The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.7-mile (increased from a 6.6-mile) radius of Hereford Municipal Airport, Hereford, TX; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action are the result of an airspace review caused by the decommissioning of the Hereford NDB which provided guidance to instrument procedures at this airport.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Hereford, TX [Amended]

Hereford Municipal Airport, TX
(Lat. 34°51′39″ N, long. 102°19′33″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Hereford Municipal Airport.

Issued in Fort Worth, Texas, on January 10, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–00566 Filed 1–14–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 130

[Docket No. FDA–2019–N–0463]

RIN 0910–AI02

New Method for the Analysis of Sulfites in Foods

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the requirements that specify the analytical method FDA uses to determine the concentration of sulfites in food. This action, among other things, provides a new analytical method that can be used as an alternative to the existing analytical method and will help improve the efficiency of FDA testing for sulfites in food.

DATES: This rule is effective February 17, 2022. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 17, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: 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*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final 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 may use for determining sulfite concentrations in foods.

B. Summary of the Major Provisions of the Final Rule

The final rule updates the current incorporation by reference of the AOAC International Official Method of Analysis for determining sulfite concentrations in foods and removes appendix A to part 101 (21 CFR part 101) as no longer necessary. The final rule also adds a recently developed,

accurate, and more efficient analytical method that FDA will use to determine sulfite concentrations in foods. The addition of this method does not affect parties other than FDA and will not affect industry's disclosure obligations. Manufacturers, for example, are free to use any scientifically adequate method to determine sulfite concentrations in their foods.

C. Legal Authority

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all of the ingredients in a nonstandardized food be declared on the label of that food unless FDA has exempted the ingredients from such requirements. The FD&C Act also states that a food is misbranded if its labeling is false or misleading in any particular and permits FDA to promulgate regulations for the efficient enforcement of the FD&C Act. The final rule amends part 101 under sections 403(i)(2), 403(a), 201(n), and 701(a) of the FD&C Act (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)).

D. Costs and Benefits

We estimate that this final rule will produce benefits in the form of cost savings from time saved by using the liquid chromatography (LC) tandem mass spectrometry (MS) method (LC–MS/MS method). Over a 10-year time horizon, at a three percent discount rate, the present value of estimated benefits is $1.08 million, with a lower bound of $0.57 million and an upper bound of $1.72 million. At a seven percent discount rate, the present value of estimated benefits is $0.89 million, with a lower bound of $0.47 million and an upper bound of $1.41 million. Annualized estimated benefits range from $0.07 million to $0.2 million per year, with a primary estimate of $0.13 million per year, using either a three or seven percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
CFR	Code of Federal Regulations.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
LC	Liquid chromatography.
MS	Mass spectrometry.
ppm	Parts per million.
U.S.C.	United States Cod.

III. Background

A. Need for the Regulation/History of This Rulemaking

FDA is updating regulations that include an outdated incorporation by reference as specified in this final rule and adding 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 10 parts per million (ppm) or more be labeled on foods. (See §§ 101.100(a)(4) and 130.9(a) (21 CFR 101.100(a)(4) and 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 the **Federal Register** of September 17, 2019 (84 FR 48809), we published a proposed rule that would:

- 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;
- Amend the unit of measure specified in two regulations to be consistent with the unit of measure used in the new analytical method;
- 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, as no longer necessary.

B. Summary of Comments to the Proposed Rule

Two comments to the proposed rule expressed general support. For example, one comment said that we should ''take up this new method'' and should do all that we can ''to continue to use the best science available'' to protect consumers. The other comment said that the rule would benefit consumer safety. We received no other comments.

C. General Overview of the Final Rule

The final rule:

- Amends §§ 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,'' Section 47.3.43, *Official Methods of Analysis,* 21st Edition (2019), and to remove appendix A to part 101. The existing incorporation by reference was to the 14th edition, which was published in 1984;
- Amends §§ 101.100(a)(4) and 130.9(a) to add an LC–MS/MS method for determining sulfite concentrations in foods; and
- Amends 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 LC–MS/MS method.

