DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Additives: Food Contact Substance Notification That Is No Longer Effective

Docket No. FDA-2021-N-0403

Final Regulatory Impact Analysis

Regulatory Flexibility Analysis

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Executive Summary

The final rule amends the Food and Drug Administration's (FDA or we) food additive regulations relating to premarket notifications for food contact substances (FCNs) and the procedures by which we determine that an FCN is no longer effective. The final rule will allow manufacturers or suppliers of food contact substances (FCSs) to request that FDA determine that an FCN is longer effective for reasons other than safety. Cost savings of the final rule to manufacturers and suppliers and FDA range from zero to $0.4 million, with a central estimate of $0.1 million, annualized over ten years at a 2 percent discount rate. We estimate that there will be little to no costs associated with the final rule.

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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 Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), 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, 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).

A rule is "major" under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act if it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional

Review Act. OIRA has determined that this final rule is not a major rule under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule is unlikely to impose a substantial burden on the affected small entities, 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 an assessment 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. We do not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Cost and Benefits

We expect the final rule to lead to cost savings for manufacturers and suppliers of food contact substances and FDA. The final rule would revise FDA's current process of determining whether an FCN is no longer effective. The final rule would provide manufacturers and suppliers the opportunity to demonstrate why an FCN should continue to be effective before we could determine that an FCN is no longer effective. Additionally, the final rule would revise the current process to cover situations in which it is determined that an FCN is no longer effective for reasons other than safety, including

that a manufacturer or supplier may request that FDA determine that an FCN is no longer effective on the basis that the manufacturer or supplier no longer produces, supplies, or uses the food contact substance for the intended use. Cost savings will be incurred by manufacturers and suppliers of food contact substances (FCS) who will be able to request that FDA determine the FCN is no longer effective for reasons other than safety. FDA will also experience cost savings from being able to act more efficiently upon such a request by the manufacturer or supplier. As the revisions in the final rule would not require significant additional action to be taken by manufacturers and suppliers, we expect the costs of the final rule to be minimal.

The estimated total cost savings of the final rule are estimated in 2021 U.S. dollars and range from zero to $0.4 million, with a central estimate of $0.1 million, annualized at 2 percent over 10 years. We estimate that the costs of the final rule are minimal. The cost savings and costs of the final rule are summarized in Table 1.

Table 1. Summary of Cost Savings, Costs, and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Cost Savings	One-time							
	Monetized millions/year							
	Annualized	$0.1M	$0	$0.4M	2021	2%	10 years	
	Quantified							
	Qualitative							
Costs	Annualized							
	Monetized millions/year							
	Annualized							
	Quantified							
	Qualitative	$0			2021		10 years	
Transfers	Federal Annualized							
	Monetized $millions/year							
		From:			To:			

	Other Annualized							
	Monetized $millions/year							
		From:			To:			
Effects	State, Local or Tribal Government:							
	Small Business: Increased cost savings of zero to $147.31 per affected small entity							
	Wages:							
	Growth:							

II. Final Regulatory Impact Analysis

A. Need for Regulation

This rule creates needed administrative procedures that do not currently exist in our food additive regulations at 21 CFR part 170, subpart D, which provide the process by which FDA may determine an FCN is no longer effective. Our regulations currently do not provide reasons other than safety as the basis for FDA to determine that an FCN is no longer effective. In some cases, a manufacturer may want to stop using an FCS for its originally intended use or an FCS may become obsolete, but this does not mean the intended use of the FCS is no longer safe. In other cases, FDA may inform a manufacturer of potential safety concerns for the intended use of a FCS, and a manufacturer may choose to stop manufacturing the FCS rather than obtaining information and data to address FDA's safety concerns. Responding to FDA's safety concerns can be costly and time intensive. In order to respond, manufacturers may employ lawyers, administrative support staff, and specialized scientists, including chemists and toxicologists. Similarly, processing submitted information on an intended

use of an FCS is costly to FDA and requires time-intensive labor of consumer safety officers, scientists, supervisors, and support staff. The final rule will increase the efficiency of current FCN review processes by reducing the amount of labor expended by manufacturers and suppliers as well as FDA to determine that an FCN is no longer effective while incurring minimal additional costs.

