

inputting Export Express loans into SBA's E-Tran system?

7. How can SBA revise the Export Express Loan Program Requirements to increase the number of lenders using the Export Express program and increase the number of eligible U.S. small businesses receiving loans under the program?

8. How can SBA revise the Export Express Loan Program Requirements to more closely align with how lenders finance export transactions conventionally?

#### *B. Questions About the Export Working Capital Program*

1. Although EWCP provides guarantees for short-term loans with maturities of up to 3 years, EWCP loans with a maturity of 12 months or less are charged a guaranty fee of one quarter of one (.25) percent, while EWCP loans with a maturity over 12 months and up to 3 years are charged a guaranty fee of between 2 percent and 3 and 3 quarters (3.75) percent depending on the amount of the loan. What fee structure do lenders use for similarly sized working capital loans, including asset-based loans? Would an alternative fee structure increase participation in EWCP?

2. Currently, the maximum loan amount for EWCP is \$5,000,000, and all loans receive a 90 percent guaranty. Per 7(a) loan program parameters, these loan guarantees must only be provided to eligible small businesses. Are these loan limits and credit facility types sufficient to serve the needs of U.S. small business exporters, particularly in light of the availability of a similar program with higher loan amounts at the Export-Import Bank of the United States (EXIM) which are not restricted to eligible small business?

3. Which, if any existing EWCP collateral requirements set forth in 13 CFR 120.343 differ from conventional lending standards for similarly sized commercial loans for collateral on asset-based lending export credit facilities?

4. Should SBA consider allowing lenders to advance loan proceeds under an EWCP line with sufficient collateral to ensure there is a 1:1 collateral ratio or better, rather than using a Borrowing Base Certificate, as is currently available in the 7(a) Working Capital CAPLine program? Would such a change increase usage of EWCP?

5. SBA understands that lenders and EXIM allow overseas accounts receivable and inventory owned by an affiliated entity of a borrower, located in overseas markets, to be included in a borrowing base on conventional export loans. What additional risks are

associated with such a policy and what experience do lenders have recovering funds from the liquidation of such collateral for their non-SBA guaranteed loans of similar size?

6. What cash flow analysis (including projections) and documentation do lenders require on their conventional asset-based export loans similarly sized to SBA guaranteed loans?

7. What fees do lenders currently charge on conventional export loans similar in size to SBA guaranteed loans? What interest rates do lenders currently charge on conventional export loans similar in size to SBA guaranteed loans?

8. Non-bank lenders are allowed to participate in the EWCP program provided they are Small Business Lending Companies (SBLCs) or Non-Federally Regulated Lenders (NFRs). Historically, Non-bank lender participation in the EWCP has been low. What outreach efforts and EWCP program changes would increase Non-bank lender utilization?

9. Would the inclusion of SBA One for electronic submission of EWCP loan applications increase usage of the program?

10. How can SBA revise the EWCP Loan Program Requirements to increase the number of lenders using the EWCP program and increase the number of eligible U.S. small businesses receiving loans under the program?

11. How can SBA revise the EWCP Loan Program Requirements to more closely align with how lenders finance export transactions conventionally?

#### *C. Questions About the International Trade Loan Program*

1. Currently, an ITL loan must be secured by a first lien position on the property or equipment financed by the loan or on other assets of the borrower, except that an ITL loan may be secured by a second lien position on the property or equipment or other assets of the borrower if SBA determines that the second lien position provides adequate assurance of payment of the ITL loan. Do the existing ITL collateral requirements align with commercial lending standards for collateralization of term facilities for capital assets? What other options for collateral are used in the extension of conventional commercial export loans of similar size?

2. ITL applicants must have a business plan reasonably supporting their projected export sales. Is there a need for additional policy guidance regarding this requirement?

3. Although ITL loans can be processed under a lender's delegated authority, is there a need for a streamlined delivery method for ITL

loans with a maximum limit of \$350,000 or less? Would such a delivery method increase lender usage of the ITL loan program?

