4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2986]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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.

Color Additive Certification

OMB Control Number 0910-0216--Extension

This information collection supports FDA 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 (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. 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 does not meet the requirements, the batch will be rejected. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

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 at color.cert@fda.hhs.gov. System certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates.

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.

The purpose for collecting this information is to help the Agency assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States.

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).

In the *Federal Register* of August 10, 2023 (88 FR 54329), 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; Activity	No. of Respondents	No. 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	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
80.39; Record 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.

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 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.

Based on a review of the information collection since our last request for OMB approval, we have slightly decreased our burden estimate based on our experience with this program. As a result, although the number of respondents increased, the number of responses per respondent decreased.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-22971 Filed: 10/17/2023 8:45 am; Publication Date: 10/18/2023]