15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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. 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on April 1, 2022.

Thomas J Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CRF part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 19 May 2022

Palm Springs, CA, KTRM, RNAV (GPS) RWY 35, Amdt 2
Miami, FL, KMIA, ILS OR LOC RWY 9, Amdt 11
Mapleton, IA, KMEY, RNAV (GPS) RWY 2, Amdt 1
Mapleton, IA, KMEY, RNAV (GPS) RWY 20, Amdt 1
Olney-Noble, IL, KOLY, LOC RWY 11, Amdt 7
Marion, KY, KGDA, RNAV (GPS) RWY 7, Amdt 3
Marion, KY, KGDA, RNAV (GPS) RWY 25, Amdt 3
O'Neill, NE, KONL, VOR RWY 13, Amdt 5F
O'Neill, NE, KONL, VOR RWY 31, Amdt 1E
Berlin, NH, KBML, Takeoff Minimums and Obstacle DP, Amdt 3
Las Vegas, NV, KLAS, ILS OR LOC RWY 1L, Amdt 4
Las Vegas, NV, KLAS, RNAV (GPS) RWY 1R, Amdt 4
Las Vegas, NV, KLAS, RNAV (RNP) RWY 26R, Amdt 1
Babelthuap Island, PW, PTRO, NDB RWY 9, Orig-B
Babelthuap Island, PW, PTRO, RNAV (GPS) RWY 9, Orig-B
Babelthuap Island, PW, PTRO, RNAV (GPS) RWY 27, Orig-B
Mc Minnville, TN, KRNC, Takeoff Minimums and Obstacle DP, Amdt 3
Burlington, VT, KBTV, RNAV (GPS) RWY 1, Amdt 1

[FR Doc. 2022–08312 Filed 4–19–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. FDA–2018–N–1815]

RIN 0910–AI03

Beverages: Bottled Water

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 revising the quality standard for bottled water to specify that bottled water to which fluoride is added by the manufacturer may not contain fluoride in excess of 0.7 milligrams per liter (mg/L), which available data suggests provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis. This final rule revises the current allowable levels, which range from 0.8 to 1.7 mg/L, for fluoride in domestically packaged and imported bottled water to which fluoride is added. We are taking this action to make

the quality standard regulation for fluoride added to bottled water consistent with the 2015 recommendation by the U.S. Public Health Service (PHS) for community water systems that add fluoride for the prevention of dental caries. This action will not affect the allowable levels for fluoride in bottled water to which fluoride is not added by the manufacturer (such bottled water may contain fluoride from its source water).

DATES: This rule is effective June 21, 2022. The compliance date is October 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: David Whitman, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3754, *David.Whitman@fda.hhs.gov*; or Deirdre Jurand, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

We are amending the allowable levels for fluoride in bottled water to which fluoride is added, to be consistent with the updated recommendation by the PHS on the optimal fluoride concentration in community water systems that add fluoride for the prevention of dental caries.

B. Summary of the Major Provisions of the Final Rule

The final rule revises the quality standard for bottled water (found in § 165.110(b) (21 CFR 165.110(b)) to set the allowable level for fluoride at 0.7 mg/L in domestically packaged and imported bottled water to which fluoride has been added.

C. Legal Authority

This final rule updates the quality standard for bottled water, consistent with our authority in sections 401, 403, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341, 343, and 371(a)). We discuss our legal authority in greater detail in section III.

D. Costs and Benefits

This final rule revises the quality standard regulations so that the allowable level for fluoride is 0.7 mg/L in bottled water to which fluoride has been added, which is consistent with the current PHS recommendation on the optimal level of fluoride in community water systems that add fluoride for the prevention of dental caries. We estimate that there will be one-time costs to read and understand the rule for all bottled water manufacturers and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. The one-time costs range between $214,370.26 and $333,338.24. When discounted at 7 percent over 10 years, the annualized costs range from $30,521.50 to $47,459.87. When discounted at 3 percent over 10 years the annualized costs range from $25,130.73 to $39,077.41.

