



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

December 17, 2025 | 12:30 - 1:30 pm

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

MEETING SUMMARY

The meeting focused on CHPA Proposal 2, the stepwise labeling review process, with discussions centered on clarifying when sponsors can use representative labeling during review cycles. CHPA and FDA explored the differences between pre-submission and post-submission use of representative labeling, the benefits and potential drawbacks (*e.g.*, extending the development timeline) of using pre-submission meetings, and documentation approaches for consistent guidance across divisions. Both parties acknowledged the need to better define criteria for representative labeling use while recognizing that different supplement complexities may warrant different approaches. Proposal 1 was not discussed but remains to conclude contingent on the publication of the meeting summary from December 2, 2025, which documents CHPA's agreement with FDA's counterproposal to address in a guidance document that FDA is statutorily required to publish.

Proposal 2: Stepwise Labeling Review Process

FDA reiterated the proposal for sponsors to use available formal meetings to request pre-submission feedback on representative labeling, which can be acknowledged in the meeting guidance. The Agency emphasized that sponsors using pre-submission meetings for labeling discussions will likely experience smoother review cycles, though FDA acknowledged not all sponsors will use this pathway due to varying supplement complexity. CHPA sought clarification on why representative labeling is acceptable for pre-submission meetings but questioned its availability post-submission. FDA indicated that representative labeling can be used post-submission but needs better definition and documentation. While FDA aims to minimize requests for complete labeling suites during labeling negotiations, FDA explained that it cannot commit to never requesting full labeling sets more than once during review. CHPA proposed modifying its recommended approach for using representative labeling to provide FDA with the full set of draft labeling at the time the application is submitted. Representative labeling would be used during the labeling negotiation and review cycles, with the full set of draft final labeling submitted prior to approval once negotiations have concluded. The parties discussed capturing this in negotiations meeting minutes and CHPA raised the possibility of updating a MAPP (more specifically, MAPP 6020.5). CHPA raised questions about defined criteria for appropriate use of representative labeling and establishing consistent approaches across review divisions, which remain topics for further discussion.

Next Steps

FDA will discuss Proposal 2 (representative labeling) internally and will seek alignment on it at the next meeting on January 6, 2026. The Agency will consider how to best document the representative labeling process and will consider CHPA's suggestion of a MAPP update. Industry is encouraged to leverage the pre-submission meeting pathway for labeling discussions. Confirmation for Proposal 1 (SPAs for nonprescription studies) will also be sought at the next meeting.