auditor must, as soon as practical, report through the methods indicated below, all instances of fraud, illegal acts, and all indications or instances of noncompliance with laws, whether material or not, to:

(1) The president of the auditee's governance board via the auditor's preferred method;

(2) RUS via email;

(3) OC–ECD via email; and

(4) OIG, as follows:

(i) For all audits performed in accordance with § 1773.3(d) (audits conducted in accordance with 2 CFR part 200), report to the USDA–OIG–Audit, National Single Audit Coordinator for USDA, 1400 Independence Ave. SW, Ste. 419, Washington, DC 20250, email: *OIG-USDAsingleaudit@oig.usda.gov,* or online at: *http://usdaoig.oversight.gov.*

(ii) For all other audits conducted in accordance with § 1773.3 report to the USDA Office of Inspector General online at: *https://usdaoig.oversight.gov.*

Subpart C—RUS Requirements for the Submission and Review of the Reporting Package

■ 7. Amend § 1773.21 by revising paragraph (d) to read as follows:

§ 1773.21 Auditee's review and submission of the reporting package.

* * * * *

(d) The auditee must include a complete reporting package as defined in § 1773.2.

* * * * *

Subpart D—RUS Reporting Requirements

■ 8. Amend § 1773.32 by revising paragraph (a) and removing paragraph (d).

The revision reads as follows:

§ 1773.32 Reports on internal control; compliance with provisions of laws, regulations, contracts, and grant agreements; and instances of fraud.

(a) As required by GAGAS, the auditor must prepare a written report describing the scope of the auditor's testing of internal control over financial reporting and of compliance with provisions of laws, regulations, contracts, and grant agreements, and state whether the tests provided sufficient, appropriate evidence to support opinions on the effectiveness of internal control and on compliance with provisions of laws, regulations, contracts, and grant agreements. This report must include the manual or printed signature of the audit firm and must include the following items as appropriate:

(1) Significant deficiencies and material weaknesses in internal control;

(2) Identified or suspected instances of noncompliance with provisions of laws, regulations, contracts and grant agreements that have a material effect on the financial statements or other financial data significant to the audit objectives and any other instances that warrant the attention of those charged with governance;

(3) Identified or suspected instances of fraud that have a material effect, either quantitatively or qualitatively, to the financial statements or other financial data significant to the audit objectives; and

(4) Identified or suspected instances of abuse that have a material effect, either quantitatively or qualitatively, to the financial statements or other financial data significant to the audit objectives.

* * * * *

■ 9. Revise § 1773.34 to read as follows:

§ 1773.34 Schedule of findings and recommendations.

The auditor must prepare a schedule of findings and recommendations to be included with the reports on internal control; compliance with laws, regulations, contracts, and grant agreements; and instances of fraud. The report must contain the status of known but uncorrected deficiencies from prior audits that affect the current audit objective. The schedule of findings and recommendations shall be developed and presented utilizing the elements of a finding discussed in GAGAS and shall include recommendations for remediation. If the schedule does not include responses from management, as well as any planned corrective actions, those items must be submitted directly to RUS by management in accordance with § 1773.4(j).

Subpart E—RUS Audit Requirements and Documentation

■ 10. Revise § 1773.40 to read as follows:

§ 1773.40 Regulatory assets.

The auditor's audit documentation shall support that the auditor tested whether all regulatory assets comply with the requirements of FASB Accounting Standards Codification (ASC) 980 or GASB Statement (GASBS) 62, as appropriate. For Electric auditees only, the auditor's audit documentation shall support that all regulatory assets have received RUS approval.

■ 11. Revise § 1773.45 to read as follows:

§ 1773.45 Regulatory liabilities.

The auditor's audit documentation shall support that all regulatory liabilities comply with the requirements of FASB Accounting Standards Codification (ASC) 980 or GASB Statement (GASBS) 62, as appropriate. For electric auditees only, the auditor's audit documentation shall document whether all regulatory liabilities have received RUS approval.

Andrew Berke,

Administrator, Rural Utilities Service, Rural Development.

