4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

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

RIN 0910-AI69

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule, "Color Additive Certification; Increase in Fees for Certification Services," which published in the *Federal Register* of November 2, 2022. We are taking this action to add supporting information to the administrative record and to adjust the record to reflect the same cost and benefits figures that were published in the preliminary regulatory impact analysis. We are reopening the comment period for 30 days specifically to invite public comments on the new information being added to the administrative record.

DATES: FDA is reopening the comment period on the proposed rule "Color Additive Certification; Increase in Fees for Certification Services," which published in the *Federal Register* on November 2, 2022 (87 FR 66116). Either electronic or written comments must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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; Reopening 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." We will review this copy, including the claimed confidential information, in our 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, Office of Cosmetics and Colors (HFS-105), Center for Food Safety and Applied Nutrition, 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. The change in fees would allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act. The fees are intended to recover the full costs of operation of FDA's color certification program. We originally gave interested persons until January 3, 2023, to provide comments on the proposed rule. On January 24, 2023, in response to a stakeholder request, we reopened the comment period for an additional 45 days to allow interested parties more time to collect, analyze, and incorporate data and submit comments to the proposed rule.

Subsequently, we determined that additional supporting information should be included in the administrative record. Therefore, we are adding a Color Certification Fee Study (March 2024) to the administrative record that further explains the basis for the proposed rule. The fee study documents the need for increased fees and outlines the basis on which we developed the fee schedule in the proposed rule. We are adding the fee study to the administrative record and reopening the comment period for 30 days to provide the public an opportunity to comment on the document. Comments are invited, and will be considered, only to the extent they are focused on the information being newly added to the record.

Additionally, for transparency, we are adjusting the Preliminary Economic Analysis of Impacts, in Section V. B. Summary of Costs and Benefits (87 FR 66116 at 66118). The

proposed rule did not include the same estimates that were published in the Preliminary Regulatory Impact Analysis (PRIA) listed in the reference section (87 FR 66116 at 66119). The PRIA, entitled "Color Additive Certification; Increase in Fees for Certification Services" Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, and available at https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria describes the estimates of the costs and benefits of the proposed rule.

Consistent with the published PRIA, Section V.B. Summary of Costs and Benefits should read as follows:

This proposed rule, if finalized, would amend existing color additive regulations by increasing fees for certification services. The fee schedule for color additive certification, as provided for in this proposed regulation, is designed to cover all the costs of operation of FDA's color certification program. This includes both the cost of specific tests required by the regulations and the general costs associated with the certification program, such as the costs of accounting, reviewing data, issuing certificates, conducting research, inspecting establishments, and purchasing and maintaining equipment. The fee for certification services of straight colors including lakes would increase from $0.35 per pound to $0.45 per pound, with the minimum fee increasing from $224 to $288. The fees for repacks of certified color additives and color additive mixtures would increase from $35 for 100 pounds or less to $45 for 100 pounds or less. The fee for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds would increase from $35 plus $0.06 for each pound over 100 pounds to $45 plus $0.08 for each pound over 100 pounds. The fee for repacks of certified color additives and color additive mixtures over 1,000 pounds would increase from $89 plus $0.02 for each pound over 1,000 pounds to $114 plus $0.03 for each pound over 1,000 pounds.

The economic burdens of this proposed rule, if finalized, would accrue to color additive manufacturers. We estimate a one-time cost to read and understand the rule for all color additive

manufacturers. The present value of this cost is approximately $2,307 at a 3 percent rate of discount, and $2,221 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately $270 at a 3 percent discount rate and $316 at a 7 percent discount rate. Because the value of these impacts is small relative to manufacturer revenues, we assume that the supply of color additives would not be affected by this proposed rule. Consequently, we estimate no other impacts associated with this proposed rule.

As noted in the preamble, the fees are intended to recover the full costs of operation of FDA's color certification program. Since 2005, the costs of the certification program significantly increased as a result of escalating staff payroll, rent and facility charges, as well as general operational expenses including purchasing and maintaining equipment. As the increase in fees is not associated with any change in the FDA certification program, no economic benefits are expected to result from the proposed rule. Similarly, the impact of the increase in certification fees on color additive manufacturers is considered a transfer, rather than an economic cost. Accordingly, we do not estimate economic benefits associated with this proposed rule, and the impact of the increase in color certification fees is estimated as an ongoing transfer from manufacturers of color additives to the federal government. Our estimates are summarized in Table 1, below.

Table 1--Summary of Benefits, Costs, and Distributional Effects of Proposed Rule (Millions of 2020 Dollars over 10-year Time Horizon)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $/year	$0.00032			2020	7%	10 years	
		$0.00027			2020	3%	10 years	
	Annualized Quantified					7%		
						3%		

	Qualitative							
Transfers	Federal Annualized Monetized $/year	$2.46			2020	7%	10 years	
		$2.46			2020	3%	10 years	
	From/ To	From: Manufacturers of color additives			To: Federal Government			
	Other Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No effect							
	Small Business: The proposed rule, if finalized, would generate costs to small businesses, as well as transfers from small businesses to FDA that we treat as costs from the perspective of the small business. On average, these costs amount to approximately 0.2733% of annual average revenues of the small firms in the affected industry.							
	Wages: No effect							
	Growth: No effect							

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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