guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17771 Filed 8–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2978]

Animal Food Ingredient Consultation; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft guidance for industry #294 entitled ''Animal Food Ingredient Consultation (AFIC).'' This draft guidance describes FDA's interim AFIC process and explains one way FDA intends to work with firms that are developing animal food ingredients after the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) expires on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and generally recognized as safe (GRAS) Notification programs. The new AFIC process will provide 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 will also allow for public awareness of and input on such ingredients. In addition, this draft guidance describes FDA's enforcement policy for certain ingredients assessed using the AFIC process.

DATES: Submit either electronic or written comments on the draft guidance by September 9, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6768, *Charlotte.Conway@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft guidance for industry #294 entitled ''Animal Food Ingredient Consultation (AFIC).'' This draft guidance describes FDA's interim AFIC process and explains one way FDA intends to work with firms that are developing animal

food ingredients after the MOU with AAFCO expires on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and GRAS Notification programs. In addition, this draft guidance describes FDA's enforcement policy for certain ingredients reviewed using the AFIC process.

The Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food, including substances that are food additives and substances that are GRAS for their intended uses in food.[1]

Since 1920, AAFCO has maintained the AAFCO Official Publication (OP), which contains, among other things, a comprehensive list of animal food ingredients, including FDA-approved food additives, substances that are GRAS for one or more intended uses, and animal food ingredient definitions established through the AAFCO Ingredient Definition Request Process. In 2007, FDA entered into an MOU, 225–07–7001, with AAFCO that outlines how FDA would provide its scientific and technical expertise to AAFCO in reviewing requested ingredient definitions requested by industry or AAFCO. This MOU has been renewed and revised several times. The current MOU 225–07–7001 expires in October 2024 and will not be renewed. See *https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou.*

Following the expiration of the MOU, FDA plans to evaluate its animal Food Additive Petition and GRAS Notification programs to determine if changes are needed to promote the efficient development and review of new animal food ingredients.

We are issuing this draft guidance to announce the creation of the AFIC process to provide an additional way for engagement with FDA regarding animal food ingredients following the expiration of the MOU with AAFCO and during this interim evaluation period. AFIC will provide a process that will help FDA be aware of new ingredients that are marketed in interstate commerce and any potential safety concerns associated with such ingredients. AFIC will serve to provide a baseline of safety information available about such an ingredient, making it easier to compare developments that might occur during marketing. AFIC also will give FDA an opportunity to discuss any potential safety concerns with the developer, ideally before the ingredient is marketed.

AFIC also will allow for public awareness of and input on ingredients for which FDA is providing consultation. Our goal is to support innovation in animal food technologies while maintaining as our priority the production of safe animal food.

FDA generally does not intend to initiate enforcement action with respect to the food additive approval requirements of the FD&C Act for an ingredient, or animal food containing such ingredient, if such an ingredient has been reviewed and is the subject of a ''consultation complete'' letter under the AFIC process, and is used in accordance with the ''consultation complete'' letter, as long as there continues to be no questions or concerns about the safety of the ingredient.

Elsewhere in this issue of the **Federal Register**, we are publishing a notice of availability for a draft guidance #293, ''FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients.'' This draft guidance communicates FDA's enforcement policy regarding certain ingredients listed in chapter 6 of the 2024 AAFCO OP (or recommended by FDA for inclusion in the AAFCO OP) after the expiration of the Agency's MOU with AAFCO.

Elsewhere in this issue of the **Federal Register**, we also are publishing a notice seeking stakeholder input regarding our current Food Additive Petition and GRAS Notification review processes for animal food ingredients. Additionally, we intend to hold listening sessions and will later provide scheduling information for those listening sessions.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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

FDA tentatively concludes that this draft guidance contains no collection of information subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), as at this time we believe that fewer than 10 persons will avail themselves of this process in any given year. The draft guidance does refer to previously approved FDA collections of information. The collections of information in 21 CFR 570 have been approved under 0910–0342; the collections of information in 21 CFR 571 have been approved under 0910–0546.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17778 Filed 8–8–24; 8:45 am]

BILLING CODE 4164–01–P

[1] See 21 CFR part 570, subpart E.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Infant-Toddler Court Program—National Resource Center

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing up to $1,750,000 in supplemental award funds in federal fiscal year (FY) 2024 to the current recipient of the Infant-Toddler Court Program (ITCP)—National Resource Center (NRC) award, to expand activities to help lead nationwide improvements to child welfare and early childhood systems.

FOR FURTHER INFORMATION CONTACT: Kateryna Zoubak, Early Childhood Systems Analyst, Division of Home Visiting and Early Childhood Systems, Maternal and Child Health Bureau, HRSA, at *ezoubak@hrsa.gov* or 240–475–8014.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: ZERO TO THREE National Center for Infant, Toddler and Families, Inc.

Amount of Non-Competitive Award(s): One award of up to $1,750,000.

Project Period: September 30, 2022, to September 29, 2027.

Assistance Listing (CFDA) Number: 93.110.

Award Instrument: Non-competitive supplemental funding to the existing Cooperative Agreement.

Authority: 42 U.S.C. 701(a)(2) (title V, sec. 501(a)(2) of the Social Security Act)