

thinking of FDA on “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” 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

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2024–D–2978]

### Food and Drug Administration Animal Food Ingredient Consultation; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry #294 entitled “Animal Food Ingredient Consultation (AFIC).” This guidance describes FDA’s interim AFIC process and explains one way FDA will work with firms that are developing animal food ingredients now that the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) expired on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and Generally Recognized as Safe (GRAS) Notification programs. The AFIC process provides an additional way for engagement with FDA regarding ingredients for which firms may otherwise have used the

AAFCO ingredient definition process. AFIC will help FDA identify any potential safety concerns associated with such ingredients. The AFIC process also allows for public awareness of and input on such ingredients. In addition, this guidance describes FDA’s enforcement policy for certain ingredients assessed using the AFIC process.

**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 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–2024–D–2978 for “Animal Food

Ingredient Consultation (AFIC).” 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.” The Agency will review this copy, including the claimed confidential information, in its 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 the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section

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](mailto: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.*

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**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