UNITED STATES FOOD AND DRUG ADMINISTRATION

Color Additive Certification Requests and Recordkeeping

OMB Control No. 0910-0216

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. Color additives that have been shown to be safe for their intended use are listed in Title 21 of the Code of Federal Regulations (CFR). Batch certification for all color additives are 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 information collection requirements for color additive certification are described in 21 CFR part 80. In the certification procedure, a representative sample of a new batch of color additive, accompanied by a "*request for certification*" that provides information about the batch, must be submitted to FDA's Office of Cosmetics and Colors. 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. We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification.

Form FDA 3000 is a certificate that we issue to the respondent after the submission of information and therefore we do not include an estimate of burden associated with this instrument. 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

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. The purpose for collecting this information is to help FDA assure that only safe color additives will be used in FDA-regulated foods, drugs, cosmetics, and medical devices. 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. 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. The agency estimates that about ninety-five percent (95%) of the "*requests for certification*" will be submitted electronically in the next three years.

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 4 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 aid small businesses in complying with FDA requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We provide Small Business assistance resources on our website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The information in a request for color additive certification is required by the FD&C Act and implementing regulations. Without this information, we could not assure the safety of batches of color additives. This information is collected once for each new batch of a color additive and therefore cannot be collected less frequently.

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 16, 2020 (85 FR 21250). 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

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 that 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.

Privacy Act

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. This information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. Information is collected when a company sends in a letter on company letterhead to request color certification. The PII collected is name and address of the person requesting certification. PII is collected in the context of the individual's professional capacity. The purpose of the collection is to help assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the U.S. The collection of information for this ICR is found in section 721(a) of the FD&C Act (21 U.S.C. 379e(a)). The information collection requirements for color additive certification are described in 21 CFR part 80 (§§ 80.21 and 80.22).

We 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, we do not use name or any other personal identifier to retrieve records from the information collected.

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; Request for certification	38	198	7,524	0.17 (10 minutes)	1,279
80.22; Samples to accompany requests for certification	38	198	7,524	0.05 (3 minutes)	376
Total					1,655

[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	38	198	7,524	0.25 (15 minutes)	1,881

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

We base our estimate on our review of the certification requests received over the past 3 years. The annual burden estimate for this information collection is 3,536 hours. We processed an average of 7,524 responses (requests for certification of batches of color additives) per year. There were 38 different respondents, corresponding to an average of approximately 198 responses from each respondent per year. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is $292,568.64 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 2020, $41.37/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $82.74/hour. Thus, the overall estimated cost incurred by the respondents is $292,568.64 (3,536 burden hours x $82.74/hour).

21 CFR Section; Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
80.21; Requesting certification	1,279	$82.74	$105,824.46
80.22; Providing sample with request	376	$82.74	$31,110.24
80.39; Record of distribution	1,881	$82.74	$155,633.94
Total			$292,568.64

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)) provides that fees must be charged for color additive certification "as may be necessary to provide, maintain, and equip an adequate service for such purposes." Thus, it is required by law that there be no cost to the federal government for color additive certification. As noted above, we charge a fee for certification based on the batch weight in accordance with § 80.10 (21 CFR 80.10).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since last OMB approval, we have made no adjustments to our burden estimate.

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 approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.