DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 5, and 7

[Docket No. TTB–2025–0003; Notice No. 238]

RIN 1513–AC94

Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to require a labeling disclosure of all major food allergens used in the production of alcohol beverages subject to TTB's regulatory authority under the Federal Alcohol Administration Act. Under the proposed regulations, unless an exception applies, labels must declare milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame, as well as ingredients that contain protein derived from these foods, if used in the production of the alcohol beverage. TTB proposes a compliance date of 5 years from the date that a final rule resulting from this proposal is published in the **Federal Register**.

DATES: Comments must be received on or before *April 17, 2025.*

ADDRESSES: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it, within Docket No. TTB–2025–0003 as posted at *https://www.regulations.gov.* A direct link to that docket is available on the TTB website at *https://www.ttb.gov/laws-and-regulations/all-rulemaking* under Notice No. 238. Alternatively, you may submit comments via postal mail to the Director, Regulations and Ruling Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005. Please see the Public Participation section of this document for further information on the comments requested regarding this proposal and on the submission, confidentiality, and public disclosure of comments.

FOR FURTHER INFORMATION CONTACT: Curt Eilers, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone 202–453–1039, ext. 041.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at *https://www.regulations.gov/TTB-2025-0003.*

I. Background

On December 16, 2003, the Center for Science in the Public Interest (CSPI) and others petitioned the Alcohol and Tobacco Tax and Trade Bureau (TTB), requesting changes to the alcohol beverage labeling regulations to, among other things, require information about allergens. The following year, Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining what constitutes a ''major food allergen'' (21 U.S.C. 321(qq)) and requiring the presence of each major food allergen to be declared on the product label using the name of the food source from which the major food allergen is derived.

On July 26, 2006, TTB published an interim rule, T.D. TTB–53 (71 FR 42260), entitled ''Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages,'' which addressed the voluntary labeling of major food allergens used in the production of alcohol beverages. On that same date, TTB published a proposed rule, Notice No. 62 (71 FR 42329), seeking comments on mandatory allergen labeling for alcohol beverages. TTB did not finalize the proposed rule, and mandatory labeling of major food allergens on alcohol beverage labels has not been adopted.

In 2021, TTB received a letter, dated February 24, 2021, from several consumer groups and public health advocates, including CSPI, Alcohol Justice, the American Institute for Cancer Research, Breast Cancer Prevention Partners, the Consumer Federation of America, the National Consumers League, and the U.S. Alcohol Policy Alliance. The letter urged the Secretary of the Treasury to adopt regulations to mandate a standardized label that would include additional information about calories, standard drinks, and advice on moderate drinking from the U.S. Department of Agriculture and U.S. Department of Health and Human Service's *Dietary Guidelines for Americans.* The letter also urged the identification of any major food allergens present in the product and an ingredient declaration that lists each ingredient by its common or usual name.

On February 9, 2022, the Department of the Treasury, in consultation with the Department of Justice and the Federal Trade Commission, released a report entitled ''Competition in the Markets for Beer, Wine, and Spirits'' (Competition Report). The Competition Report was requested by Executive Order 14036, ''Promoting Competition in the American Economy''. One of the Competition Report's findings was that ''[r]egulatory proposals that could serve public health and foster competition by providing information to consumers, such as mandatory allergen, nutrition, and ingredient labeling proposals, have not been implemented.'' [1] The Competition Report contains several recommendations, including that ''TTB should revive or initiate rulemaking proposing ingredient labeling and mandatory information on alcohol content, nutritional content, and appropriate serving sizes.'' [2]

Consistent with the Competition Report's recommendations, and considering the February 2021 letter referenced above, TTB decided to revisit the issue of mandatory allergen labeling for alcohol beverages. In addition, TTB had received several comments in favor of reopening this issue during the public comment period for proposals to modernize alcohol beverage labeling in 2018. See Notice No. 176, 83 FR 60562, November 26, 2018. Because it has been almost 20 years since TTB solicited comments on allergen labeling, TTB published Notice No. 232, which announced two virtual listening sessions, on February 28 and 29, 2024, and the opening of a docket to receive public input on labeling of wine, distilled spirits, and malt beverages with per-serving alcohol and nutritional information, major food allergens, and/or ingredients.

TTB is now publishing for public comment a new proposal that would require allergen labeling for wines, distilled spirits, and malt beverages. TTB is addressing the Competition Report's recommendations and Notice No. 232 comments from the listening sessions on mandatory alcohol facts and ingredient labeling in separate rulemaking projects.

II. TTB's Authority To Regulate Alcohol Beverage Labeling

A. TTB's Statutory Authority Under the FAA Act

TTB is responsible for the administration of the Federal Alcohol Administration Act, 27 U.S.C. 201 *et seq.* (FAA Act), which sets forth

[1] See page 3 of the report, available at *https://home.treasury.gov/system/files/136/Competition-Report.pdf.*

[2] Id. at page 61.

standards for the regulation of the labeling of wine (containing at least 7 percent alcohol by volume), distilled spirits, and malt beverages that will be sold or otherwise introduced in interstate or foreign commerce. (This document generally refers to these products as ''alcohol beverages.'') Section 105(e) of the FAA Act (27 U.S.C. 205(e)) gives the Secretary authority to issue labeling regulations to prevent deception of the consumer, to provide the consumer with ''adequate information'' as to the identity, quality, and alcohol content of the product, and to prohibit false or misleading statements. Additionally, the FAA Act gives the Secretary the authority to prohibit, irrespective of falsity, labeling statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters which are likely to mislead the consumer. In the case of malt beverages, the labeling provisions of the FAA Act apply only if the laws or regulations of the State into which the malt beverages are to be shipped impose similar requirements.

The FAA Act generally requires bottlers and importers to obtain a certificate of label approval (COLA) from TTB prior to bottling wine, distilled spirits, or malt beverages for introduction into interstate commerce, or removing alcohol beverages from customs custody, in bottles, for sale or any other commercial purpose. The law provides that COLAs are to be issued in such manner and form as the Secretary shall prescribe by regulations.

TTB administers the FAA Act provisions pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120–01.

Current TTB regulations do not require the disclosure of ingredients or major food allergens on alcohol beverage labels. However, as explained in the next section, labels must disclose the presence of FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame for health-related reasons. A health warning statement applicable to all alcohol beverages containing 0.5 percent or more alcohol by volume is also required by the Alcoholic Beverage Labeling Act of 1988, codified at 27 U.S.C. 213–219 and 219a and implemented in the TTB regulations at 27 CFR part 16.

B. Current Ingredient Disclosures on Alcohol Beverage Labels

TTB's predecessor agency, the Bureau of Alcohol, Tobacco, and Firearms (ATF), proposed on several occasions to adopt mandatory ingredient disclosure requirements for alcohol beverages. In each case, ATF ultimately decided not to adopt full ingredient labeling requirements. (See Notice No. 41, 70 FR 22274, April 29, 2005, for a more complete history of those ingredient labeling regulatory initiatives.)

