DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Color Additive Certification; Increase in Fees for Certification Services

Docket No. 2022-N-1635

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Table of Contents

I. Introduction and Summary

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 additive certification, as provided for in this final rule, 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 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 operation of 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 the FDA 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, below.

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	
Effects on small businesses	This final rule generates costs to small businesses, as well as transfers from small businesses to the 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	

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

There were no comments submitted regarding the Preliminary Regulatory Impact Analysis.

D. Summary of Changes

The analysis has been updated to reflect updates in data sources. Specifically, we have updated data on wages (Bureau of Labor Statistics, 2023), data on small business size standards (Small Business Administration, 2024), and employment data for firms in the affected industry (U.S. Census, 2021). Additionally, the analysis has been updated to reflect changes in standards for regulatory analysis (US Office of Management and Budget, 2023).

II. Final Economic Analysis of Impacts

A. Background

Federal law requires that certain color additives be certified for use by FDA. These include color additives used in food, drugs, cosmetics, and certain medical devices. To certify, FDA samples each batch of color additive from a manufacturer and verifies that it meets composition and purity rules for that specific color additive. Uncertified color additives may contain impurities that pose health risks to consumers.

In order to obtain certification, color additive manufacturers must comply with FDA's batch certification process. This requires manufacturers to seek certification of each batch of color additive they produce. Certification is performed before the additives are used in products. Manufacturers pay fees based on the weight of each batch, for certification. These fees support FDA's certification program.

B. Potential Need for Federal Regulatory Action

This final rule is not intended to address an existing market failure. Rather, the purpose of the fee increase is to maintain an existing government service delivery. The color certification fee pays for the operating expenses of the FDA color certification program, ensuring the continuity of this government service.

However, the FDA color certification program itself does address a market failure. The requirement that manufacturers meet specific standards for purity and composition ensures that products containing color additives do not contain unsafe levels of contaminants. This is critical because consumers cannot observe contaminant levels when selecting a product for purchase.

Consequently, consumers are unable to determine whether goods containing color additives are optimal for their health and well-being. Because consumers may not understand the health risks associated with specific contaminants and impurities and would not likely be able to detect many of the contaminants, this problem is unlikely to be resolved by information provision alone. This is a form of market failure where imperfect information could lead consumers to purchase goods containing more contaminants than they otherwise would if fully informed. Certification of color additives alleviates this information problem and prevents consumers from incurring unintended health consequences.

C. Purpose of the Rule

This final rule increases the fee for color additive certification services to pay for the operating costs of the FDA color certification program.

D. Baseline Conditions

Table 2 shows information from recent data provided by the FDA Office of the Chief Scientist, Office of Cosmetics and Colors, Division of Color Certification and Technology. These data are published in annual fourth quarter reports and include information on total pounds of color additive certified by the FDA in each fiscal year. Also included in Table 2 are data from the 2005 Interim Final Rule (IFR) (70 FR 15755 (March 29, 2005)). Between 2012 and 2019, annual submission of color additives for certification was relatively stable. Since 2020, annual submissions have been more variable, likely reflecting disruptions to operations attributable to the pandemic. However, although annual submissions have been more variable since 2020, the average annual submissions between 2020 and 2023 (approximately 25.07 million pounds) are similar to the average annual submission in the four years prior to the pandemic (approximately 24.78 million pounds). We therefore use the average annual submissions between 2020 and 2023 as an estimate for expected annual submissions over the next ten years.

Table 2. Recent color additive certification data from FDA

Fiscal Year	Number of certifying color additive firms	Total Pounds Analyzed	Percentage change from 2004	Percentage change from 2010
2004*	23	16,992,520		
2010	29	21,890,365	28.82%	
2011	31	22,016,806	29.57%	0.58%
2012	38	24,250,684	42.71%	10.78%
2013	33	24,723,778	45.50%	12.94%
2014	35	23,848,279	40.35%	8.94%
2015	35	24,588,279	44.70%	12.32%
2016	40	24,448,637	43.88%	11.69%
2017	53	25,612,986	50.73%	17.01%
2018	58	24,514,614	44.27%	11.99%
2019	52	24,560,135	44.53%	12.20%
2020	55	23,066,421	35.73%	5.36%
2021	52	23,414,572	37.79%	6.96%
2022	49	28,068,897	65.12%	28.17%
2023	51	25,742,305	51.46%	17.57%

*Numbers are from 2005 IFR (70 FR 15755).

E. Benefits of the Rule

Although the FDA color certification program generates benefits, this final rule only amends existing color additive regulations by increasing fees for certification services. Accordingly, we do not estimate benefits associated with this final rule.

