



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and CHPA Nonprescription Drug Products Subgroup

January 20, 2026 | 3:30 - 5:00 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
Lucy Vereshchagina	PhRMA
Ryan Kaat	PhRMA

MEETING SUMMARY

During negotiations between FDA and CHPA representatives, discussions focused on establishing awareness for a representative labeling process for nonprescription drug applications. CHPA expressed concerns that both CHPA members and some FDA reviewers lack awareness of an already available process in which sponsors may use a representative label. After deliberation, FDA agreed to include representative labeling information on its public website, and CHPA agreed to communicate the process to its members. This agreement concluded negotiations for the Nonprescription NDA Products subgroup.

Proposal 2: Stepwise Labeling Review Process

In the January 6, 2026 meeting, FDA and CHPA had agreed that a representative labeling process is available. That process is to: (1) submit an application with a full suite of labeling, (2) negotiate using representative labeling, where appropriate, (3) submit a full suite of revised labeling for an

approval decision, and (4) submit final printed labeling post-approval. CHPA indicated that some in industry are not aware of this process and some FDA reviewers may not be, either. CHPA and FDA had discussed possible ways for FDA to indicate publicly that this process is available, but further discussion was needed after the January 6 meeting.

In a meeting on December 17, 2025, FDA had stated that while FDA aims to minimize requests for complete labeling suites during labeling negotiations, FDA cannot commit to never requesting full labeling suites more than once during review.

In the January 20 meeting, FDA reiterated that although use of representative labeling is available, there may be circumstances where representative labeling is not appropriate, or where FDA does not agree on which particular pieces of labeling are representative.

In the January 20 meeting, FDA and CHPA discussed possible ways for FDA to indicate publicly that the representative labeling process is available. FDA did not agree with inclusion of language in the PDUFA commitment letter or in a Manual of Policies and Procedures (MAPP). FDA proposed using the negotiation minutes to document the availability of the process because the minutes are available online. Industry expressed concern that their members would not know where to look for the information and proposed inclusion of language on an FDA webpage. After discussion, FDA stated that it is willing to indicate the availability of representative labeling in materials on its webpage. FDA also agreed to inform its staff about the current process allowing for the use of representative labeling where appropriate.

Industry stated it will communicate the availability of this process to its members.

These agreements concluded the negotiations between FDA and Industry for the Nonprescription NDA Products subgroup, and no further subgroup meetings will occur.

Next Steps

FDA will include information about representative labeling availability on a webpage to improve visibility and searchability for industry members. CHPA representatives committed to communicating the availability of this process to their members through their own channels. With this agreement reached, negotiations for the Nonprescription NDA Products subgroup have concluded with no further meetings planned.