In 1980, ATF published regulations that required ingredient labeling for alcohol beverages, with a delayed effective date. See T.D. ATF–66 (45 FR 40538, June 13, 1980). ATF subsequently rescinded those regulations before they went into effect. See T.D. ATF–94 (46 FR 55093, November 6, 1981). CSPI and others challenged this action in court. ATF subsequently undertook a new round of rulemaking, and issued another final rule, T.D. ATF–150 (48 FR 45549, October 6, 1983), which rescinded ingredient labeling but mandated the disclosure of one ingredient, FD&C Yellow No. 5, on alcohol beverage labels. In the preamble to T.D. ATF–150, ATF stated that there was ''no clear evidence in the record that any other ingredient besides FD&C Yellow No. 5 poses any special health problem. The Department will look at the necessity of mandatory labeling of other ingredients on a case-by-case basis through its own rulemaking initiative, or on the basis of petitions for rulemaking. . . .'' Ultimately, the D.C. Circuit Court of Appeals upheld ATF's actions in rescinding mandatory ingredient labeling in favor of a policy that would require the agency to consider the necessity of mandatory labeling of specific ingredients on a case-by-case basis. See *Center for Science in the Public Interest* v. *Department of the Treasury,* 797 F.2d 995, 1004 (D.C. Cir. 1986).

Consistent with that case-by-case review policy, ATF subsequently undertook rulemaking that resulted in the issuance of regulations requiring the disclosure on labels of sulfites in alcohol beverages (T.D. ATF–236, 51 FR 34706, September 30, 1986) because it was determined that the presence of undeclared sulfites in alcohol beverages posed a recognized health problem to sulfite-sensitive individuals. See 27 CFR 4.32, 5.63, and 7.63.

In 1987, ATF entered a Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA) which continues in effect. See Notice No. 648 (52 FR 45502, November 30, 1987). The MOU states that ATF would initiate rulemaking proceedings to promulgate labeling regulations for alcohol beverages when FDA determined that the presence of an ingredient in food products, including alcohol beverages, posed a recognized public health problem and that the ingredient must be identified on a food product label.

Pursuant to the policies set forth in the MOU, and based on FDA determinations as reflected in its regulations, ATF, and later TTB, subsequently engaged in rulemaking that resulted in regulations requiring a declaration on labels when aspartame is used in the production of malt beverages (T.D. ATF–347, 58 FR 44131, August 19, 1993) and distilled spirits (T.D. TTB–176, 87 FR 7526, February 9, 2022). The following statement must appear in capital letters, separate and apart from all other information: ''PHENYLKETONURICS: CONTAINS PHENYLALANINE.'' [3] On April 16, 2012, TTB amended its regulations to require alcohol beverage labels to disclose the presence of cochineal extract and carmine so consumers who are allergic to these color additives would be able to identify and thus avoid alcohol beverage products that contain them. See T.D. TTB–103 (77 FR 22485, April 16, 2012). See also 27 CFR 4.32, 5.63, and 7.63.

C. Enactment of FALCPA

In 2004, Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). FALCPA amended the Federal Food, Drug and Cosmetic Act (FD&C Act) to require food labels to declare the presence of each major food allergen using the name of the food source from which the major food allergen is derived. For example, instead of merely listing ''semolina,'' the label must also list ''wheat,'' and instead of merely listing ''sodium casein,'' the label must also list ''milk.'' The 2004 FALCPA amendments defined ''major food allergens'' as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as most ingredients [4]

[3] The evidence FDA considered showed a need to alert certain individuals with specific medical conditions to the presence of phenylalanine in products containing aspartame. This statement is directed towards individuals with Phenylketonuria (PKU), an inherited disorder of the metabolism of phenylalanine, who need to carefully restrict their phenylalanine intake.

[4] As explained further in this document, FALCPA provides exemptions for any highly refined oil derived from a major food allergen and any ingredient derived from such a highly refined oil, and for food ingredients that are exempt from major food allergen labeling requirements pursuant to a

containing proteins derived from these foods.

The FALCPA amendments provide two ways for a manufacturer to disclose major food allergens on the label:

- The label can show the name of the food source from which the major food allergen is derived within parentheses in the ingredient list, for example, ''Ingredients: Water, wheat, whey (milk), albumen (eggs), and peanuts.''
- The label can list the name of the food source from which the allergen is derived in a ''Contains'' statement after, or adjacent to, an ingredient list, for example: ''Ingredients: Water, sugar, whey, and albumen. Contains Milk and egg.''

The label can also declare the allergen in the ingredient list as well as in a ''Contains'' statement but when this occurs, the ''Contains'' statement must be complete, which means that the ''Contains'' statement must include all the major food allergens in the product. The allergen labeling requirements in FALCPA apply to any packaged FDA-regulated food, as that term is defined in section 201(f) of the FD&C Act, other than raw agricultural commodities. However, the FAA Act assigns TTB jurisdiction to regulate the labeling of wine, distilled spirits, and malt beverages. See *Brown-Forman Distillers Corp.* v. *Mathews,* 435 F. Supp. 5 (W.D. Ky. 1976) and 1987 MOU with FDA.

In its report on FALCPA, the House of Representatives Committee on Energy and Commerce recognized that FALCPA does not apply to alcohol beverages regulated by TTB under the FAA Act and called for TTB to work with FDA to promulgate appropriate allergen labeling regulations, consistent with the 1987 MOU with FDA. The committee report accompanying FALCPA stated:

> The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products.

H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004) (hereafter ''House committee report''). Congress thus recognized TTB's longstanding policy of consulting with FDA in determining what ingredients in alcohol beverages should be disclosed on labels and indicated that TTB should issue appropriate allergen regulations for alcohol beverage products, pursuant to the policies expressed in the MOU with FDA and the authority of the FAA Act.

Consistent with the expectations expressed in the House committee report, TTB consulted with FDA prior to issuing this proposed rule. However, TTB's legal authority to issue regulations on allergen labeling of alcohol beverages is based on the FAA Act, and thus differs in some respects from the requirements of FALCPA. Accordingly, this proposed rule reflects TTB's interpretation of its authority under the FAA Act, as informed by the language in the House committee report.

The proposed regulations do not necessarily represent the views of FDA regarding allergen labeling or the requirements of FALCPA. One of the key differences between the food labeling regulations implemented by FDA and the alcohol beverage labeling regulations implemented by TTB is that the TTB regulations currently do not require the disclosure of all ingredients on labels. As explained later in this document, this is especially important because there are many allergens other than the major food allergens identified in FALCPA.