II. Background

A. Need for the Regulation/History of This Rulemaking

In 1973, FDA established standards of quality for bottled water, including allowable levels for fluoride, based on the PHS' 1962 Drinking Water Standards (38 FR 32558, November 26, 1973). In adopting the 1962 PHS drinking water standard for fluoride, FDA concluded that the addition of fluoride to bottled water should be permitted to be consistent with the policy of allowing community water fluoridation (38 FR 32558 at 32561). For bottled water to which fluoride is added that is packaged in the United States, FDA established as the allowable level a range (0.8 to 1.7 mg/L) based on the annual average maximum daily air temperatures at the location where the bottled water is sold at retail. For imported bottled water, we established a single allowable level for fluoride in bottled water to which fluoride is added (0.8 mg/L).

In 2015, the PHS updated and replaced its 1962 Drinking Water Standards related to community water fluoridation and recommended an optimal fluoride concentration of 0.7 mg/L. This recommendation is published in a **Federal Register** notice entitled ''Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries'' (80 FR 24936, May 1, 2015). The same year, we issued a letter to industry recommending, based on the updated PHS recommendation, that bottled water manufacturers not add fluoride to bottled water at concentrations greater than a final concentration of 0.7 mg/L (Ref. 1). In our letter, we also stated our intent to revise the allowable levels for fluoride in bottled water to which fluoride has been added to be consistent with the updated PHS recommendation. We did not receive any objections to the letter, and bottled water manufacturer input indicates that most bottled water to which fluoride has been added that is sold or offered for sale in the United States, whether domestic or imported, now has no more than 0.7 mg/L fluoride (Ref. 2).

In the **Federal Register** of April 3, 2019, we issued a proposed rule to amend the quality standard for bottled water (found in § 165.110(b)) to set the allowable level for fluoride at 0.7 mg/L in domestically packaged and imported bottled water to which fluoride has been added (84 FR 12975) (''proposed rule''). We explained the basis for the PHS's 2015 optimal fluoride concentration recommendation for drinking water, concluded that the basis is a sound public health measure that should also apply to bottled water, and noted that amending the allowable level for fluoride in bottled water to which fluoride had been added to 0.7 mg/L would be consistent with the updated PHS fluoride recommendation. We also

stated that this may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation (84 FR 12975 at 12978).

In addition, consistent with the updated PHS recommendation, we proposed to remove references to annual averages of maximum daily air temperatures in § 165.110(b) because, as discussed in the updated PHS recommendation, data do not show a convincing relationship between fluid intake and ambient air temperature (84 FR 12975 at 12977).

We also proposed that the final rule be effective 60 days after the date of the final rule's publication in the **Federal Register** and a compliance date 120 days after the effective date.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 60-day comment period. We received more than 90 comments. The comments came from individuals, academia, healthcare professionals, consumer advocacy groups, research associations, and industry trade associations. Among other things, the comments discussed:

- *The level of added fluoride that should be in bottled water.* Many comments supported our proposed level, but some opposed the addition of any fluoride to bottled water or supported an amount less than 0.7 mg/L. Additionally, some comments suggested that consumers should be able to choose between bottled water with and without added fluoride. Other comments suggested that we should do our own studies or consider additional research.
- *The health effects of added fluoride to water.* While some comments agreed that the proposed level would help prevent dental caries, some other comments expressed concern that the ingestion of fluoride could have adverse health effects, such as dental fluorosis, skeletal fluorosis, neurological toxicity, endocrine disruption, and lower IQ.

III. Legal Authority

We are updating the quality standard establishing the allowable levels for fluoride in bottled water to which fluoride has been added, as set forth in this final rule, consistent with our authority in sections 401, 403, and 701(a) of the FD&C Act.

Section 401 of the FD&C Act directs the Secretary of the Department of Health and Human Services (the Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers.

Under section 403(h)(1) of the FD&C Act, a food is misbranded if it purports to be or is represented as a food for which a standard of quality has been prescribed by regulations under section 401 of the FD&C Act, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n* v. *FDA,* 484 F. Supp. 1179, 1183 (D. Del. 1980)). Updating this allowable level for fluoride in bottled water to be consistent with the updated PHS recommendation would help effectuate the congressional objective expressed in sections 401 and 403 of the FD&C Act.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received no comments on our proposal to remove references to annual averages of maximum daily air temperatures in § 165.110(b) and are finalizing it without change. We received more than 90 comments on other provisions of the proposed rule, and each comment discussed one or more issues. The comments came from individuals, academia, healthcare professionals, consumer advocacy groups, research associations, and industry trade associations.

