DATE: February 9, 2023

TO: Secretary Xavier Becerra

THROUGH: Angela Ramirez, Deputy Chief of Staff
Stephen Cha, Counselor to the Secretary
Sarah Despres, Counselor to the Secretary
Kim Miller-Tolbert, Policy Advisor

FROM: Lindsay Tobias, Special Assistant to the Chief of Staff, FDA
Tristan Colonius, Deputy Chief of Staff, FDA

SUBJECT: Weekly Check-In with FDA

Details
What: Weekly Check-In with FDA
Date: Thursday, February 16, 2023
Time: 11:30 AM – 12:00pm ET
Location: Via teleconference
Call: Yes
Internal or External Event: Internal to HHS/FDA

Topic:

FDA Weekly Check-In: Front-of-Package (FOP) Nutrition Labeling and Plant-Based Milk Alternatives (PBMA) guidance update

Objective:

FDA will update the Secretary on the science supporting front-of-package nutrition labeling, which helps consumers quickly and easily identify foods that are part of a healthy eating pattern. In addition, FDA will provide an update on the Plant-Based Milk Alternatives guidance.

List of Participants:
IOS:

- Deputy Secretary Andrea Palm
- Sean McCluskie, Chief of Staff
- Angela Ramirez, Deputy Chief of Staff
- Sarah Despres, Counselor to the Secretary
- Steve Cha, Counselor to the Secretary

Other HHS Divisions:

- Kamara Jones, Acting Assistant Secretary for Public Affairs
- Melanie Egorin, Assistant Secretary for Legislation
- Sam Bagenstos, General Counsel
- John Kraus, Deputy Assistant Secretary for Public Affairs
- Robert Califf, Commissioner, FDA
- Janet Woodcock, Principal Deputy Commissioner, FDA
- Julie Tierney, Chief of Staff, FDA
- Tristan Colonius, Deputy Chief of Staff, FDA
- Andi Fristedt, Deputy Commissioner, Office of Policy, Legislation, and International Affairs (OPLIA), FDA
- Ritu Nalubola, Deputy Director, OPLIA, FDA
- Lauren Roth, Associate Commissioner for Policy, OPLIA, FDA
- Susan Mayne, Director, Center for Food Safety and Applied Nutrition (CFSAN), FDA
- Linda Verrill, Acting Branch Chief, Consumer Studies Branch, CFSAN, FDA
- Megan Velez, Director, Office of Regulations and Policy, CFSAN, FDA
- Mark Raza, Chief Counsel, Office of the Chief Counsel (OCC), FDA
- Pete Beckerman, Principal Deputy Chief Counsel, OCC, FDA
- Halley Kropa, Acting Deputy Chief Counsel for Program Review, OCC, FDA

Agenda/Run of Show:

- Introductions and FOP Rationale (5 minutes, FDA – CFSAN, OPLIA)
- FOP Labeling and Discussion (20 minutes, FDA – OPLIA, CFSAN, OCC)
- PBMA guidance update (5 minutes, FDA - OPLIA)

Background:

The recent White House Conference and National Strategy on Hunger, Nutrition, and Health included numerous actions for HHS agencies to undertake to combat the epidemic of diet-related diseases, including cardiovascular disease, type 2 diabetes, and obesity, which are experienced disproportionally by racial and ethnic minority groups and rural populations, and are leading causes of death and disease in the U.S. Several of those actions relate to FDA's nutrition efforts, including reducing sodium content in processed and prepared foods and efforts to help consumers make more informed decisions about their added sugar intake. The National Strategy also calls on FDA to develop a front-of-package (FOP) labeling scheme for food packages; this initiative will be a highly visible symbol of the Department's efforts to improve our nation's health and leverage and expand upon other work done to reduce intakes of sodium and added sugars.

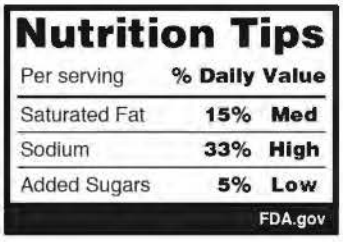
HHS implemented its first mandatory nutrition labeling 32 years ago. The resulting Nutrition Facts label is iconic and 87% of American consumers report using the label. However, many consumers, particularly those with lower nutrition literacy, may find additional information on food packaging helpful in constructing a healthy diet.

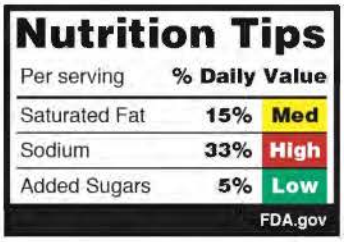
Front-of-Package Labeling

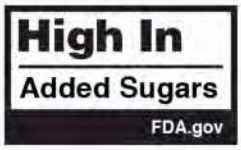
Front-of-Package, or "FOP," labeling is intended to complement the Nutrition Facts label by giving consumers a simple, easy-to-understand aid in making healthy food selections. The use of FOP systems has grown substantially around the world, and FDA has been urged by numerous bodies, including the National Academy of Medicine, to adopt FOP in the U.S. As noted above, the White House National Strategy released in September announced that the Administration will "develop a front-of-package (FOP) labeling system to quickly and easily communicate nutrition information."