4. Would the inclusion of the ITL programs in SBA One increase usage of the program? Do lending partners encounter any challenges in inputting ITL loans into SBA's E-Tran system?

5. How can SBA revise the ITL Loan Program Requirements to increase the number of lenders using the ITL program and increase the number of eligible U.S. small businesses receiving loans under the program?

6. How can SBA revise the ITL Loan Program Requirements to more closely align with how lenders finance export transactions conventionally?

#### *D. Export Financing General Comments*

SBA is seeking comments and recommendations on additional 7(a) Loan Program changes in order to increase the number of U.S. small business exporters and the volume of U.S. small business exports. Comments and recommendations are not limited to specific financial products. SBA would be interested in hearing from commenters on the need for loan guarantees for financial products specifically tailored for standby letters of credit, lease financing, purchase order financing, receivable factoring platforms, or supply chain finance.

Interested parties are invited to provide any other comments that they may have relating to the concerns described in this ANPRM. We ask that you provide a brief justification for any suggested changes.

**Christopher Pilkerton,**

*Acting Administrator.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Parts 101 and 130**

[Docket No. FDA-2019-N-0463]

**RIN 0910-A102**

#### **Addition of a New Method for the Analysis of Sulfites in Foods**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is proposing to amend the requirements

that specify the analytical method FDA uses to determine the concentration of sulfites in food. This action, if finalized, would, among other things, provide a new analytical method that can be used as an alternative to the existing analytical method and should improve the efficiency of FDA testing for sulfites in food.

**DATES:** Submit either electronic or written comments on the proposed rule by October 17, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2019-N-0463 for "Amendment to Add a New Method for the Analysis of Sulfites in Foods." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Katherine S. Carlos, Center for Food Safety and Applied Nutrition (HFS-706), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1835, [Katherine.Carlos@fda.hhs.gov](mailto:Katherine.Carlos@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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#### **I. Executive Summary**

##### *A. Purpose of the Proposed Rule*

FDA is issuing this proposed rule primarily to provide an alternative to the current analytical method that is incorporated by reference and establish a new, more efficient analytical method that FDA could use for determining sulfite concentrations in foods. This action is part of FDA's implementation of Executive Orders 13771 and 13777. Under these Executive Orders, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations.

##### *B. Summary of the Major Provisions of the Proposed Rule*

This proposed rule, if finalized, would update the current incorporation by reference of the AOAC International Official Method of Analysis for determining sulfite concentrations in foods and remove Appendix A to Part 101 (21 CFR part 101), as no longer necessary. The rule would also add a recently developed, accurate, and more efficient analytical method to determine sulfite concentrations in foods. If finalized, FDA would use this more modern method; the addition of this method would not affect parties other than FDA. The addition of this method would not affect industry's disclosure obligations. Manufacturers, for example, would be free to use any method to

determine sulfite concentrations in their foods.

### C. Legal Authority

FDA is issuing this proposed rule to amend part 101 under sections 403(i)(2), 403(a), 201(n), and 701(a) (21 U.S.C. 343(i)(2), 21 U.S.C. 343(a), 21 U.S.C. 321(n), and 371(a)) of the FD&C Act.

### D. Costs and Benefits

The benefit of this proposed rule would be the cost savings, in the form of time savings, associated with use of the new method. We estimate that, at the mean, the present value of the benefits of this proposed rule is \$1.0 million using a 3 percent discount rate and \$0.9 million using a 7 percent discount rate (2017\$). The cost of this proposed rule would consist of both one-time validation costs and materials costs associated with use of the new method. We estimate that, at the mean, the present value of the costs of this proposed rule would be \$0.2 million using either a 3 or a 7 percent discount rate (2017\$). At the mean, the estimated present value of the net benefits of this proposed rule would be \$0.8 million using a 3 percent discount rate and \$0.7 million using a 7 percent discount rate (2017\$).

