end users' of a country identified in this section not located in that same country are exhaustively listed on either the Entity List with a footnote 3 designation or on the MEU List under supplement no. 7 this part. Exporters, reexporters, and transferors are responsible for determining whether transactions with entities not listed on supplement no. 7 or 4 to this part are subject to a license requirement under paragraph (a) of this section. The process in this paragraph (b)(1) for placing entities on the MEU List and Entity List is only one method BIS may use to inform exporters, reexporters, and transferors of license requirements under this section.

(i) *End-User Review Committee (ERC).* The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the MEU List and Entity List. Decisions by the ERC for purposes of the MEU List and Entity List will be made following the procedures identified in this section and in supplement no. 5 to this part (Procedures for End-User Review Committee Entity List and 'Military End User' (MEU) List Decisions).

(ii) *License requirement for parties to the transaction.* Consistent with paragraph (a) of this section, a license is required for the export, reexport, or transfer (in-country) of any item subject to the EAR listed in supplement no. 2 to this part when an entity that is listed on the MEU List as a Burmese, Cambodian, Chinese, Nicaraguan, or Venezuelan 'military end user' is a party to the transaction as described in § 748.5(c) through (f) of the EAR. Consistent with paragraph (a) of this section, a license is required for the export, reexport, or transfer (in-country) of any item subject to the EAR when a Belarusian or Russian 'military end user' that is listed on the Entity List pursuant to this section is a party to the transaction as described in § 748.5(c) through (f) of the EAR.

* * * * *

(e) * * *

(3) Applications for items requiring a license for any reason that are destined for a 'military end use' in Belarus, Burma, Cambodia, China, Nicaragua, the Russian Federation, or Venezuela or for a Belarusian, Burmese, Cambodian, Chinese, Nicaraguan, Russian, or Venezuelan 'military end user,' wherever located, also will be subject to the review policy stated in paragraph (e)(1) of this section.

* * * * *

■ 7. Supplement no. 7 to part 744 is amended in the table by adding in alphabetical order an entry for ''Nicaragua'' to read as follows:

Supplement No. 7 to Part 744—'Military End-User' (Meu) List

* * * * *

Country	Entity	Federal Register citation
* *	* *	*
NICARAGUA	[Reserved]	[Reserved].
* *	* *	*

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024–05696 Filed 3–14–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 152

[Docket No. FDA–2020–N–1690]

RIN 0910–AI17

Frozen Cherry Pie; Revocation of a Standard of Identity and a Standard of Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is revoking the standard of identity and the standard of quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the American Bakers Association (ABA). We conclude that these standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. Revocation of the standards of identity and quality for frozen cherry pie will provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

DATES: This rule is effective April 15, 2024.

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: Rumana Yasmeen, Office of Nutrition and Food Labeling (HFS–820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Alexandra Beliveau, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, 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

The final rule revokes the standards of identity and quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the ABA. We conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest of consumers. Revoking these standards will provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

B. Summary of the Major Provisions of the Final Rule

The final rule revokes the standards of identity and quality for frozen cherry pie.

C. Legal Authority

We are issuing the final rule to revoke the standards of identity and quality for frozen cherry pie consistent with our authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act), which directs the Secretary of Health and Human Services (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 Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

D. Costs and Benefits

The final rule affects manufacturers of frozen cherry pie and does not require firms within the frozen cherry pie industry to change their manufacturing practices. Our analyses of current food manufacturing practices and the petition to revoke the standards indicate that revoking the standards of identity and quality could provide benefits in terms of additional flexibility and the opportunity for innovation to manufacturers. Therefore, we conclude that the final rule to revoke the standards for frozen cherry pie will provide social benefits at no cost to the respective industries.

II. Background

A. Need for the Regulation/History of This Rulemaking

Section 401 of the FD&C Act (21 U.S.C. 341) directs 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 Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers. The purpose of these standards is to protect consumers against economic adulteration and reflect consumers' expectations about food.

We proposed the standards of identity and quality for frozen cherry pie in the **Federal Register** of November 1, 1967 (32 FR 15116) and finalized them in the **Federal Register** of February 23, 1971 (36 FR 3364); the requirements were codified at 21 CFR 28.1 (''Frozen cherry pie; identity; label statement of optional ingredients'') and 21 CFR 28.2 (''Frozen cherry pie; quality; label statement of substandard quality''). We later amended the standards of identity and quality in the **Federal Register** of June 13, 1973 (38 FR 15504), by removing minimum frozen cherry pie weight requirements, aligning the definition of blemished cherries with that in the U.S. Department of Agriculture's (USDA's) U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, and adding clarifying language. We renumbered the two sections in the **Federal Register** of March 15, 1977 (42 FR 14302 at 14449) and combined them into § 152.126 (21 CFR 152.126), with the new section covering both the standards of identity and quality.