B. Cost Savings of the Rule

The cost savings of the final rule stem from cost savings to FCS manufacturers and suppliers and cost savings to FDA. Under the final rule, manufacturers and suppliers will be able to request that FDA determine that an FCN is no longer effective for reasons other than safety. Such a request would be based on the manufacturer or supplier no longer producing, using, or supplying the FCS for the intended use, or intending to stop producing, using, or supplying the FCS for the intended use at a specified date in the future. Cost savings to manufacturers and suppliers are estimated to be the forgone time burden of responding to FDA's safety concerns about the intended use of the FCS. FDA may deny this request for safety or public health reasons. Cost savings to FDA are estimated to be the reduced time burden of reviewing whether an intended use of an FCS is no longer safe.

We have reviewed the FCN submissions data and estimate that the final rule will lead to between zero and approximately 5 requests by FCS manufacturers and suppliers per year (Ref. 1). We use these values to estimate low and high estimates of cost savings to manufacturers and suppliers, using the midpoint of 2.5 FCNs as a central estimate. The lower bound of zero requests per year takes into consideration the possibility that FCS manufacturers and suppliers may request that FDA determine the FCN is no longer

effective for reasons other than safety, such as ceasing production and distribution of an FCS; such requests would not have an associated reduced time burden, as FCS manufacturers and suppliers would not incur costs of obtaining information and data to address safety concerns. Many FCS manufacturers and suppliers outsource the research and paperwork associated with an FCN submission to an outside agent, usually a law firm specializing in regulatory law and technical assistance to manufacturers and suppliers of food contact surfaces. Based on our examination of FCN submissions data, we estimate that approximately 71.4 percent of FCN submissions received are submitted by agents on behalf of manufacturers and suppliers. We estimate that the percentage of manufacturers and suppliers affected by the final rule is also approximately 71.4 percent and that the annual number of FCN submissions completed by agents ranges from zero (= 0 x 0.714) to approximately 3.6 (= 5 x 0.714), with a central estimate of approximately 1.8 FCN submissions (= 2.5 x 0.71).

Currently, an agent may employ a group of experts to respond to an FDA safety concern about the intended use of the FCS. Under the final rule, this process may no longer be necessary if the manufacturer or supplier requests that FDA determine the FCN is no longer effective for reasons other than safety, resulting in cost savings to manufacturers and suppliers. We estimate the time burden to manufacturers and suppliers of completing a response to FDA's safety concern about the intended use of the FCS that is the subject of the FCN is greater than the FDA time burden to review the response. Based on timekeeping records for previous FCN submissions (Ref. 2), we estimate that FDA spends approximately 3,000 person-hours reviewing a single FCN submission. We use 3,000 person-hours as an upper estimate of the reduced time burden of the final rule,

and zero as a lower estimate, with the midpoint of approximately 1,500 person-hours as a central estimate. We estimate that the time burden to manufacturers and suppliers of responding to an FDA safety concern about the intended use of an FCS is 1.5 times that of the time burden to FDA, ranging from zero to approximately 4,500 person-hours (= 3,000 x 1.5), with a central estimate of approximately 2,250 (= 1,500 x 1.5).

We estimate that an agent will employ a lawyer, a food scientist, a biochemist, a chemist, a legal support staff member, and an administrative assistant to respond to an FDA safety concern about the intended use of an FCS. Using Bureau of Labor Statistics (BLS) wage data, we estimate wage rates in 2021 dollars for each employee, adjusting for 100 percent overhead. Fully-loaded hourly mean wage rates are estimated to be $142.34 (= $71.17 x 2) for lawyers (Ref. 3), $80.92 (= $40.46 x 2) for food scientists (Ref. 4), $109.10 (= $54.55 x 2) for biochemists (Ref. 5), $85.70 (= $42.85 x 2) for chemists (Ref. 6), $70.20 (= $35.10 x 2) for legal support (Ref. 7), and $64.30 (= $32.15 x 2) for administrative assistants (Ref. 8). We estimate that the time burden of a response to an FDA safety concern about the intended use of an FCS (*i.e.,* an FCN response submission) is split between each of these employees, with lawyers bearing approximately 20 percent of the burden, food scientists bearing approximately 20 percent of the burden, biochemists bearing approximately 20 percent of the burden, legal support bearing approximately 10 percent of the burden, and administrative assistants bearing approximately 10 percent of the burden.

