United States Food and Drug Administration

Color Additive Certification

OMB Control No. 0910-0216

SUPPORTING STATEMENT

EXTENSION

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations governing certification for color additives used in foods, drugs, cosmetics, and medical devices. All color additives must have FDA-approval for their intended use and be listed in the color additive regulations before they are permitted for use in food, drugs, cosmetics, and many medical devices. Some color additives have an additional requirement: they are permitted only if they are from batches that FDA has certified under section 721(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(a)). This means that FDA chemists have analyzed a sample from the batch and have found that it meets the requirements for composition and purity stated in the regulation, called a "listing regulation," for that color additive. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are established in 21 CFR part 80. Procedures for color additive certification are set forth in part 80, subpart B (§§ 80.21 through 80.39) and communicate required data elements for requests for certification, limitations of certificates, exemptions from certification for color additive mixtures, treatment of batches pending and after certification, and recordkeeping requirements for respondents to whom a certificate is issued. During the batch certification procedure, a manufacturer of color additives must submit a "request for certification" that provides information about the batch, accompanied by a representative sample of a new batch of color additive, to FDA's Office of Cosmetics and Colors in the Office of the Chief Scientist. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate that contains a certification lot number for the batch. The batch can then be used in FDA-regulated products marketed in the United States, in compliance with the uses and restrictions in that color additive's listing regulation. If the sample doesn't meet the requirements, we reject the batch. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification. The user fees support FDA's color certification program. Additional information about color additive certification is available at: https://www.fda.gov/industry/color-additives/color-certification.

A request for certification must include information such as the name of color additive, manufacturer's batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. A request for certification must also include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show the name of color additive, manufacturer's batch number and quantity, and name and address of person requesting certification. In addition, the person to whom a certificate is issued must keep complete records showing the disposal of all of the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR §§ 80.21, 80.22, and 80.39, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose for collecting this information is to help us assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. As described above, our regulations require that a representative sample of each new batch of color additive, accompanied by a "*request for certification*" that provides information about the batch be submitted to FDA's Office of Cosmetics and Colors in the Office of the Chief Scientist. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch.

The manufacturer's batch number is used for temporarily identifying a batch of color additive until we issue a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been refused certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-rejected color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations.

Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. We check storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

Description of Respondents: The respondents include businesses engaged in the manufacture of color additives used in FDA-regulated foods, drugs, cosmetics, and medical devices. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FDA's web-based Color Certification information system is available for respondents to request color certification online, track their submissions, and obtain account status information. Prior to

submitting a request for certification, the manufacturer must open a color certification account by sending a letter, as an email attachment, signed by responsible company representative, to FDA's Office of Cosmetics and Colors in the Office of the Chief Scientist at color.cert@fda.hhs.gov. System certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates. Any delays in the system result are only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that ten percent (10% or 7 total) of respondents are small businesses. The reporting and recordkeeping requirements of these regulations are mandated by the FD&C Act, and there is no statutory exception for small businesses. We assist small businesses in understanding and complying with FDA requirements through the agency's scientific and administrative staff. We also provide resources and assistance through the FDA Small Business Assistance webpage at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. Without this information, we could not assure the safety of batches of color additives.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of April 10, 2026 (91 FR 18464). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Freedom of Information Act

Sections 80.21, 80.22, and 80.39 do not specify confidentiality. However, we consider the information collected in the requests for color additive certification to be privileged commercial information exempt from release under the provisions of the Freedom of Information Act (FOIA) to the maximum extent permitted by statute and FDA regulations. Confidentiality of the information submitted is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The information also is safeguarded by section 301(j) of the FD&C Act (21 U.S.C. 331(j)). Accordingly, all color additive certification files are maintained in a secured area.

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This information collection request (ICR) collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via the Color Additive Certificate includes point of contact name and business address. The PII submitted for electronic request for certification includes point of contact name, business email address, and business telephone number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
80.21 and 80.22; Request for certification accompanied by sample	67	112	7,504	0.22 (13 minutes)	1,651

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section; Activity	Number of Recordkeepers	Number of Records per Recordkeeping	Total Annual Records	Average Burden per Recordkeeping	Total Hours
80.39; Records of distribution	67	112	7,504	0.25 (15 minutes)	1,876

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

Under § 80.21 (21 CFR 80.21), a request for certification must include: name of color additive, manufacturer's batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. Under § 80.22 (21 CFR 80.22), a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show name of color

additive, manufacturer's batch number and quantity, and name and address of person requesting certification. Under § 80.39 (21 CFR 80.39), the person to whom a certificate is issued must keep complete records showing the disposal of all of the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive

We base our estimate on our review of the certification requests received over the past 3 years. Using information from industry personnel, we estimate that an average of 0.22 hours per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hours per response is required for recordkeeping.

The burden hour total for this ICR is 3,527 hours (1,651 reporting hours + 1,876 recordkeeping hours).

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is $346,139.78 per year. We estimate that the average hourly wage for the employee preparing and submitting the request for certification would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2026, $49.07/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $98.14/hour. Thus, the overall estimated cost incurred by the respondents is $346,139.78 (3,527 burden hours x $98.14/hour).

Table 3.--Estimated Annual Reporting Cost Burden

21 CFR Section; Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
80.21 and 80.22; Requesting certification accompanied by a sample	1,651	$98.14	$162,029.14
80.39; Record of distribution	1,876	$98.14	$184,110.64
Total			$346,139.78

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Section 721(e) of the FD&C Act (21 U.S.C. 379e(e)) requires FDA to charge fees sufficient to provide, maintain, and equip an adequate color additive certification service. FDA charges certification fees based on batch weight in accordance with 21 CFR 80.10.

The estimated annual cost to FDA to administer the color additive certification program is $10.9 million. These costs are expected to be fully offset by certification fees, resulting in no net cost to the Federal Government.

15. Explanation for Program Changes or Adjustments

There have been no program changes or adjustments to the information collection since our last request for OMB approval.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated. No comprehensive tabulation of the data is planned or anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We have no reason for not displaying the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.