[FR Doc. 2024–25914 Filed 11–7–24; 8:45 am]

BILLING CODE 3410–15–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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the regulation setting fees for color additive certification services to increase these fees. This increase will allow FDA to continue to provide, maintain, and equip an adequate color additive certification program as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This rule is effective December 9, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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:

With regard to the final rule: Bryan Bowes, Office of the Chief Scientist, Office of Cosmetics and Colors, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1122; or Carrol Bascus, Office of Policy, Regulations and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The Food and Drug Administration (FDA or we) is amending the regulation setting fees for color additive certification services to increase these fees. This increase will allow FDA to continue to provide, maintain, and equip an adequate color additive certification program as required by the FD&C Act. The fees will help to recover the full costs of operating FDA's color additive certification program.

B. Summary of the Major Provisions of the Final Rule

The final rule amends the color additive regulation to increase the fees for certification services. The fees for straight colors including lakes will be $0.45 per pound ($0.10 per pound increase) with a minimum fee of $288. There will be similar increases in fees for repacks of certified color additives and color additive mixtures.

C. Legal Authority

We are issuing the final rule consistent with our statutory authority, under the FD&C Act, which requires fees to provide, maintain, and equip an adequate color additive certification program, as specified in our regulations.

D. Costs and Benefits

The final rule amends existing color additive regulations to increase fees for certification services. The costs of the rule include the cost to read and understand the rule. As the increase in fees is not associated with any change in our certification program, no economic benefits are expected to result from the final 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 final 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. The economic burden of the final rule accrues 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 $5,384 at a 3 percent rate of discount, and $5,183 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately $631 at a 3 percent discount rate and $738 at a 7 percent discount rate.

II. Background

A. Need for the Regulation/History of the Rulemaking

In accordance with section 721(a)(1)(B) of the FD&C Act (21 U.S.C. 379e(a)(1)(B)), certain color additives must be certified for use by FDA in food, drugs, cosmetics, and certain medical devices. Section 721(e) of the FD&C Act provides in relevant part that the certification of color additives must only be performed upon payment of fees, to be specified by regulation, as necessary to provide, maintain, and equip an adequate service for such purpose. When certifying a color additive, FDA analyzes samples from each batch of color additive received from a manufacturer and verifies that it meets composition and purity specifications. FDA certification is necessary before color additives that are subject to certification are permitted to be used in these FDA-regulated products. Under the color additive certification fee regulation, manufacturers pay fees, based on the weight of each batch for certification. These fees support the full costs of operating FDA's color additive certification program.

The current fee schedule specified in part 80 (21 CFR part 80) became effective in 2005 (and was amended in 2006 to correct a typographical error). Since 2005, the costs of the certification program have significantly increased because of the increase in general operating expenses, including the purchase and maintenance of critical equipment, rent and facility charges, and staff payroll. Therefore, in the **Federal Register** of November 2, 2022 (87 FR 66116), we published a proposed rule to amend the color additive regulation to increase the fees for certification services. The change in fees will allow FDA to continue to provide, maintain, and equip an adequate color additive certification program as required by section 721(e) of the FD&C Act. We proposed to increase the fees for certifying color additives to reflect increasing operating costs for the certification program. The fee schedule for color certification, as provided for in our regulations, is designed to cover all the costs involved in certifying batches of color additives. This includes the cost of specific tests required by the regulations and the general costs associated with the certification program, such as costs of accounting, reviewing data, issuing certificates, conducting research, inspecting establishments, and purchasing and maintaining equipment. The current fee schedule is insufficient to provide, maintain, and equip an adequate color additive certification program. As fees have not kept pace with inflation, we have struggled to recover the full costs of operating FDA's color certification program, resulting in a financial shortfall for the program.

Our Color Certification Fee Study (Fee Study) (Ref. 1) provides data and information about the current financial condition of the color additive certification program. As noted in our Fee Study, in recent years, successful operation of color certification activities has relied upon prior year carryover funding to address a deficit between program expenses and annual fee collections. This is not sustainable because carryover funding and annual fee collections are diminishing due to increased costs and low collections.

