-the-counter (OTC) drug development. CHPA representatives presented detailed responses to FDA's questions and provided examples to illustrate the problems their proposals seek to address. FDA expressed varying levels of receptivity to the proposals and raised concerns related to resource implications and regulatory precedent. At the end of the meeting, FDA agreed to further consider CHPA's Proposal #1 (SPAs for OTCs) and Proposal #2 (representative labeling) but stated that Proposal #3 (PMCs for labeling) is problematic, expressing concerns about consumers' need for proper labeling for safe and effective use of OTCs at the time of approval.

CHPA agreed that proposal #3 could be removed but would seek confirmation from its stakeholders.

Proposal 1: Expansion of Special Protocol Assessment (SPA) Program for OTC Studies

CHPA proposed that a sponsor could notify FDA when they deem a protocol pivotal, or that any study required by the Agency for approval would be eligible for SPA review, including consumer behavior studies (e.g., actual use studies). CHPA emphasized that the benefits of increased regulatory certainty and predictable 45-day response timelines are particularly valuable given lengthy review timelines and staffing changes. FDA raised concerns about the expansive nature of the proposal and noted that many critical studies supporting marketing applications would not qualify as Phase 3 protocols under current SPA criteria. FDA also highlighted the iterative nature of consumer behavior studies. As sponsors make changes to the protocol with successive learnings, it would be challenging to know which version of the protocol would be pivotal. FDA questioned the assumption that the proposal would be resource-neutral and emphasized that SPAs require contract-like precision in review and lead to binding obligations for both parties.

Proposal 2: Stepwise Labeling Review Process

Representative Labeling discussions focused on operational efficiency during the label negotiation phase. CHPA presented examples showing how a product with multiple SKUs (stock keeping units), e.g., different counts and flavors, currently requires submission of 24 separate labels and proposed instead to submit just two representative labels for text negotiation. CHPA emphasized their intent was to reduce the administrative burden of the iterative feedback process while providing FDA with all final formatted labels before approval. However, FDA expressed significant concerns about compressing review timelines and missing PDUFA goal dates. FDA noted that graphics and trade dress are often the most challenging aspects of label review and expressed concern that not seeing potential variations in graphics, panel layouts, and readability issues during the negotiation phase could lengthen timelines and increase FDA resource needs. Both parties acknowledged the need for granular discussion about what aspects would be in scope for representative labeling.

Proposal 3: Use of Post-Market Commitments for Labeling Elements

CHPA provided examples of approved products with PMCs and cases where they believed PMCs could have enabled earlier market entry with post-approval labeling refinements. However, FDA firmly rejected this approach, clarifying that PMCs cannot be used to fine-tune labeling that is necessary for safe and effective use. FDA emphasized that approved labeling must contain sufficient information for safe and effective use at the time of approval, and that PMCs are inappropriate when labeling instructions cannot adequately ensure proper product use. FDA also noted enforcement challenges with existing PMCs and stated they would not re-adjudicate

previous regulatory decisions. The Agency made clear that while sponsors can request PMCs, PMCs cannot substitute for studies needed to establish proper labeling for safe and effective use.

Next Steps

FDA stated that FDA and CHPA are unlikely to reach agreement on Proposal #3. Both parties agreed to focus future discussions on Proposal #1 (SPAs for OTCs) and Proposal #2 (representative labeling), and FDA committed to internal discussions about these remaining proposals. CHPA agreed to confirm with their stakeholders that Proposal # 3 could be removed from consideration. The next meeting will continue detailed discussions on the SPA pathway (Proposal #1) and representative labeling proposal (Proposal #2) given that FDA and CHPA recognize the need for more specific parameters and implementation details to address FDA's resource and timeline concerns.