III. Rulemaking History

A. 2005 Advance Notice of Proposed Rulemaking

Consistent with the FALCPA House committee report, on April 29, 2005, TTB published in the **Federal Register** (70 FR 22274) Notice No. 41, an advance notice of proposed rulemaking (ANPRM) entitled ''Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages; Request for Public Comment.'' Notice No. 41 sought public comment on a wide range of alcohol beverage labeling and advertising issues to help TTB determine what regulatory changes in alcohol beverage labeling and advertising requirements, if any, TTB should propose in future rulemaking documents. These included calorie and carbohydrate claims, ''Serving Facts'' or ''Alcohol Facts'' statements, ingredient labeling, and allergen labeling. TTB invited comments on specific issues related to allergen labeling, including:

- Whether TTB regulations should require allergen labeling to be part of or adjacent to a list of ingredients, similar to the FALCPA requirements;
- Whether an allergen must be labeled in an allergen statement even when the allergen name already appears in the product name;
- How processing or fining agents should be labeled;
- Whether TTB should consider threshold levels in allergen labeling;
- What costs industry might incur from new labeling requirements; and
- How consumers might benefit from allergen labeling.

TTB also invited submission of any other relevant information about allergen labeling.

TTB received over 19,000 comments in response to the ANPRM, approximately 50 of which specifically addressed the subject of allergen labeling. Of those, the vast majority favored mandatory labeling of the major food allergens. Industry members, including major trade associations, as well as consumer and public health advocates commented in support of major food allergen labeling. Although commenters took different positions on some of the specific issues TTB sought comment on in the ANPRM, only a few comments questioned the usefulness of requiring allergen information on alcohol beverage labels.

B. 2006 Interim Rule on Voluntary Allergen Labeling

While TTB is not reproposing its 2006 interim regulations which established standards for voluntary labeling of major allergens, there are similarities in this proposal, such as the procedures for obtaining an exemption, that warrant a brief summary of the 2006 regulations. Under the interim regulations, producers, bottlers, and importers of wines, distilled spirits, and malt beverages may voluntarily declare on their labels the presence of milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as ingredients that contain protein derived from these foods. However, if industry members choose to disclose allergens, the interim regulations set forth mandatory rules on how to undertake those disclosures—unless one of three exceptions applies.

Two of these exceptions from major food allergen labeling are based on FALCPA's definition of the term ''major food allergen,'' which excludes both highly refined oil and food ingredients exempt from allergen labeling under the FDA procedures at 21 U.S.C. 343(w)(6) and (7). The third is an exemption through a TTB petition process created by the interim regulations. All three are described in the following paragraphs.

The original FALCPA definition of ''major food allergen'' excluded any highly refined oil derived from one of the eight foods or food groups listed in

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petition for exemption approved by FDA under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

that definition and any ingredient derived from such highly refined oil.[5] TTB included this as an exception from the definition of a major food allergen in the interim regulations.

The second FALCPA exclusion from the definition of ''major food allergen'' arises from two processes FALCPA added to the FD&C Act at 21 U.S.C. 343(w)(6) and (7), by which any person may obtain an exemption from the allergen labeling requirements imposed by the statute. Subsection (w)(6) allows any person to petition the Secretary of Health and Human Services to exempt a food ingredient from the allergen labeling requirements. Under its delegated authority, FDA performs the function of the Secretary in this area. In this situation, the burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health. FDA must approve or deny any such petition within 180 days of receipt, or the petition will be deemed denied, unless an extension is mutually agreed upon by FDA and the petitioner.

Subsection (w)(7) allows any person to file a notification containing scientific evidence demonstrating that a food ingredient ''does not contain allergenic protein.'' The scientific evidence must include the analytical method used to produce the evidence that the food ingredient, as derived by the method specified in the notification, does not contain allergenic protein. Alternatively, the notification may contain a determination from FDA under a premarket approval or notification program provided for in section 409 of the FD&C Act (21 U.S.C. 348) that the food ingredient does not cause an allergic response that poses a risk to human health. FDA has 90 days to object to a notification. Absent an objection, the food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen.

Many ingredients and food additives used in the production of foods regulated by FDA are also used in the production of alcohol beverages regulated by TTB. Accordingly, the interim regulations included in the definition of the term ''major food allergen'' an exception for uses of food ingredients that are exempt pursuant to 21 U.S.C. 343(w)(6) or (7) discussed above. Alcohol beverage industry members also must establish that the proposed use of the ingredient is consistent with any conditions of use in the FD&C Act exemption for the ingredient.

As noted above, the interim regulations' third exception from allergen labeling is through a TTB petition process. TTB recognized that major food allergens are used in alcohol beverage production in ways that may differ from the way they are used in the production of foods regulated by FDA. For this reason, the interim regulations refer to an exception for a product covered by a petition for exemption approved by TTB. See 27 CFR 4.32a–b, 5.82–5.83, and 7.82–7.83. A petition may pertain to the use of a major food allergen in the production of one specific alcohol beverage product or it may pertain to a class of products using a particular process involving a major food allergen.

The TTB petition process is like that of the petition and notification processes provided for at 21 U.S.C. 343(w)(6) and (7), except that the TTB petition procedure focuses on finished products instead of ingredients. The TTB petition process may be used:

- When it is asserted that the product or class of products, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health; or
- When it is asserted that the product or class of products, as derived by the method specified in the petition, does not contain allergenic protein, even though a major food allergen was used in production.

The interim TTB regulations provide for only a petition procedure, rather than both the petition procedure and the notification procedure provided for in the FALCPA amendments to the FD&C Act. In addition, the interim regulations provide that if TTB does not approve or deny the petition for exemption within 180 days of receipt, the petition is deemed denied, unless an extension of time is mutually agreed upon by TTB and the petitioner. TTB's petition procedure is therefore like the petition procedure in 21 U.S.C. 343(w)(6) in that both procedures place the burden on the petitioner to provide evidence in support of the exemption and give the agency 180 days to respond.

The regulations also provide that a determination under this section constitutes a final agency action and that even though a petition is deemed denied because no action was taken within the 180-day period, the petitioner may resubmit the petition at any time. A resubmitted petition will be treated as a new petition.

C. 2006 Proposed Rule on Mandatory Allergen Labeling

As noted above, on the same date that TTB published interim regulations on the voluntary labeling of major food allergens, the agency also published Notice No. 62 (71 FR 42329 July 26, 2006), proposing to adopt mandatory alcohol beverage labeling requirements when one or more major food allergens, or ingredients derived from such allergens, are used in the production of the alcohol beverage. The proposed regulations were almost identical to those in the interim rule, except where necessary to note that major food allergen labeling would be mandatory. The proposed regulations set forth the same procedures for petitioning for an exemption from allergen labeling.

TTB received 51 comments in response to Notice No. 62. While most commenters were generally supportive of mandatory allergen labeling, concerns were raised about various implementation issues, including the absence of thresholds for the testing of finished alcohol beverages to determine if the products contained major food allergens; whether distillation should be recognized as a process that removed allergenic proteins; and the treatment of fining agents or processing aids, such as eggs, used in the production of alcohol beverages and then filtered out so that only trace amounts of the major food allergen remained in the finished product. While TTB did not finalize the 2006 proposed rule on mandatory allergen labeling, the interim regulations providing for voluntary allergen labeling remain in effect.

IV. Reasons for Issuing a New Notice on Mandatory Allergen Labeling

A. Comments in Response to Notice No. 176

On November 26, 2018, TTB published in the **Federal Register** Notice No. 176 (83 FR 60562), ''Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages,'' which sought comments on the modernization of the labeling regulations, but specifically stated that it would not address issues such as ingredient or allergen labeling. Nonetheless, TTB received several comments critical of that omission. Some of these comments specifically addressed mandatory allergen labeling.

[5] On April 23, 2021, the President signed the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act into law, declaring sesame as the ninth major food allergen. Accordingly, there are now nine major food allergens described in 21 U.S.C. 321(qq).

On February 22, 2019, CSPI, the Consumer Federation of America, and the National Consumers League commented on Notice No. 176 in a letter directed to the Secretary of the Treasury. The comment stated that while the consumer organizations supported the modernization of the labeling regulations, Notice No. 176 ''falls dramatically short of what is needed to truly 'modernize' alcohol labeling by failing to require uniform disclosure of key information—alcohol content, serving size, calories, ingredients, and allergen information—that consumers need to make informed choices.''

The comment stated that ''TTB has similarly failed to follow through on protections for consumers with food allergies. Disclosure of allergen information can have life-and-death consequences for some consumers, a harsh reality that led to passage of [FALCPA], which requires allergen labeling for FDA-regulated foods and beverages.'' The comment questioned why TTB had issued only an interim rule on voluntary allergen labeling, given that in its rulemaking, TTB noted that the major trade associations had expressed support for mandatory labeling of major food allergens. The comment suggested that the voluntary disclosure allowed by the interim rule ''creates a patchwork system that leaves consumers guessing. It may actually undermine public health to the extent that consumers with allergies may assume that an alcoholic beverage is safe to drink if its label has no allergen content declaration, when in fact the manufacturer simply has not bothered to label allergens that may be present.''

The Brewers Association also urged TTB to adopt mandatory allergen labeling, stating that ''the allergen disclosures required by FALCPA should be included in the mandatory information on malt beverage labels.'' The comment also stated that if TTB did not address allergen labeling in this rulemaking, the issue warranted a separate rulemaking in the future. On the other hand, the Distilled Spirits Council of the United States (DISCUS) stated that it supported the proposal to maintain the existing rule on voluntary allergen labeling and suggested that ''TTB should continue to point to FDA as the lead federal agency with regard to allergens.''

B. Letter From Public Health Advocates (2021 CSPI Letter)

On February 24, 2021, a letter was submitted on behalf of CSPI, the Consumer Federation of America, the National Consumers League, Alcohol Justice, the American Institute for Cancer Research, Breast Cancer Prevention Partners, and the U.S. Alcohol Policy Alliance, urging the Secretary to adopt regulations to mandate alcohol content statements and a standardized Serving Facts label on all wine, distilled spirits, and malt beverage products regulated under the FAA Act. The letter also urged the adoption of regulations mandating an ingredient declaration that lists each ingredient by its common or usual name and identifies any major food allergens present in the product.

C. Treasury Report on Competition in the Markets for Beer, Wine, and Spirits

As noted above, on February 9, 2022, the Department of the Treasury, in consultation with the Department of Justice and the Federal Trade Commission, released a report on competition in the markets for alcohol beverages. One of the Competition Report's findings was that ''[r]egulatory proposals that could serve public health and foster competition by providing information to consumers, such as mandatory allergen, nutrition, and ingredient labeling proposals, have not been implemented.'' [6] The Competition Report made some labeling recommendations, including a recommendation that TTB ''should revive or initiate rulemaking proposing ingredient labeling and mandatory information on alcohol content, nutritional content, and appropriate serving sizes.'' [7]

D. 2024 Virtual Public Listening Sessions

In light of the Competition Report, TTB announced in the Spring 2022 Unified Agenda of Federal Regulatory and Deregulatory Actions that it would publish an NPRM on possible changes to its regulations related to allergen labeling for alcohol beverages. Executive Order 14094, ''Modernizing Regulatory Review,'' was subsequently published on April 6, 2023, directing agencies, to the extent practicable and consistent with applicable laws, to provide opportunities for public participation designed to promote equitable and meaningful participation by a range of interested or affected parties to inform regulatory actions.

On January 31, 2024, TTB issued Notice No. 232, which announced two virtual listening sessions and the opening of a public docket to receive written comments on the labeling of alcohol beverages with per-serving alcohol and nutritional information, major food allergens, and/or ingredients. Consistent with Executive Order 14094, TTB sought input from a wide range of stakeholders, including those who may not usually comment on its proposals, to inform rulemaking, particularly given the broad implications of these issues. TTB also posed specific questions. Those related to major food allergens included whether consumers believe that they are adequately informed by information currently provided on alcohol beverage labels and whether listing major food allergens would be important information for consumers in making purchasing or consumption decisions. TTB also asked whether requiring additional information about major food allergens, alcohol or nutritional information, and ingredients on labels would be expected to increase the cost of products, and whether there are alternative ways of providing the information, for example by allowing information to be provided through a website using a quick response code (QR code) or website address on the label.

The listening sessions, held on February 28 and 29, 2024, engaged consumers, public health stakeholders, and industry members representing businesses of different sizes. Approximately 700 registrants attended the two virtual sessions, including 47 different speakers. In addition to the oral comments received during the listening sessions, TTB received 5,159 written comments in response to Notice No. 232.

The vast majority of the comments TTB received on allergens either favored mandatory labeling of major food allergens or did not express opposition to it. This included consumer and public health stakeholders as well as industry members and trade associations representing the alcohol beverage industry. However, some small sized producers opposed any new regulatory requirements. For example, Carriage House Vineyards and Travelers Cellar commented that ''The proposed changes regarding nutritional information, major food allergens and ingredients would significantly and negatively impact our small farm winery. . . . In our years of operation, consumers have shown no interest, nor have to this point inquired on any of the items that the proposal is looking to add.''

Consumers and public health stakeholders stated that major food allergen disclosures are necessary due to the implications for individuals with

[6] See page 3 of the Competition Report, available at *https://home.treasury.gov/system/files/136/Competition-Report.pdf.*

[7] Id. at page 61.

such allergies. TTB received substantially identical comments from 4,724 individuals supporting allergen disclosures, as well as other disclosures for alcohol content, serving size, nutritional information, and ingredients, which stated that ''For the 33 million Americans with food allergies, knowing what is in a product from ingredient and allergen labeling can be a matter of life or death.'' Other individual commenters stressed the uncertainty they face without mandatory allergen disclosures. For example, one individual commented that ''Without this information on alcoholic beverages, consuming them is like playing a lottery—I never know if a product may contain an ingredient I need to avoid until it's too late.'' The Centers for Disease Control and Prevention commented that ''Accurate labeling for major food allergens is crucial information to ensure safety for the consumer.'' AllergyStrong commented that ''The majority of people are not aware alcohol falls outside [FALCPA]—mistakenly believing that any consumable product is accurately labeled for allergens.'' CSPI stated that ''TTB should follow the lead of FDA and other countries and require ingredient and allergen labeling.''