Therefore, the fee increase will help to ensure that collected fees are sufficient to fund the full cost of our color certification activities. Consistent with section 721(e) of the FD&C Act, the fee increase in the final rule is necessary to cover rising operating costs and maintain an adequate color additive certification program.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 60-day comment period. Based on a request from stakeholders, we re-opened the comment period for an additional 45 days (88 FR 4117 (January 24, 2023)). In April 2024, we reopened the comment period a second time to add the Fee

Study to the docket (89 FR 32384 (April 26, 2024)). In May 2024, based on a request from stakeholders, we extended the comment period again for 30 days (89 FR 46042 (May 28, 2024)). We received fewer than 15 comments on the proposed rule. The comments were from individuals and an industry trade association. A few comments supported the rulemaking. Other comments raised questions and concerns about our rationale for the $0.10 per pound increase. The comments urged FDA to provide supporting data to justify the need for the fee increase.

We address the comments in more detail in section IV.

C. General Overview of the Final Rule

This final rule revises § 80.10, ''Fees for certification services,'' to:

- increase the fee for certification services from $0.35 to $0.45 per pound for straight colors including lakes, and change the minimum fee from $224 to $288 (§ 80.10(a));
- increase the fees for repacks of certified color additives and color additive mixtures from $35 for 100 pounds or less to $45 (§ 80.10(b)(1));
- increase the fees for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds, from $35 plus $0.06 for each pound over 100 pounds to $45 plus $0.08 for each pound over 100 pounds (§ 80.10(b)(2)); and
- increase the fees for repacks of certified color additives and color additive mixtures over 1,000 pounds from $89 plus $0.02 for each pound over 1,000 pounds to $114 plus $0.03 for each pound over 1,000 pounds (§ 80.10(b)(3)).

The fee increase will help to ensure the continued viability of an adequate certification program in accordance with section 721(e) of the FD&C Act.

III. Legal Authority

FDA is issuing this final rule consistent with our authority under section 721(e) of the FD&C Act which requires that fees necessary to provide, maintain, and equip an adequate color additive certification program be specified in our regulations. FDA is also issuing this final rule under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received fewer than 15 comments on the proposed rule. The comments were from individuals and an industry trade association. Some comments supported the rulemaking, including a few that expressed general support without focusing on a particular provision in the proposed rule. Other comments questioned the fee increase and asked that we provide additional information to support the increase in fees. Some comments expressed concerns about our rationale for the $0.10 per pound increase for straight colors including lakes and urged FDA to explain the need more thoroughly for the fee increase. One comment suggested that we consider an alternative increase of $0.05 per pound instead of the proposed fee of $0.10 per pound, which they stated, would significantly impact costs for color manufacturers. Another comment questioned if the color certification fee is used only to fund activities that support color certification. A comment also argued that annual financial reserves would be sufficient to allow the program to operate with no additional fee increase.

We describe and respond to the comments in section B of this document. We numbered each comment to help distinguish between different comments. We grouped similar comments together under the same number, and, in some cases, we separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of Comments and FDA Response

(Comment 1) A few comments expressed general support for FDA's color additive certification program. The comments stated that the regulations, ''particularly for food and cosmetics products are necessary to ensure the safety and well-being of Americans.'' With respect to the proposed fee increase in the proposed rule, one comment stated that the proposed rule ''would aid funding of a federal agency, but it would take into account recent inflation.'' Another comment noted that ''recovering the operational costs will provide the FDA with more resources to test and evaluate color additives in consumer products, which could help protect public health.''

(Response 1) We agree that the final rule will help FDA's color additive certification program by covering the increased costs of certifying the color additives. The fee increase will also benefit public health by maintaining an adequate certification program that continues to ensure the safety of the color additives used in food and other products.

(Comment 2) One comment stated that ''there does not seem to be reason for the sudden want to increase the fees.'' It suggests that the process for analyzing color additives has not changed much and asserts that ''an explanation that more thoroughly explains the need to spend more on analyzing color additives'' should be provided.

(Response 2) As stated in the proposed rule, the current fee schedule is insufficient to provide, maintain, and equip an adequate color additive certification program (87 FR 66116 at 66117). In our Fee Study, we explain that a diminishing prior year carryover and reduced collections is placing the color certification program in a financially precarious position, necessitating the fee increase. Further, the funding shortfall prevents FDA from updating and replacing laboratory equipment necessary for color certification. The additional funding will allow FDA to replace obsolete items and invest in new laboratory equipment, contributing to the overall efficiency of the certification program, and ensure we cover all the costs of our color certification activities and continue to meet our statutory obligation to maintain an adequate certification program in accordance with section 721(e) of the FD&C Act.

