for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6768, *Charlotte.Conway@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2024 (89 FR 65368), FDA published the notice of availability for a draft guidance #294 entitled ''Animal Food Ingredient Consultation (AFIC),'' giving interested persons until September 9, 2024, to comment on the draft guidance. FDA received numerous comments on the draft guidance, including comments from the animal food and drug industries, AAFCO, a veterinary association, a State food and agriculture department, and private citizens, and those comments were considered as the guidance was finalized. In response to comments, the guidance was revised. First, we clarified the scope of the AFIC process as including any animal food ingredient for which firms may have otherwise utilized the AAFCO ingredient definition process. We also clarified that a proposed ingredient name and definition should be included in the consultation for FDA's consideration. We removed the recommendation to submit a statement of environmental risk. In addition, we clarified that firms participating in the AFIC process should not resubmit information they have already provided to FDA and added clarification regarding what information interested parties should include when providing comments on pending AFICs through the docket. Lastly, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 9, 2024.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Animal Food Ingredient Consultation (AFIC).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative 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. FDA is issuing this guidance, as final, that includes information collection recommendations regarding animal food ingredient consultations with FDA, which are subject to review and approval by OMB under the PRA. FDA will implement the information collection recommendations upon OMB approval and will announce OMB approval in the **Federal Register**. Information collection pertaining to animal food ingredient safety is currently provided for in FDA regulations in 21 CFR parts 570 and 571, currently approved in OMB control numbers 0910–0342 and 0910–0546, respectively. Disclosures under 21 CFR 501.22 requiring animal food manufacturers to declare the presence of certified and noncertified color additives in animal food product labeling are also currently approved in OMB control number 0910–0546. However, upon our review of the latter information collection, we note that while we account for general reporting activities applicable to animal food ingredient regulations, we do not discuss activities that may be specifically attributable to animal food ingredient consultations with FDA. We also acknowledge that discontinuation of the MOU with AAFCO may result in an adjustment for some respondents with regard to how they engage in consultation with FDA. On December 19, 2024, FDA published a notice (89 FR 103838) under the PRA of its intent to revise the information collection to explicitly discuss animal food ingredient consultations that we believe are implicitly contemplated by the existing regulations in 21 CFR parts 570 and 571 specifically to invite comment on the associated burden.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31525 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1102]

Labeling of Plant-Based Alternatives to Animal-Derived Foods: 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 Alternatives to Animal-Derived Foods.'' This draft guidance, when finalized, will provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods (plant-based alternative foods), especially in the absence of a common or usual name for the product. This draft guidance does not address the naming and labeling of plant-based milk alternatives; FDA is providing recommendations regarding these products in a separate guidance document.

DATES: Submit either electronic or written comments on the draft guidance by May 7, 2025 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by March 10, 2025.

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–2022–D–1102 for ''Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry; Availability; 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 guidance to Office of Nutrition and Food Labeling (HFS–800), Human Foods Program, 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 guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Andrea Krause, Office of Nutrition and Food Labeling (HFS–820), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Lauren Kleinman, Office of Policy, Regulations, and Information, Human Foods Program, 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

We are announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-Based Alternatives to Animal-Derived Foods.'' This draft guidance is intended to provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods (plant-based alternative foods), especially in the absence of a common or usual name for the product. Consumer demand for plant-based alternative foods has increased and FDA is committed to helping ensure consumers understand the foods they buy, to help them make informed dietary choices. The scope of this draft guidance includes plant-based alternatives to eggs, seafood, poultry, meat, and dairy (excluding plant-based milk alternatives) that fall under FDA jurisdiction. (In the **Federal Register** of February 23, 2023 (88 FR 11449), we announced the availability of a draft guidance entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Draft Guidance for Industry.'' When finalized, the guidance will provide 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. The draft guidance entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Draft Guidance for Industry'' is available online at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements.*)

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA 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 alternative 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 Alternatives to Animal-Derived Foods: Draft Guidance for Industry

OMB Control Number 0910–0381—Revision

The draft guidance, once finalized, will provide recommendations on best practices for naming and labeling of certain plant-based alternative foods. Industry's use of these recommendations for naming and labeling plant-based alternative foods will help ensure consumers understand the nature of individual plant-based alternative foods, including differences among these products, and have the information they need to make informed purchasing decisions.

Standards of identity have not been established for plant-based alternative foods. As such, plant-based alternative foods are non-standardized foods and must be labeled with their common or usual name, or in the absence thereof, a statement of identity that accurately describes the food. See 21 CFR 101.3(b). Many plant-based alternative foods are novel foods and do not have common or usual names established by common usage. Currently, products appear to be identified in multiple ways, sometimes inconsistently across the category. Thus, the purpose of this guidance is to provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods.

Description of respondents: Respondents to this information collection are manufacturers, packers, and distributors of plant-based alternative foods that are marketed and sold in the United States. Respondents are from the private sector (for-profit businesses).

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 ''Labeling of Plant-Based Alternatives to Animal-Derived Foods''	160	5	800	1	800	$1,231,200

[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 160 manufacturers will relabel their products following recommendations found in the draft guidance. We estimate that each manufacturer will relabel 5 products for 800 total annual disclosures (160 manufacturers × 5 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 800 hours (800 disclosures × 1 hour). We estimate that there will be an annual capital cost of $1,231,200 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. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/FoodGuidances,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31535 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3067]

Recommendations To Reduce the Risk of Transmission of Disease Agents Associated With Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' FDA is issuing this guidance to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of infections due to sepsis by HCT/Ps. This notice is being issued to respond to a public health safety concern and to address the urgent need for updated recommendations in making a donor eligibility determination when screening a donor for clinical evidence of sepsis and clinical signs to consider.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the