We multiply the time burden per FCN response submission by the hourly wage for each employee and its associated percentage of time burden and sum to yield estimated cost savings ranging from zero to approximately $436.8 thousand (= 4,500 x

$142.34x 0.20 + 4,500 x $80.92 x 0.20 + 4,500 x $109.10 x 0.20 + 4,500 x $85.70 x 0.20 + 4,500 x $70.20 x 0.10 + 4,500 x $64.30 x 0.10), with a central estimate of approximately $218.4 thousand (= 2,250 x $142.34x 0.20 + 2,250 x $80.92 x 0.20 + 2,250 x $109.10 x 0.20 + 2,250 x $85.70 x 0.20 + 2,250 x $70.20 x 0.10 + 2,250 x $64.30 x 0.10). We multiple these cost savings by the estimated number of FCN response submissions completed by agents per year to yield cost savings ranging from zero to approximately $1.6 million (= 3.6 x $436.8 thousand), with a central estimate of approximately $390.0 thousand (= 1.8 x $218.4 thousand). The estimated cost savings to manufacturers and suppliers that utilize agents to complete FCN response submissions are summarized in Table 2.

Table 2. Annual Cost Savings to FCS Manufacturers and Suppliers That Utilize Agents (2021$)

	Low	Middle	High
Number of affected FCNs per year	0	2.5	5
Percentage of FCNs completed by agents	71.4%	71.4%	71.4%
Number of FCNs completed by agents	0	1.8	3.6
Time burden per FCN	0	2,250	4,500
Hourly wage of lawyers	$142.34	$142.34	$142.34
Hourly wage of food scientists	$80.92	$80.92	$80.92
Hourly wage of biochemists	$109.10	$109.10	$109.10
Hourly wage of chemists	$85.70	$85.70	$85.70
Hourly wage of legal support	$70.20	$70.20	$70.20
Hourly wage of administrative assistants	$64.30	$64.30	$64.30
Percent of time burden for lawyers	20%	20%	20%
Percent of time burden for food scientists	20%	20%	20%
Percent of time burden for biochemists	20%	20%	20%
Percent of time burden for chemists	20%	20%	20%
Percent of time burden for legal support	10%	10%	10%
Percent of time burden for administrative assistants	10%	10%	10%
Annual cost savings per FCN	$0	$218,390	$436,779
Annual cost savings of manufacturers and suppliers that utilize agents to complete FCNs	**$0**	**$389,981**	**$1,559,925**

Because we estimate that approximately 71.4 percent of FCN response submissions received by FDA are submitted by agents on behalf of manufacturers and suppliers, we estimate that the remainder (approximately 28.6 percent) of FCN response submissions are completed by manufacturers and suppliers. Using our previous estimate of zero to approximately 5 annual FCN response submissions, we estimate that the annual number of FCN response submissions completed by manufacturers and suppliers that are affected by the final rule ranges from zero (= 0 x 0.286) to approximately 1.4 (= 5 x 0.286), with a central estimate of approximately 0.7 FCN response submissions (= 2.5 x 0.286). We estimate that the time burden of completing an FCN response submission is the same for manufacturers and suppliers as the time burden estimated for agents, ranging from zero to approximately 4,500 hours, with a central estimate of approximately 2,250 hours.

Based on our examination of prior FCN response submissions to FDA's safety concerns about the intended use of an FCS, we estimate that manufacturers and suppliers will employ a group consisting of a lawyer, a biochemist, and an administrative assistant to complete an FCN response submission. Using BLS wage data, we estimate wage rates in 2021 dollars for each group, adjusting for 100 percent overhead. Fully-loaded hourly mean wage rates are estimated to be $142.34 (= $71.17 x 2) for lawyers (Ref. 3), $109.10 (= $54.55 x 2) for biochemists (Ref. 5), and $64.30 (= $32.15 x 2) for administrative assistants (Ref. 8). We estimate that the time burden associated with an FCN response submission is split between each of these employees, with lawyers bearing approximately 40 percent of the burden, biochemists bearing approximately 40 percent of the burden, and administrative assistants bearing approximately 20 percent of the burden. We

