DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

# Color Additive Certification; Increase in Fees for Certification Services

Docket No. 2022-N-1635

Preliminary Regulatory Impact Analysis

Initial Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

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### A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits 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). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

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 propose to certify that the proposed 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 an assessment of anticipated costs and benefits, before proposing "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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

### B. Summary of Costs and Benefits

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. 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 | | | | | | | |

## II. Preliminary Regulatory Impact Analysis

### A. Background

Federal Law requires that certain color additives be certified for use by the United States FDA. These include color additives used in food, drugs, cosmetics, and 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. Market Failure Requiring Federal Regulatory Action

This proposed rule is not intended to address an existing market failure. Rather, the purpose of the fee increase is to pay for operating expenses of the FDA certification program.

However, the FDA 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 Proposed Rule

This proposed rule, if finalized, would increase the fee for color additive certification services to pay for the operating costs of the FDA certification program.

## D. Baseline Conditions

Table 2 shows information from recent data provided by the FDA Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors, Color Certification Branch. 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 original Interim Final Rule (IFR). The amount of color additives submitted for certification has been stable in recent years. From 2012 to 2019, we analyzed between 24 and 26 million pounds of color additive in each year. The long run trend, however, shows that submissions for certification increased over time. The amount analyzed in 2019, approximately 25 million pounds, is over 12 percent greater than in 2010. Relative to 2004, the 2019 value is nearly 45 percent greater. Due to the observed stability in recent years, we do not predict certification trends to change in the future.

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 | 16,992,520.00 | | |
| 2010 | 29 | 21,890,365.44 | 28.82% | |
| 2011 | 31 | 22,016,805.75 | 29.57% | 0.58% |
| 2012 | 38 | 24,250,684.45 | 42.71% | 10.78% |
| 2013 | 33 | 24,723,777.71 | 45.50% | 12.94% |
| 2014 | 35 | 23,848,279.14 | 40.35% | 8.94% |
| 2015 | 35 | 24,588,278.89 | 44.70% | 12.32% |
| 2016 | 40 | 24,448,637.08 | 43.88% | 11.69% |
| 2017 | 53 | 25,612,986.39 | 50.73% | 17.01% |
| 2018 | 58 | 24,514,614.01 | 44.27% | 11.99% |

| | | | | |
|---|---|---|---|---|
| 2019 | 52 | 24,560,135.44 | 44.53% | 12.20% |

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

**E. Benefits of the Proposed Rule**

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

**F. Costs of the Proposed Rule**

As the increase in fees for certification services amounts to a transfer, the only costs associated with the 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 proposed rule consists of 3,621 words. The time required to read the rule comes out to slightly more than 16 minutes, or 0.268 hours (3,621 words / 225 words per minute = 16.09 minutes; 16.09 minutes/60 = 0.268 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 would 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 (2021) is $85.19. We double this wage to account for the value of benefits and other indirect costs. This fully-loaded hourly wage is $170.38. For each firm, the cost to read and understand the rule is just under $46 ($170.38 per hour x approximately 0.268 hours = $45.70). Across all 52 firms in the 2019 data, the total cost is nearly $2,376.38 ($45.70 per firm x 52 firms = $2,376.38). 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 $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.

Table 3. Summary of costs in 10-year period following effective date

| | Discount Rate | Total Costs |
|---|---|---|
| Present Value of Costs | 3% | $2,307 |
| | 7% | $2,221 |
| Annualized Value of Costs | 3% | $270 |
| | 7% | $316 |

Note: Monetary estimates are reported in 2020 dollars

## G. Distributional Effects

We do not anticipate that this proposed rule, if finalized, would result in differential effects across varying income, ethnic, geographic, gender, or age groups.