Some commenters expressed a preference that mandatory allergen labeling for alcohol beverages be consistent with FDA requirements. The Asthma and Allergy Foundation of America stated that ''To the extent possible, labeling information should be displayed on alcoholic beverages similar to labeling on FDA-regulated foods. Consumers with food allergies are accustomed to FDA labeling, and would be able to easily transition to a similar model for checking the safety of alcoholic beverages . . .'' The Brewers Association commented that ''TTB should strive to make [major allergen] disclosures as consistent as possible with FDA disclosure rules under the FALCPA and its implementing regulations and guidance documents, while taking into account the different underlying labeling rules that apply to malt and other alcohol beverages versus most foods.''

Other commenters discussed the effect of distillation on allergenic ingredients used in the production of alcohol beverages, suggesting that any mandatory allergen disclosures should be based on the product post-distillation rather than the raw materials prior to distillation. DISCUS stated that ''Scientifically-based major food allergen labeling . . . that properly identifies products containing allergenic protein capable of causing an adverse reaction—can provide beneficial information to consumers with allergies,'' but also noted that distillation removes the proteins that cause allergic reactions and thus, ''any new allergen labeling regulations need to be focused on the post distillation final product.'' The Scotch Whisky Association commented that ''The distillation process completely transforms the raw materials used to produce a distilled spirit, so they are undetectable in the final product. Therefore, distillers should only list the elements and ingredients that have been added to the final product. Otherwise, consumers could be misled into thinking that they would be affected by the properties of the raw material used in the distillation process.''

Many of the comments TTB received from industry members and their trade associations advocated for the use of QR codes to satisfy new labeling requirements generally. However, among those who spoke about major food allergens specifically, some commenters otherwise in favor of QR codes still supported allergen declarations on the product's label. The American Distilled Spirits Alliance (ADSA) commented that ''while certain important information to consumers, including alcohol content and allergen information, may efficiently and effectively be included on a physical product label, more detailed information and information that is subject to periodic modification or update over time may be better communicated through a QR code. . . .'' Similarly, the National Association of Beverage Importers commented that ''The presence of a major allergen is also such an important piece of information'' that it ''must be available to all consumers and appear on a label on the bottle or container.''

Comments from industry also noted concerns about costs associated with new labeling requirements generally, including costs to conduct laboratory testing. While commenters did not specifically refer to costs of laboratory analysis related to mandatory labeling of major food allergens, ADSA commented that ''further discussion must be had around testing, requirements for good manufacturing practices and other safety protocols.''

E. International Developments

TTB participates in the Codex Alimentarius Commission by working with the FDA and the U.S. Codex Office at the U.S. Department of Agriculture. The Commission, which was established by the Food and Agriculture Organization and the World Health Organization, publishes the Codex Alimentarius, or ''Food Code,'' a collection of standards designed to protect the health of consumers and ensure fair practices in food trade. In recent years, the Codex Committee on Food Labelling has been discussing food allergen standards, allergen labeling provisions, and a possible framework for evaluating exemptions for food allergens. TTB is actively monitoring these developments and other Codex Alimentarius work related to alcohol labeling.

V. Proposed Regulatory Changes

For the reasons stated above, TTB is proposing rules for the mandatory labeling of major food allergens used in the production of alcohol beverages. Consistent with the FALCPA House committee report and TTB's statutory mandate under the FAA Act to promulgate regulations ensuring that consumers receive adequate information about the identity and quality of alcohol beverages, TTB believes that alcohol beverage labels should provide consumers with sufficient information about the use of major food allergens in the production of alcohol beverages so that consumers with food allergies may make an informed decision as to whether consumption of a particular beverage may pose a risk of an allergic reaction.

Existing regulations in 27 CFR 4.32, 5.63, and 7.63 list the mandatory information that must appear on labels of wine, distilled spirits, and malt beverages, respectively. TTB proposes to amend these sections to include mandatory allergen labeling requirements, with a cross-reference to the proposed new regulations that provide more detail about the mandatory allergen labeling requirements.

A. Labeling of Major Food Allergens and other Mandatory Disclosures

1. Wording of the Labeling Statement and Other Mandatory Disclosures

TTB is proposing that the mandatory food allergen statement consist of the words ''Contains Major Food Allergen(s)'' followed by a colon and the name of the food source(s) from which each major food allergen is derived, for example, ''Contains Major Food Allergen: milk'' or ''Contains Major Food Allergens: wheat and milk.'' This wording differs from the current voluntary allergen statement and is intended to make clear that the statement only relates to the nine major

food allergens [8] and does not include other, non-major food allergens, or other ingredients that may cause adverse reactions in some individuals.[9] TTB specifically seeks comments below on this wording and other related issues as described in this section.

TTB recognizes that changes in the wording or format of allergen disclosures may be warranted if TTB also requires ingredient disclosures. For example, if TTB requires both, aligning such labeling with food labeling may be warranted. Unlike foods labeled under FDA regulations, alcohol beverages subject to TTB's labeling rules do not currently require the listing of ingredients on labels. TTB is conducting a separate rulemaking on this issue and is not proposing to adopt mandatory ingredient labeling in this document. For food products, FDA allows major food allergens to be listed within the ingredient statement by their common or usual name, or in a separate ''contains'' statement. See 21 U.S.C. 343(w)(1). If TTB adopts mandatory ingredient labeling, allowing a major food allergen disclosure within such a statement, or allowing the statement to simply say ''contains'' instead of ''Contains Major Food Allergen(s),'' may be warranted. TTB seeks comment on these wording and format issues and the issues discussed below.

Under current TTB regulations, certain ingredients that are not ''major food allergens'' but nevertheless pose a recognized public health problem must be disclosed on labels. Currently this includes FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame.[10] See 27 CFR 4.32, 5.63, and 7.63. If an alcohol beverage contains any of the first four of these ingredients, the label must include a statement to that effect. While examples of such statements are provided, such as ''FD&C Yellow No. 5'' or ''contains carmine,'' the specific wording of the disclosure is left to the industry member. In the case of aspartame, the following statement, in capital letters, must appear, separate and apart from all other information: ''PHENYLKETONURICS: CONTAINS PHENYLALANINE.'' Sometimes industry members combine such disclosures, along with voluntary disclosures of other ingredients, for example, ''contains: cochineal extract and sulfites,'' or ''contains: sulfites and vanilla beans.''

In this notice of proposed rulemaking, TTB is currently only proposing to change its regulations to require the mandatory major food allergen statement ''Contains Major Food Allergen(s): . . .'', which would be separate from and not affect other required disclosures.[11] However, TTB solicits comments on the wording of the proposed mandatory major food allergen statement and the possible inclusion of other mandatory ingredient disclosures. Specifically, TTB solicits comments on the following:

1. Should TTB adopt the proposed wording of the major food allergen statement (''Contains major food allergen(s)'' followed by a colon and the name of the food source from which each major food allergen is derived)? Alternately, should TTB require or allow alternative formats, including the following:

- ''Contains'' followed by a colon and the name of the food source from which each major food allergen is derived; or
- A heading such as ''Major Food Allergen Information'' followed by ''Contains:'' or other language and the name of the food source from which each major food allergen is derived.