(Comment 3) One comment agreed with the necessity to adjust fees and our goal of maintaining an effective certification program. However, the comment noted that ''careful consideration is warranted to strike a balance between covering program costs and avoiding undue financial burden on manufacturers.'' It also stated that we must ''assess the proposed fee adjustment to ensure they are reasonable and justified.''

(Response 3) We carefully considered the need for the fee increase and decided on an amount that would help to ensure funding to provide, maintain, and equip an adequate color certification program. Our Fee Study further explains and illustrates the funding challenges we are experiencing in the color certification program. We did not raise color certification fees for almost 20 years. As a result, in recent years, collections have cumulatively lagged behind expenditures by more than $3 million (Ref. 1). This is causing significant funding shortfalls and preventing the color certification

program from operating efficiently (*e.g.,* causing longer batch certification times). Also, as described in the previous response, additional funding will allow FDA to replace obsolete items and invest in new laboratory equipment. Therefore, it is necessary to increase the fees to ensure collected fees cover all the costs of our color certification activities as required by law. In light of the increased costs of the color certification program, the increase in fees is reasonable and justified.

(Comment 4) One comment disagreed with the proposed rule and stated that it was ''not sufficiently clear as to the accounting or the rationale to warrant a $0.10 per pound increase.'' The comment asserted that the last fee increase was $0.05 per pound and ''based on recent account figures, even a $0.05 increase would be sufficient.''

(Response 4) Our Fee Study lists the costs and the collections for the color additive certification program. Color certification fees have not kept up with inflation and as a result, current collections are not sufficient to sustain the program. The Fee Study also compared the proposed increase to an alternate amount of $0.05. The resulting estimates show that an increase that is 50 percent less than the proposed $0.10 per pound would not be sufficient to maintain an adequate color certification program. The last color certification fees increase was almost 20 years ago. Given the current funding shortfall, the increase is necessary to sustain and maintain an adequate color additive certification program.

(Comment 5) One comment that opposed the proposed fee increase argued that the proposed rule does not ''explain or identify with any specificity where increases in operating costs'' may warrant the increase.

(Response 5) We disagree with this assertion. In the proposed rule, we stated ''since 2005, the costs of the certification program have significantly increased because of general operating expenses, including the purchase and maintenance of critical equipment, rent and facility charges, and escalating staff payroll'' (87 FR 66116 at 66117). We also added a Fee Study to the administrative record to explain the funding challenges for the certification program as well as provide additional information to support the fee increase.

(Comment 6) One comment asserted that the proposal to increase the fee by $0.10 per pound ''is a more significant increase than the agency has proposed in the past.''

(Response 6) The comment's assertion is incorrect. In 1982, we also implemented a $0.10 per pound increase (47 FR 24691, June 8, 1982).

(Comment 7) One comment suggested that if we are not able to justify the need for a $0.10 per pound increase, we should provide for a $0.05 increase as we have done previously.

(Response 7) We have justified the need for a $0.10 per pound increase. Our Fee Study provides additional information to support this increase. The data and information show that dwindling carryover balances, coupled with reduced collections and high inflation, are not sufficient to sustain an adequate color additive certification program as required by the FD&C Act. Without the fee increase, continuing shortfalls will limit the operation of the color certification program. Therefore, a $0.10 per pound increase is necessary to provide, maintain, and equip an adequate color certification program.

(Comment 8) One comment recommended that FDA establish a maximum fee of $1,600 for batches of 4,000 pounds or more. Further, the comment said this would incentivize industry to submit larger batches while also saving Agency resources.

(Response 8) We disagree with the comment. If implemented, the maximum fee proposed by the comment would be based on a certification fee of $0.40 per pound, a $0.05 increase over the current fee. As outlined in our Fee Study, an increase of $0.05 per pound is not sufficient to maintain an adequate color certification program.