We describe and respond to the comments in sections B through F of this section. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Many comments expressed general support for the proposed rule. A few comments stated that the proposed rule, if finalized, would provide consistency between domestically packaged and imported bottled water.

(Response 1) We proposed to revise, and are revising, the allowable level for fluoride to 0.7 mg/L in bottled water to which fluoride has been added, a level consistent with the current PHS recommendations for the optimal level of fluoride in community water systems to prevent dental caries. The revised allowable level is consistent between domestically packaged and imported bottled water. As stated in the 2011 Department of Health and Human Services (HHS) notice proposing the revised recommended fluoride concentration, available data suggest that a concentration of 0.7 mg/L provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis (76 FR 2383 at 2386). The PHS confirmed this in 2015 (80 FR 24936).

(Comment 2) A few comments advocated the availability of both fluoridated and non-fluoridated bottled water so that consumers have choices. One comment stated that FDA should not ask all bottlers to fluoridate to the 2015 PHS recommended level of 0.7 mg/L. Another said that consumers have a right to be aware of the content of their drinking water, and so FDA should require manufacturers who add fluoride to their water to label the amount added.

(Response 2) Our final rule revises the allowable level for fluoride to 0.7 mg/L for bottled water to which fluoride is added. Manufacturers are not required to fluoridate their water, or to fluoridate to a level of 0.7 mg/L. Instead, our regulations, at § 165.110(a)(1), provide that fluoride may be optionally added up to the allowable level.

Consumers can examine bottled water labeling to determine whether fluoride has been added. In the preamble to the 1995 final rule establishing the standard of identity and standard of quality for bottled water, we explained that bottled water with added fluoride would be a multi-ingredient food and, as such, its label must bear ingredient labeling (60 FR 57076 at 57079, November 13, 1995).

If fluoride is added to bottled water, it must be declared in the ingredients list (21 CFR 101.4(a)(1)). In addition, the terms ''fluoridated,'' ''fluoride added,'' or ''with added fluoride'' may be used on the label or in labeling of bottled water that contains added fluoride (21 CFR 101.13(q)(8)). Finally, our regulations, at § 101.9(c)(5) (21 CFR 101.9(c)(5)), require the label declaration of fluoride in certain circumstances and allow for it voluntarily in all other cases.

While labeling the amount of fluoride added to bottled water is outside the scope of this rule, we note that mandatory declaration of the amount of fluoride is required if a claim about fluoride content is made on the label or in the labeling of foods (see § 101.9(c)(5)). We also addressed this in the preamble to our 2016 final rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742, May 27, 2016) (Nutrition Facts Label final rule). We declined to require the declaration of fluoride because, among other reasons, fluoride is a nonessential nutrient, a daily reference intake cannot be established based on available quantitative intake recommendations, and total fluoride intake can come from sources other than bottled water (81 FR 33742 at 33881).

(Comment 3) Some comments stated that FDA should not rely on the PHS recommendation and FDA should provide its own scientific justification for the fluoride level in the proposed rule. A few others asked FDA to review studies published on the safety of fluoride and community water fluoridation after the 2015 PHS recommendation.

(Response 3) We disagree with the comments stating that FDA should not rely on the PHS recommendation. In the preamble to the proposed rule, we explained the basis for the PHS's 2015 recommendation and concluded that the basis is a sound public health measure that should also apply to bottled water to which fluoride is added. Furthermore, the PHS recommended 0.7 mg/L fluoride after systematic reviews of existing science by a Federal interdepartmental, interagency panel of scientists, including scientists from FDA (76 FR 2383, January 13, 2011; 80 FR 24936, May 1, 2015). This is consistent with our approach in 1973, when we established the allowable levels for fluoride in bottled water based on the PHS's 1962 Drinking Water Standards. At that time we also concluded that the addition of fluoride to bottled water should be permitted to be consistent with the policy of community water fluoridation (38 FR 32558 at 32561). We also believe this will help promote honesty and fair dealing in the interest of consumers under section 401 of the FD&C Act (21 U.S.C. 341) in that consumers may expect the levels of fluoride added to bottled water to be consistent with the levels of fluoride in public drinking water.

