



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

November 18, 2025 | 3:30 pm-5:00 pm

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

MEETING PURPOSE

To continue discussions as part of the ongoing PDUFA VIII negotiation process on nonprescription drug products.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Theresa Michele	CDER
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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

This meeting focused on CHPA proposals for improving FDA's nonprescription drug review processes. CHPA withdrew their third proposal and presented detailed discussions on the two remaining proposals: expanding the Special Protocol Assessment (SPA) program to include certain Over-the-Counter (OTC) studies (Proposal #1) and implementing a stepwise labeling review process using representative labeling (Proposal #2). The FDA raised concerns about resource implications and practical implementation challenges for both proposals.

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

CHPA presented their rationale for expanding the SPA pathway to include certain OTC studies, seeking greater certainty and predictability in the review process. They emphasized this would be used judiciously as a tool, particularly for self-selection studies and actual use studies and believed it would be resource neutral. However, FDA clarified that SPAs are not resource neutral as CHPA anticipated, because there is a 45-day review goal and a comprehensive evaluation is needed, with additional complexity in the nonprescription space due to cross-divisional reviews

and device components. FDA committed to providing additional data on resource requirements, while CHPA will discuss the feedback with members to determine if SPAs would provide anticipated benefits given the identified constraints.

Proposal 2: Stepwise Labeling Review Process

CHPA justified their representative labeling proposal by presenting a real-world case study, explaining that seemingly simple changes require coordination across multifunctional teams and can disrupt production cycles, leading to time and opportunity costs. Their proposed approach would have sponsors provide transparency about total SKUs (stock keeping units), justify representative labeling rationale, and submit sample layouts for FDA review and acceptance to manage iterative changes more efficiently. FDA expressed difficulty understanding how to scale this approach given label complexity, raised concerns about adequately representing graphic elements that often cause review difficulties, and questioned how sponsors would determine truly representative samples. The Agency also questioned why CHPA doesn't already use representative labeling internally if they find it effective and noted that the provided example was relatively simple compared to more complex scenarios typically encountered. CHPA agreed to seek input on whether industry is currently using a representative labeling process internally. CHPA acknowledged the need to provide clearer descriptions of what would constitute representative labeling and how variants would be justified, with implementation details remaining undefined.

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

CHPA formally withdrew this proposal at the beginning of the meeting.

Next Steps

A goal regarding the SPA for nonprescription studies (Proposal 1) is for CHPA to discuss FDA's feedback with their members, particularly given the resource implications and constraints identified by the Agency. FDA is to provide additional data on resource requirements and time allocation for SPA reviews to inform further discussions on Proposal 1.

In addition, a goal for CHPA is to provide more comprehensive information for representative labeling (Proposal 2), including how graphic elements would be handled and what level of description would accompany representative samples to ensure FDA can adequately assess whether the submitted materials truly represent the full range of labeling variations. CHPA agreed to inquire whether industry currently utilizes representative labeling.