(Comment 9) One comment expressed concern about whether color certification fees were being used to only fund color certification activities. Specifically, the comment questioned if the lab equipment in the color certification lab ''are used solely for the certification of color additives.'' Further, the comment questioned if ''all the costs accounted for in the Study provided, such as payroll costs and equipment usage, are specific to color certification activities.'' The comment asserted that ''equipment used for activities beyond color certification should not serve as the basis for a fee increase.''

(Response 9): Certification fees are used to cover the costs of the color certification program and are not used to support unrelated activities. To ensure the safety of color additives, the color certification program engages in many functions, including testing, research, methods development, publication of scientific research, subject matter expertise for inspections of color additive manufacturers, as well as other related administrative and operational activities. Fees are collected, pooled, and used to support all color certification-related activities. As outlined in the Fee Study, collected fees are used to fund labor (*e.g.,* payroll) and nonpayroll operating expenses (*e.g.,* equipment usage) because such activities are necessary to provide, maintain, and equip an adequate color additive certification program, as required by the FD&C Act.

(Comment 10) One comment opposed the proposed rule and stated that ''recent account figures provide no basis or suggest any financial deficit that would require a fee increase.'' Further, the comment asserted that the ''Lab has a financial reserve that would allow the Lab to operate with no additional fee increase.'' The comment argued that the certification program ''does not operate on deficit spending and typically has carryover from year-to-year.'' For these reasons, the comment questioned the need for the proposed fee increase.

(Response 10) We disagree with the comment. Our Fee Study provides data and information that describes the current financial condition of the color additive certification program. The Fee Study explains that we previously relied upon prior year carryover funding to address the deficit between program expenses and annual fee collections. However, carryover funding and annual fee collections are diminishing due to low collections and the increased costs of maintaining an adequate certification program, which make the fee increases necessary. Relying on the carryover balance is no longer viable to support the color certification program.

(Comment 11) Another comment suggested that we ''establish a policy on the management of the color certification lab's reserves.'' The policy would ''ensure the agency is maintaining an appropriate reserve and that future refunds or fee increases are based on specific metrics.''

(Response 11) Fees that are collected and not obligated at the end of the fiscal year are available to support the color certification program in future fiscal years. We refer to this as ''carryover'' while the comment refers to these funds as ''reserves.'' The FDA color certification program maintains a modest carryover balance to operate the color certification program successfully, which enables us to mitigate financial risks to the color certification program, such as the risk of under collecting fees and issues relating to funds availability during the transition to a new fiscal year. FDA constantly monitors and analyzes its carryover balance, but, due to the complexity of program operations, it is unrealistic to target a specific reserve balance as several factors outside of our control impact

funds availability, including fee collections, inflation, unexpected equipment costs, etc. As explained in our Fee Study, we cannot rely on dwindling carryover balances to sustain the color certification program. A fee increase is necessary to cover the full costs of our color certification activities.

(Comment 12) Another comment stated that a ''manufacturer's suggested end-of-life is not indicative of an equipment's actual lifespan'' and that ''the lab should be able to continue to utilize any equipment that is still operable.'' The comments speculated if there are reasons beyond end-of-life that explain why we are seeking new equipment and ''would new equipment result in a demonstrable benefit to the companies receiving certification?''

(Response 12) We agree that the manufacturer's suggested end-of-life does not mean that a piece of laboratory equipment is no longer useful. However, when the manufacturer stops servicing the laboratory equipment, it can be costly and inefficient to maintain the aged items. We require properly functioning laboratory equipment to conduct color certification activities and maintain an adequate color certification program. It would not be prudent for us to wait for equipment to fail before seeking to replace it because this would contribute to delays in the color certification process and reduce the program's efficiency. Therefore, when a manufacturer notifies us that a piece of equipment is reaching end-of-life, we begin the procurement process to obtain new equipment. The procurement process is lengthy and can take months. In recent years, we were unable to purchase new equipment because of ongoing budget concerns.

The fee increase will help to resolve budget concerns and enable us to timely purchase new, more efficient equipment to replace those items that have reached end-of life, cannot be maintained, or are obsolete. The fee increase will also help to address delays in batch certification times caused by reduced resources. The purchase of new equipment will allow FDA to maintain an adequate color certification program while supporting efficient operations, which, in turn, benefits companies that require certification.