2. Should TTB allow the inclusion of major food allergens within a voluntary ingredient statement on labels as an alternative to a separate major food allergen statement?

3. If mandatory ingredient labeling is ultimately adopted, should TTB allow the inclusion of major food allergens in the list of ingredients as an alternative to a separate major food allergen statement? If mandatory ingredient labeling is ultimately adopted, should TTB use the ''Contains'' statement for major food allergens, consistent with FDA's approach? Should TTB limit the use of the ''Contains'' statement only for major food allergens?

4. Should other ingredients that are required to be disclosed under current TTB regulations (FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame) be required to be listed in one statement on the label? If so, should the other ingredients be included in a ''Contains'' statement that includes the major food allergens? (For example, ''Contains egg and sulfites''). Or should the major food allergens be identified as such, and the other ingredients listed separately (for example, ''Contains Major Food Allergen: egg. Contains sulfites'')? Should another statement be used for ingredients that are required to be disclosed under current TTB regulations (FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame) to differentiate from the ''Contains'' statement for major food allergens?

5. Would requiring all mandatory disclosures to be in one place on the label, including the proposed major food allergen statement, make it easier for consumers to find this information? Would such a requirement impose additional costs or regulatory burdens on industry members as compared to allowing the mandatory disclosures to appear separately?

6. Should TTB mandate specific placement, type size, and presentation requirements for major allergen labeling statements in addition to the requirements already applicable to all mandatory information on alcohol beverage labels? For example, should the required allergen disclosure statement be set off by a box? Or, to the extent practicable, should TTB mandate formatting consistent with FDA requirements for major allergen labeling?

2. Definition of Major Food Allergen

The definition of the term ''major food allergen'' is consistent with the statutory definition in the FD&C Act, as amended by FALCPA and the FASTER Act. TTB is proposing the same definition used by FALCPA, the FASTER Act, and FDA for consistency in labeling disclosures of major food allergens across products regulated by TTB and FDA. Thus, the proposed regulations define the term ''major food allergen'' as any of the following: ''Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.'' The term as defined also includes any food ingredient that contains protein derived from one of these nine foods or food groups, subject to certain exceptions explained below in Section V.B.

It should be noted that, consistent with guidance provided by FDA to the food industry, the proposed regulations allow the terms ''soybean,'' ''soy,'' and ''soya'' as synonyms for the term

[8] As noted previously, the FASTER Act of 2021 revised 21 U.S.C. 321(gg) such that there are now nine major food allergens: milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame.

[9] In a draft guidance published in April 2022, FDA notes the distinction between food allergies and other food intolerances, as well as the existence of more than 160 known food allergens, including the 9 currently identified major food allergens. See Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders (Draft), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-fda-staff-and-stakeholders-evaluating-public-health-importance-food-allergens-other.*

[10] In the case of sulfites, the disclosure is required if the product contains ''10 or more parts per million of sulfur dioxide or other sulfiting agent(s) measured as total sulfur dioxide.''

[11] For example, ''Contains Major Food Allergen: milk'' or ''Contains Major Food Allergens: egg and milk''.

''soybeans,'' as used in the statute.[12] Furthermore, consistent with FDA guidance, the singular term ''peanut'' may be substituted for the plural term ''peanuts,'' and singular terms (for example, almond, pecan, or walnut) may be used in place of plural terms to describe the different types of tree nuts. FALCPA provides that in the case of tree nuts, the label must list the common name of the specific type of nut (for example, almonds, pecans, or walnuts), and in the case of Crustacean shellfish, the label must list the name of the species of shellfish (for example, crab, lobster, or shrimp). 21 U.S.C. 343(w)(2). The proposed regulations are consistent with the FALCPA amendments with respect to the labeling of tree nuts and Crustacean shellfish.

3. Labeling of Fish Species

In the case of fish, the FALCPA amendments also provide that the name of the species of fish (for example, bass, flounder, or cod) must appear on the label. Id. However, for the reasons outlined below, the proposed regulations set forth in this document would not require labeling of the specific fish species. The proposed regulations would instead require simply listing ''fish'' when any type of finfish protein is used in the production of an alcohol beverage.

Isinglass and fish gelatin are often used to clarify wines and beers. Isinglass is a substance obtained from the swim bladders of sturgeon and other fish. Fish gelatin is obtained from the skin of a fish. Fish gelatin is often made from cod skins but can be made from any species of fish.

It is TTB's understanding that vintners and brewers, when purchasing isinglass or fish gelatin from a manufacturer for fining purposes, often do not know, and have no way of easily finding out, which species of fish was used to make the product. Moreover, it may be difficult for industry members to determine by chemical analysis which fish species was the source of the isinglass or fish gelatin.

TTB recognizes that the FALCPA amendments require the labeling of the species of fish used as an ingredient in a food product. However, it is TTB's responsibility to implement allergen labeling regulations that are appropriate for alcohol beverages, as noted in the FALCPA House committee report. It is likely that declarations of the use of fish in the production of alcohol beverages will generally involve the use of isinglass or fish gelatin as a processing aid, rather than the use of fish or foods derived from fish as an ingredient or a flavor for an alcohol beverage, where the specific fish species may be more easily identified. Because of the particular difficulty faced by producers in determining the specific species of fish used in producing the isinglass or fish gelatin, and because at least some consumers may be allergic to more than one species of fish, requiring labeling with the name of the specific species of fish may impose a difficult fact-finding burden on the alcohol beverage industry without offering consumers significant additional information to help them avoid the risk of an allergic reaction.

Accordingly, TTB solicits comments on whether labeling alcohol beverages produced using finfish protein merely as containing ''fish,'' rather than with the name of the fish species, provides adequate information to consumers. TTB also seeks comments on whether there are alternative approaches to this issue that would provide consumers with adequate information regarding the use of finfish protein in the production of alcohol beverages.

4. Processing and Fining Agents

Pursuant to the FD&C Act and its implementing regulations, incidental additives, including processing aids, are generally not subject to ingredient labeling requirements. FDA regulations exempt from the ingredient labeling requirements incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. See 21 CFR 101.100(a)(3). However, FALCPA amended the FD&C Act to require that, notwithstanding any other provision of law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen must conform to FALCPA's labeling requirements. See 21 U.S.C. 343(w)(4).

The TTB regulations on wine treatment, found at 27 CFR 24.246, authorize the use of certain materials that are approved as being consistent with good commercial practice in the production, cellar treatment, or finishing of wine and, where applicable, in the treatment of juice, subject to certain conditions. Some of these materials are processing aids derived from major food allergens. For example, albumen (egg white) is approved as a fining agent for wine, isinglass (a gelatin prepared from the swim bladders of fish) is approved to clarify wine, and casein (derived from milk) is approved to clarify wine.

