TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA (STIC) BY DRUG—Continued

Drug	Route of administration	Action taken	Therapeutic category	Date
Omadacycline	Injection, Oral	FDA updated disk breakpoints for *Streptococcus pneumoniae* for community acquired bacterial pneumonia.	Antibacterial	8/25/20

Dated: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01693 Filed 1–27–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1022]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 28, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 at §§ 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 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 at §§ 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 at §§ 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.

In the **Federal Register** of October 8, 2021 (86 FR 56277), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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
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 (15 minutes)	647
Total					119,147

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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 hours 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 numbers 0910–0546 and 0910–0721.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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