## II. Background

Executive Order 13777, “Enforcing the Regulatory Reform Agenda” (<https://www.govinfo.gov/content/pkg/FR-2017-03-01/pdf/2017-04107.pdf>, 82 FR 12285 (March 1, 2017)) was issued on February 24, 2017. One provision in the Executive Order requires agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is proposing to update regulations that include an outdated incorporation by reference as specified in this proposed rule and add a recently developed, accurate, and more efficient analytical method of analysis for determining sulfite concentrations in foods.

FDA’s food labeling regulations require that sulfites present at more than 10 parts per million (ppm) be labeled on foods. (See § 101.100(a)(4) and § 130.9(a) (21 CFR 130.9(a))). Sulfites are widely used food preservatives that have been shown to produce allergic-type responses in humans, and the presence of sulfites in foods may have serious health implications for those persons who are intolerant of sulfites. The analytical method we use for determining sulfite concentrations in foods is specified at §§ 101.100(a)(4) and 130.9(a), partially through incorporation

by reference. In this document, we propose to update the incorporation by reference of the analytical method that we use to determine sulfite concentrations in foods and establish a new, accurate, and more efficient analytical method that we would also use to determine sulfite concentrations in foods. We are also proposing to amend the unit of measure specified in §§ 101.100(a)(4) and 130.9(a) to milligrams per kilogram, which is equivalent to parts per million, to be consistent with the unit of measure specified in the new analytical method.

### III. Legal Authority

FDA is issuing this proposed rule to amend part 101 under sections 403(i)(2), 403(a), 201(n), and 701(a) (21 U.S.C. 343(i)(2), 21 U.S.C. 343(a), 21 U.S.C. 321(n), and 21 U.S.C. 371(a)) of the FD&C Act. Specifically, FDA is proposing to amend § 101.100(a)(4), which describes the analytical method FDA uses to determine whether there is a detectable amount of sulfite in a finished nonstandardized food.

Section 403(i)(2) of the FD&C Act requires that all of the ingredients in a nonstandardized food be declared on the label of that food by their common or usual names unless FDA has exempted the ingredients from such requirements. FDA established such an exemption in § 101.100(a)(3) for “incidental additives” that are present in foods at insignificant levels and that do not have any technical or functional effect in the foods. Under § 101.100(a)(4), sulfiting agents will be considered to be present in foods in insignificant amounts only if no detectable amount of sulfite is present in the finished food; a detectable amount of a sulfiting agent is 10 parts per million (ppm) or more. Additionally, section 701 of the FD&C Act permits FDA to promulgate regulations for the efficient enforcement of the FD&C Act. Updating the analytical method FDA will use to determine whether there is a detectable amount of sulfites in a finished nonstandardized food will allow FDA to use current scientific technology for the efficient enforcement of the food labeling requirements.

We are also proposing to amend parts 101 and 130 under sections 403(a) and 201(n) of the FD&C Act. Pursuant to § 130.9, standardized foods containing sulfiting agents that are functional or that are present in the finished food at a detectable amount (10 ppm or more) are deemed misbranded unless the presence of the sulfiting agents is declared on the label. This provision also describes the analytical methods,

which are the same as in part 101, for determining the presence of sulfiting agents in food. Section 403(a) of the FD&C Act states that a food is misbranded if its labeling is false or misleading in any particular. Under section 201(n) of the FD&C Act, the extent to which labeling fails to reveal material facts with respect to the consequences which may result from the use of an article under the conditions of use in the labeling or as customary or usual shall be taken into account in determining whether the labeling of that article is misleading. Because sulfiting agents can cause allergic-type responses of unpredictable severity, the presence of a detectable amount of sulfites (as defined at §§ 101.100(a)(4) and 130.9 as 10 ppm or more of sulfites) in a food is a material fact. Therefore, the failure to label a food as containing sulfiting agents renders that label misleading and the food misbranded under sections 403(a) and 201(n) of the FD&C Act.