TTB is proposing to require the disclosure of fining or processing agents that are or contain major food allergens, with the option of including the added parenthetical ''(processing aid)'' and is soliciting comments on this proposal. For example, if egg whites are used as a processing aid for wine, the industry member has the option of disclosing this on the label as follows: ''Contains Major Food Allergen: egg (processing aid).'' This is an option that industry members may choose to use, but they also may choose to list these agents without the parenthetical. TTB is not proposing parenthetical statements for other incidental additives besides processing aids. TTB seeks comments on whether this proposal, which is generally consistent with FALCPA, will provide adequate information to consumers.

TTB recognizes that some countries may handle this issue through exemptions for particular processing aids and that there are ongoing discussions about exemptions at the international level. TTB will monitor future developments to determine if they provide a scientifically supported basis for a more categorical exemption in this area, and we will continue to consult with FDA on this issue.

5. Threshold Levels

The FALCPA amendments, which took effect for foods labeled on or after January 1, 2006, require allergen labeling for packaged foods regulated by FDA without the establishment of any threshold levels for labeling. The FDA stated that a ''threshold is a value below which it is unlikely that a food allergic individual would experience an adverse effect'' and notes that ''[a]t this time, the FDA has not established a threshold level for any allergens.'' [13]

Consistent with TTB's longstanding policy of consulting with FDA in determining what ingredients in alcohol beverages should be disclosed on labels, TTB defers to FDA on this issue, and FDA has not established any thresholds for major food allergens. Accordingly, TTB is not proposing to set thresholds for the disclosure of major food allergens. Instead, the proposed rule provides that all major food allergens and proteins derived from the major food allergens used in production must be declared on the beverage label, unless the product or class of products is covered by an approved petition for exemption, or otherwise falls under an applicable exception, as discussed below. TTB believes that this position will ensure that consumers have

[12] See Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry (last revised, November 2022), page 9, available at *https://www.fda.gov/media/117410/download.*

[13] See *https://www.fda.gov/food/food-labeling-nutrition/food-allergies.*

adequate information about the potential presence of major food allergens used in the production of alcohol beverages. If FDA establishes thresholds in the future, TTB will reconsider its policy on this issue.

6. Allergen Advisory Labeling

TTB's proposal does not specifically address allergen advisory labeling, such as statements that a product *may* contain a major food allergen, *e.g.,* ''May Contain (major food allergen).'' TTB is concerned that allergen advisory labeling could be used as substitute for adherence to current good manufacturing practices and could be misleading. TTB is soliciting comments on the use of allergen advisory labeling.

B. Exceptions From Allergen Labeling Requirements

1. Exceptions Found in Current Regulations

TTB is not proposing to amend the standards set forth in the current regulations providing exceptions from major food allergen labeling for ingredients derived from highly refined oil (consistent with the definition of ''major food allergen'' in the FD&C Act) and for food ingredients that are exempt pursuant to the FDA notice and petition processes in 21 U.S.C. 343(w)(6) or (7). Furthermore, TTB is not proposing to amend the current standards in the regulations that allow an exception for a product or class of products covered by a petition for exemption that is approved by TTB. A petition may pertain to the use of a major food allergen in the production of one specific alcohol beverage product or it may pertain to a class of products using a particular process involving a major food allergen. Consistent with the 1987 MOU with FDA, TTB intends to confer with FDA, as appropriate and as FDA resources permit, on petitions submitted under the proposed rule.

2. Distillation

In previous rulemaking, commenters asked whether spirits distilled from a fermented mash containing a major food allergen (such as wheat) must be labeled as containing that major food allergen. Industry members have suggested that the distillation process removes all protein, including allergenic protein. TTB is therefore proposing in 27 CFR 5.75(b)(2) that major food allergens, or ingredients containing major food allergens, need not be declared on a label when such allergens or ingredients have been subject to distillation in such a manner that no protein, allergenic or otherwise, remains in the distilled product or distilled ingredient. As explained below, this is consistent with the position FDA has taken regarding the removal of proteins using the distillation process within the context of major food allergen labeling and gluten-free labeling of distilled foods.[14] TTB is soliciting comments on this proposal.

In June 2015, FDA published Food Allergen Labeling Exemption Petitions and Notifications: Guidance for Industry.[15] In that guidance, FDA provided general advice for when a petition or notification should be submitted under FALCPA, and specifically addressed the distillation process. In particular, the guidance stated that ''An ingredient derived from a major food allergen that does not contain protein is not subject to the labeling requirements described in section 403(w)(1) of the FD&C Act.'' FDA recognized that ''there are some technologies (*e.g.,* distillation) that may be able to produce protein-free ingredients because of the nature of the process and fundamental biochemical properties of proteins, peptides, and amino acids.''

On August 13, 2020, FDA addressed the distillation issue in more detail in its final rule to establish compliance requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, bearing a ''gluten-free'' claim. See ''*Food Labeling: Gluten-Free Labeling of Fermented or Hydrolyzed Foods*'' *(85 FR 49240).* The preamble to the FDA final rule explained that ''[i]f good manufacturing practices are followed, the process of distillation must remove all protein (and thus gluten), regardless if the product has been distilled from gluten-containing grains.'' 85 FR 49248. FDA noted that ''the process of distillation heats a liquid, which vaporizes components with lower boiling points and separates them from components with higher boiling points. The remaining compounds, whose boiling points are too high to undergo vaporization, are left behind.'' Id. FDA concluded that ''[i]f distillation is done properly, the process removes gluten because gluten does not vaporize.'' Id. For this reason, FDA determined that ''a distilled product's labeling may bear a 'gluten-free' claim and should be safe for people with celiac disease to consume.'' Id. The final rule provides that when a scientifically valid method for verifying that a distilled product is gluten-free is not available, FDA will evaluate compliance ''by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food.'' 21 CFR 101.91(c)(5). The preamble to the FDA final rule noted that the ''[t]ransfer of gluten into the distillate would only be expected to occur under poor manufacturing practices in which the initial material is splashing into the distillate due to poor design of the still. Protein testing can be done to confirm that protein (and thus gluten) is absent in the distilled product.'' 85 FR 49248. FDA also noted that ''any ingredients (such as flavors) added to the distilled product would need to be 'gluten-free' under § 101.91(a)*(3)* for the finished product labeling to bear a gluten-free claim.'' Id.

Consistent with the FDA's findings in its guidance on major food allergens and its final rule on the labeling of distilled food products with ''gluten-free'' claims, TTB is proposing to amend the distilled spirits regulations in proposed 27 CFR 5.75(b)(2) to specifically provide that the mandatory labeling requirements do not apply to major food allergens used in the production of a distilled spirits product if they have been completely distilled in such a manner that no protein remains in the distilled spirits. As needed, TTB will evaluate compliance by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the finished product. If ingredients containing protein are added to the distilled spirits product after distillation, and no major food allergens are listed on the label, industry members must be prepared to substantiate, upon request, the absence of protein in the distillate, the absence of any major food allergens in the added ingredients, and the precautions taken to prevent cross-contact. TTB is soliciting comments on whether this method of verifying compliance is adequate to protect consumers and whether there are better alternatives.