We recognize that additional studies on the safety of fluoride have published since the publication of the 2015 PHS recommendation. We do not believe these studies contradict the PHS recommendation, and neither these studies nor the body of literature we have reviewed show adverse health effects of fluoride in humans up to the level we are finalizing. The PHS recommendation has not changed, and we maintain that the addition of fluoride to bottled water should be permitted to be consistent with the policy of community water fluoridation. Given that the comments provided no new information indicating the need to duplicate the scientific evaluation already conducted by PHS, we are revising the allowable level for fluoride in bottled water to which fluoride is added based on the 2015 PHS recommendation.

(Comment 4) Some comments opposed the addition of any fluoride to bottled water. A few stated that fluoride is a contaminant, poison, or an industrial waste product, and suggested that our adoption of an optimal fluoride concentration, or use of the term ''optimal,'' is an endorsement of fluoridation or encourages the fluoridation of bottled water. Some comments listed possible adverse health effects of water fluoridation, such as dental fluorosis, skeletal fluorosis, neurological toxicity, endocrine disruption, and lower IQ. Some stated that the prevention of dental caries by ingesting fluoride does not have adequate scientific support and topical application of fluoride through toothpaste or mouthwash, or by a dentist, is a better way to prevent dental caries.

(Response 4) As an initial matter, we consider fluoride to be a nutrient. As stated in our response to comment 3, the addition of fluoride to bottled water should be permitted to be consistent with the PHS recommended level of community water fluoridation, and the PHS recommendation is a sound public health measure that should also apply to bottled water to which fluoride is added. The PHS recommendation addressed the potential for dental fluorosis as well as concerns about other adverse effects from water fluoridation (80 FR 24936 at 24940 through 24942). The PHS recommendation also addressed the concerns regarding the safety of fluoride additives (80 FR 24936 at 24942 through 24943). The comments did not provide, and we are not aware of, evidence that fluoride added to bottled water up to 0.7 mg/L is a contaminant or poison, or that fluoride is an industrial waste product.

Regarding the comments suggesting that this rule endorses or encourages bottled water fluoridation, we note in our response to comment 2 that the rule does not require manufacturers to fluoridate their water, or to fluoridate to a level of 0.7 mg/L. Instead, our regulations, at § 165.110(a)(1), provide that fluoride may be optionally added up to the allowable level. We also note that we are not adopting or identifying an optimum fluoride level for bottled water to which fluoride has been added, and we maintain that the addition of fluoride to bottled water should be consistent with the policy of community water fluoridation.

Regarding the ingestion of fluoride, we recognize that consumers are also exposed to fluoride from other sources. The PHS considered the availability of other fluoride-containing products, including toothpastes, mouth rinses, and professionally applied fluoride compounds, when establishing the 0.7 mg/L optimum level for community water fluoridation (80 FR 24936 at 24937 through 24938). The PHS also stated that community water fluoridation is a major factor responsible for the decline of the prevalence and severity of dental caries during the second half of the 20th century, and that, when analyses were limited to studies conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (80 FR 24936 at 24937).

(Comment 5) One comment supported the proposal but asked whether the reduction of the amount of added fluoride in bottled water will have any other unforeseen long-term effects on the population.

(Response 5) The comment did not provide, and we are not aware of, any information regarding unforeseen long-term effects on the population of a 0.7 mg/L fluoride limit in bottled water to which fluoride is added.

C. Comments on the Level of Added Fluoride in Bottled Water and FDA Response

(Comment 6) Some comments that supported the proposed rule specifically supported the proposed level of 0.7 mg/L and stated that the level is consistent with public health

recommendations, FDA guidance, and current industry practice.

(Response 6) As we noted in our response to comment 1, we proposed to revise the standard for the allowable level for fluoride to 0.7 mg/L in bottled water to which fluoride has been added, a level consistent with the updated PHS recommendations. As stated in the 2011 HHS notice proposing the revised recommended fluoride concentration, available data suggest that a fluoride concentration of 0.7 mg/L provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis (76 FR 2383 at 2386). Moreover, this may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation, or different standards for domestically packaged and imported bottled water.

(Comment 7) One comment said that there is no need for this rule because there is no immediate danger in the levels of fluoride in bottled water.