multiply the time burden per FCN response submission by the hourly wage for each employee and its associated percentage of time burden and sum to yield an estimated cost saving ranging from zero to approximately $510.5 thousand (= 4,500 x $142.34 x 0.40 + 4,500 x $109.10 x 0.40 + 4,500 x $64.30 x 0.20), with a central estimate of approximately $255.2 thousand (= 2,250 x $142.34 x 0.40 + 2,250 x $109.10 x 0.40 + 2,250 x $64.30 x 0.20). We multiply these cost savings by the estimated number of affected FCN response submissions completed by agents per year to yield cost savings ranging from zero to approximately $729.2 thousand (= 1.4 x $510,462), with a central estimate of approximately $182.3 thousand (= 0.7 x $255,231). The estimated cost savings to manufacturers and suppliers that complete FCN response submissions are summarized in Table 3.

Table 3. Cost Savings to Manufacturers and Suppliers That Complete FCNs (2021$)

	Low	Middle	High
Number of affected FCNs per year	0	2.5	5
Percentage of FCNs completed by manufacturers or suppliers	28.6%	28.6%	28.6%
Number of FCNs completed by manufacturers or suppliers	0	0.7	1.4
Time burden per FCN	0	2,250	4,500
Hourly wage of lawyers	$142.34	$142.34	$142.34
Hourly wage of biochemists	$109.10	$109.10	$109.10
Hourly wage of administrative assistants	$64.30	$64.30	$64.30
Percent of time burden for lawyer	40%	40%	40%
Percent of time burden for biochemist	40%	40%	40%
Percent of time burden for administrative assistant	20%	20%	20%
Annual cost savings per FCN	$0	$255,231	$510,462
Annual cost savings to manufacturers and suppliers that complete FCNs	**$0**	**$182,308**	**$729,231**

We total the estimated cost savings to manufacturers and suppliers that utilize agents to complete FCN response submissions and those who do not to estimate the total cost savings of the final rule to FCS manufacturers and suppliers. We estimate that the total cost savings range from zero to approximately $2.3 million (= $1.6 million + $729.2 thousand), with a central cost savings estimate of approximately $572.3 thousand (= $390.0 thousand + $182.3 thousand). The estimated cost savings of the final rule to manufacturers and suppliers are summarized in Table 4.

Table 4. Cost Savings of the Final Rule to FCS Manufacturers and Suppliers (2021$)

	Low	Middle	High
Annual cost savings to manufacturers and suppliers that utilize agents to complete FCNs	$0	$389,981	$1,559,925
Annual cost savings to manufacturers and suppliers that complete FCNs	$0	$182,308	$729,231
Total annual cost savings of the final rule to manufacturers and suppliers	**$0**	**$572,289**	**$2,289,156**

When this final rule becomes effective, manufacturers and suppliers will be able to request that FDA determine an FCN is no longer effective for reasons other than safety. We anticipate that this new process may reduce the time burden to FDA of determining that an FCS is no longer safe for its intended use, yielding cost savings. We estimate that the annual number of FCN response submissions affected by this rule is between zero and approximately 5, with a midpoint of approximately 2.5, and FDA time burden of reviewing an FCN response submission is between zero and approximately 3,000 hours, with a midpoint of approximately 1,500 hours. We estimate that FDA will employ consumer safety officers and scientists at the GS-13 and GS-14 levels to review FCN response submissions. Using the 2021 General Schedule (GS) Locality Pay Table for the Washington-Baltimore-Arlington pay area (Ref. 9), we calculate the average

salary for all GS-13 and GS-14 pay steps, divide this average by 2,080, the annual number of hours worked (= 40 hours x 52 weeks), and double the result to account for overhead. This yields a composite hourly wage of $125.07 (= $130,076 / 2080 x 2). To estimate the cost savings of the final rule to FDA, we multiply the estimated time burden to FDA of reviewing an FCN response submission by the composite hourly wage rate for FDA reviewers, yielding estimated cost savings ranging from zero to approximately $375.2 thousand (= 3,000 x $125.07), with a central estimate of approximately $187.6 thousand (= 1,500 x $125.07). We multiply these cost savings by the estimated number of affected FCN response submissions to yield cost savings ranging from zero to approximately $1.9 million (= 5 x $375,219), with a central estimate of approximately $469.0 thousand (= 2.5 x $187,609). The cost savings of the final rule to FDA are summarized in Table 5.

