

**SUPPORTING STATEMENT FOR INFORMATION COLLECTION
“COLOR ADDITIVE CERTIFICATION REQUESTS AND RECORDKEEPING”
OMB No. 0910-0216**

Part A. – JUSTIFICATION.

1. Circumstances Which Make This Information Collection Necessary.

The Food and Drug Administration (FDA) has 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 act) (Attachment 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. FDA lists color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). FDA requires 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 (Attachment A). 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 (OCAC). 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. FDA charges a fee for certification based on the batch weight and requires manufacturers to keep records of the batch pending and after certification.

The color additive certification regulations in 21 CFR part 80 that require information collection are summarized as follows:

§ 80.21 Request for certification. – 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.

§ 80.22 Samples to accompany requests for certification. – 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 weight in pounds, and name and address of the person requesting certification. The sample must be accompanied by a copy of the label or labeling to be used for the batch when it is sold.

§ 80.39 Records of distribution. – 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 of the color additive.

2. How, By Whom, and the Purpose for Collecting This Information.

21 CFR 80.21 describes how to submit the information required in a request for certification of a new batch of color additive. FDA personnel summarize the submitted information on Form FDA 3000 “Color Additive Certificate” (Attachment B).

The purpose for collecting this information is to help FDA assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification.

Some uses for the information required in 21 CFR part 80 are summarized as follows:

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.

3. Use of Technology to Reduce the Burden on the Public.

FDA continually seeks ways to reduce reporting burden through advances in information technology. Because the information is submitted in the form of a letter, OCAC has found that many respondents compile and arrange their submissions by personal computer using word processing software. Submission capability by this medium reduces the reporting burden for respondents.

4. Identification and Use of Duplicate 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.

5. FDA's Efforts to Reduce Burden on Small Business.

This information collection may include small businesses. The information needed to assure the safety of certifiable color additives is established by the act, and there is no authority to modify the information criteria based on the size of a business. However, data collection and recordkeeping are expected to increase with the size of a color additive manufacturer and the number of batches of color additive certified. Large manufacturers with large production capacity submit the vast majority of requests for certification. Small manufacturers submit correspondingly smaller numbers of requests. FDA aids small businesses in complying with certification requirements through the Office of Small Manufacturers Assistance and through its scientific and administrative staffs.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently.

The information in a request for color additive certification is required by the 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 That Occur When Collecting This Information.

No special circumstances occur when collecting this information.

8. Identification of Outside FDA Sources.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 26, 2004 (69 FR 8977) (Attachment C). No comments were received.

FDA personnel are in continuous communication with representatives of the regulated industry by mail, email, telephone, and occasional personal visits. In addition, FDA

conducts regular inspections of domestic certifiable color additive manufacturers, usually every 3 years. An integral part of these inspections is a discussion period in which manufacturer personnel and the FDA inspectors exchange questions and viewpoints. FDA has received no complaints about the format or the content of the information required in requests for certification. FDA personnel have never heard any objections to furnishing this information and FDA has received no written communications or requests for reviews of this information collection. Industry representatives ask about FDA's certification analytical procedures and regulatory decisions. In addition, FDA receives questions from new companies seeking help with first time certification requests.

9. Payment or Gifts Offered to Respondents.

There are no payments or gifts offered to respondents.

10. Method of Assuring Respondent Confidentiality.

Because information that is considered of a competitive nature is collected in the requests for color additive certification and summarized on FDA Form 3000, all color additive certification files are maintained in a secured area. Only information that is found to be releasable under FDA compliance with the Freedom of Information Act is released to the public. The information also is safeguarded by Section 301(j) of the act.

11. Use of Sensitive Questions.

Requests for color additive certification do not include use of sensitive questions.

12. Burden Hours and Cost Associated with This Information Collection.

(a) Hour Burden Estimate

The annual hour burden estimate for this information collection is 2,302 hours. The estimated annual reporting burden for this information collection is 1,151 hours and the estimated annual recordkeeping burden for this information collection is 1,151 hours. From fiscal year (FY) 2001 to FY 2003, FDA processed an average of 4,603 responses (requests for certification of batches of color additives) per year. There were 23 different respondents, corresponding to an average of approximately 200 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.25 hour per response is required for reporting (preparing certification requests and accompanying sample labels) and an average of 0.25 hour per response is required for recordkeeping.

The following tables summarize the annual hour burden estimate for this information collection:

Table 1. –Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80.21	23	200	4,603	0.20	921
80.22	23	200	4,603	0.05	230
Total				0.25	1,151

Table 2. –Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
80.39	23	200	4,603	0.25	1,151
Total					1,151

(b) Hour Cost Burden

The annual hour cost burden to respondents is approximately \$64,456 per year. This cost is estimated using an hourly wage of \$28 per hour (corresponding to a GS-12, step 1, federal government hourly salary), and 2,302 burden hours times \$28 per hour equals \$64,456.

From FY 2001 to FY 2003, FDA collected fees averaging approximately \$4.8 million per year for color additive certification. Therefore, the annual hour cost burden of this information collection is approximately 1.3% of the annual cost of obtaining color additive certification.

13. Annual Cost Estimate to Respondents.

There are no capital costs or operating and maintenance costs associated with this information collection.

14. Annual Cost Estimate to FDA.

Section 721(e) of the act 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. The fees for certification services are given in 21 CFR 80.10.

15. Changes from Previous Approval.

The change in annual hour burden is an increase of 130 hours over that of the previous approval. The number of batches certified per year over the last few years has remained

relatively steady and it is anticipated that this overall trend will continue. The increase in burden is due to an average increase in sales by the color additive manufacturers.

The change in annual hour burden cost is an increase of \$20,996 over that of the previous approval. This is due to an average increase in sales by the color additive manufacturers and estimated cost of living increases.

16. Publishing the Results of this Information Collection.

No comprehensive tabulation of the data is planned or anticipated.

17. Reason for Not Displaying the OMB Approval Date.

FDA has no reason for not displaying the OMB approval date.

18. Explanations to Section 19, “Certification for Paperwork Reduction Act Submissions.”

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I, “Certification for Paperwork Reduction Act Submissions.”

Part B. – COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection does not employ statistical methods.