(Response 7) We disagree that there is no need for this rule or that an ''immediate danger'' is needed to take this action. This final rule is consistent with our authority in sections 401, 403, and 701(a) of the FD&C Act. We have concluded that the basis for PHS' updated recommendation of optimum fluoridation level of 0.7 mg/L in community water is a sound public health measure that should also apply to bottled water.

When we adopted the 1962 PHS drinking water standard for fluoride, we concluded that the addition of fluoride to bottled water should be permitted to be consistent with the policy of allowing community water fluoridation (38 FR 32558 at 32561). In addition, this rule may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation, or different standards for domestically packaged and imported bottled water.

(Comment 8) Some comments asked FDA to regulate the level of fluoride naturally present in bottled water. A few comments specifically asked FDA to reduce the allowable levels for naturally occurring fluoride to 0.7 mg/L, and a few others indicated that FDA should not permit the sale of bottled water with natural fluoride concentrations above 0.7 mg/L.

(Response 8) The regulation of bottled water to which no fluoride is added is outside the scope of this rule. Our regulations, at § 165.110(b)(4)(ii)(A) and (B), limit the amount of fluoride in domestic and imported bottled water to which no fluoride is added. Those levels range from 1.4 to 2.4 mg/L. Our current revision of the allowable levels of fluoride in bottled water is based on the 2015 PHS recommendation, which does not affect community water systems with naturally occurring fluoride in water at concentrations greater than 0.7 mg/L (80 FR 24936 at 24937). Therefore, we are not revising the allowable levels for fluoride in bottled water to which fluoride has not been added by the manufacturer.

We note that the maximum fluoride level we are finalizing limits the total amount of fluoride that may be present in bottled water to which fluoride is added—that is, the sum of added and naturally occurring fluoride amounts in bottled water to which fluoride is added may not exceed 0.7 mg/L.

(Comment 9) Several comments expressed concern that even if the amount of added fluoride is safe, the final fluoride level in bottled water to which fluoride is added may be unsafe because either: (a) The water to which fluoride is added may already contain fluoride; or (b) ingestion of both fluoridated community water and bottled water to which fluoride is added would lead to fluoride overconsumption.

(Response 9) As we noted in our response to comment 8, the maximum fluoride level we are finalizing limits the total amount of fluoride that may be present in bottled water to which fluoride is added—that is, the sum of added and naturally occurring fluoride amounts in bottled water to which fluoride is added may not exceed 0.7 mg/L. The regulation of bottled water to which no fluoride is added (which may contain naturally occurring fluoride) and of municipal water is outside the scope of this rule. However, the PHS considered the availability of other fluoride-containing products when establishing the 0.7 mg/L optimum level for community water fluoridation (80 FR 24936 at 24937).

(Comment 10) One comment recommended a level of 0.6 mg/L and cited the recommendation from the New Hampshire Department of Environmental Services (NH DES) (Ref. 3).

(Response 10) The NH DES recommends a drinking water fluoride level of 0.6 to 0.8 mg/L. It references the Centers for Disease Control and Prevention (CDC) community water fluoridation website (Ref. 4), which further references the 2015 U.S. PHS recommended level of 0.7 mg/L. As such, the NH DES's recommendation is consistent with the 2015 PHS recommendation. The comment did not provide other information to support the 0.6 mg/L level. Therefore, we are not revising the allowable level to 0.6 mg/L.

(Comment 11) One comment asked FDA to create an acceptable range of fluoride for the purposes of compliance with the rule, because such a range would appropriately recognize that: (a) Adding fluoride to bottled water is not an exact process; and (b) existing FDA regulations require added minerals to be present at least at the level declared on the label. The comment stated that this type of operational flexibility is needed because the level of fluoride in a bottled water product with added fluoride will be subject to some variation, consistent with good manufacturing practices. The comment said that, if the proposed rule is finalized without the requested range for compliance, the rule would appear to create a paradox with respect to compliance with two sets of FDA regulations: (1) This rule, which establishes 0.7 mg/L as the maximum or ceiling for bottled water to which fluoride is added; and (2) the FDA compliance standard for nutrition labeling, which establishes the declared level as the minimum or floor by requiring a composite sample tested for an added mineral like fluoride to contain the mineral at least 100 percent of the declared level. The comment specifically asked FDA to establish a range of 0.6 to 1.0 mg/L for fluoride in bottled water intended for children 4 years and older and adults, and a separate range of 0.4 to 0.7 mg/L for fluoride in bottled water intended for infants and toddlers under 4 years of age.