Table 5. Cost Savings to FDA FCN Reviewers (2021$)

	Low	Middle	High
Number of affected FCNs per year	0	2.5	5
FDA time burden per FCN	0	1,500	3,000
Hourly wage of FDA FCN reviewers	$125.07	$125.07	$125.07
Annual FDA cost savings per FCN	$0	$187,609	$375,219
Total annual cost savings to FDA FCN reviewers	**$0**	**$469,024**	**$1,876,095**

We sum the estimated cost savings to manufacturers and suppliers and the estimated cost savings to FDA to yield total estimated costs of the final rule ranging from zero to approximately $4.2 million (= $2.3 million + $1.9 million), with a central estimate of approximately $1.0 million (= $572.3 thousand + $469.0 thousand). The net present value of the cost savings of the final rule ranges from zero to approximately $4.1 million, with a central estimate of approximately $1.0 million, discounted at 2 percent. The annualized cost savings over 10 years range from zero to approximately $433.4

thousand, with a central estimate of approximately $108.3 thousand, discounted at 2 percent. The total estimated cost savings of the final rule are summarized in Table 6.

Table 6. Total Cost Savings of the Final Rule (2021$)

	Low	Middle	High
Cost savings to FCS manufacturers and suppliers	$0	$572,289	$2,289,156
Cost savings to FDA FCN reviewers	$0	$469,024	$1,876,095
Total cost savings of the final rule	$0	$1,041,313	$4,165,251
Net present value of cost savings (2%)	$0	$1,020,895	$4,083,580
Annualized cost savings (2%)	**$0**	**$108,342**	**$433,367**

Notes: Cost savings are annualized over 10 years.

C. Costs of the Rule

We estimate that the final rule yields cost savings to manufacturers and suppliers and FDA with minimal or no costs. The final rule increases the efficiency of the process by which FDA can determine that an FCN is no longer effective. As a result, a manufacturer or supplier can request that FDA determine an FCN is no longer effective for reasons other than safety. We estimate that the time burden to FCS manufacturers and suppliers responding to FDA's safety concerns with information that they no longer produce, use, or supply the FCS for the intended use is minimal and that the time burden to FDA associated with reviewing such information is minimal.

D. Uncertainty and Sensitivity Analysis

We have identified several sources of uncertainty in our estimation of cost savings. As part of our uncertainty and sensitivity analysis, we estimate cost savings in which the values of all sources of uncertainty are decreased and increased. This yields lower and upper estimates of the estimated cost savings. One source of uncertainty is the estimated time burden to FCS manufacturers and suppliers of responding to an FDA

safety concern about the intended use of the FCS that may be forgone under the final rule, which we calculate as being approximately 150 percent of FDA's time burden of reviewing a response to our safety concern (2,250 hours = 1,500 hours x 1.5). We calculate a lower bound on the manufacturer and supplier time burden by estimating that the time burden is equal to that of FDA, and we calculate an upper bound on manufacturer and supplier time burden that is approximately 200 percent of FDA's time burden of reviewing a response submission (3,000 = 1,500 hours x 2).

Another source of uncertainty is the percentage of the time burden incurred by those who create FCN response submissions. As an upper bound of cost savings incurred by manufacturers and suppliers that utilize agents, we calculate that the time burden of an FCN response submission is split between an agent's employees, with lawyers bearing approximately 25 percent of the burden, food scientists bearing approximately 25 percent of the burden, biochemists bearing approximately 25 percent of the burden, and chemists bearing approximately 25 percent of the burden. For manufacturers and suppliers completing their own FCN response submissions, we calculate that the time burden is split between a manufacturer's employees, with lawyers bearing approximately 50 percent of the burden and biochemists bearing approximately 50 percent of the burden. These calculations result in higher estimated cost savings by shifting the burden of labor that may be forgone due to the final rule toward employees with higher wages and away from employees with lower wages.

