duration of comments may be limited by time constraints.

Streaming Webcast of the Public Meeting: This public meeting will be streamed via a webcast in both English and Spanish languages. Please register for the webcast by visiting *https://www.surveymonkey.com/r/LongCOVIDPFDD.*

The English-language webcast can be accessed via: *https://fda.yorkcast.com/webcast/Play/4eba453a2412474e98fff1fabcc63ac51d.* The Spanish-language webcast can be accessed via: *https://fda.yorkcast.com/webcast/Play/0385884d5655420fabd3a55a237926691d.* Simply click on the link and hit the ''play'' button and it will start. A test signal will be playing 30 minutes prior to the event, so you can click on the link at any point during that time to start. You will hear music playing during the test period and then the event will begin at 10 a.m. ET. If you would like to check your system now, you can click on the link and the page will open with a ''waiting'' statement showing.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible on the meeting website at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-long-covid-04252023.*

Dated: February 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03714 Filed 2–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0451]

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry.'' The draft guidance, when finalized, will provide industry with our view on the naming of plant-based food products that are marketed and sold as alternatives to milk (plant-based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. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 24, 2023 to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 24, 2023.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–0451 for ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry; Agency Information Collection Activities; Proposed Collection; Comment Request.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Jeanmaire Hryshko, Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling (HFS–800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Meadow Platt, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

An increase in purchase and consumption of plant-based milk alternatives has occurred over the last 10 years. Many products are labeled with names that include the term ''milk.'' Plant-based milk alternatives are made from liquid-based extracts of plant materials, such as tree nuts, legumes, seeds, or grains. FDA has established a standard of identity or compositional requirements for milk (see 21 CFR 131.110) but has not established standards of identity or compositional requirements for plant-based milk alternatives. The composition, including the nutrient profile, of these plant-based milk alternative products varies depending on the plant source(s), processing methods, and added ingredients.

We are committed to clear and transparent food labels that are truthful and not misleading. We are also committed to using our tools and authorities to empower consumers with information to quickly ascertain the types of products they are purchasing for themselves and their families and enhance their ability to make informed choices about the foods they buy and eat. To further this goal, in the **Federal Register** of September 28, 2018 (83 FR 49103), FDA issued a notice requesting comment on the labeling of plant-based alternatives with names that include the names of dairy foods. We invited comment on a variety of issues, including how consumers use plant-based dairy alternatives, how consumers understand terms included in the names of plant-based dairy alternatives, and whether consumers are aware of and understand differences between plant-based dairy alternatives and their dairy counterparts. We received over 13,000 comments, which helped to inform the development of this draft guidance.

We are announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry.'' The draft guidance provides our view on the naming of plant-based milk alternatives and recommendations on voluntary nutrient statements for the labeling of these products. The draft guidance does not address other plant-based dairy alternatives such as plant-based cheese, yogurt, or kefir alternatives. The draft guidance is limited to plant-based milk alternatives because: (1) most comments and consumer research submitted to the notice were limited to plant-based milk alternatives; (2) the overall market for plant-based milk alternatives is greater than the market for other plant-based dairy alternatives such as yogurts and cheeses; and (3) data indicates that consumers may not understand the nutritional differences between plant-based milk alternatives and a potential public health concern may exist if plant-based milk alternatives are substituted for milk.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry

OMB Control Number 0910–0381

This draft guidance, once finalized, provides recommendations on the naming of plant-based milk alternatives and on voluntary nutrient statements for the labeling of these products. The draft guidance's recommendations for labeling plant-based beverages that are used in place of milk will provide consumers with additional nutrition information to help them compare these products to milk and make informed dietary choices.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [1] [2]
Labeling recommendations in ''Best Practices for Labeling of Plant-based Milk Alternatives''	56	6	336	1	336	$500,000

[1] One-time relabeling costs.
[2] There are no operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar labeling programs. We estimate that each year 56 manufacturers will relabel their products following recommendations found in the draft guidance. We estimate that each manufacturer will relabel 6 products for 336 total annual disclosures (56 manufacturers × 6 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 336 hours (336 disclosures × 1 hour). We estimate that there will be an annual capital cost of $500,000 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden per respondent.

III. Other Issues for Consideration

Although FDA welcomes comments on any aspect of the guidance, we particularly invite comment on the following:

- The voluntary nutrient statement recommendations provided in section III.2 of the draft guidance. We acknowledge that the labeling of some plant-based milk alternatives may have space constraints that limit listing of multiple nutrients in the voluntary nutrient statement. Therefore, we are interested in comments about the placement of and possible space constraints for the voluntary nutrient statement on product labels.
- FDA is recommending nutrient disclosure statements on the labels of plant-based milk alternatives that contain less of the following nutrients compared to milk: calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B12. We chose these specific nutrients because the Dietary Guidelines for Americans identifies the Dairy Group as being a key contributor of those nutrients and to align with the nutritional standards set by the U.S. Department of Agriculture's (USDA) Food and Nutrition Service for fluid milk substitutes served in the National School Lunch Program, School Breakfast Program, and Child and Adult Care Food Program (USDA criteria) (see 7 CFR 210.10(d)(3), 220.8(d), and 226.20(g)(3)).
- For the purpose of this draft guidance, are the USDA criteria that identifies minimum levels of nutrients for fluid milk substitutes the most appropriate criteria to use? If yes, why? If not, what criteria (*i.e.,* nutrients and nutrient levels, minimums versus ranges of nutrient levels, etc.) should we consider and why? Please provide information, research, and data to help us understand your reasoning.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03513 Filed 2–22–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

ACTION: Notice of public listening session; request for comments.

DATES: The listening session will be held on Wednesday, March 15, 2023, from 12:00 p.m. to 2:00 p.m., Eastern Daylight Time.

ADDRESSES: The session will be held virtually, with online slide share and dial-in information shared with registered participants.

Status: This meeting is open to the public, but requires RSVP to *OGA.RSVP@hhs.gov* by March 6, 2023. *See RSVP section below for details.*

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS) and the Department of State are charged with co-leading the U.S. delegation to the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response and will convene an informal Stakeholder Listening Session.

The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help inform and prepare for U.S. government engagement with the Intergovernmental Negotiating Body.

Matters To Be Discussed: The listening session will discuss potential areas that could be included in a pandemic accord to promote pandemic prevention, preparedness, and response. Topics will include those found in the Zero Draft of the Pandemic Accord. The Zero draft of the Intergovernmental Negotiating Body (INB) can be found at this website: *https://apps.who.int/gb/inb/index.html.* Participation is welcome from stakeholder communities, including:

- Public health and advocacy groups
- State, local, and Tribal groups
- Private industry
- Minority health organizations
- Academic and scientific organizations, etc.

RSVP: Persons seeking to attend or speak at the listening session *must register by March 6, 2023*.

Registrants must include their full name and organization, if any, and indicate whether they are registering as a listen-only attendee or as a speaker participant to *OGA.RSVP@hhs.gov*.

Requests to participate as a speaker must include:

1. The name of the person desiring to participate;

2. The organization(s) that person represents, if any;

3. Identification of the primary topic of interest.