(Response 11) We decline to create a compliance range and are finalizing the revision of the standard for the allowable level for fluoride to 0.7 mg/L in bottled water to which fluoride has been added.

We recognize that there are potential variabilities in adding fluoride in bottled water during manufacturing and variabilities during fluoride measurement. We also recognize that the CDC proposed an operational control range of 0.6 to 1.0 mg/L in community water systems that adjust fluoride (83 FR 32666, July 13, 2018). The proposed range is based on the ability of community water systems to stay successfully within a particular operational control range (83 FR 32666 at 32667). The comment did not provide information on fluoride variations within community water systems that are applicable to a bottled water manufacturing environment or to

support the requested compliance ranges. Additionally, we have no information, and received no comments, suggesting that some current single-level fluoride standards that have no compliance range (*e.g.,* 0.8 mg/L for bottled water to which fluoride is added and that is at an annual average of maximum daily air temperature between 79.3 to 90.5 °F) have posed unreasonable challenges to the bottled water industry.

We agree that our regulations require added minerals to be present at least at the level declared on the label. Our regulations, at § 101.9(g)(4)(i), state that a food with a label declaration of, among other things, a mineral that meets our definition of a Class I nutrient is misbranded under section 403(a) of the FD&C Act unless its nutrient content is formulated to be at least equal to the value for that nutrient declared on the label. We explained in the Nutrition Facts Label final rule that we consider fluoride to be a nutrient, and specifically, a mineral (81 FR 33742 at 33883). Added fluoride is a Class I nutrient for nutrition labeling purposes because it is an added nutrient in fortified or fabricated foods (§ 101.9(g)(3)(i)).

A label declaration is required if a claim about fluoride content is made on the label or in the labeling of foods (see § 101.9(c)(5)). Our regulations would require the fluoride levels in such products to be at least at the level declared on the label. That minimum fluoride level is not incompatible with the fluoride level finalized in this rule. We understand that, to account for process variability, industry may formulate to a slightly higher fluoride content to ensure the impacted products consistently meet the minimum requirement for nutrient declaration as described in § 101.9(g)(4)(i). We expect that the slight overage of fluoride used to account for process variability is small and would be consistent with current good manufacturing practice (§ 101.9(g)(6)). In addition, an FDA sample for nutrient analysis consists of a composite of 12 subsamples (consumer units), with one sample taken from each of 12 different randomly chosen shipping cases, to be representative of a lot (§ 101.9(g)(2)). FDA conducts nutrient analyses using appropriate methods as given in the Official Methods of Analysis of the AOAC International (id.). Therefore, our sampling procedure for compliance purposes already takes into account the sample variabilities within a lot. Furthermore, as discussed in our response to comment 2, bottled water manufacturers that fluoridate their water are not required to fluoridate to a level of 0.7 mg/L—lower levels are permitted. A bottled water manufacturer could target a fluoridation level below 0.7 mg/L, and, even with the slight overage consistent with current good manufacturing practices, we would expect the finished product to be in compliance with both the labeling requirement in § 101.9(g)(4)(i) and the allowable level for fluoride finalized in this rule.

D. Comment on the Health Effects of Added Fluoride and FDA Response

(Comment 12) A few comments expressed concern that dental fluorosis could occur in infants who consume infant formula reconstituted with fluoridated bottled water.

(Response 12) The PHS considered this when they issued their 2015 recommendation. They stated that, if an infant is consuming only infant formula mixed with fluoridated water, there may be an increased chance for permanent teeth to have mild dental fluorosis (80 FR 24936 at 24940 through 24941). To lessen this chance, parents may choose to use low-fluoride bottled water some of the time to mix infant formula, *e.g.,* bottled waters labeled as deionized, purified, demineralized, or distilled, and without any fluoride added after purification treatment (80 FR 24936 at 24940). However, the PHS concluded that their recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through 8 years of age for most permanent teeth, and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water (80 FR 24936). We expect the same balance between the prevention of dental caries and the risk of dental fluorosis from consumption of bottled water to which fluoride is added because this rule revises the allowable fluoride level in those products to be consistent with the 2015 PHS recommendation. The comments provided no new information on this topic, and we agree with PHS' analysis.

