DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0258]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Regarded As Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Form FDA 3503--21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179 and 180 (OMB Control Number 0910-0016)--Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective. Food Additive Petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of

the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency's regulations specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Under section 201(s) of the FD&C Act (21 U.S.C.321(s)), a substance is generally regarded as safe (GRAS) if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The FD&C Act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). To implement the GRAS provisions of the FD&C Act, FDA has set forth procedures for the GRAS affirmation petition process in § 170.35(c)(1) of its regulations.

While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

Interested persons may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a Master File submitted in support of Petitions according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals. FDA estimates that the amount of time for respondents to complete Form FDA 3503 will continue to be 1 hour.

Description of Respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the Federal Register of April 16, 2014 (79 FR 21469) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden

21 CFR Section/FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
CAPs						
70.25, 71.1	2	1	2	1,337	2,674	$5,600
GRAS Affirmation Petitions						

170.35	1 or fewer	1	1 or fewer	2,614	2,614	0
FAPs						
171.1	3	1	3	7,093	21,279	0
Form FDA 3503	6	1	6	1	6	0
Total					26,573	$5,600

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience with the petition process. FDA is retaining its prior estimate of the number of petitions received because the average number of petitions received annually has varied little over the past 10 years. The figures for hours per response are based on estimates from experienced persons in the Agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of two color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to $5,600 (1 × $2,600 + 1 × $3,000 listing fees = $5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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