When costs are estimated with lower values for all sources of uncertainty, we estimate total cost savings to be approximately $723.4 thousand. Annualized over 10 years, the lower bound of estimated cost savings is approximately $75.3 thousand,

discounted at 2 percent. When costs are estimated with higher values for all sources of uncertainty, the total cost savings of the final rule are estimated to be approximately $1.6 million. Annualized over 10 years, we estimate the upper bound of cost savings is approximately $163.8 thousand, discounted at 2 percent. Our sensitivity analysis and initial central estimates of cost savings are summarized in Table 7.

Table 7. Sensitivity Analysis of Cost Savings of the Final Rule (thousands 2021$)

	Low	Mean	High
Total cost savings	$723.4	$1,041.3	$1,574.8
Annualized cost savings (2%)	**$75.3**	**$108.3**	**$163.8**

Notes: Estimates are based on sensitivity analysis of central cost savings estimates. Cost savings are annualized over 10 years.

E. Analysis of Regulatory Alternatives to the Final Rule

FDA has identified and assessed regulatory alternatives to the final rule including:

1. No Regulatory Action

In the absence of the final rule, FDA would rely on the existing processes for FCN submissions and FCS manufacturers and suppliers would be unable to request that FDA determine an FCN is no longer effective for reasons other than safety. This option serves as our baseline and we estimate cost savings of the final rule relative to this baseline. This baseline has no cost savings. The disadvantage of this alternative is that it forgoes the cost savings and efficiencies we estimate for FCS manufacturers and suppliers and FDA under the final rule. The estimated cost savings of this alternative to the final rule are presented in Table 8.

Table 8. Cost Savings of Taking No Regulatory Action

Total cost savings of taking no regulatory action	$0

The estimated cost savings of the final rule and the final alternative are

summarized in Table 9. Cost savings estimates of the alternative to the final rule range from zero to approximately $1.0 million. Annualized cost savings range from zero to approximately $108.3 thousand, discounted at 2 percent over 10 years.

Table 9. Summary of Cost Savings of Regulatory Alternatives to the Final Rule (in thousands 2021$)

	Initial Estimate	No Regulatory Action
Total cost savings	$1,041.3	$0
Annualized cost savings (2%)	**$108.3**	**$0**

Notes: Cost savings are annualized over 10 years.

III. 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. Small entities have fewer resources to devote to regulatory compliance and, therefore, may be more affected by regulatory compliance costs. We certify that the final rule will not have a significant economic impact on a substantial number of small entities.

A. Description and Number of Affected Small Entities

We utilize the Dun & Bradstreet database (Ref. 10) to estimate the number of small entities that may be affected by the final rule. We examine data for all entities classified by 8-digit Standard Industrial Code as Paper; coated and laminated packaging (SIC 26710000), Paper; coated and laminated packaging, nec (SIC 26719900), Bread wrappers, waxed or laminated: purchased material (SIC 26719901), Paper, coated or laminated for packaging (SIC 26719902), Plastic film, coated or laminated for packaging (SIC 26719903), Resinous impregnated paper for packaging (SIC 26719904), Thermoplastic coated paper for packaging (SIC 26719905), Waxed paper: made from