As discussed in our response to comment 2, fluoride added to bottled water must be declared in the ingredient list in accordance with § 101.4. Consumers can examine bottled water labeling to determine whether fluoride has been added by, for instance, noting the type of bottled water (*e.g.,* purified) and reading the ingredient declaration (*i.e.,* for whether fluoride is listed as an ingredient).

E. Comment on the Compliance Date and FDA Response

(Comment 13) One comment expressed concern over bottled water manufactured prior to the effective date of the final rule. It asked whether these products can continue to be sold, and if these products would impact consumer health. The comment suggested FDA state publicly that bottled water produced under the current standard will not adversely influence consumers health so that the consumer can keep buying in the period between the effective date and the compliance date. The comment also stated that the proposed compliance date of 120 days after the effective date is too tight for large companies, which may need a longer time to adjust all of their fluoridated water products.

(Response 13) The comment provided, and we are aware of, no information suggesting that that there will be product remaining in inventories that does not comply with the rule after the compliance date, and that large companies may need a longer time to adjust their fluoridated products. We stated in the proposed rule that many bottled water manufacturers in the United States have already adjusted their addition of fluoride to obtain the 0.7 mg/L fluoride in their finished bottled water in response to the updated 2015 PHS recommendation and FDA's April 27, 2015, letter to manufacturers, distributors or importers of bottled water (84 FR 12975 at 12977). We received no comments from bottled water manufacturers or industry groups expressing concerns with inventory remaining after the compliance date. Therefore, we do not expect any significant amount of bottled water products to which fluoride has been added and whose fluoride are at levels above 0.7 mg/L to remain in inventory after the compliance date. We are finalizing the effective and compliance dates as proposed. With regard to the comment's question about the impact on public health of bottled water manufactured prior to this rule's effective date that meets the previous quality standard for added fluoride, we do not have safety concerns. We note that any such bottled water would be misbranded if it did not comply with the label statement requirements under § 165.110(c).

F. Miscellaneous Comments and FDA Response

Many comments addressed aspects of fluoride other than the allowable level in bottled water to which fluoride is added. Some aspects, such as allowable

fluoride levels in municipal water systems, the price of bottled water, and other substances that we could consider requiring or allowing in bottled water, are outside the scope of the rule, and we will not address them here.

We discuss the other miscellaneous comments in the following paragraphs.

(Comment 14) One comment said that too many children, especially infants, are ingesting too much fluoride. The comment said that the warning statement ''Do Not Use Fluoridated Water For Infants or Making Formula'' must be placed on fluoridated water, and the warning statement ''For Adult Use Only'' should be placed on fluoridated water.

(Response 14) As discussed in our response to comment 2, fluoride added to bottled water must be declared in the ingredient list in accordance with § 101.4. Consumers can examine bottled water labeling to determine whether fluoride has been added by, for instance, noting the type of bottled water (*e.g.,* purified) and reading the ingredient declaration (*i.e.,* for whether fluoride is listed as an ingredient). Parents may choose whether to give fluoridated bottled water to children and whether to use bottled water with added fluoride to mix infant formula. Additionally, as we explained in our response to comment 12, the level we are finalizing balances the prevention of dental caries and the risk of dental fluorosis from consumption of bottled water to which fluoride is added. The comment provided no new information on this topic. Therefore, we decline to revise the rule as suggested by the comment.

(Comment 15) One comment asked whether the determination about Indian Tribal Governments in the proposed rule has changed.

(Response 15) In the proposed rule, we tentatively concluded 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. Our tentative conclusion has not changed. The comment did not provide any information that would cause us to reexamine or alter our tentative conclusion.

V. Effective/Compliance Dates

Effective date: This rule is effective June 21, 2022.

Compliance date: The compliance date of this final rule is October 17, 2022.