1. Transfer from Manufacturers of Color Additives to Government

This proposed rule, if finalized, would increase the fees that color additive manufacturers would 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 52 firms submitted nearly 25 million pounds of color additives for testing in 2019. For simplicity, we assume that these values would not change in the future. To determine the total fee payments in the baseline, we multiply the pounds of color additives submitted for certification in 2019 by the existing fee of $0.35 per pound. This results in a baseline fee of nearly $8.6 million (24,560,135 pounds x $0.35 per pound = $8,596,047). Under the new fee of $0.45 per pound, future certification submissions would result in a total fee payment of approximately $11.1 million (24,560,135 pounds x $0.45 per pound = $11,052,061). The incremental fee increase is roughly $2.5 million

(11,052,061 - $8,596,047 = $2,456,014). This final value is the transfer from manufacturers of color additives to the federal government associated with the fee increase.

We note that this proposed 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 proposed rule, if finalized, would increase 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 proposed rule, if finalized, would increase 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 proposed rule, if finalized, would increase 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 | Proposed |
|---|---|---|
| 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 proposed rule. Over the 10-year period following the effective date, the present value of these transfers is approximately $21

million at a 3 percent rate of discount, and $17.3 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. Summary of transfers in 10-year period following effective date

| | Discount Rate | Total Costs |
|---|---|---|
| Present Value of Transfers | 3% | $20,950,294 |
| | 7% | $17,250,011 |
| Annualized Value of Transfers | 3% | $2,456,014 |
| | 7% | $2,456,014 |

Note: Monetary estimates are reported in 2020 dollars

## H. International Effects

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

## I. Analysis of Regulatory Alternatives

We consider two alternatives to the proposed rule. Both alternatives would affect only the size of the transfer associated with the proposed 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 proposed rule. This alternative would result in a total fee increase of roughly $1.2 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 proposed rule. This would result in a total fee increase of over $4.9 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.

## III. Initial Small Entity Analysis

We have examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities. Consequently, this analysis, together with other relevant sections of this document and the Preamble to the proposed rule, serves as the Initial 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 1,000 or fewer employees as small (US Small Business Administration, 2019). We compare this threshold with firm data from the Economic Census (US Census Bureau, 2021). Based on these data, shown in Table 6, there were 112 firms under NAICS code 325130 in 2017. All but 18 of these establishments had fewer than 500 employees. This implies that at least 94 firms in 2017 were small under the SBA standard.[1] The remaining 18 firms are potentially small under the SBA standard, but the data does not allow us to determine the number of firms with less than 1,000 employees.

Table 6. Distribution of firms under NAICS code 325130 by number of employees

| Number of Employees | Number of Firms in NAICS 325130 | Percent of Total Firms | Revenue ($millions) |
|---|---|---|---|
| Less than 5 | 30 | 27% | $27 |
| 5 to 9 | 20 | 18% | $72 |
| 10 to 19 | 8 | 7% | $56 |
| 20 to 99 | 24 | 21% | $365 |

[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.

| | | | |
|---|---|---|---|
| 100 to 499 | 12 | 11% | $1,119 |
| 500+ | 18 | 16% | $5,934 |
| Total | 112 | 100% | $7,573 |

Note: Monetary estimates are reported in 2020 dollars

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

Based on data from the Economic Census, the average revenue per firm among the 94 firms with less than 500 employees under NAICS code 325130 is over $17 million, in 2020 dollars (US Census Bureau, 2021). Recall from Section II.F that the average cost of this proposed rule, if finalized, would be $45.70, which is approximately 0.0003% of average annual revenue of color additive manufacturing firms with less than 500 employees. Although the fee increase in this proposed rule is a transfer from a social perspective, it is experienced as a cost by the affected firms. As presented above in Table 5, the total annualized value of the fee increase is approximately $2.5 million. The average annualized cost per color additive manufacturing firm would be approximately $47,231 ($2,456,014/52). For the average firm under NAICS code 325130 with less than 500 employees, the fee increase would amount to approximately 0.27% of annual revenue. We propose to certify that this proposed rule, if finalized, will not have a significant impact on a substantial number of small entities.

## 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

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