Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription NDA Drug Products Subgroup

November 4, 2025 | 3:30 pm–4:45 pm

FDA White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

To have CHPA members of the Nonprescription NDA Drug Products Subgroup present proposals and respond to clarifying questions from FDA.

PARTICIPANTS

FDA		Industry	
Mary Thanh Hai	CDER	Marcia Howard	CHPA
Theresa Michele	CDER	Glen Murphy	CHPA (Kenvue)
Karen Murry	CDER	Erin Oliver	CHPA (Haleon)
Kate Greenwood	OCC	David Spangler	CHPA
Nana Adjeiwaa-Manu	CDER	Carolyn Herrmann	CHPA
Sara Abdollahi	CDER	Annetta Beauregard	BIO
		Lucy Vereshchagina	PhRMA
		Ryan Kaat	PhRMA

MEETING SUMMARY

CHPA presented three proposals for consideration in PDUFA VIII negotiations. The three proposals reflect CHPA's interests in (1) expanding the Special Protocol Assessment (SPA) program to include nonprescription over-the-counter (OTC) studies, (2) implementing stepwise labeling submissions for nonprescription OTC New Drug Applications (NDAs), and (3) using postmarketing commitments (PMCs) for aspects of labeling for nonprescription OTC NDAs. FDA staff provided feedback and requested additional clarification and examples for all proposals, particularly regarding the use of PMCs for labeling.

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

CHPA presented a proposal to either (1) change the criteria for protocols eligible for Special Protocol Assessment to include key nonprescription OTC studies within the existing SPA program or (2) develop a nonprescription-OTC-specific SPA category. CHPA shared that their

goal is to provide sponsors with greater certainty regarding nonprescription study protocols that CHPA wishes to designate as "pivotal" (e.g., certain label comprehension, self-selection, and actual use studies). CHPA emphasized that this change could reduce development time and regulatory burden and accelerate review timelines by establishing clear agreement on study designs upfront.

FDA staff sought clarification on several key aspects of the proposal, including how pivotal studies would be designated, whether multiple studies per application could qualify for SPA review, and how this proposal would integrate with existing meeting processes. CHPA had suggested that this proposal could leverage the written-response-only (WRO) PDUFA meeting format and therefore would not be burdensome to FDA. FDA noted that SPA review is distinct from formal PDUFA meetings and therefore requires separate resources.

Proposal 2: Stepwise Labeling Review Process

CHPA proposed introducing an approach to labeling review in which applicants would initially submit representative labeling from each unique variant as opposed to submitting labeling from all planned stock-keeping units (SKUs). CHPA suggested that after reaching agreement with FDA on the representative samples, applicants would submit the complete set of final labeling prior to approval. CHPA stated this approach could streamline the labeling review process while maintaining appropriate oversight.

FDA noted that they must review and approve each specific piece of labeling for nonprescription NDA products. FDA staff asked clarifying questions about CHPA's view of how this proposal might be implemented, including what elements of labeling CHPA considers appropriate for submitting as "representative", and the expected effect on review timelines in the setting of receiving the full suite of final labeling late in the review cycle.

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

CHPA proposed increasing the use of postmarket commitments (PMCs) to address labeling elements that they consider 'fine-tuning' of the label that don't impact core safety and determinations issues. CHPA suggested that the concept would allow products to reach market while gathering additional data to optimize certain labeling aspects through postmarket studies and commitments rather than delaying approval while seeking a "perfect label".

FDA expressed significant concerns about this proposal and the context of conducting studies as PMCs to further modify labeling that might otherwise be done prior to approval. FDA reminded CHPA that PMCs can be proposed by applicants without a new PDUFA commitment and, if appropriate, would not be objectionable. FDA staff emphasized that the FDA-approved labeling of prescription or non-prescription drugs needs to convey adequate information to ensure safe and effective use of the product for its intended use. This is particularly important for nonprescription drugs where consumers must be able to use the drug safely and effectively without the assistance

of a healthcare professional. A PMC that would allow a nonprescription product to market while awaiting additional results to fine-tune labeling is not a typical use of PMCs. An example cited by FDA of PMCs included a Chemistry, Manufacturing, and Controls (CMC) study to extend shelf-life of an approved product when such a study was not necessary for the safe and effective use of the product as currently labeled. The agency requested specific examples of scenarios where a PMC approach for a nonprescription product would be appropriate, noting challenges with postmarket data collection for OTC nonprescription products and the difficulty of identifying truly "minor" labeling elements that wouldn't affect consumer safety.

Next Steps

CHPA agreed to provide additional examples, specifically for proposal #3 on PMCs for labeling, and further develop their proposals based on FDA feedback. The Agency will discuss the information presented and provide formal feedback in subsequent meetings.