F. Costs of the Rule

As the increase in fees for certification services amounts to a transfer, the only costs associated with this final rule are those faced by color additive manufacturers in order to read and understand the rule. Manufacturers incur a one-time cost in order to read and understand the rule. As recommended by HHS guidance, we assume a reading speed of between 200 and 250 words per minute (Office of the Assistant Secretary for Planning and Evaluation, 2016). For simplicity, we take the midpoint of this range, 225 words per minute, as our estimate of reading

speed. The text of this final rule consists of 6,326 words. The time required to read the rule comes out to slightly more than 28 minutes, or 0.47 hours (6,326 words / 225 words per minute = 28.12 minutes; 28.12 minutes/60 = 0.469 hours).

We use this estimate to calculate the monetary costs associated with reading and understanding the rule. To do so, we use information on hourly wages. We assume that one lawyer will read and interpret the rule for their firm. The mean hourly wage for lawyers in the chemical manufacturing industry, as reported by the US Bureau of Labor Statistics (2023) is $116.02. We double this wage to account for the value of benefits and other indirect costs. This fully-loaded hourly wage is $232.04. For each firm, the cost to read and understand the rule is just over $62 ($232.04 per hour x approximately 0.469 hours = $108.73). Across all 51 firms in the 2023 data, the total cost is $5,545.34 ($108.73 per firm x 51 firms = $5,545.34). We assume that firms incur this cost immediately after publication of the final rule.

Table 3 summarizes the costs associated with this proposed rule, if finalized. Over the 10-year period following the effective date, the present value of this cost is approximately $3,082 at a 3 percent rate of discount, and $2,967 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately $361 at a 3 percent discount rate and $422 at a 7 percent discount rate.

Table 3. Cost to Read and Understand the Rule

	Discount Rate	Total Costs
Present Value of Costs	3%	$5,383.8
	7%	$5,182.6
Annualized Value of Costs	3%	$631.1
	7%	$737.9

G. Transfers Caused by the Rule

1. Transfer from Manufacturers of Color Additives to Government

This final rule increases the fees that color additive manufacturers will have to pay the federal government for certification services. The increase in fees is not associated with a change in the operation of the FDA certification program and is only intended to reflect the increase in

operating expenses associated with the program. Therefore, the increase in fees amounts to a transfer from color additive manufacturers to the federal government, rather than an economic cost. Here, we estimate the size of the transfer from the color additive manufacturers to the federal government.

Recent FDA certification data, shown in Table 2 above, indicate that over the last four years firms submitted an average of 25.07 million pounds of color additives for testing. For simplicity, we assume that these values will not change in the future. To determine the total fee payments in the baseline, we multiply the average annual pounds of color additives submitted for certification from 2020 to 2023 by the existing fee of $0.35 per pound. This results in a baseline fee of nearly $8.8 million (25,073,049 pounds x $0.35 per pound = $8,775,567). Under the new fee of $0.45 per pound, future certification submissions will result in a total fee payment of approximately $11.3 million (25,073,049 pounds x $0.45 per pound = $11,282,872). The incremental fee increase is roughly $2.5 million ($11,282,872 - $8,775,567 = $2,507,305). This final value is the transfer from manufacturers of color additives to the federal government associated with the fee increase.

We note that this final rule imposes a different fee structure for repacks of color additives and color additive mixtures. Fees for repacks of certified color additives and color additive mixtures are presented in Table 4. This final rule increases the fee for repacks of certified color additives and color additive mixtures of 100 pounds or less from $35 to $45. For repacks of certified color additives and color additive mixtures weighing more than 100 pounds but not over 1,000 pounds, firms are currently charged $35 for the first 100 pounds and then $0.06 per pound. This final rule increases the fee for repacks of certified color additives and color additive mixtures weighing more than 100 pounds but not over 1,000 pounds to $45 plus $0.08 for each pound over 100 pounds. For batches weighing more than 1,000 pounds, current total fees include $89 for the first 1,000 pounds and then $0.02 per pound. This final rule increases the fee for repacks of certified color additives and color additive mixtures weighing more than 1,000 pounds to $114 plus $0.03 for each pound over 1,000 pounds.

Table 4. Fees for repacks of certified color additives and color additive mixtures

Size	Current Fee Structure	New Fee Structure
Less than 100 pounds	$35	$45

More than 100 pounds & less than 1,000 pounds	$35 plus $0.06 per pound (for each pound over 100 pounds)	$45 plus $0.08 per pound (for each pound over 100 pounds)
Over 1,000 pounds	$89 plus $0.02 per pound (for each pound over 1,000 pounds)	$114 plus $0.03 per pound (for each pound over 1,000 pounds)

Although we have aggregate data on color certification submissions, we lack the data required to account for the fee structure of each batch submitted. Therefore, we cannot determine the ultimate fee structure that should be applied to repacks. Instead, we assume all repacks are charged a fee of $0.45 per pound. Consequently, our estimates in this section represent the upper-bound of the total fee increase for color additive testing.