This proposed rule would update the incorporation by reference for the current analytical method in parts 101 and 130 and also identify a new analytical method that we would use in testing for sulfites in foods to determine compliance. The rule, if finalized, would not require other entities to use these methods. Other entities are free to determine the correlation between the official FDA-designated methods and the entity’s method of choice for determining sulfite concentrations in foods and to use their method of choice as they see fit, recognizing that FDA would rely on the methods established by any final rule resulting from this rulemaking.

### IV. Description of the Proposed Rule

We are proposing to amend the regulations that specify the method of analysis that FDA uses when determining sulfite concentrations in foods. These changes are intended to update an outdated incorporation by reference in two provisions, remove an obsolete appendix, and establish a new analytical method that is accurate and more efficient than the current method.

Our regulations at §§ 101.100(a)(4) and 130.9(a) specify the analytical method that FDA uses for determining sulfite concentrations in food. Both of these regulations establish the method of analysis in two steps. The first step incorporates by reference §§ 20.123–20.125, “Total Sulfurous Acid,” in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 14th Ed. (1984); this method is known as the Monier-Williams method. The second step refines the

Monier-Williams method to improve accuracy and reproducibility and make the method suitable for detecting sulfite concentrations as low as 10 ppm; the modifications are included in Appendix A to Part 101. Collectively, the Monier-Williams method with the Appendix A to Part 101 modifications is referred to as the “optimized Monier-Williams method.” After we incorporated by reference the Monier-Williams method and implemented the modifications to that method in Appendix A to Part 101, the AOAC amended the Official Methods of Analysis to include “Official Method 990.28, Optimized Monier-Williams Method,” which is the same as the two-step process in FDA’s regulations; i.e., the Monier-Williams method and the refinements to the Monier-Williams method in Appendix A to Part 101. As such, this portion of the proposed rule would modernize our regulations to reflect the citation to the current AOAC method for determining sulfite concentrations in food, but would not result in a change in FDA methodology. We are, therefore, proposing to amend §§ 101.100(a)(4) and 130.9(a) to replace the existing incorporation by reference with “AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,” (Final Action 1994), Section 47.3.43, Official Methods of Analysis of AOAC INTERNATIONAL, 21st Edition (2019), and to remove Appendix A to Part 101.

We are also proposing to amend §§ 101.100(a)(4) and 130.9(a) to add a recently developed and published new analytical method for determining sulfite concentrations in foods. A liquid chromatography (LC) tandem mass spectrometry (MS) method (LC-MS/MS method) was recently published (Ref. 1). This method proved to be a faster and more sensitive way to determine sulfite concentrations in foods. FDA’s current methodology is an acceptable method for quantifying sulfites, but it is time-consuming, has a method detection limit of 10 ppm, and is unable to accurately determine sulfite concentrations in some samples. The current method also requires specialty glassware, strong familiarity with the method, and almost two hours of distillation, meaning that only three samples per apparatus can be run in one 8-hour work day.

The newly published LC-MS/MS method is a more rapid, specific alternative to Official Method 990.28, with a lower detection limit, and has been validated by other labs to ensure its accuracy for widespread use (Ref. 2). Sample preparation using the LC-MS/MS method involves routine extraction

techniques that can easily be batched, allowing for the completion of as many as 30 samples by a single analyst in a single day. By using the LC-MS/MS method, FDA would improve efficiency in testing and could better enforce the labeling requirements for sulfites.

We are also proposing to amend the unit of measure specified in § 101.100(a)(4) and 130.9(a) to include milligrams per kilogram, which is equivalent to parts per million, to be consistent with the unit of measure specified in the new analytical method.

#### **V. Incorporation by Reference**

FDA is proposing to incorporate by reference “AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,” (Final Action 1994), Section 47.3.43, Official Methods of Analysis of AOAC INTERNATIONAL, 21st Edition (2019). You may purchase a copy of the material from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, 301–924–7077 ext. 170, [www.aoc.org](http://www.aoc.org). This method is an updated version of the method currently referenced in FDA’s regulations as the method that FDA uses to determine sulfite concentrations in foods.

FDA is also proposing to incorporate by reference “Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study,” Journal of AOAC International Vol. 100, No. 6, pp. 1785–1794. You may purchase a copy of the material from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, 301–924–7077 ext. 170, [www.aoc.org](http://www.aoc.org). The study describes a liquid chromatography tandem mass spectrometry method that FDA would use for the determination of sulfite concentrations in foods as an alternative to AOAC Official Method 990.28.

#### **VI. Proposed Effective Date**

We are proposing that any final rule resulting from this rulemaking become effective 30 days after the date of its publication in the **Federal Register**.

#### **VII. Economic Analysis of Impacts**

We have examined this proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule would not be a significant regulatory action as defined by Executive Order 12866 and would be a deregulatory action for purposes of Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would amend the regulations that specify the method of analysis that FDA uses to determine the concentration of sulfites in foods and would not require other entities to use these methods. Hence, the scope of this proposed rule is limited to FDA. We, therefore, propose to certify that this proposed rule would 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 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 \$154 million, using the most current (2018) 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.

This proposed rule would amend the regulations that specify the method of analysis that FDA uses to determine the concentration of sulfites in foods. The currently specified method of analysis is the optimized Monier-Williams method. This rule proposes to update the incorporation by reference for FDA’s current methodology and add to this a recently developed, accurate, and more efficient analytical method of analysis, referred to as the LC-MS/MS method. The LC-MS/MS method would serve as the primary method used by FDA to determine sulfite concentrations in foods if this proposed rule becomes finalized.

The benefit of this proposed rule would be the cost savings, in the form of time savings, associated with use of the LC-MS/MS method. There would be no impact from the update to the incorporation by reference for FDA’s

current methodology (*i.e.*, the optimized Monier-Williams method) because only the reference would change, not the method. Using a standard 10-year time horizon, we estimate that the present value of the benefits of this proposed rule ranges from \$0.5 million to \$1.7 million, with a mean estimate of \$1.0 million, using a 3 percent discount rate, and ranges from \$0.4 million to \$1.4 million, with a mean estimate of \$0.9 million, using a 7 percent discount rate (2017\$). Annualized benefits, which are illustrated below in table 1, are estimated to range from \$0.06 million per year to \$0.2 million per year, with a mean estimate of \$0.1 million per year, using either a 3 percent or a 7 percent discount rate (2017\$).

The cost of this proposed rule would consist of both one-time validation costs and materials costs associated with use of the LC-MS/MS method. Using a standard 10-year time horizon, we estimate that the present value of the total costs of this proposed rule is \$0.2 million, using a 3 percent discount rate, and ranges from \$0.1 million to \$0.2 million, with a mean estimate of \$0.2 million, using a 7 percent discount rate (2017\$). We estimate that annualized costs, which are presented below in table 1, are \$0.02 million per year, using either a 3 percent or a 7 percent discount rate (2017\$).

The estimated net benefits of this proposed rule are defined as the difference between the estimated

benefits and the estimated costs of the rule. Using a standard 10-year time horizon, we estimate that the present value of the net benefits of this proposed rule ranges from \$0.3 million to \$1.5 million, with a mean estimate of \$0.8 million, using a 3 percent discount rate, and ranges from \$0.3 million to \$1.2 million, with a mean estimate of \$0.7 million, using a 7 percent discount rate (2017\$). Annualized net benefits are estimated to range from \$0.04 million per year to \$0.18 million per year, with a mean estimate of \$0.09 million per year, using a 3 percent discount rate, and from \$0.04 million per year to \$0.17 million per year, with a mean estimate of \$0.10 million per year, using a 7 percent discount rate (2017\$).

