Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

January 6, 2026 | 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
Karen Murry	CDER	Glen Murphy	CHPA (Kenvue)
Kate Greenwood	OCC	Erin Oliver	CHPA (Haleon)
Nana Adjeiwaa-Manu	CDER	David Spangler	CHPA
Sara Abdollahi	CDER	Carolyn Herrmann	CHPA
		Annetta Beauregard	BIO
		Ryan Kaat	PhRMA
		Lucy Vereshchagina	PhRMA

MEETING SUMMARY

The meeting focused on CHPA's revised proposal for a stepwise labeling review process for over-the-counter (OTC) drug applications. CHPA representatives presented their updated approach, which maintains submission of all labeling artwork at the time of submission but allows for negotiation using representative labeling during the review cycle. Under this process, sponsors would submit the complete set of labeling materials initially, then engage with FDA to identify a representative subset for negotiation purposes. Once content and layout agreements are reached on the representative pieces, sponsors would provide the full labeling suite again for final review.

FDA expressed general alignment with the proposed process and acknowledged that this approach is already available under current regulations but may not be widely known or consistently applied. The discussion revealed that the primary challenge is ensuring uniform awareness and application of this existing option rather than creating a new process. Both parties recognized that the process could benefit from better communication.

Proposal 2: Stepwise Labeling Review Process

CHPA's refined proposal provides for full labeling submission followed by a negotiation phase using representative labeling samples, if appropriate. The example provided by CHPA illustrated how 48 pieces of artwork could be negotiated using 8 representative pieces, significantly streamlining the review process while maintaining regulatory oversight. The key modification from previous discussions is that all artwork would be submitted initially, addressing FDA's concerns about incomplete applications while providing efficiency during the negotiation phase.

FDA confirmed that this process aligns with existing regulatory frameworks and does not require new policy development. The Agency emphasized that sponsors can currently use this approach and do not need to wait for additional guidance or documentation updates. However, FDA acknowledged that better communication could help inform sponsors and ensure that review staff consistently use this option when appropriate.

Next Steps

FDA will not include this process in the PDUFA VIII commitment letter, as it does not involve new commitments. Instead, the Agency will take back for internal discussion the question how to increase awareness and ensure consistent application.