We received a citizen petition from ABA asking us, in part, to revoke the frozen cherry pie standards of identity and quality (Citizen Petition from the American Bakers Association, dated August 18, 2005, Docket No. FDA–2005–P–0435 (''petition'')). Among other things, the petition stated that there is no basis for singling out frozen cherry pie for the imposition of standards of identity and quality (petition at page 10). The petition observed that there are no standards of identity and quality for any other types of frozen fruit pies, or for any non-frozen fruit pies, including those filled with cherries (id.). The petition further asserted that nonstandardized fruit pies have been sold throughout the country for many years without any evidence of public confusion (id.).

In the **Federal Register** of December 18, 2020 (85 FR 82395), we issued a proposed rule to revoke the standards of identity and quality for frozen cherry pie, which, in part, responded to the petitioner's request. We tentatively concluded that the frozen cherry pie standards of identity and quality were no longer needed to promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act (85 FR 82395 at 82396). The preamble to the proposed rule also noted that the proposed revocation is consistent with section 6 of Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), which requires Agencies to periodically conduct retrospective analyses of existing regulations to identify those ''that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them'' accordingly (85 FR 82395 at 82397). Consequently, we proposed to revoke part 152 (21 CFR part 152) (''Fruit pies'') in its entirety because the standards for frozen cherry pie are the only standards in part 152.

We stated that we were unaware of any evidence suggesting that consumers have different expectations for unbaked, frozen cherry pies than for other cherry pies (85 FR 82395 at 82396). At the same time, no other cherry pies are subject to a standard of identity or a standard of quality, and we stated that we were unaware of any evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that those cherry pies meet consumer expectations (id.). Similarly, other fruit pies are not subject to standards of identity or quality, and we stated that we were unaware of any evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that the pies meet consumer expectations (id.).

We also tentatively concluded that the prohibition of artificial sweeteners in § 152.126(a)(2) (21 CFR 152.126(a)(2)) does not promote honesty and fair dealing in the interest of consumers (85 FR 82395 at 82397). Baked, frozen cherry pie and baked, non-frozen cherry pie may be made with artificial sweeteners to produce reduced-sugar varieties to accommodate consumer preferences and dietary restrictions. Other types of fruit pies are manufactured with artificial sweeteners to produce reduced-sugar varieties. These varieties appear to cater to consumer preferences and needs, and we stated that we were unaware of any evidence that these varieties create confusion or circumvent consumer expectations (id.).

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 90-day comment period. We received over 60 comments to the proposed rule, and each comment discussed one or more issues. Trade associations, consumer advocacy organizations, individuals, academia, and industry submitted comments. Some comments appeared to have been submitted as part of a university exercise or assignment.

The comments discussed, among other things, the need for standards of identity and quality for frozen cherry pie. Some comments supported our proposed revocation, but others opposed it, expressing concerns that the revocation could reduce product quality or impact public health.

III. Legal Authority

We are issuing this final rule to revoke the standards of identity and quality for frozen cherry pie consistent with our authority under section 401 of the FD&C Act, which directs 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 Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

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

(Comment 1) In general, most comments opposed the revocation of the frozen cherry pie standards of identity and quality. A majority of comments opposed revoking the standards because of general quality, safety, and public health concerns, without any supporting evidence. The comments asserted that revoking the standards would lower, or remove, the requirements for frozen cherry pie, would not benefit or protect consumers, and would provide frozen cherry pie manufacturers too much flexibility in the manufacture of frozen cherry pie.

(Response 1) We disagree that removing the standards of identity and quality for frozen cherry pie will result in lower protection for consumers. While there will no longer be a standard of quality that prescribes a required weight for the fruit content of frozen cherry pie or a standard of identity specifying requirements for products labeled as frozen cherry pie, other safeguards exist under the FD&C Act to prevent adulterated and misbranded frozen cherry pie products. For example, under section 403(a) of the FD&C Act (21 U.S.C. 343(a)), manufacturers must ensure that all labeling is truthful and not misleading.