D. Incorporation by Reference

FDA is incorporating by reference ''AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,'' Section 47.3.43, *Official Methods of Analysis,* 21st Edition (2019). A copy of the material can be obtained from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, 301–924–7077 ext. 170, *https://www.aoac.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 incorporating by reference ''Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study,'' Katherine S. Carlos and Lowri S. De Jager, *Journal of AOAC International,* Vol. 100, No. 6 pp. 1785–1794. A copy of the material can be obtained from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, 301–924–7077 ext. 170, *https://www.aoac.org/*. The study describes an LC–MS/MS method that FDA can use as an alternative to AOAC Official Method 990.28 to determine sulfite concentrations in foods.

On our own initiative, we have revised the rule to add another location where the referenced materials can be found. For example, the proposed rule, at § 101.100(a)(4)(i) and (ii), stated that the referenced materials are available from AOAC International and are available for inspection at the National Archives and Records Administration (NARA). The final rule now contains a new § 101.100(j), which states that the referenced materials are available from AOAC International, are available for inspection at NARA, and also are available at FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. We made a similar change to § 130.9.

IV. Legal Authority

FDA is issuing this final rule to amend part 101 under sections 403(i)(2), 403(a), 201(n), and 701(a) of the FD&C Act. Specifically, FDA is amending § 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 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 also are amending 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 that 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.

The final rule updates the incorporation by reference for the current analytical method in parts 101 and 130 and also identifies a new analytical method that we can use in testing for sulfites in foods to determine compliance. The final rule does 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 scientifically appropriate method of choice for determining sulfite concentrations in foods and to use their method of choice as they see fit, recognizing that FDA will rely on the methods established by this rulemaking.

V. Comments on the Proposed Rule and FDA Response

There were two comments to the proposed rule. Both comments expressed general support for the rule.

As the comments did not raise any issues, we have not revised the rule in response to the comments. However, as mentioned earlier, we have, on our own initiative, revised the citation to refer to the ''Official Methods of Analysis'' instead of ''Official Methods of Analysis of AOAC INTERNATIONAL'' to correspond to how the publication is named currently.

We describe the final rule as follows:

- 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 regulations establish the method of analysis in two steps. The first step incorporates by reference Sections 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 at part 101. Collectively, the Monier-Williams method with the appendix A at 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 at 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 at part 101. Consequently, the final rule revises our regulations to reflect the citation to the current AOAC method for determining sulfite concentrations in food but does not result in a change in FDA methodology. Specifically, the final rule amends §§ 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,'' Section 47.3.43, *Official Methods of Analysis,* 21st Edition (2019), and to remove appendix A at part 101. (On our own initiative, we also revised the citation to refer to the *Official Methods of Analysis* instead of *Official Methods of Analysis of AOAC INTERNATIONAL* to correspond to how the publication is named currently.)

- The final rule also amends §§ 101.100(a)(4) and 130.9(a) to add an LC–MS/MS method for determining sulfite concentrations in foods. This method is a faster and more sensitive way to determine sulfite concentrations in foods. FDA's current methodology is an acceptable method for quantifying sulfites, but (among other things) is time-consuming, has a method detection limit of 10 ppm, and is unable to accurately determine sulfite concentrations in some samples. The 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. 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 can improve efficiency in testing and better enforce the labeling requirements for sulfites.
- The final rule also amends 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.
- As explained earlier in section III, we also revised the final rule to restate where the referenced materials can be found and included FDA's Dockets Management Staff as a location where the referenced materials can be found.

VI. Effective/Compliance Date(s)

The preamble to the proposed rule said that we would make any final rule resulting from the rulemaking effective 30 days after its date of publication in the **Federal Register** (84 FR 48809 at 48812).

We did not receive any comments on the proposed effective date. Therefore, the final rule will become effective on February 17, 2022.

VII. Economic Analysis of Impacts

We have examined the impacts of this 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 the final 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 scope of this rule is limited to FDA, 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 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 $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. The final rule will not result in an expenditure in any year that meets or exceeds this amount.

