DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1022]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration of Color Additives on Animal Food Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with food additive petitions, investigational food additive files exemptions, and declaration of color additives on animal food labels.

DATES: Submit either electronic or written comments on the collection of information by December 7, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 7, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 7, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2021–N–1022 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated with Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration of Color Additives on Animal Food Labels.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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, including each proposed extension of an existing 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.

Reporting Associated With Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration of Color Additives on Animal Food Labels—21 CFR 501.22(k), 570.17, 571.1, and 571.6

OMB Control Number 0910–0546—Extension

This information collection supports FDA regulations as discussed below. In this notice, we are combining all reporting burden associated with FDA's regulations §§ 501.22(k), 570.17, 571.1, and 571.6 (21 CFR 501.22(k), 570.17, 571.1, and 571.6) into one collection and are consolidating the burden for OMB control numbers 0910–0546 and OMB control number 0910–0721. Upon approval of the consolidated collection OMB control number 0910–0546, we will ask OMB to discontinue OMB control number 0910–0721. The information collection provisions approved under OMB control numbers 0910–0546, and 0910–0721 are similar in that they support FDA's regulations §§ 501.22(k), 570.17, 571.1, and 571.6. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for government efficiency and to allow the public to look to one OMB control number for all reporting associated with FDA's regulations §§ 501.22(k), 570.17, 571.1, and 571.6.

Food Additive Petitions and Investigational Food Additive Files Exemptions

Section 409(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of FD&C Act specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of section 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act but attempt to explain these requirements and provide a standard format for submission to speed processing of the food additive petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in parts 501, 573, and 579 (21 CFR parts 501, 573, and 579). The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

Regarding the investigational use of food additives, section 409(j) of the FD&C Act provides that any food additive or any food bearing or containing such an additive may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive. To implement the provisions of section 409(j) of the FD&C Act, we issued regulations under § 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additive files are also set forth in various regulations contained in part 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether the data establish the identity of the substance, justify its intended effect in/on the food, and establish that its intended use in/on food is safe.

Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

FDA has the authority under the FD&C Act to issue regulations concerning animal food. Specifically, section 403(i) of the FD&C Act (21 U.S.C. 343(i)) requires that certified color additives used in or on a food must be declared by their common or usual names and not be designated by the collective term ''colorings.'' Our regulations in part 501 set forth the requirements for animal food labeling. Under § 501.22(k), animal food manufacturers must declare on the animal food label the presence of certified and noncertified color additives in their animal food products. Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. The purpose of the labeling is to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals.

Description of Respondents: Respondents to this collection of information are manufacturers of animal food products that contain color additives or are manufacturers of food additives.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions					
571.1(c) Moderate Category	6	1	6	3,000	18,000
571.1(c) Complex Category	5	1	5	10,000	50,000
571.6 Amendment of Petition	5	1	5	1,300	6,500

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Investigational Food Additive Files					
570.17 Moderate Category	6	1	6	1,500	9,000
570.17 Complex Category	7	1	7	5,000	35,000
Color Additives					
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification	3,120	0.8292	2,587	*0.25	647
Total Hours					119,147

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (15 minutes).

For the purpose of this consolidation, we base our estimate of the total annual responses on submissions received during fiscal years 2019 and 2020. We base our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

The information collection reflects a net decrease of 70,453 hours (189,600 OMB approved hours—119,147 estimated hours). We also experienced a net increase of 2,587 responses from 35 OMB approved annual responses to 2,616 estimated annual responses. These changes were due to the consolidating of the information collection covered by OMB control number 0910–0721 and due to estimated changes of the number of respondents for food additive petitions and investigational food additive files.

Section 571.1(c) Moderate Category: The estimated time requirement per food additive petition remains at approximately 3,000 hours; however, we now estimate that the number of annual respondents has decreased from 12 to 6 respondents for a total of 18,000 hours.

Section 571.1(c) Complex Category: The estimated time requirement per food additive petition remains at approximately 10,000 hours; however, we now estimate that the number of annual respondents has decreased from 12 to 5 respondents for a total of 50,000 hours.

Section 571.6 Amendment of Petition: We estimated that the number of annual respondents that will submit an amendment has increased from two to five respondents who will each submit one amendment for a total of 6,500 hours. This is an increase of three respondents and 3,900 hours from the burden approved by OMB.

Section 570.17 Moderate Category: We estimated that the number of annual respondents for investigational food additive files has increased from four to six respondents who will each submit one file for a total of 9,000 hours. This is an increase of two respondents and 3,000 hours from the burden approved by OMB.

Section 570.17 Complex Category: We estimated that the number of annual respondents for investigational food additive files has increased from five to seven respondents who will each submit one such file, for a total of 35,000 hours. This is an increase of 10,000 hour from the burden approved by OMB.

Section 501.22(k) Labeling of Color Additive or Lake of Color Additive; Labeling of Color Additives Not Subject to Certification: The information collection reflects an adjustment in burden by 647 hours and 2,587 responses. We attribute this adjustment due to the consolidation of OMB control number 0910–0546 and OMB control number 0910–0721.

Dated: October 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906–0016, Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than November 8, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.