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE  
[Millions of 2017\$]

| Category                                      | Primary estimate | Low estimate | High estimate | Units        |                   |                        | Notes             |
|-----------------------------------------------|------------------|--------------|---------------|--------------|-------------------|------------------------|-------------------|
|                                               |                  |              |               | Year dollars | Discount rate (%) | Period covered (years) |                   |
| Benefits:                                     |                  |              |               |              |                   |                        |                   |
| Annualized Monetized \$millions/year          | \$0.10           | \$0.06       | \$0.20        | 2017         | 7                 | 10 .....               | Are cost savings. |
|                                               | \$0.10           | \$0.06       | \$0.20        | 2017         | 3                 | 10 .....               | Are cost savings. |
| Annualized Quantified .....                   |                  |              |               |              | 7                 |                        |                   |
| Qualitative.                                  |                  |              |               |              | 3                 |                        |                   |
| Costs:                                        |                  |              |               |              |                   |                        |                   |
| Annualized Monetized \$millions/year          | \$0.02           | \$0.02       | \$0.02        | 2017         | 7                 | 10.                    |                   |
|                                               | 0.02             | 0.02         | 0.02          | 2017         | 3                 | 10.                    |                   |
| Annualized Quantified .....                   |                  |              |               |              | 7                 |                        |                   |
| Qualitative.                                  |                  |              |               |              | 3                 |                        |                   |
| Transfers:                                    |                  |              |               |              |                   |                        |                   |
| Federal Annualized Monetized \$millions/year. |                  |              |               |              | 7                 |                        |                   |
|                                               |                  |              |               |              | 3                 |                        |                   |
| From/To .....                                 | From:            |              |               | To:          |                   |                        |                   |
| Other Annualized Monetized \$millions/year.   |                  |              |               |              | 7                 |                        |                   |
|                                               |                  |              |               |              | 3                 |                        |                   |
| From/To .....                                 | From:            |              |               | To:          |                   |                        |                   |
| Effects:                                      |                  |              |               |              |                   |                        |                   |
| State, Local or Tribal Government:            |                  |              |               |              |                   |                        |                   |
| Small Business:                               |                  |              |               |              |                   |                        |                   |
| Wages:                                        |                  |              |               |              |                   |                        |                   |
| Growth:                                       |                  |              |               |              |                   |                        |                   |

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost

savings over an infinite time horizon. Based on these cost savings, this proposed rule would be considered a

deregulatory action under Executive Order 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE  
[Millions of 2016\$, over an infinite time horizon]

| Item                                | Primary estimate (7%) | Lower estimate (7%) | Upper estimate (7%) | Primary estimate (3%) | Lower estimate (3%) | Upper estimate (3%) |
|-------------------------------------|-----------------------|---------------------|---------------------|-----------------------|---------------------|---------------------|
| Present Value of Costs .....        | \$0.2                 | \$0.2               | \$0.2               | \$0.6                 | \$0.6               | \$0.6               |
| Present Value of Cost Savings ..... | 1.4                   | 0.7                 | 2.2                 | 3.6                   | 1.9                 | 5.8                 |
| Present Value of Net Costs .....    | (1.2)                 | (0.5)               | (2.0)               | (3.0)                 | (1.3)               | (5.2)               |
| Annualized Costs .....              | 0.02                  | 0.02                | 0.02                | 0.02                  | 0.02                | 0.02                |
| Annualized Cost Savings .....       | 0.10                  | 0.05                | 0.20                | 0.10                  | 0.06                | 0.20                |

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE—Continued

[Millions of 2016\$, over an infinite time horizon]

| Item                       | Primary estimate (7%) | Lower estimate (7%) | Upper estimate (7%) | Primary estimate (3%) | Lower estimate (3%) | Upper estimate (3%) |
|----------------------------|-----------------------|---------------------|---------------------|-----------------------|---------------------|---------------------|
| Annualized Net Costs ..... | (0.08)                | (0.04)              | (0.14)              | (0.09)                | (0.04)              | (0.16)              |

**Notes:** All amounts are in 2016\$ and have been discounted relative to year 2016 from year 2019, the latter which is the estimated year in which the proposed rule would become effective if finalized.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 3) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

#### VIII. 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.

#### IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

#### X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed 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.

#### XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

#### XII. References

The following references marked with an asterisk (\*) are on display in 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>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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.

1. Robbins, K.S., Shah, R., MacMahon, and de Jager, L.S. (2015), "Development of a Liquid Chromatography-Tandem Mass Spectrometry Method for the Determination of Sulfite in Food," *Journal of Agricultural and Food Chemistry* 63, 5126–5132, <https://www.ncbi.nlm.nih.gov/pubmed/25695590>.
2. Carlos, K.S. and L.S. de Jager (2017), "Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study," *Journal of AOAC International*, 100, 6, 1785–1794, <https://www.ncbi.nlm.nih.gov/pubmed/29137699>.
- \*3. FDA, "Amendment to Add a New Method for the Analysis of Sulfites in Foods: Preliminary Regulatory Impact Analysis," 2018, available at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

#### List of Subjects

##### 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

##### 21 CFR Part 130

Food additives, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 101 and 130 be amended as follows:

#### PART 101—FOOD LABELING

- 1. The authority citation for part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

- 2. Amend § 101.100 by revising paragraph (a)(4) to read as follows:

##### § 101.100 Food; exemptions from labeling.

(a) \* \* \*

(4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food. A detectable amount of sulfiting agent is 10 parts per million (ppm or mg/kg) or more of the sulfite in the finished food. Compliance with this paragraph will be determined using either:

(i) "Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry," in *Journal of AOAC International*, Vol. 100, No. 6, pp. 1785–1794, which is incorporated by reference. A copy of *Journal of AOAC International*, Vol. 100, No. 6, is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>; or

(ii) “AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,” in *Official Methods of Analysis of AOAC International*, Sec. 47.3.43 (2019), which is incorporated by reference. A copy of AOAC Official Method 990.28 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

■ 3. Remove and reserve Appendix A to Part 101.

## PART 130—FOOD STANDARDS: GENERAL

■ 4. The authority citation for part 130 continues to read as follows:

**Authority:** 21 U.S.C. 321, 336, 341, 343, 371.

■ 5. Amend § 130.9 by revising paragraph (a) to read as follows:

### § 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable concentration is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million (ppm or mg/kg) or more of the sulfite in the finished food. The concentration of sulfite in the finished food will be determined using either:

(1) “Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry,” in *Journal of AOAC International*, Vol. 100, No. 6, pp. 1785–1794, which is incorporated by reference. A copy of *Journal of AOAC International*, Vol. 100, No. 6 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>; or

(2) “AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,” in *Official Methods of Analysis of AOAC International*, Sec. 47.3.43 (2019), which is incorporated by reference. A copy of AOAC Official

Method 990.28 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Dated: July 16, 2019.

**Norman E. Sharpless,**

*Acting Commissioner of Food and Drugs.*

Dated: September 3, 2019.

**Eric D. Hargan,**

*Deputy Secretary, Department of Health and Human Services.*

[FR Doc. 2019–19862 Filed 9–16–19; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–496]

#### Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) proposes to designate the precursor chemical, *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) as an immediate precursor for the schedule II controlled substance fentanyl. Furthermore, the DEA proposes to control norfentanyl as a schedule II substance under the Controlled Substances Act (CSA). Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for the illicit manufacture of the schedule II controlled substance fentanyl. The distribution of illicitly manufactured fentanyl has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years. The DEA believes that the control of norfentanyl as a schedule II controlled substance is necessary to prevent its diversion as an immediate chemical intermediary for the illicit production of fentanyl.

**DATES:** Comments must be submitted electronically or postmarked on or before November 18, 2019. Commenters should be aware that the electronic Federal Docket Management System

will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA–496” on all electronic and written correspondence, including any attachments.

• **Electronic comments:** The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](http://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• **Paper comments:** Paper comments that duplicate the electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

#### SUPPLEMENTARY INFORMATION:

##### Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the DEA for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL