



# The Nonprescription Drug Facts Label in a Changing Consumer Marketplace 2021

## Virtual Public Workshop

Date: June 9<sup>th</sup>, 2021  
Time: 8:30 am – 4:30 pm EST

## Agenda

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8:30 am – 8:45 am      **Welcome and Opening Remarks**  
Peter Stein, Office of New Drugs, FDA  
Theresa Michele, Office of Nonprescription Drugs, FDA

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## Session 1: The Current Landscape of the Drug Facts Label and Barriers to Consumer Comprehension

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8:45 am – 9:00 am      **A Brief History of the Drug Facts Label for Nonprescription Drugs**  
Kevin Lorick, Office of Nonprescription Drugs, FDA

9:00 am – 9:20 am      **Overview of the Drug Facts Labeling Regulatory Requirements**  
Betsy Scroggs, Office of Nonprescription Drugs, FDA

9:20 am – 9:35 am      **Rationale for the Current Drug Facts Label Format**  
Amanda Pike-McCrudden, Office of Nonprescription Drugs, FDA

9:35 am – 9:55 am      **Drug Facts Label Communication: Successes and Challenges**  
Jesse Catlin, California State University, Sacramento

9:55 am – 10:05 am      **Break**

10:05 am – 10:25 am      **Consumer Experience with the Drug Facts Label (what's working and what's not)**  
Julie Aker, Concentrics Research



10:25 am – 10:45 am	<b>The Familiar OTC Drug Facts Label: Obstacles and Opportunities</b> Clark Richardson, PEGUS Research
10:45 am – 11:00 am	<b>Strategies to Improve the Nonprescription Drug Facts Label: A Review of the Literature</b> H. Shonna Yin, New York University
11:00 am – 11:25 am	<b>PANEL 1: The Current Landscape of the Drug Facts Label and Barriers to Consumer Comprehension</b> <b>Moderator:</b> Ruth Parker, Emory University <b>Panelists:</b> Amanda Pike-McCrudden, Jesse Catlin, Julie Aker, Clark Richardson, H. Shonna Yin
11:25 am – 12:25 pm	Lunch

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## Session 2: Health Literacy and Individual Level Factors in Drug Facts Label Comprehension

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12:25 pm – 12:45 pm	<b>Pharmacy Health Literacy: Making Labels Easier to Use</b> Cindy Brach, Agency for Healthcare Research and Quality, HHS
12:45 pm – 1:05 pm	<b>Addressing Safe OTC Use in Older Adults</b> Michael Wolf, Northwestern University
1:05 pm – 1:20 pm	<b>Nonprescription Medication Use in Children: A Health Literacy Perspective</b> H. Shonna Yin, New York University
1:20 pm – 1:40 pm	<b>Bridging the Gap to Address Health Literacy Needs Among Diverse Groups</b> Jovonni Spinner, Office of Minority Health and Health Equity, FDA
1:40 pm – 2:05 pm	<b>PANEL 2: Health Literacy and Individual Level Factors in Drug Facts Label Comprehension</b> <b>Moderator:</b> Terry Davis, Louisiana State University <b>Panelists:</b> Cindy Brach, Michael Wolf, H. Shonna Yin, Jovonni Spinner
2:05 pm – 2:15 pm	Break

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## Session 3: The Future of the Drug Facts Label

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2:15 pm – 2:35 pm	<b>The Drug Facts Label – Looking to the Future with the Consumer in Mind</b> Barbara Kochanowski, Consumer Healthcare Products Association
2:35 pm – 2:55 pm	<b>Plain Language Labeling of Nonprescription Drugs in Canada</b> Jason DiMuzio, Health Canada
2:55 pm – 3:15 pm	<b>Supporting Innovation with DFL Standards</b> Stephen Konya, Office of the National Coordinator for Health IT, HHS
3:15 pm – 3:35 pm	<b>To See or Not to See? What does research say about the future of the Drug Facts Label?</b> Laura Bix and Mark Becker, Michigan State University
3:35 pm – 3:40 pm	<b>Break</b>
3:40 pm – 4:00 pm	<b>The Future of the Drug Facts Label: Thinking Outside of the Box</b> Eric Brass, University of California, Los Angeles
4:00 pm – 4:25 pm	<b>PANEL 3: The Future of the Drug Facts Label</b> <b>Moderator:</b> Elisabeth Walther, Office of Nonprescription Drugs, FDA <b>Panelists:</b> Barbara Kochanowski, Jason DiMuzio, Stephen Konya, Laura Bix, Mark Becker, Eric Brass
4:25 pm – 4:30 pm	<b>Closing Remarks and Next Steps</b> Theresa Michele, Office of Nonprescription Drugs, FDA

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### Additional Information

FDA invites all interested parties to submit comments to the public docket: FDA-2021-N-0353

Following the workshop, meeting materials including speaker biographical summaries, speaker slides, recordings, and transcripts, will be available on the workshop webpage: <https://www.fda.gov/drugs/news-events-human-drugs/nonprescription-drug-facts-label-changing-consumer-marketplace-2021-06092021-06092021>