collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Irradiation in the Production, Processing and Handling of Food	0910–0186	7/31/2027
State Enforcement Notifications	0910–0275	7/31/2027
Veterinary Feed Directive	0910–0363	7/31/2027
Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring	0910–0409	7/31/2027
Record Retention Requirements for the Soy Protein and Reduced Risk of Coronary Heart Disease Health Claim	0910–0428	7/31/2027

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17661 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–N–2979]

Pre-Market Animal Food Ingredient Review Programs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is soliciting comments from the public regarding the Food Additive Petition and Generally Recognized as Safe (GRAS) Notification programs to determine if changes are needed to promote their efficiency. Specific questions and information requests are included in this notice to help guide input from stakeholders and other members of the public.

DATES: Submit either electronic or written comments on the notice by December 9, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–N–2979 for ''Pre-Market Animal Food Ingredient Review Programs, Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

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

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food. Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a food additive, in part, as any substance whose intended use results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use. Substances that are ''generally recognized as safe'' (GRAS) [1] for their intended uses in food are not food additives.

Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) and FDA's implementing regulations at title 21 of the Code of Federal Regulations (21 CFR) part 571 describe the animal food additive petition process and the data and information that must be submitted to FDA as part of an animal food additive petition to support premarket approval. In general, to be legally marketed and used, a food additive must be approved, covered by an FDA regulation, and used as described in the FDA regulation. Otherwise, the food additive is considered unsafe under section 409(a)(2) of the FD&C Act, and the food additive and any food that bears or contains it is adulterated under section 402(a)(2)(C)(i) of the FD&C Act. Approved food additives for animal food use are found in 21 CFR parts 573 and 579.

FDA has affirmed certain substances as GRAS for their intended use in animal food and these are listed in 21 CFR parts 582 and 584. Importantly, these lists are not all-inclusive. FDA's Animal Food GRAS Notification Program allows individuals and firms to voluntarily notify FDA that they have concluded that an animal food substance is GRAS under the conditions of its intended use. FDA evaluates the notifier's supporting data and responds to the notifier with a letter stating whether FDA has questions about the notifier's conclusion. If FDA does not have questions, it issues a ''no questions'' letter. A ''no questions'' letter is not a legal determination by FDA that the use of a substance is GRAS. These notices are posted on FDA's website under ''Current Animal Food GRAS Notices Inventory,'' along with FDA's letter to the notifier regarding its evaluation of the notice.[2] FDA encourages any person who intends to market a food substance on the basis of a conclusion of GRAS status to submit a GRAS notice to FDA.

The Association of American Feed Control Officials (AAFCO) is an independent organization with voluntary membership of State and Federal regulatory officials in the United States, as well as officials from government agencies in other countries, that are responsible for the execution of laws and regulations in their jurisdictions pertaining to the production, labeling, distribution, use, or sale of animal food (including ingredients). FDA is a member of AAFCO and provides scientific and technical expertise to the organization.

Since 1920, AAFCO has maintained the AAFCO Official Publication, which contains, among other things, a comprehensive list of animal food ingredients, many of which include definitions established through the AAFCO ingredient definition request process. In 2007, FDA entered into a memorandum of understanding (MOU) with AAFCO that outlines how FDA would provide its scientific and technical expertise to AAFCO in reviewing requested ingredient definitions. This MOU has been renewed and revised several times. The current MOU 225–07–7001 expires on October 1, 2024, and will not be renewed. See *https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou.*

Elsewhere in this issue of the **Federal Register**, we are publishing a notice of availability for a draft guidance for industry #293, ''FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients.'' This draft guidance, when finalized, will communicate FDA's current thinking on an enforcement policy regarding certain ingredients listed in chapter six of the 2024 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 of availability for a draft guidance on our new Animal Food Ingredient Consultation (AFIC) process to provide an additional way for firms developing animal food ingredients to consult with CVM following the expiration of the MOU with AAFCO while FDA evaluates the Food Additive Petition and GRAS Notification programs to determine if changes are needed to promote their efficiency.

II. Questions for Consideration

We seek input on the following questions regarding the oversight of animal food ingredients:

1. What do you perceive as barriers and/or benefits to pursuing a Food Additive Petition or GRAS Notification?
2. Are there changes that could make the Food Additive Petition and GRAS Notification programs more feasible, such as regulatory changes, changes to guidance, or changes to FDA policy or processes?
3. Is there information that is currently required to be submitted in a Food Additive Petition or GRAS Notification that you do not think is necessary for evaluating the ingredient?
4. Is there information that is not currently required to be submitted in a Food Additive Petition or GRAS Notification, but should be to better enable FDA's evaluation?
5. What review process for proposed animal food ingredients would best enable FDA to review their safety?
6. If you have submitted a request for an ingredient definition through the AAFCO ingredient definition process, what was your reason for doing so instead of filing a Food Additive Petition or submitting a GRAS Notification with FDA?

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17779 Filed 8–8–24; 8:45 am]

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

[2] *https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3617]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Clozapine Risk Evaluation and Mitigation Strategy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.