naturally occurring cases of diseases or conditions that are identified in the Centers for Disease Control and Prevention's list of category ''A'' biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to prepare each certification. We estimate the operating and maintenance cost of $200 for copying and mailing the information to FDA.

Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare a report disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device and submit it to the health care provider and, where appropriate, to public health authorities.

In the **Federal Register** of April 18, 2017 (82 FR 18294), 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 [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Written certification (sent to FDA)—50.23(e)(3).	150	3	450	0.25 (15 minutes)	113	$200

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Written certification (sent to IRB)—50.23(e)(1) and (2)	150	3	450	2	900
Informed consent information—50.23(e)(4)	150	3	450	1	450
Total	.....	.....	.....	.....	1,350

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

Dated: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17702 Filed 8–21–17; 8:45 am]

BILLING CODE 4164–01–P

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), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503

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 September 21, 2017.

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 and title ''Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila 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: 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), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503—21 CFR 70.25, 71.1, and 171.1, and 21 CFR parts 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) 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 (21 CFR 171.1) specifies the information that a petitioner must submit 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 (21 CFR 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). 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 (21 CFR 71.1) 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 (21 CFR 70.25) require that color additives that are to be used in food, drugs, medical 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, medical devices, or cosmetics.

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 May 30, 2017 (82 FR 24718), 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 [1]

21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Color Additive Petitions						
70.25, 71.1	2	1	2	1,337	2,674	$5,600
Food Additive Petitions						
171.1	3	1	3	7,093	21,279	0
FDA Form 3503	6	1	6	1	6	0
Total					23,959	5,600

[1] There are no capital costs associated with this collection of information.

The estimate of burden for food additive or color additive petitions is based on FDA's experience with the petition process. The burden for this information collection has changed since the last OMB approval because the Generally Recognized as Safe affirmations have been removed pursuant to the implementation of ''Substances Generally Recognized as Safe; Final Rule,'' August 17, 2016 (81 FR 54960), 21 CFR parts 20, 25, 170, 184, 186, and 570. 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 additive and the scope of 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. Labeling 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. Labeling 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: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17703 Filed 8–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Cosmetic Registration Program

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 (PRA).

DATES: Fax written comments on the collection of information by September 21, 2017.

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 0910–0027. 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, 10A63, 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.

Voluntary Cosmetic Registration Program—21 CFR Parts 710 and 720

OMB Control Number 0910–0027—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides us with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C. 361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. We have developed the Voluntary Cosmetic Registration Program (VCRP) to assist us in carrying out our responsibility to regulate cosmetics.

FDA is revising forms for the VCRP (Forms FDA 2511, 2512, 2512a, and 2514) currently approved under OMB control number 0910–0027, ''Voluntary Cosmetic Registration Program,'' for the following reasons: (1) Modernizing the forms; (2) Making it easier for filers who complete the forms; and (3) reducing the time it will take FDA to review each submission. In addition, Form FDA 2514 will be eliminated as it duplicates information that is currently located on Form FDA 2512. FDA requests PRA approval for the proposed changes to these forms, and for the elimination of Form FDA 2514.

Participation in the VCRP is voluntary under provisions found in sections parts 710 and 720 (21 CFR parts 710 and 720). Participants have the option of submitting information via paper forms or via the online interface. The term ''form'' refers to both the paper form and the online system.

Currently, in part 710, we request that establishments that manufacture or package cosmetic products voluntarily register with us using Form FDA 2511 entitled ''Registration of Cosmetic Product Establishment.'' The online version of Form FDA 2511 is available on our VCRP Web site at *https://www.fda.gov/Cosmetics/RegistrationProgram/default.htm.* We strongly encourage online registration with Form FDA 2511 because it is faster and more efficient for the filer and the Agency. A registering facility will receive confirmation of online registration, including a registration number by email. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We place the registration information in a computer database and use the information to generate lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

FDA's proposed changes to the forms through the use of an electronic submission system have been designed to make it easier for participants to provide information to FDA about their products. The system also assists participants, through interactive question and response scenarios, to identify submissions that will be ineligible to be accepted in VCRP because they do not meet parts 710 and 720 requirements. The electronic submission system is expected to reduce burden currently associated with the manual identification process for filers and FDA. The rejection rate for ineligible submissions when using the current forms is high: 51 percent for new accounts, 43 percent for Form FDA 2511 registrations, and 7 percent for Form FDA 2512 filings (2010–2016).

The revised forms include the addition of links between Forms FDA 2511 and 2512, clarification of what information should be entered onto the forms, additional self-identifying fields, removal of certain duplicative fields, and the deletion of Form FDA 2514. These changes are needed because both VCRP voluntary filer participation and FDA resources required to administer VCRP have increased significantly since 2014 (*i.e.,* increases in new accounts (156 percent), Form FDA 2511 registrations (405 percent), Form FDA 2512 filings (67 percent), and FDA review hours (59 percent) in 2016.)

FDA's current process confirms that each submission meets the requirements established in parts 710 and 720 by using a manual process for both filers and FDA reviewers that may result in a long waiting period where filers must wait and respond to questions generated by FDA, which may result in a high rejection rate. FDA projects a significant reduction in rejection rates when using the revised forms. Examples of possible burden savings for participants and FDA include:

(1) Form FDA 2511 asks filers if they are a manufacturer or packer; however, in the past, distributors and retailers have checked these boxes in error when neither applies to them because there are no distributor or retailer checkboxes on Form FDA 2511. Retailers have also filed Form FDA 2512 in error even though only manufacturers, packers,