

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 <sup>1 2</sup>
Labeling recommendations in “Best Practices for Labeling of Plant-based Milk Alternatives” .....	56	6	336	1	336	\$500,000

<sup>1</sup> One-time relabeling costs.

<sup>2</sup> 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 We estimate that each year 56 manufacturers will relabel their products following recommendations found in the draft guidance.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- The voluntary nutrient statement recommendations provided in section III.2 of the draft guidance.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.*

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**BILLING CODE 4164–01–P**

## 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](mailto: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](mailto: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.

*Other Information:* Written comments should be emailed to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov) with the subject line “Written Comment Re: Stakeholder Listening Session 1 for the INB” by Friday, March 31, 2023.

We look forward to your comments on the Intergovernmental Negotiating Body (INB) agenda items.

Dated: February 8, 2023.

**Susan Kim,**

*Chief of Staff, Office of Global Affairs.*

[FR Doc. 2023-03680 Filed 2-22-23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0390]

### Agency Father Generic Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before April 24, 2023.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:**

When submitting comments or requesting information, please include the document identifier 0990-0390-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), [PRA@HHS.GOV](mailto:PRA@HHS.GOV) or call 202-264-0041.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Challenge and Prize Competition Solicitations.

*Type of Collection:* Father generic extension.

### OMB No. 0990-0390—Office of the Assistant Secretary for Health (OASH)

*Abstract:* The Office of the Secretary (OS), Department of Health & Human Services (HHS) requests that the Office of Management and Budget (OMB) approve a request for an extension of generic clearance approval of the information collected for challenge and prize competition solicitations. Burden hours were increased from 333 to 558.3 total burden hours to provide more time for respondents to complete forms that may include more questions.

Challenges and prize competitions enable HHS to tap into the expertise and creativity of the public in new ways as well as extend awareness of HHS programs and priorities. Within HHS, the Office of the Assistant Secretary for Health (OASH) has taken lead responsibility in coordinating challenges and prize competitions and implementing policies regarding the use of these tools. HHS's goal is to engage a broader number of stakeholders who are inspired to work on some of our most pressing health issues, thus supporting a new ecosystem of scientists, developers, and entrepreneurs who can continue to innovate for public health.

The generic clearance is necessary for HHS to launch several challenges or prize competitions annually in a short turnaround. The information collected for these challenges and prize competitions will generally include the submitter's or other contact person's first and last name, organizational affiliation and role in the organization (for identification purposes); email address or other contact information (to follow up if the submitted solution is selected as a finalist or winner); street address (to confirm that the submitter or affiliated organization is located in the United States, for eligibility purposes); information confirming whether the submitter's age is 13 years or older (to ensure compliance with the Children's Online Privacy Protection Act of 1998, 15 U.S.C. 6501-6505 (COPPA)) or 18 years or older (to ensure necessary

consents are obtained); and a narrative description of the solution. HHS may also request information indicating the submitter's technical background, educational level, ethnicity, age range, gender, and race (to evaluate entrants' diversity and backgrounds), how the submitter learned about the challenge or prize competition and what the submitter currently understands about the HHS agency hosting the challenge or prize competition (to gauge the effect of the challenge or prize competition on increasing public awareness of HHS programs and priorities, and generally to enable HHS to improve its outreach strategies to ensure a diverse and broad innovator constituency is fostered through the use of challenges and prize competitions). Finally, HHS may ask for additional information tailored to the particular challenge or prize competition through structured questions. This information will enable HHS to more effectively create and administer challenges and prize competitions.

Upon entry or during the judging process, solvers under the age of 18 will be asked to confirm parental consent, which will require them to obtain and provide a parent or guardian signature in a format outlined in the specific criteria of each challenge or prize competition in order to qualify for the contest. To protect online privacy of minors, birthdate may be required by the website host to ensure the challenge platform meets the requirements of COPPA. Eligibility to win a cash prize will be outlined in the specific criteria of each contest and will only apply to U.S. citizens, permanent residents, or private entities incorporated in and maintaining a primary place of business in the U.S. To administer the cash prize, HHS will need to collect additional relevant payment information—such as Social Security Number and/or Taxpayer ID and information regarding the winners' financial institutions—in order to comply with financial accounting and income tax reporting processes.

*Likely Respondents:* Likely respondents include individuals, businesses, and state and local governments who choose to participate in a challenge or prize competition hosted or overseen (*i.e.*, via contract, etc.) by HHS.