Many foods are nonstandardized foods, and they must be labeled with and sold under common or usual names that have been established by common usage. See 21 U.S.C. 343(i)(1) and § 102.5(d) (21 CFR 102.5(d)). As a nonstandardized food, frozen cherry pie must be labeled with its common or usual name, ''frozen cherry pie,'' which is still in common usage. The final rule recategorizes unbaked, frozen cherry pie as a nonstandardized food, like baked, non-frozen and baked, frozen cherry pies, as well as frozen and non-frozen fruit pies of other varieties. We are unaware of any evidence to suggest aligning unbaked, frozen cherry pie with baked, non-frozen cherry pies, baked, frozen cherry pies, as well as frozen and non-frozen fruit pies of other varieties as a nonstandardized food would create confusion or circumvent consumer expectations. Revoking these standards will provide greater flexibility in the product's manufacture while leaving other requirements under the FD&C Act, such as product quality, ingredient safety, and labeling, in place, consistent with comparable, nonstandardized foods available in the marketplace. For example, revoking the standards will allow for new varieties of frozen cherry pies that cater to consumer preferences and needs, such as those lower in added sugars. We conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest of consumers.

(Comment 2) Some comments supported revoking the standards of identity and quality for frozen cherry pie. In general, the comments agreed that the standards of identity and quality are no longer needed to promote honesty and fair dealing in the interest of consumers, and revoking the standards would:

- Provide benefits in terms of additional flexibility to the manufacturers of frozen cherry pie products; and
- Promote innovation and the introduction of new unbaked, frozen cherry pie products, providing benefits to both consumers and industry.

(Response 2) We agree with these comments. The final rule revokes the standards of identity and quality for frozen cherry pie.

(Comment 3) One comment provided a neutral summary of the frozen cherry pie proposed rule but did not raise any issues or concerns for us to address.

(Response 3) We generally agree with the comment's summary of the proposed rule. We conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest of consumers. The final rule revokes the standards of identity and quality for frozen cherry pie.

C. Comments Related to Labeling of Frozen Cherry Pie

(Comment 4) Some comments contended that, upon revocation, consumers would not know what ingredients have been added to frozen cherry pies. A couple comments interpreted the proposed rule as eliminating labeling requirements, stating that if the standards are revoked, there would be no labeling requirements. One comment stated that labeling requirements are not stringent enough for consumers to receive honest information from manufacturers as to what a product is. Other comments stated that consumers deserve to know and should be confident and able to trust that unbaked, frozen cherry pies contain a significant or adequate amount of cherries. Another comment, while supportive of the revocation of the standards, stated concern about improperly labeled food products in various settings.

(Response 4) Although we are revoking the standards of identity and quality for frozen cherry pie, labeling requirements will continue to apply to these products. While standards of identity are typically established under the common or usual name of the food (see 21 U.S.C. 341), a standard of identity does not need to be established for a food to be labeled with and sold under its common or usual name. Most foods are nonstandardized foods, which must be labeled with and sold under common or usual names that have been established by common usage. See 21 U.S.C. 343(i)(1) and § 102.5(d). The use of a common or usual name allows consumers to identify more efficiently the type of nonstandardized food product they find in the store. Revocation of the frozen cherry pie standards of identity and quality will eliminate requirements related to the content and production of frozen cherry pie, and frozen cherry pie will become a nonstandardized food. As a nonstandardized food, frozen cherry pie must be labeled with its common or usual name, ''frozen cherry pie,'' which is still in common usage (see 21 U.S.C. 343(i)(1)). Thus, products with the name frozen cherry pie will continue to be available to consumers.

Manufacturers must also comply with identity labeling requirements, which require that a food in package form bear a statement of the identity of the product on the principal display panel (§ 101.3 (21 CFR 101.3)), and ingredient labeling requirements, which state that ingredients must be listed by their common or usual name, in descending order of predominance by weight unless

ingredients are present in amounts of 2 percent or less by weight, in which case they can be listed at the end of the ingredient statement following an appropriate quantifying statement (§ 101.4 (21 CFR 101.4)). Therefore, consumers will have information available to them about the ingredients in the frozen cherry pies they purchase, as well as other product information.

As for the comment about the labeling of food products in different settings, different food labeling requirements exist, depending on whether the food product is, for example, a packaged food sold at a grocery store or a prepared food at a restaurant or cafeteria (see 21 CFR part 101). In the case of noncompliance with our regulations, FDA may take enforcement actions, as appropriate.

(Comment 5) One comment noted that there is no need to revoke the standards of identity and quality because manufacturers can already make frozen cherry pie products that do not conform to the standards and can simply identify on the label that the product falls below the standard of quality.

(Response 5) It is true that manufacturers could produce a frozen cherry pie product not conforming to the standard of quality (*e.g.,* using fewer cherries than prescribed by the standard of quality) and label the product with a general statement of substandard quality. However, the fact that such products could legally be made and marketed does not justify keeping the current standards of identity and quality if they are no longer serving their purpose. We no longer believe that the standards of quality and identity are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that frozen cherry pies meet consumer expectations, and, therefore, we are revoking the standards of identity and quality for frozen cherry pie.

D. Comments Related to Quality of Frozen Cherry Pie

(Comment 6) Several comments expressed concern that revoking the standards for frozen cherry pie may compromise the quality of product and that FDA has a duty to maintain minimum standards of quality. A few comments stressed the importance of retaining the standards to maintain food quality standards and freshness.

(Response 6) Manufacturers must comply with Federal statutes and regulations to ensure a quality product. For example, quite apart from whether a food product is subject to a standard of quality or standard of identity, food products, including raw materials and ingredients, must comply with the quality control operations requirements set forth in current good manufacturing practices (CGMP) (see generally 21 CFR part 117) and are also required to bear truthful and non-misleading labeling, including a listing of their ingredients. We are unaware of, and the comments did not provide, any specific quality concerns for other varieties of unbaked, frozen fruit pies that are currently on the market. Nor did the comments provide support for the concern that revoking the standards for frozen cherry pie may compromise the quality of the product. Similarly, the comments did not describe how revoking the standards would affect the freshness of the product. As a general matter, the standard of quality for frozen cherry pie did not have a requirement for freshness, and we note that the standard of identity allowed for the use of fresh, frozen, and canned cherries in frozen cherry pies. If the comments are referring to freshness in terms of quality of the ingredients, we note that, under the FD&C Act, a food is adulterated if it consists in whole or in part of a filthy, putrid, or decomposed substance or is otherwise unfit for food. See 21 U.S.C. 342(a)(3).

(Comment 7) A few comments asserted that, in the absence of a standard of quality, manufacturers would be free to use subpar or substandard ingredients in their frozen cherry pie products in order to cut costs. Some comments expressed concern that the revocation of the standards for frozen cherry pie would allow manufacturers to add an unlimited number of blemished cherries, lower-quality cherries, or rotten cherries to their pies, or alternatively, that manufacturers would use fewer cherries, any amount or type of cherry, or no real cherries at all in frozen cherry pies. Several comments stated that cherry pie should be required to have cherries or that the standards should require more cherries. Other comments suggested that FDA should require manufacturers to label that a food contains numerous blemished cherries or to otherwise hold industry accountable to ensure that the cherries used are not spoiled. One comment suggested that revocation of the standards might even benefit consumers who are looking to make conscious purchases that mitigate food waste by purchasing a frozen cherry pie using blemished cherries.

(Response 7) We are unaware of any evidence that suggests revocation of the standards of identity and quality of frozen cherry pie may result in manufacturers adding subpar or substandard ingredients. In addition, other safeguards exist to ensure the quality of the food supply. A food is deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. See 21 U.S.C. 342(a)(3). Therefore, a food would be adulterated if it used rotten, spoiled, or otherwise unfit cherries. We also note that any food, including raw materials and ingredients, must comply with the quality control operations requirements set forth in CGMPs (21 CFR 117.80(b)).

As explained in the preamble to the proposed rule, frozen cherry pie is the only fruit pie, either frozen or non-frozen, that is currently subject to a standard of identity or quality (85 FR 82395 at 82396). We are unaware of any evidence suggesting that consumers have different expectations for unbaked, frozen cherry pies than for other fruit pies. We are also unaware of any evidence indicating that such standards are necessary to ensure that frozen cherry pie products continue to be produced with the characteristics consumers expect. FDA disagrees that revocation of the standards may result in having unbaked, frozen cherry pies in the marketplace with fewer cherries. As shown by widespread consumer acceptance of the variety of non-standardized fruit pies in the marketplace, such products meet consumer expectations and demands. Additionally, under the FD&C Act, manufacturers must ensure that all labeling is truthful and not misleading; otherwise, it is deemed misbranded (21 U.S.C. 343(a)). Therefore, a product marketed as frozen cherry pie that does not contain any cherries, would be misbranded. See 21 U.S.C. 343(a) and (b).

Manufacturers also must comply with identity labeling requirements, which require that a food in package form be labeled with its common or usual name, or in the absence thereof, a statement of identity that accurately describes the food on the principal display panel (§ 101.3). If a product is offered for sale under the name of another food (*e.g.,* a frozen cherry pie that does not contain cherries), it would be misbranded under 21 U.S.C. 343(b).

Regarding the comment stating that manufacturers will now be able to use any type of cherry, we note that neither the existing standard of identity nor the existing standard of quality for frozen cherry pie specified the variety of cherry to be used; however, the standard of identity did allow for fresh, frozen, or canned cherries to be used. Consumers will be able to continue to purchase

products that align with their tastes and preferences.

(Comment 8) Some comments stated that revoking the standards would allow manufacturers to use unknown additives and fillers to make frozen cherry pies less expensive to produce.

(Response 8) In the absence of a standard of identity, manufacturers will have the flexibility to use different ingredients than those previously allowed to produce products that meet consumer expectations for frozen cherry pie. However, those different ingredients must still be lawful. Manufacturers must comply with ingredient labeling requirements (§ 101.4), as well as food and color additive regulations, which require additives to meet the safety standard of reasonable certainty of no harm under its intended conditions of use (21 CFR 70.3 and § 170.3 (21 CFR 170.3)). Consumers can also look at the product labeling to see the ingredients in frozen cherry pies and can purchase based on their preferences. Removing the standard of identity for frozen cherry pie will allow manufacturers to make products with different ingredients than those allowed under the prior standard of identity, but those products must still comply with the FD&C Act and implementing regulations. We conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest of consumers, and we are revoking the standards of identity and quality for frozen cherry pie.

E. Comments Related to Safety of Frozen Cherry Pie

(Comment 9) Some comments expressed concern over the potential use of unsafe ingredients or dangerous substitutes by manufacturers if we revoked the standards. Some comments stated that revoking the standards would allow manufacturers to use cheaper ingredients, such as artificial sweeteners, that the comments claimed pose serious health risks to consumers. One comment stated that FDA should conduct a comprehensive safety re-assessment of specific artificial sweeteners before encouraging reformulation with them. A few comments supported the revocation on the grounds that it would allow marketing of low-sugar varieties that some consumers may desire and classified artificial sweeteners as acceptable, sometimes desirable, and healthier than the current sweeteners used. Many comments expressed concerns about not knowing whether future frozen cherry pie products would meet any safety standards.

(Response 9) Our regulations, at 21 CFR 70.42 and 170.20, require evidence that each color or food additive used in food, such as an artificial sweetener, is safe at its intended level of use before it may be added to foods. All food additives or ingredients are required to undergo a premarket approval process unless the substance is generally recognized as safe (GRAS) or was approved for use by FDA or USDA prior to the food additive amendments of the FD&C Act (21 U.S.C. 321) (see also 21 CFR parts 170, 171, 130, and 181). Our regulations in § 170.30 (21 CFR 170.30) require that a GRAS determination based on scientific procedures be made by experts qualified by scientific training and experience to evaluate its safety, who have concluded, based on publicly available information, that the substance is safe under the conditions of its intended use. Both substances approved for use as a food additive and those determined to be GRAS must meet the safety standard of reasonable certainty of no harm under its intended conditions of use (§§ 170.3 and 170.30). A prior sanction for a food substance exists only for a specific use(s) in food for which there was explicit approval by FDA or USDA prior to September 6, 1958 (21 CFR 181.5(a)). All known prior sanctions are listed in our regulations, and any such regulation is subject to amendment to impose whatever limitations or conditions are necessary for the safe use of the ingredient (21 CFR 181.5(b)).

Furthermore, all FDA-approved food additives are subject to ongoing safety review. If new evidence indicates that a food ingredient in use may be unsafe, we may prohibit its use or conduct further studies to determine if the use can still be considered safe (21 CFR 180.1). We also note that, under the FD&C Act, a food is adulterated if it bears or contains a naturally occurring poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 342).

As for the comments concerning the safety of artificial sweeteners, we disagree that we should conduct a comprehensive safety reassessment on specific artificial sweeteners before revoking the standards. Our regulations require that only safe and suitable ingredients are used in food production (21 CFR 130.3). An artificial sweetener is regulated as a food additive unless its use as a sweetener is GRAS. FDA-approved artificial sweeteners, as well as those that are GRAS, are safe for the general population. We also disagree with the assertion that we are encouraging reformulation with artificial sweeteners. As a result of revoking the standards, manufacturers will simply have greater flexibility and the opportunity for greater product innovation, consistent with what is currently allowed for other fruit pies. Revocation of the standards of identity and quality will permit the use of artificial sweeteners in frozen cherry pies, thus allowing reduced-sugar frozen cherry pie varieties to be sold in the marketplace under the same common or usual name of frozen cherry pie. We have seen no evidence of dishonesty, confusion, or the use of low-quality ingredients in other nonstandardized fruit pies, and we have no reason to believe that frozen cherry pies would be treated any differently. Therefore, we are revoking the standards of identity and quality for frozen cherry pie.

F. Miscellaneous Comments

(Comment 10) A few comments suggested a revision of the standard, instead of a revocation. One comment stated that the requirement to have at least a minimum of 25 percent cherries relative to the pie's weight should not be repealed in order for consumers to know that a frozen cherry pie is made with real cherries. In an effort to prevent substitution of fillers, one comment proposed to eliminate the requirements for sieving and percent blemished fruit but retain the requirement for a minimum of 25 percent fruit, and another comment said we should remove regulations that require certain inspection processes for pies but keep in place the regulations requiring 25 percent minimum cherries and no greater than 15 percent blemished cherries.

(Response 10) We do not see a need for any such modification of the existing standards. As stated in the proposed rule, frozen cherry pie is the only fruit pie, either frozen or non-frozen, that is subject to standards of identity and quality (85 FR 82395 at 82396). Other fruit pies, including baked frozen cherry pie and baked non-frozen cherry pie, are not standardized, and these foods appear to meet consumer expectations in the absence of established definitions and standards. There appears to be no need to treat frozen cherry pie differently from other fruit pies available in the marketplace. Therefore, we have concluded that the frozen cherry pie standards of identity and quality are no longer needed to promote honesty and fair dealing in the interest of consumers or to ensure that those cherry pies meet consumer expectations. Revocation of the standards will provide greater flexibility

and allow for innovation in product manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

(Comment 11) Some comments questioned why there are not standards for other types of fruit pies besides frozen cherry pie and stated that the standards of identity and quality for frozen cherry pie should not be revoked but rather extended to other fruit pies available in the marketplace. One comment questioned why FDA fails to place more regulations, restrictions, and standards on other pies and food items on the American market.

(Response 11) Section 401 of the FD&C Act directs 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 Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers. The purpose of these standards is to protect consumers against economic adulteration and reflect consumers' expectations about food. Regarding other types of fruit pies, we are unaware of any evidence, and the comments provided no evidence, indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that the pies meet consumer expectations. Most fruit pies available in the marketplace, including baked cherry pies (both frozen and non-frozen varieties), are nonstandardized foods that are labeled with and sold under common or usual names. These foods appear to meet consumer expectations in the absence of established definitions and standards. Thus, we simply do not see a need to extend or to create standards of identity for other fruit pies in the marketplace that are currently regulated as nonstandardized foods.

We have the authority to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers, and we will continue to use this authority as needed to protect consumers.

(Comment 12) One comment stated that it is not clear if revoking the standards of identity and quality for frozen cherry pie would benefit consumers. The comment noted a lack of consumer calls asking for a greater variety of frozen cherry pie products and a lack of complaints about frozen cherry pies having too many cherries. The comment added that frozen cherry pie manufacturers could sell reduced-sugar frozen cherry pie products while the standards of identity and quality existed, and therefore, the standards did not create a barrier to marketing or selling reduced sugar varieties.

(Response 12) Standards of identity and quality are established to promote honesty and fair dealing in the interest of consumers. Standards protect consumers against economic adulteration and reflect consumers' expectations about food. Many fruit pies have been in the marketplace as nonstandardized foods for many years, and non-cherry fruit pies, either frozen or unfrozen, are not subject to the requirements of any standard. Unbaked, frozen cherry pie is the only fruit pie that is subject to standards of identity or quality. While these standards did not mandate that a certain amount of sugar be used in product formulation and, therefore, manufacturers could already sell reduced-sugar frozen cherry pie products, the standard of identity prohibited the use of artificial sweeteners (see § 152.126(a)(2)). Revocation of the standards of identity and quality for frozen cherry pie will not only provide greater flexibility in the product's manufacture (*e.g.,* by allowing the use of artificial sweeteners to lower the sugar content of frozen cherry pies), but revocation of the standards will also align frozen cherry pies with other comparable fruit pies available in the marketplace. We conclude that standards of identity and quality for frozen cherry pie are no longer needed to promote honesty and fair dealing in the interest of consumers. Therefore, we are revoking the standards of identity and quality for frozen cherry pie.

(Comment 13) One comment stated that the proposed rule was the result of a food industry association's petition and not a petition from consumers, and FDA should reject industry attempts to revoke consumer protections.

(Response 13) We disagree that FDA should reject the petition that requested the revocation of the standards because it was from a food industry association and not from consumers. We evaluate all citizen petitions that meet the requirements of our citizen petition regulation at 21 CFR 10.30. After considering the petition and related information, including comments to the proposed rule, we conclude that the standards of identity and quality for frozen cherry pie are no longer needed to promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act, and we are revoking the standards of identity and quality for frozen cherry pie.

(Comment 14) One comment stated that this proposal is a poor expenditure of FDA's resources. This comment urged FDA to direct its efforts to priorities that align with the goals of FDA's Nutrition Innovation Strategy by, for example, allowing the use of sodium substitutes such as potassium chloride across standardized foods.

(Response 14) Since FDA first announced its Nutrition Innovation Strategy in 2018, we have shifted our efforts to a general national nutrition strategy. We are prioritizing our nutrition initiatives to ensure people in the United States have greater access to healthier foods and nutrition information that everyone can use to identify healthier choices more easily. The key elements of this strategy are sodium reduction, maternal and infant health and nutrition, labeling and claims, consumer education, and innovation support. FDA is continuing to update its standards of identity program with the goal of maintaining the basic nature and essential characteristics of standardized foods while permitting flexibility with respect to their composition. In the **Federal Register** of April 10, 2023 (88 FR 21148), we published a proposed rule entitled ''Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods,'' which, if finalized, would amend FDA standard of identity regulations that specify salt (sodium chloride) as a required or optional ingredient to permit the use of salt substitutes in standardized foods, to reduce the sodium content. This action represents an example of a recent initiative under our general national nutrition strategy, and, if finalized, it would help support a healthier food supply by providing flexibility to facilitate industry innovation in the production of standardized foods lower in sodium while maintaining the basic nature and essential characteristics of the foods.

We have the authority to issue regulations establishing standards of identity and quality to promote honesty and fair dealing in the interest of consumers (21 U.S.C. 341). Standards of identity and quality are intended to protect consumers against economic adulteration, maintain the integrity of food, and reflect consumers' expectations about the food. We will continue to prioritize our efforts as time and resources permit. While our general national nutrition strategy is just one of many priorities for FDA, we have many other projects that we simultaneously work on to carry out our work. For example, Executive Order 13563, ''Improving Regulation and Regulatory

Review'' (January 18, 2011), requires Agencies to periodically conduct retrospective analyses of existing regulations to identify those that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them accordingly. In this case, we conclude that standards of identity and quality for frozen cherry pie are no longer needed to promote honesty and fair dealing in the interest of consumers. Therefore, we are revoking the standards of identity and quality for frozen cherry pie.

(Comment 15) One comment urged FDA to review and identify what factors have changed since the promulgation of the initial rule creating standards of identity and quality for frozen cherry pie, to the extent that evidence remains available to us. The comment also stated that we should explain our reasons for eliminating this specific standard, as distinguished from other identity standards that we would preserve.

(Response 15) In the **Federal Register** of February 23, 1971 (36 FR 3364), FDA finalized the standards of identity and quality for frozen cherry pie. We concluded at that time that the standards would promote honesty and fair dealing in the interest of consumers, and we noted that abuse had been recognized by certain members of the frozen food industry. Around the same time, the President signed into law the Fair Packaging and Labeling Act (Pub. L. 89–755), which is designed to prevent unfair or deceptive packaging and labeling of many household consumer commodities, including food (15 U.S.C. 1452). These and other regulatory changes, including mandatory ingredient labeling, have led to a different environment than that which existed when the standards were established.

Consistent with FDA priorities on nutrition initiatives and Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), we will continue to evaluate the necessity of different standards, as appropriate, and may propose changes in the future if we determine a standard is no longer needed to promote honesty and fair dealing in the interest of consumers.

(Comment 16) Some comments mentioned that revocation of the standards of quality and identity would further contribute to the health disparities experienced among lower-income Americans. The comments state that access to quality foods should not be a luxury that only some can afford.

(Response 16) The standards of identity and quality for frozen cherry pie were established to promote honesty and fair dealing in the interest of consumers. Standards of identity do not ensure access to a food nor do they address the price(s) of a standardized food. Standards of identity also do not address consumer health disparity issues. Matters pertaining to access to food, food prices, and health disparities between different populations are outside the scope of this rulemaking.

(Comment 17) One comment mentioned that frozen cherry pie should have to maintain, at a minimum, the standards for frozen foods during transport and storage.

(Response 17) Frozen food product must follow our CGMPs (21 CFR 117.80) and risk-based preventive controls (21 CFR 117.206) among other regulations. The final rule does not impact the other statutory requirements or regulations that food manufacturers must follow.

(Comment 18) One comment stated that revocation of the standards of identity and quality will allow manufacturers to substitute cherries with yams.

(Response 18) A product labeled as cherry pie, but containing yams rather than cherries, would be misbranded under 21 U.S.C. 343(a)(1) because the labeling would be false or misleading. Additionally, section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce any food that is misbranded.

V. Effective Date

This rule is effective 30 days after the date of publication in the **Federal Register**.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we conclude that this rule would not generate significant compliance costs, 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 estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

The final rule would not require firms within the frozen cherry pie industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the petition to revoke the standards indicate that revoking the standards of identity and quality could provide benefits in terms of additional flexibility to manufacturers of frozen cherry pie products. We also conclude that these standards are obsolete because the requirements are not necessary to ensure that frozen cherry pie meets consumers' expectations about the food, and in some respect, place restrictions on the food that are inconsistent with consumers' expectations. Revocation of the standards would allow additional flexibility for, and the opportunity for

innovation regarding, frozen cherry pie, providing benefits to both consumers and industry. Therefore, we conclude that the final rule to revoke the standards for frozen cherry pie would provide social benefits at little to no cost to the respective industries (table 1).

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

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$0	$0	$0	2023	7 3		
Annualized Quantified					7 3		
Qualitative	Benefits to manufacturers would be from additional flexibility and the opportunity for innovation regarding frozen cherry pie products.						
Costs:							
Annualized Monetized $millions/year	0	0	0	2023	7 3		
Annualized Quantified					7 3		
Qualitative							
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:							

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/economics-staff/regulatory-impact-analyses-ria.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) 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. FDA has 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.

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. Reference

The following reference is on display at 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.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Regulatory Impact Analysis: Frozen Cherry Pie; Revocation of a Standard of Identity and a Standard of Quality (Final Rule).'' Available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 152

Bakery products, Food grades and standards, Frozen foods, Fruits.

PART 152—[REMOVED]

■ Therefore, for the reasons discussed in the preamble, under the Federal Food, Drug and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration removes 21 CFR part 152.

Dated: February 27, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–04598 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807 and 814

[Docket No. FDA–2024–N–1052]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to update a citation for information collection and conform the regulatory provisions to the Federal Food, Drug, and Cosmetics Act (FD&C Act). The rule does not impose any new requirements on affected parties. This action is editorial in nature to correct errors and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is March 15, 2024.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

As a part of this technical amendment, FDA is making changes to 21 CFR parts 807 and 814 to update a citation for information collection and to conform the regulatory provisions to the FD&C Act to ensure accuracy and clarity in the Agency's medical device regulations. The changes published in this notice are nonsubstantive and editorial in nature.

On December 29, 2022, Congress enacted the Food and Drug Omnibus Reform Act of 2022, Title III of 131 Division FF of the Consolidated Appropriations Act, 2023 (FDORA) (Pub. L. 117–328), which added and amended various sections of the FD&C Act. Section 3308 of FDORA added section 515C of the FD&C Act (21 U.S.C. 360e–4). Section 515C provides FDA with express authority to approve or clear predetermined change control plans (PCCPs) for devices requiring premarket approval applications (PMAs) under section 515 of the FD&C Act (21 U.S.C. 360e) or premarket notification under section 510(k) of the FD&C Act (510(k)) (21 U.S.C. 360). Under section 515C manufacturers will not need to submit PMAs, including a supplemental application, or a new 510(k) as long as the change is consistent with a PCCP approved or cleared by FDA.

II. Description of the Technical Amendments

We are amending 21 CFR 807.81(b) and 814.39(b) to include predetermined change control plans cleared or approved, respectively, under 515C consistent with the statutory language in section 515C of the FD&C Act. The regulation, 21 CFR 807.87(m), is being revised to make a nonsubstantive editorial change to remove the incorrect information collection requirement citation. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA generally exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking (5 U.S.C. 553(b)(A)). Rules are also exempt when an agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements under 5 U.S.C. 553(b)(3)(B). All the revisions in this rule are technical or nonsubstantive changes. Some of these revisions update the language in certain regulations to be consistent with the FD&C Act. The balance of these revisions updates an incorrect citation for information collection. Such technical, nonsubstantive changes are ''a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for these amendments.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). An effective date 30 or more days from the date of publication is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to ''adjust to the new regulation'' before the rule takes effect. *Am. Federation of Government Emp., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 807 and 814 are amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for part 807 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360e–4, 360i, 360j, 360bbb–8b, 371, 374, 379k–1, 381, 393; 42 U.S.C. 264, 271.

■ 2. In § 807.81, revise paragraph (b)(1) to read as follows:

§ 807.81 When a premarket notification submission is required.

* * * * *

(b)(1) A premarket notification under this subpart is not required for a device for which:

(i) A premarket approval application under section 515 of the act, or for which a petition to reclassify under