Table 5 summarizes the transfers associated with this final rule. Over the 10-year period following the effective date, the present value of these transfers is approximately $21.4 million at a 3 percent rate of discount, and $17.6 million at a 7 percent rate of discount. The annualized value of these transfer estimates is approximately $2.5 million at both the 3 and 7 percent discount rate.

Table 5. Present and Annualized Value of Transfers

	Discount Rate	Transfers
Present Value of Transfers	3%	$21,387,819
	7%	$17,610,260
Annualized Value of Transfers	3%	$2,507,305
	7%	$2,507,305

H. Analysis of Regulatory Alternatives to the Rule

We consider two alternatives to the rule. Both alternatives would affect only the size of the transfer associated with the rule. The first alternative is a smaller fee increase of $0.05 per

pound, for a total fee of $0.40 per pound. This payment increase is half of the fee increase associated with this final rule. This alternative would result in a total fee increase of roughly $1.25 million each year.

The second alternative is a larger fee increase of $0.20 per pound, for a total fee of $0.55 per pound. This payment increase is 100 percent greater than the fee increase in this final rule. This would result in a total fee increase of over $5.0 million each year. Like the main analysis, we do not anticipate either alternative substantially affecting the supply of color additives. Consequently, we do not estimate other impacts associated with these alternatives.

I. Distributional Effects

We do not anticipate that this final rule will result in differential effects across varying income, ethnic, geographic, gender, or age groups.

J. International Effects

We do not anticipate that this final rule will substantially impact color additives imported from foreign countries. Although many of the certifying manufacturers are foreign entities, the costs associated with the rule represent a small fraction of total revenue for these firms.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the total burden of the rule (including costs and transfers) does not exceed 0.25 percent of average annual revenues of small businesses in this sector, we certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We find that most firms in the color additive industry are classified as small. Color additive firms belongs to a broader set of manufacturing firms classified under the synthetic dye and pigment industry. The North American Industry Classification System (NAICS) code for this industry is 325130. For this code, the Small Business Administration (SBA) defines firms with

1,050 or fewer employees as small (US Small Business Administration, 2023). We compare this threshold with firm data from the Economic Census (US Census Bureau, 2023). Based on these data, shown in Table 6, there were 107 firms under NAICS code 325130 in 2021. All but 17 of these establishments had fewer than 500 employees. This implies that at least 90 firms in 2021 were small under the current SBA standard.[1] The remaining 17 firms are potentially small under the SBA standard, but the data does not allow us to determine the precise number of firms with less than 1,050 employees.

Table 6. Distribution of firms under NAICS code 325130 by number of employees and Average Revenues (thousands of dollars)

Number of Employees	Number of Firms in NAICS 325130 (2021 SUSB)	Percent of Total Firms	Average Revenue of Firms (2017 SUSB)
Less than 5	26	24%	$1,046
Less than 20	54	50%	$800
Less than 500	90	84%	$20,216
More than 500	17	16%	$382,123
Total	107	100%	$78,380

Note: Monetary estimates are reported in 2023 dollars

B. Description of the Potential Impacts of the Rule on Small Entities

Although we use 2021 Economic Census data for the count of small businesses, we must use 2017 data for firm receipts because that was last year for which the data is available. Based on data from the Economic Census, the average revenue per firm for firms with less than 500 employees under NAICS code 325130 is over $20 million, in 2023 dollars (US Census Bureau, 2021). Recall from Section II.F that the average cost of this final rule per firm is $108.73, which is approximately 0.00054% of average annual revenue of color additive manufacturing firms with less than 500 employees. Although the fee increase in this final rule is a transfer from a social perspective, it is experienced as a cost by each of the affected firms. As presented above in

[1] Based on these data, we conclude that most color additive firms are considered small under the SBA standard. This conclusion relies on two assumptions. The first is that the distribution of employee size across firms did not change substantially since 2017. The second is that the distribution of employee size within the color additive industry is similar to the other firms within NAICS code 325130.

Table 5, the total annualized value of the fee increase is approximately $2.51 million. The average annualized cost per color additive manufacturing firm would be approximately $49,162.84 ($2,507,304.9/51). For the average firm under NAICS code 325130 with less than 500 employees, the fee increase would amount to approximately 0.24% of annual revenue.

IV. References

Office of the Assistant Secretary for Planning and Evaluation. (2016). Guidelines for Regulatory Impact Analysis. Retrieved from https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis

US Bureau of Labor Statistics. (2023, March) May 2020 National Industry-Specific Occupational Employment and Wage Estimates. In Occupational Employment Statistics. Retrieved from https://www.bls.gov/oes/current/naics4_3250A1.htm#23-0000

US Census Bureau. (2021, May). In 2017 SUSB Annual Data Tables by Establishment Industry. Retrieved from https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html

US Small Business Administration. (2023, March). In Table of Size Standards. Retrieved from https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023_.xlsx

US Census Bureau. (2021, May). In 2017 SUSB Annual Data Tables by Establishment Industry. Retrieved from https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html