



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. FDA-2022-N-1635]

Color Additive Certification; Increase in Fees for Certification Services; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the reopening notice entitled “Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period” that appeared in the *Federal Register* of April 26, 2024. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice “Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period” published in the *Federal Register* of April 26, 2024 (89 FR 32384). Either electronic or written comments must be submitted by June 27, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 27, 2024. Comments received by mail/hand delivery/courier (for written paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2022-N-1635 for “Color Additive Certification; Increase in Fees for Certification Services; Extension of the Comment Period.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Bryan Bowes, Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors (HFS-105), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1122; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 2, 2022 (87 FR 66116), FDA published a proposed rule to amend the color additive regulations to increase the fee for certification services. On April 26, 2024, we published a notice of reopening entitled “Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period” (89 FR 32384). We reopened the comment period because we added supporting information to the administrative record and adjusted the administrative record to reflect the same cost and benefits figures that were published in the preliminary regulatory impact analysis. This action invited public comments on the new information and provided a 30-day comment period.

FDA received a request for a 90-day extension of the comment period for the reopening notice. We are extending the comment period for 30 days until June 27, 2024. The Agency believes that the extension is reasonable and allows adequate time for interested parties to review the supporting information added to the administrative record and to develop and submit additional comments to the proposed rule.

Dated: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-11639 Filed: 5/24/2024 8:45 am; Publication Date: 5/28/2024]