The final rule amends 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. The final rule updates the incorporation by reference for FDA's current methodology and adds 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 will serve as the primary method used by FDA to determine sulfite concentrations in foods.

The benefits of this final rule are the cost savings, in the form of time savings, associated with use of the LC–MS/MS method. There is 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 will change, not the method. Over a 10-year time horizon, at a three percent discount rate, the present value of estimated benefits is $1.08 million, with a lower bound of $0.57 million and an upper bound of $1.72 million. At a seven percent discount rate, the present value of estimated benefits is $0.89 million, with a lower bound of $0.47 million and an upper bound of $1.41 million. In table 1, annualized estimated benefits range from $0.07 million to $0.2 million per year, with a primary estimate of $0.13 million per year, using either a three or seven percent discount rate.

The cost of this final rule consists of both one-time validation costs and recurring materials costs associated with use of the LC–MS/MS method. Over a 10-year time horizon, at a three percent discount rate, the present value of total estimated costs is $0.20 million, with a lower bound of $0.19 million and an upper bound of $0.21 million. At a seven percent discount rate, the present value of total estimated costs is $0.17 million, with a lower bound of $0.16 million and an upper bound of $0.18 million. In table 1, estimated annualized costs are $0.02 million per year, using either a three or seven percent discount rate.

The estimated net benefits of this final rule are defined as the difference between the estimated benefits and the estimated costs of the rule. Over a 10-year time horizon, at a three percent discount rate, the present value of estimated net benefits ranges from $0.38 million to $1.51 million, with a primary estimate of $0.88 million. At a seven percent discount rate, the present value of estimated net benefits ranges from $0.31 million to $1.24 million, with a primary estimate of $0.72 million. Using either a three or seven percent discount rate, annualized estimated net benefits range from $0.04 million to $0.18 million per year, with a primary estimate of $0.10 million per year.

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

[Millions of 2019$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.13	$0.07	$0.20	2019	7	10	Are cost savings.
	0.13	0.07	0.20	2019	3	10	Are cost savings.
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.02	0.02	0.03	2019	7	10	
	0.02	0.02	0.02	2019	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued
[Millions of 2019$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
From/To	From:			To:			
Effects: State, Local or Tribal Government. Small Business. Wages. Growth.							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

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

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

X. Federalism

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

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. Reference

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; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''Amendment to Add a New Method for the Analysis of Sulfites in Foods: Final Regulatory Impact Analysis,'' 2020. Also 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, 21 CFR parts 101 and 130 are 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) and adding paragraph (j) 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 (a)(4) will be determined using either:

(i) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry; or

(ii) AOAC Official Method 990.28.

* * * * *

(j) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and available from the other sources listed in this paragraph (j). It is also 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* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(1) AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250.

(i) AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method, Section 47.3.43,

Official Methods of Analysis, 21st edition, 2019.

(ii) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study, Katherine S. Carlos and Lowri S. De Jager; *Journal of AOAC International,* Vol. 100, No. 6, 2017, pp. 1785–1794.

(2) [Reserved]

Appendix A to Part 101 [Removed and Reserved]

■ 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) and adding paragraph (c) 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; or

(2) AOAC Official Method 990.28.

* * * * *

(c) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250. It is also 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* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method, Section 47.3.43, Official Methods of Analysis, 21st edition, 2019.

(2) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study, Katherine S. Carlos and Lowri S. De Jager; *Journal of AOAC International,* Vol. 100, No. 6, 2017, pp. 1785–1794.

Dated: January 11, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00816 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2021–N–0914]

Medical Devices; Cardiovascular Devices; Classification of the Electrocardiograph Software for Over-the-Counter Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the electrocardiograph software for over-the-counter use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the electrocardiograph software for over-the-counter use's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 18, 2022. The classification was applicable on September 11, 2018.

FOR FURTHER INFORMATION CONTACT: Luke Ralston, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2311, Silver Spring, MD 20993–0002, 301–796–6362, *Luke.Ralston@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the electrocardiograph software for over-the-counter use as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial