Color Additive Certification Requests and Recordkeeping

0910-0216

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

We have regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. 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. 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 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.

We request the extension of OMB approval for the following collection of information requirements:

21 CFR 80.21 -- Reporting
Under § 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.

21 CFR 80.22 -- Reporting
Under § 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.

21 CFR 80.39 -- Recordkeeping
Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all 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 the color additive.

2. Purpose and Use of the Information Collection

As described above, FDA's 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 FDA issues 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. FDA checks 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 likely 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

On February 13, 2006, FDA introduced a Web-based Color Certification information system. The system was fully operational for FY 2007. This system allows submitters to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hard copy certificates. Any delays in the system result 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

To the best of our knowledge, no other federal government agency is engaged in the collection of

this information. No other government agency has either the need or the authority to request the information required in a request for certification of a color additive. There can be no duplicative collection of this information because the required information is unique to the batch of color additive that is the subject of a request for certification.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10%) 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. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

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, FDA 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), FDA published a 60-day notice for public comment in the Federal Register of February 6, 2014 (79 FR 7199). FDA received no comments in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does 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, FDA considers 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.

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 Costs

Description of Respondents: The likely 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).

12 a. Annualized Hour Burden Estimate

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

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
80.21; Request for certification	35	199	6,965	0.17	1,184
80.22; Samples to accompany requests for certification	35	199	6,965	0.05	348
Total				0.22	1,532

[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	No. of Recordkeepers	No. of Records per Recordkeeping	Total Annual Records	Average Burden per Recordkeeping	Total Hours
80.39; Records of distribution	35	199	6,965	0.25	1,741

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

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 3,273 hours. The estimated reporting burden for this information collection is 1,532 hours and the estimated recordkeeping burden for this information collection is 1,741 hours. From FY 2011 to FY 2013, FDA processed an average of 6,954 responses (requests for certification of batches of color additives) per year. There were 35 different respondents, corresponding to an average of approximately 199 responses from each respondent per year. Using information from industry personnel, FDA estimates 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.

FDA's Web-based color certification information system allows submitters to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA has estimated an increase in the estimated burden for reporting and recordkeeping. In Table 1, the number of respondents increased from 32 to 35. Also the number of responses increased from 5,932 to 6,965. In Table 2, the number of recordkeepers increased from 32 to 35 as well. Also, the number of records increased from 5,932 to 6,965.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $237,161.58 per year. FDA estimates 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 2014, approximately $36.23/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $72.46/hour. Thus, the overall estimated cost incurred by the respondents is $237,161.58 (3,273 burden hours x $72.46/hour = $237,161.58).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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, FDA charges 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

This is an extension request in which both the total annual number of responses/records and the total annual hour burden are being increased. The total annual number of responses/records increased from 17,760 to 20,895 responses/records (**an increase of 3,135**) and the total annual hour burden has increased from 2,782 to 3,273 hours (**an increase of 491**). The increase was due to industry growth, resulting in an increased number of respondents and recordkeepers. Thus, we are characterizing the increases as adjustments.

For IC#1, we estimate that the number of respondents have increased from 32 to 35, causing the annual number of responses to increase from 5,920 to 6,965 (an increase of 1,045) and the annual hour burden to increase from 1,006 to 1,184 (an increase of 178). We are characterizing the increase as an adjustment because it is based on the increase in the number of reports received by FDA in FY 2011, FY 2012, and FY 2013, caused by industry growth.

For IC#2, we estimate that the number of respondents have increased from 32 to 35, causing the annual number of responses to increase from 5,920 to 6,965 (an increase of 1,045) and the annual hour burden to increase from 296 to 348 (an increase of 52). We also are characterizing this increase as an adjustment because it is based on the increase in the number of reports received by FDA in FY 2011, FY 2012, and FY 2013.

For IC#3, we estimate that the number of recordkeepers have increased from 32 to 35, causing the annual number of records to increase from 5,920 to 6,965 (an increase of 1,045) and the annual hour burden to increase from 1,480 to 1,741 (an increase of 261). We are characterizing the increase as an adjustment because it is based on the increase in the number of records maintained by industry in FY 2011, FY 2012, and FY 2013.

Table 3—Summary of Change in Responses and Hour Burden		
IC Number	Change in Responses	Change in Hour Burden
IC#1	1,045	178
IC#2	1,045	52
IC#3	1,045	261
Total Change	3,135	491

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive tabulation of the data is planned or anticipated.

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

FDA has 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.