(Comment 13) One comment stated that our recent decision to stop providing bottles for sample submission ''passes a significant cost to manufacturers'' and required ''manufacturers to use the same vendor, removing a company's ability to negotiate a reasonable price.'' The comment argued that continuing to pass the cost on to manufacturers should be ''factored into any decision to raise fees.''

(Response 13) In April 2024, we notified color manufacturers that we would stop providing bottles for sample submission. We previously supplied sample bottles to all color certification customers. We stopped the service as part of our overall effort to conserve funds and reduce program costs. While this action helped reduce some program costs, the fee increase is still necessary to cover many other program expenses. Contrary to the claim in the comment, we are not requiring manufacturers to use the same vendor. The notice instructs manufacturers to use the same type of bottles because of our storage limitations; however, the bottles are available from multiple vendors.

(Comment 14) In arguing against the fee increase, one comment asserted that lower color certification volumes ''can most likely be attributed to destocking occurring by companies with products containing certified colors.'' Because companies are destocking certified colors ''that built up during the recent COVID pandemic,'' the comment claimed that ''manufacturers expect the collection to adjust as companies work through their existing stock.''

(Response 14) We appreciate the information about destocking, but disagree with the suggestion. The color certification program is sustained by collected fees. Lower certification volumes contribute to a reduction in the amount of collected fees we receive. This directly affects our ability to provide, maintain, and equip an adequate color certification program. Relying on industry's assertion that collections will adjust does not resolve the ongoing funding concerns of the color certification program. Given that collected fees are meant to cover the full costs of the color certification program, lower certification volumes support the need for a fee increase.

(Comment 15) Using the example of FD&C Red No. 3, one comment claimed that ''if a certified color suffers a downward trend in response to regulatory activity'' by FDA, ''the lab should be able to foresee the resulting impacts on its activity and cut costs accordingly.'' The comment stated that the downward trend ''should not be a reason to trigger a fee increase.''

(Response 15) We note that we continue to certify batches of FD&C Red No. 3 for its listed uses. We disagree with the suggestion that FDA activities related to certain color additive listings triggered FDA's proposed fee increase. As discussed in our Fee Study, collections that have not kept pace with inflation and a diminishing carryover balance explain the need for a fee increase. These funding concerns for the color certification program predate FDA's filing of the pending color additive petition requesting that FDA remove the color additive listing for FD&C Red No. 3 (88 FR 10245).

(Comment 16) One comment expressed concern about ''the lack of communication and transparency'' by our color certification laboratory. Specifically, the comment raised questions and sought information about FDA's method development and publication process.

(Response 16) This rule does not cover methods development and publication. These activities are outside the scope of this rulemaking.

(Comment 17) A few comments questioned the safety of FD&C Red. No. 40. They urged FDA to either ban this color additive or, alternatively, replace the additive in certain products.

(Response 17) The comments are outside the scope of this rulemaking, so we decline to address them.

V. Effective/Compliance Date(s)

The preamble to the proposed rule stated that we would make any final rule resulting from this rulemaking effective 30 days after its date of publication in the **Federal Register** (87 FR 66116 at 66117).

We did not receive any comments on the proposed effective date for the final rule. Therefore, the final rule will become effective December 9, 2024.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of

Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the increase in fees for color certification services would not significantly increase costs to manufacturers, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

This final rule amends existing color additive regulations by increasing fees for certification services. The fee schedule for color certification, as provided for in this final rule, is designed to cover all the costs of operating 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 will 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 will increase from $35 for 100 pounds or less to $45. The fee for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds will 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 will 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 final rule 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 $5,384 at a 3 percent rate of discount and $5,183 at a 7 percent rate of discount. The annualized value of these cost estimates are approximately $631 at a 3 percent discount rate and $738 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 will not be affected by this final rule. Consequently, we estimate no other impacts associated with this final rule.

As noted in the preamble, the fees are intended to recover the full costs of operating FDA's color certification program. Since 2005, the costs of the certification program have 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 FDA's certification program, no economic benefits are expected to result from this final 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 final 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.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE

[Thousands of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes (*e.g.,* risk assumptions; source citations; whether inclusion of capital effects differs across low, primary, high estimates; etc.)
Benefits:							
Annualized monetized benefits	.....	.....	.....	.....	.....	.....	
Annualized quantified, but non-monetized, benefits	.....	.....	.....	.....	.....	.....	
Unquantified benefits	.....	.....	.....	.....	.....	.....	
Costs:							
Annualized monetized costs	$0.63	.....	.....	.....	3	.....	
	$0.74	.....	.....	.....	7	.....	
Annualized quantified, but non-monetized, costs	.....	.....	.....	.....	.....	.....	
Unquantified costs	.....	.....	.....	.....	.....	.....	
Transfers:							
Annualized monetized Federal budgetary transfers	$2,507	.....	.....	.....	3	.....	
	$2,507	.....	.....	.....	7	.....	
Bearers of transfer gain and loss?	Bearer of transfer loss: Manufacturers of color additives			Bearer of transfer gain: Federal Government			
Category	Effects			Notes			
Effects on State, local, or Tribal governments	No effect						

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE—Continued
[Thousands of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes (*e.g.,* risk assumptions; source citations; whether inclusion of capital effects differs across low, primary, high estimates; etc.)
Category	Effects			Notes			
Effects on small businesses	This final rule generates 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 0.25% of annual average revenues of the small firms in the affected industry						
Effects on wages	No Effect						
Effects on growth	No Effect						

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (docket number FDA–2022–N–1635) (Ref. 2) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XI. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Color Certification Fee Study,'' March 2024.
2. FDA, ''Color Additive Certification; Increase in Fees for Certification Services'' Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. Available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 80

Color additives, Cosmetics, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 80 is amended as follows:

PART 80—COLOR ADDITIVE CERTIFICATION

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 21 U.S.C. 371, 379e.

■ 2. In § 80.10, revise paragraphs (a) and (b) to read as follows:

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (2) shall be $0.45 per pound of the batch covered by such requests, but no such fee shall be less than $288.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (4) shall be:

(1) 100 pounds or less—$45.

(2) Over 100 pounds but not over 1,000 pounds—$45 plus $0.08 for each pound over 100 pounds.

(3) Over 1,000 pounds—$114 plus $0.03 for each pound over 1,000 pounds.

* * * * *

Dated: October 30, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–25974 Filed 11–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2560 and 2590

Extension of Certain Timeframes for Employee Benefit Plans, Participants, Beneficiaries, Qualified Beneficiaries, and Claimants Affected by Hurricane Helene, Tropical Storm Helene, or Hurricane Milton

AGENCIES: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, Department of the Treasury.

ACTION: Extension of timeframes.

SUMMARY: This document announces the extension of certain timeframes under the Employee Retirement Income Security Act and the Internal Revenue Code for group health plans, disability and other welfare plans, pension plans, and participants, beneficiaries, qualified beneficiaries, and claimants of these plans affected by Hurricane Helene, Tropical Storm Helene, or Hurricane Milton.

DATES: November 8, 2024.

FOR FURTHER INFORMATION CONTACT: Department of Labor, Elizabeth Schumacher or David Sydlik, Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, at 202–693–8335, and Thomas Hindmarch, Office of Regulations and Interpretations, Employee Benefits Security Administration, at 202–693–8500; or William Fischer, Internal Revenue Service, Department of the Treasury at 202–317–5500.

SUPPLEMENTARY INFORMATION:

I. Purpose

In this document, the Employee Benefits Security Administration, Department of Labor, Internal Revenue Service, and Department of the Treasury (the Agencies) are extending certain timeframes otherwise applicable to group health plans, disability and other welfare benefit plans, pension plans, and their participants, beneficiaries, qualified beneficiaries, and claimants under the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code of 1986 (the Code), under the authority of section 518 of ERISA and section 7508A(b) of the Code.[1] [2] In order to ensure that plans, participants, beneficiaries, qualified beneficiaries, and claimants in disaster areas are not further adversely affected by Hurricane Helene, Tropical Storm Helene, and Hurricane Milton with respect to their employee benefit plans, certain timeframes are extended during the Relief Period established by this document, as explained in further detail below.

As a result of Hurricane Helene, Tropical Storm Helene, and Hurricane Milton, participants, beneficiaries, qualified beneficiaries, and claimants covered by group health plans, disability or other employee welfare benefit plans, and employee pension benefit plans may encounter problems in exercising their health coverage portability and continuation coverage rights, or in filing or perfecting their benefit claims. Recognizing the numerous challenges such individuals already face as a result of these natural disasters, it is important that the Agencies take steps to minimize the possibility of such individuals losing benefits because of a failure to comply with certain pre-established timeframes. Similarly, the Agencies recognize that affected group health plans may have difficulty in complying with the timing of certain notice obligations.

The Agencies believe the relief established by this document is immediately needed to preserve and protect the benefits of participants, beneficiaries, qualified beneficiaries, and claimants in affected plans. Accordingly, the Agencies have determined, pursuant to section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(A), (B) and 553(d), that there is good cause for granting the relief provided by this document effective immediately upon publication, and that notice and public participation may result in undue delay and, therefore, be contrary to the public interest.

This document has been reviewed by the Department of Health and Human Services (HHS), which has advised the Agencies that HHS concurs with the relief specified in this document in the application of the laws under its jurisdiction.[3]

HHS has advised the Agencies that HHS encourages plan sponsors of non-Federal governmental plans and health insurance issuers offering group or individual health insurance coverage to extend otherwise applicable timeframes under titles XXII and XXVII of the Public Health Service Act (PHS Act)[4] for participants, beneficiaries, and

[1] ERISA section 518 and Code section 7508A(b) generally provide that, in the case of an employee benefit plan, sponsor, administrator, participant, beneficiary, or other person with respect to such a plan affected by a federally declared disaster (as defined in section 162(i)(5) of the Code), a terroristic or military action, or a public health emergency declared by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, notwithstanding any other provision of law, the Secretaries of Labor and the Treasury may prescribe (by notice or otherwise) a period of up to 1 year that may be disregarded in determining the date by which any action is required or permitted to be completed. Section 518 of ERISA and section 7508A(b) of the Code further provide that no plan shall be treated as failing to be operated in accordance with the terms of the plan solely as a result of complying with the postponement of a deadline under those sections.

[2] See, *e.g.,* Hurricane Helene Recovery: Brief Overview of FEMA Programs and Resources, (October 3, 2024), available at *https://crsreports.congress.gov/product/pdf/IN/IN12429;* 89 FR 84908 (October 24, 2024); 89 FR 84923 (October 24, 2024); 89 FR 84919 (October 24, 2024); 89 FR 84914 (October 24, 2024); 89 FR 84912 (October 24, 2024); 89 FR 84920 (October 24, 2024).

[3] Section 104 of Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that the Secretaries of Labor, the Treasury, and Health and Human Services (the Departments) ensure through an interagency Memorandum of Understanding (MOU) that regulations, rulings, and interpretations issued by each of the Departments relating to the same matter over which two or more departments have jurisdiction, are administered so as to have the same effect at all times. Under section 104 of HIPAA, the Departments, through the MOU, are to provide for coordination of policies relating to enforcement of the same requirements in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement. See section 104 of HIPAA and Memorandum of Understanding applicable to Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code, published at 64 FR 70164, December 15, 1999.

[4] The applicable PHS Act provisions are (1) the 30-day period (or 60-day period, if applicable) to request special enrollment under PHS Act section 2704(f); (2) the 60-day election period for COBRA continuation coverage under PHS Act section 2205; (3) the date for making COBRA premium payments pursuant to PHS Act section 2202(2)(C) and (3); (4) the date for individuals to notify the plan of a qualifying event or determination of disability under PHS Act section 2206(3); (5) the date within which individuals may file a benefit claim under the plan's claims procedure pursuant to 45 CFR 147.136(b) (incorporating 29 CFR 2560.503–1); (6) the date within which claimants may file an appeal of an adverse benefit determination under the plan's claims procedure pursuant to 45 CFR 147.136(b) (incorporating 29 CFR 2560.503–1(h)); (7) the date within which claimants may file a request for an external review after receipt of an adverse benefit determination or final internal adverse benefit determination pursuant to 45 CFR 147.136(c)(2)(vi) and (d)(2)(i), and (8) the date within which a claimant may file information to perfect a request for external review upon a finding that the request was not complete pursuant to 45 CFR 147.136(d)(2)(ii).