



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

December 9, 2025 | 3:30 - 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
Karen Murry	CDER
Kate Greenwood	OCC
Nana Adjeiwaa-Manu	CDER
Emily Ewing	CDER
Sara Abdollahi	CDER

INDUSTRY

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

MEETING SUMMARY

The meeting focused on two key proposals from CHPA regarding FDA review processes for nonprescription drug products. Proposal #1 focuses on expanding the Special Protocol Assessment (SPA) Program for nonprescription studies, while Proposal #2 targets implementation of a stepwise labeling review process using representative labeling to improve efficiency. FDA and Industry reached tentative agreement on Proposal #1, while Proposal #2 requires further discussion.

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

In a previous meeting on December 2, 2025, FDA proposed developing a guidance (already required by statute) to provide clarity on the topic of this proposal. Given this FDA counterproposal and the statutory requirement, CHPA indicated that their original SPA proposal may no longer be necessary. In the meeting on December 9th, CHPA representatives confirmed that their members agreed to move forward with FDA's proposed approach to address the topic of

this proposal in guidance. These meeting minutes, which publicize FDA's commitment to provide clarity and predictability for relevant studies essential to demonstrating safety and efficacy in a nonprescription setting, and ways to facilitate and expedite nonprescription drug development based on timely feedback from FDA on protocols, serve to document CHPA's agreement with FDA's counterproposal.

Proposal 2: Stepwise Labeling Review Process

CHPA presented a detailed proposal for representative labeling that they indicated would significantly reduce the number of labels requiring immediate FDA review. Using an example of 48 total label variations for a single product, CHPA demonstrated how representative labeling could reduce this number to approximately 8 representative labels covering different package types (bottles, blisters, sachets) and configurations. CHPA proposed a timeline in which representative labeling negotiations would conclude two months before the action date. Under this proposed timeline, sponsors would submit final labels one month before the action date, providing one month for Agency review before the deadline. FDA countered with a proposal for sponsors to use available formal meetings to request FDA feedback on representative labeling. FDA proposed that this meeting would occur prior to submission of labeling supplements. FDA also suggested that this meeting would provide early feedback to help sponsors prepare more appropriate initial submissions that would include all labeling. Overall, questions remain about implementation details and timeline impacts.

Next Steps

The next meeting will focus on negotiating the details of Proposal #2 on representative labeling. FDA indicated they need internal discussions to evaluate CHPA's suggestions about using representative labeling during the review cycle and the flexibility around when full labeling packages would be required.