purchased material (SIC 26719906), Wrapping paper, waterproof or coated (SIC 26719907), Bags: plastic, laminated, and coated (SIC 26730000), Food storage and trash bags (plastic) (SIC 26730200), Food storage and frozen food bags, plastic (SIC 26730201), Plastic bags: made from purchased materials (SIC 26730301), Pliofilm bags: made from purchased materials (SIC 26730302), Bags: plastic, laminated, and coated, nec (SIC 26739900), Cellophane bags, unprinted: made from purchased materials (SIC 26739901), Unsupported plastics film and sheet (SIC 30810000), Plastics film and sheet (SIC 30810100), Packing materials, plastics sheet (SIC 30810101), Polyethylene film (SIC 30810103), Polypropylene film and sheet (SIC 30810104), Polyvinyl film and sheet (SIC 30810105), Vinyl film and sheet (SIC 30810106), Unsupported plastics film and sheet, nec (SIC 30819900), Film base, cellulose acetate or nitrocellulose plastics (SIC 30819901), Plastics bottles (SIC 30850000), Plastics products, nec (SIC 30890000), Plastics containers, except foam (SIC 30890100), Boxes, plastics (SIC 30890102), Buckets, plastics (SIC 30890103), Cases, plastics (SIC 30890104), Jars, plastics (SIC 30890106), Bottle caps, molded plastics (SIC 30890201), Carafes, plastics (SIC 30890204), Cups, plastics, except foam (SIC 30890207), Dishes, plastics, except foam (SIC 30890208), Kitchenware, plastics (SIC 30890211), Picnic jugs, plastics (SIC 30890213), Plates, plastics (SIC 30890214), Saucers, plastics (SIC 30890215), Tableware, plastics (SIC 30890216), Tops: dispenser, shaker, etc.: plastics (SIC 30890218), Trays, plastics (SIC 30890219), and Tumblers, plastics (SIC 30890220).

The Small Business Administration (SBA) defines entities classified under SIC codes 26719903, 26719904, 26719905, 26719906, 26719907, 26730000, 26730200, 26730201, 26730301, 26730302, 26739900, 26739901, 30810000, 30810100, 30810101,

30810103, 30810104, 30810105, 30810106, 30819900, and 30819901 as small businesses if they hire 750 or fewer employees (Ref. 11). The SBA defines entities classified under SIC code 326160 as small businesses if they hire 1,250 or fewer employees (Ref. 11). The SBA defines entities classified under SIC codes 30890000, 30890100, 30890102, 30890103, 30890104, 30890106, 30890201, 30890204, 30890207, 30890208, 30890211, 30890213, 30890214, 30890215, 30890216, 30890218, 30890219, and 30890220 as small businesses if they hire 500 or fewer employees (Ref. 11). We estimate that there are approximately 4,425 entities that may be potentially affected by this rule and approximately 51 percent, or 2,250 (= 4,425 x 0.51) are classified as small businesses by SBA definition. We estimate that the total annual sales volume of all 4,425 entities is approximately $322.5 billion, $25.7 billion of which is attributed to small entities (approximately 8 percent of the industry total).

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

We estimate that small entities are likely to experience cost savings stemming from the final rule. We estimate that the total cost savings of the final rule range from zero to approximately $4.2 million, with a central estimate of approximately $1,041.3 thousand, and that these cost savings will be passed to FCS manufacturers and suppliers. We estimate that the percentage of these cost savings incurred by small entities is approximately 8 percent, the percentage of total industry sales volume associated with small entities. This yields total cost savings of the final rule for small entities ranging from zero to $331.5 thousand (= $4.2 million x 0.0796), with a central estimate of $82.9 thousand (= $1,041.3 thousand x 0.0796). We divide the estimated total cost savings to small entities by the estimated number of small entities to yield cost savings ranging from

zero to approximately $147.31 per small entity (= $331.5 thousand / 2,250), with a central estimate of approximately $36.83 per small entity (= $82.9 thousand / 2,250). The results of our small entity analysis are summarized in Table 10.

Table 10. Analysis of Impacts of the Final Rule on Small Entities (2021$)

	Low	Middle	High
Number of affected entities	4,425	4,425	4,425
Number of affected small entities	2,250	2,250	2,250
Total cost savings of the final rule (millions)	$0	$976,764	$3,907,055
Total sales volume of all entities (millions)	$322,534.4	$322,534.4	$322,534.4
Sales volume of small entities (millions)	$25,665.7	$25,665.7	$25,665.7
Percentage of total sales volume attributed to small entities	7.96%	7.96%	7.96%
Total cost savings of the final rule to small entities	$0	$82,863	$331,450
Cost savings of the final rule per small entity	**$0**	**$36.83**	**$147.31**

IV. References

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is 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. FDA has verified the website addresses, as of the date this document publishes in the *Federal* Register, but websites are subject to change over time.

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10. Dun & Bradstreet, Dun & Bradstreet Global Business Database. 2016

11. U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," available at: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, accessed March 8, 2023.