The increased attention in recent years to FOP, and the experiences of countries that have adopted FOP labeling, has prompted numerous studies of FOP labeling's effectiveness. Numerous research studies have shown that FOP aids nutrition comprehension, ability to make healthier choices, and has a positive effect on purchase decisions. The simplicity of FOP is particularly helpful to lower nutrition literacy consumers, who often disproportionally experience diet-related diseases, and therefore FOP may be helpful in advancing health equity. Other countries have noted another significant benefit: food manufacturers have lowered their levels of the nutrients of concern that are commonly the focus of FOP efforts -- sodium, added sugar, and saturated fat.

We are in the process of identifying potential FOP labeling schemes that can be evaluated in consumer research for simplicity, effectiveness, and feasibility. Below are a few illustrative examples of FOP schemes that might be further explored in consumer research.







Timeline/Anticipated Stakeholder Reaction:

We are pursuing an aggressive timeline so that the proposed rule can publish this year. As an immediate next step, we have started the process for obtaining OMB approval to move from focus group testing to experimental consumer research to evaluate FOP schemes to inform scheme selection for the proposed rule. Pending OMB approval of the information collection, we anticipate research will begin in the second quarter of 2023. Below is FDA's draft timeline for the proposed rule:

Initiative	Q1 2023	Q2 2023	Q3 2023	Q4 2023
FOP Proposed Rule*	Experimental research PRA / Draft NPRM	Experimental research / Draft NPRM	FDA Clearance	HHS, OMB Review; Issue NPRM

*Timelines assume expedited review and clearance

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Background: Plant-Based Milk Alternatives guidance

Next week, FDA plans to issue a draft guidance for industry entitled "Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements." The draft guidance would provide industry with FDA's view on the naming of plant-based food products that are marketed and sold as alternatives to milk (plant-based milk alternatives) and our recommendations on the use of voluntary nutrient statements. Industry's use of these recommendations for labeling plant-based milk alternatives will provide consumers with additional nutrition information to help them understand certain nutritional differences between these products and milk and make informed dietary choices.

We anticipate this action to generate significant interest, especially from the dairy industry, plant-based foods industry, and Congress. FDA will proactively communicate the availability of the draft guidance through a news release and Constituent Update. FDA will also make available a Consumer Update that will discuss the nutritional differences between PBMA and milk and explain why the agency is recommending as a best practice to include the voluntary nutrient statements on their PBMA products. FDA plans targeted outreach to certain members of Congress, including Senator Baldwin.

Attachments:

1. Slide deck

DATE: February 15, 2023

TO: Secretary Xavier Becerra

THROUGH: Kim Miller-Tolbert, Policy Advisor
Angela Ramirez, Deputy Chief of Staff
Stephen Cha, Counselor to the Secretary
Sarah Despres, Counselor to the Secretary

FROM: Lindsay Tobias, Special Assistant to the Chief of Staff, FDA
Julie Tierney, Chief of Staff, FDA

SUBJECT: Weekly Check-In with FDA

Details
What: Weekly Check-In with FDA
Date: Tuesday, February 21, 2023
Time: 11:00 AM – 11:30 AM
Location: Via teleconference
Call: Yes
Internal or External Event: Internal to HHS/FDA

Topic:

FDA Weekly Check-In

Objective:

FDA will update the Secretary on the status of the Foods and Tobacco Programs

Secretary's Role:

To listen and ask questions.

List of Participants:
IOS:

- Deputy Secretary Andrea Palm
- Sean McCluskie, Chief of Staff
- Angela Ramirez, Deputy Chief of Staff
- Sarah Despres, Counselor to the Secretary

- Steve Cha, Counselor to the Secretary

Other HHS Divisions:

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- Julie Tierney, Chief of Staff, FDA
- Tristan Colonius, Deputy Chief of Staff, FDA
- Andi Fristedt, Deputy Commissioner, Office of Policy, Legislation, and International Affairs (OPLIA), FDA
- Erica Jefferson, Associate Commissioner, Office of External Affairs, FDA
- Mark Raza, Chief Counsel, FDA
- Bret Koplow, Counselor to the Commissioner, FDA

Agenda/Run of Show:

- Introductions (5 minutes, FDA)
- Tobacco Update (10 minutes, FDA)
- Foods Program Update (10 minutes, FDA)
- Discussion (5 minutes, FDA)

Background:

FDA will provide an update on CTP's plans to address the recommendations provided in the Reagan-Udall Foundation (RUF) report. FDA will then provide an update on the upcoming February announcement regarding next steps on FDA's foods and field program modernization.