VI. Economic Analysis of Impacts

We have examined the impacts of the final 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). This final rule has been designated by the Office of Information and Regulatory Affairs as 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 updating the standards of the allowable level for fluoride in bottled water to which fluoride has been added specified in this final rule will not significantly increase costs to bottled water manufacturers, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes 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. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

The rule revises the bottled water quality standard for the allowable level for fluoride to 0.7 mg/L in bottled water to which fluoride has been added, a level consistent with the updated PHS recommendations for the optimal level of fluoride in community water systems to prevent dental caries (tooth decay).

There will be one-time costs to read and understand the rule for all bottled water manufacturers and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. The one-time costs range between $214,370.26 and $333,338.24. When discounted at 7 percent over 10 years, the annualized costs range from $30,521.50 to $47,459.87. When discounted at 3 percent over 10 years the annualized costs range from $25,130.73 to $39,077.41.

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. 5) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(m) 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.

VIII. 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.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this rule has federalism impacts as it amends the standard of quality regulations for bottled water. The existing standard of quality is not new and already preempts State laws because it is within the scope of section 403A of the FD&C Act, an express preemption provision.

X. 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 have substantial direct effects 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.

XI. References

The following references are on display at 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 also are 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.

1. FDA, ''Letter to Manufacturers, Distributors, or Importers of Bottled Water with an Update on Fluoride Added to Bottled Water'' (April 27, 2015). Available at *https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/bottledwatercarbonatedsoftdrinks/ucm444373.htm* (accessed March 29, 2022).
2. International Bottled Water Association Communication to H. Kim, FDA, Letter, 6/15/2018.
3. New Hampshire Department of Environmental Services, Environmental Fact Sheet: Fluoride in Drinking Water (2020). Available at *https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/2020-01/dwgb-3-5.pdf* (accessed March 29, 2022).
4. Centers for Disease Control and Prevention, ''Community Water Fluoridation.'' Available at *https://www.cdc.gov/fluoridation/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Ffluoridation%2Findex.htm* (accessed March 29, 2022).
5. FDA, ''Final Rule to Revise the Allowable Level of Fluoride in Bottled Water to which Fluoride Has Been Added, Economic Analysis of Impacts, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis.'' Available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (accessed March 29, 2022).

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

PART 165—BEVERAGES

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

■ 2. Amend § 165.110 by revising paragraphs (b)(4)(ii)(C) and (D) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(C) Bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(D) Imported bottled water to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

* * * * *

Dated: April 8, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–08273 Filed 4–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0168]

Special Local Regulations; Conch Republic Navy Parade and Battle, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the Conch Republic Navy Parade and Battle in Key West, Florida. Our regulation for Recurring Marine Events in Seventh Coast Guard District identifies the regulated area for this event. During the enforcement period no person or vessel may enter into, transit through, anchor in, or remain within the regulated area without approval from the Captain of the Port Key West or a designated representative.

DATES: The regulations in 33 CFR 100.701 will be enforced for the location identified in paragraph (b) Item 2 of Table 1 to § 100.701, from 7 p.m. until 8 p.m. on April 22, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email *SKWWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.701, Table 1 to § 100.701, paragraph (b), Item 2, from 7 p.m. until 8 p.m. on April 22, 2022 for the annual Conch Republic Navy Parade and Battle in Key West, Florida. This action is being taken to provide for the safety of life on the navigable waters of the Key West Harbor during the simulated battle event. Our regulation for Recurring Marine Events within Seventh Coast Guard District, § 100.701, Table 1 to § 100.701, paragraph (b), Item 2, specifies the location of the regulated area for the reenactment of the battle within the Key West Harbor.

During the enforcement period, as reflected in § 100.701, no person or vessel may enter, transit through, anchor within, or remain within the established regulated areas without approval from the Captain of the Port Key West or designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notice of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: April 12, 2022.

Adam A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2022–08423 Filed 4–19–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0233]

RIN 1625–AA00

Safety Zones; Cape Canaveral, Daytona, Tampa, Jacksonville, and Tallahassee, Florida

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing five temporary safety zones for the reentry of capsules launched by Space Exploration Technologies Corporation (Space X) in support of the Axiom and the National Aeronautics and Space Administration (NASA) Crew-3 capsule recovery missions. These five temporary safety zones are located within the Coast Guard District Seven area of responsibility offshore of Cape Canaveral, Daytona, Jacksonville, Tampa, and Tallahassee, Florida. The purpose of this rule is to ensure the safety of vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled