Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

December 2, 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		INDUSTRY	
Mary Thanh Hai	CDER	Marcia Howard	CHPA
Theresa Michele	CDER	Glen Murphy	CHPA (Kenvue)
Kate Greenwood	OCC	Erin Oliver	CHPA (Haleon)
Nana Adjeiwaa-Manu	CDER	David Spangler	CHPA
Emily Ewing	CDER	Carolyn Herrmann	CHPA
Sara Abdollahi	CDER	Annetta Beauregard	BIO
		Lucy Vereshchagina	PhRMA
		Ryan Kaat	PhRMA

MEETING SUMMARY

Discussions focused on two CHPA proposals: Proposal #1 - expanding the Special Protocol Assessment (SPA) program to include certain Over-the-Counter (OTC) studies, and Proposal #2 - implementing a stepwise labeling review process using representative labeling. CHPA presented an example for representative labeling (Proposal #2) showing how the labels for 8 SKUs (Stock Keeping Units) could represent the labels of 24 SKUs. FDA shared data pertaining to proposal #1, showing that SPAs for clinical protocols have declined over the past decade with high resubmission rates, suggesting that SPAs for clinical protocols may not be helpful. Related to Proposal #2, FDA asked if industry had considered requesting specific labeling meetings to discuss labels using a representative label and suggested that the PDUFA VII formal meetings guidance could be updated to provide clarification that industry can request such meetings. FDA and CHPA discussed potential paths forward in response to CHPA Proposals #1 and #2 and potentially reached agreement on Proposal #1.

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

FDA provided an outlook based on their data analysis of SPA usage over the past decade. FDA's findings revealed that few clinical SPAs have been received over the last 10 years, and these show a declining trend over the last 10 years. The data showed high resubmission rates, with SPAs commonly going through multiple rounds of FDA review without reaching agreement between FDA and industry, particularly for novel pathways where data may be insufficient. FDA believes that SPAs for label comprehension studies, self selection studies, actual use studies, and human factors studies would be similarly unhelpful to industry, since the programs requesting a SPA would likely be novel. FDA also noted a SPA is only useful to the sponsor requesting it while the resources required would be borne by the entire industry, including sponsors who do not benefit. FDA believes that that the comprehensive protocol advice they already provide is more effective than expanding SPA programs for labeling studies. As an alternative approach, both parties agreed that developing guidance would be more beneficial than expanding SPA programs. Both parties agreed that the guidance required by section 505(b)(7)(B)(i) of the FD&C Act (as enacted by PL 119-37 on November 12, 2025) would help to address the concerns that prompted CHPA's Proposal 1. FDA proposed that because the statutory timeline for FDA to publish the guidance precedes the start of PDUFA VIII, FDA's commitment to draft this guidance would not be included in the PDUFA VIII commitment letter. CHPA agreed and explained that it would like to have the minutes from this meeting reflect FDA and CHPA's agreement on this point, emphasizing sponsors' interest in comprehensive timely feedback, and less sequential feedback. Specifically, FDA explained that it will draft a guidance to increase the clarity and predictability of the process and standards for approval of applications for nonprescription drugs, in accordance with PL 119-37.

Proposal 2: Stepwise Labeling Review Process

CHPA presented a detailed framework for representative labeling submissions and demonstrated how this approach aligns with current industry practices. They explained that companies typically develop initial labels through graphics departments, then incorporate input from multiple disciplines before regulatory approval and final artwork. CHPA proposed a system where industry would submit representative labels, as a subset of the full product labeling, during the intermediate review stages, rather than all label variations. In their example, instead of submitting all 24 SKUs for review, industry would submit only 8 representative pieces of artwork that capture the key variations (different package types, count sizes, etc.). In each submission, industry would provide justification for why certain labels can represent others, while all labels would still be available to FDA at the final review stage. CHPA suggested that this proposal would streamline the intermediate review process by reducing the volume of labels FDA needs to review during negotiations. FDA's response was to suggest that instead of implementing this representative labeling system, industry could request specific labeling meetings to discuss labels using a representative label. FDA suggested that, potentially, it could be clarified that meetings can be used for this purpose in the PDUFA VII formal meetings guidance.

Next Steps

For Proposal 1, FDA agreed to draft language for the meeting minutes pertaining to FDA addressing this request through the guidance related to nonprescription drugs required by section 505(b)(7)(B)(i) of the FD&C Act. FDA noted that it would not publish these minutes until there is alignment on this specific matter. For Proposal 2, CHPA will consult with stakeholders regarding FDA's proposal to discuss representative labeling in meetings that industry can request to receive feedback on labeling prior to submission. If CHPA is aligned with this approach, it could potentially be incorporated into the PDUFA VII formal meetings guidance. FDA has also been gathering data from recent labeling submissions and will present the data at an upcoming meeting for further consideration in discussions on Proposal 2.