C. Effective Date and Compliance With the Proposed Regulations

TTB is proposing a compliance date of 5 years from the date that a final rule resulting from this proposal is published in the **Federal Register** to minimize the costs and burdens associated with the proposed new labeling information. TTB solicits comments on whether the proposed

[14] TTB's current position on gluten-free labeling of distilled foods is consistent with FDA's. See *https://www.ttb.gov/rulings/r2020-2.*

[15] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications.*

compliance date would suffice to limit the impact on small businesses and to reduce overall costs of compliance while ensuring that consumers are adequately informed. TTB also seeks comments on whether the use of a single compliance date for any new regulations on allergen, ingredient, or ''Alcohol Facts'' labeling would provide consumers with adequate information in a coherent and timely manner while also reducing costs and other regulatory burdens on industry. See Section VI, Cost Analysis, below, for additional information on coordinated labeling changes. Similarly, TTB intends to clarify that industry members will not be required to submit new COLA applications when the only change being made to a label is the inclusion of a statement of major food allergens. Therefore, this proposal would not require the submission of a new application for label approval simply to add allergen labeling statements in accordance with the new requirements.

VI. Cost Analysis

Executive Order 12866, as amended, requires TTB to design regulations in the most cost-effective manner that will achieve the regulatory objective. Accordingly, TTB seeks to tailor its regulations to impose the least burden on individuals, businesses of differing sizes, and other entities, consistent with the regulatory objective.

A. TTB's Estimate of Costs Associated With Alcohol Facts Proposed Rule

In Notice No. 237, Alcohol Facts Statements in the Labeling of Wines, Distilled Spirits, and Malt Beverages, also published in this issue of the **Federal Register**, TTB proposed an amendment to the labeling regulations that would require an ''Alcohol Facts'' statement on each wine, distilled spirits, and malt beverage label subject to the FAA Act. TTB will not repeat the substance of that analysis here, but below is a summary of the findings of that analysis.

To estimate the costs associated with the Alcohol Facts proposal, TTB utilized the 2014 FDA Labeling Cost Model,[16] adding its own data inputs, making various assumptions about the alcohol beverage industry, and adjusting costs to reflect inflation through January 2023. While FDA provided TTB with access to its model, FDA is not responsible for the assumptions made by TTB about the alcohol beverage market; nor is FDA responsible for the estimates set out in this analysis.

To determine the number of alcohol beverage Universal Product Codes (UPCs)[17] in the marketplace, TTB contracted with NielsenIQ[18] to obtain a one-time report, which consists of data for the period from September 9, 2021, through September 10, 2022,[19] for the following markets: Total U.S. all outlets combined,[20] liquor, and convenience stores.[21]

Based on the available data, TTB estimated the one-time total labeling costs associated with the proposed rule on Alcohol Facts under a 2-year compliance period to have a present discounted value (PDV)[22] of approximately $323.4 million (or approximately $161.7 million per year). If the compliance date is extended to 3 years, the total PDV would be approximately $258.5 million (or $86.5 million per year); for 42 months, the total PDV would be approximately $204.3 million (or $58.4 million per year). Finally, if the compliance period is extended to 5 years, the total PDV would be approximately $201.2 million (or $40.2 million per year).[23]

B. Costs Associated With Allergen Proposed Rule if Coordinated With Alcohol Facts Proposal

TTB is seeking comments on whether the compliance date for this proposed rule should be coordinated with the compliance dates of other labeling changes that have been proposed by TTB, including Notice No. 237, Alcohol Facts Statements in the Labeling of Wines, Distilled Spirits, and Malt Beverages, which proposed the inclusion of Alcohol Facts statements on alcohol beverage labels, as well as any proposals that may be aired as a result of the ANPRM on ingredient labeling. See Notice No. 237.

Promulgating the requirements for the final label changes together would allow bottlers and importers to undertake all the label revisions necessary to implement these changes in one label change. For example, it is TTB's preliminary conclusion that for industry members that would be required to make label changes under any new requirements resulting from the Alcohol Facts and the Allergen rulemakings, it would be more efficient and less costly to make changes to the label to accommodate both requirements at the same time. If the rules were instead promulgated and took effect at different points in time, TTB assumes that the multiple distinct label changes would result in greater costs. TTB invites comments on this preliminary conclusion.

TTB estimates that the cost savings of a coordinated regulatory compliance date for the proposed labeling change rules would be significant. For the purposes of this economic analysis, TTB is considering major label changes to subsume minor label changes. For example, a UPC subject both to the Alcohol Facts NPRM that will affect virtually all UPCs (*e.g.,* the addition of an Alcohol Facts statement), and the proposed Allergen rule would count only under the final Alcohol Facts rule because the major label change required by the proposed Alcohol Facts rule would subsume the minor label changes

[16] FDA has periodically contracted with RTI International to provide a model to estimate the costs of various product labeling changes required by regulation. The most recent version is the ''2014 FDA Labeling Cost Model, Final Report, August 2015,'' available at *https://downloads.regulations.gov/FDA-2016-N-2527-2681/content.pdf.*

[17] Each individual product may have several UPCs associated with different sizes or types of packaging.

[18] Based in part on data reported by NielsenIQ through its MarketTrack Service for the Alcohol Beverage Category for the period from September 9, 2021 through September 10, 2022, for the Total US all outlets combined, liquor, and convenience stores market. Copyright © 2022 Nielsen Consumer LLC.

[19] TTB emphasizes that the analyses, calculations and conclusions in this document may have been informed in part by the NielsenIQ RMS data through NielsenIQ's Retail Measurement Service (RMS) for the beverage alcohol product categories for the reported time period for Total US expanded all outlets combined, liquor, and convenience stores. However, any such analyses, calculations and conclusions are those of TTB and do not reflect the views of NielsenIQ. NielsenIQ is not responsible for, had no role in, and was not involved in analyzing and preparing the results reported herein, or in developing, reviewing or confirming the research approaches used in connection with this document.

[20] NielsenIQ's xAOC market includes retailers in its Food, Drug, Mass, Walmart, Club, Dollar, and Military channels. Nielsen defines those channels as follows:

—Food is inclusive of all grocery stores with greater than $2MM in annual ACV, including smaller chains and independents, and large players such as Whole Foods.

—Drug is inclusive of all chains and independents with greater than $1MM in annual ACV.

—Select Mass includes Target, K-Mart, and ShopKo.

—Walmart includes Walmart Division 1 + Supercenter's + Neighborhood Markets.

—Select Club is inclusive of Sam's Club and BJ's. Costco does not participate in market measurement with any data provider.

—Select Dollar is inclusive of Dollar General, Family Dollar, and Fred's Dollar.

—Military is inclusive of military commissary stores.

[21] Nielsen states that its Convenience channel includes ''major chains as census cooperators, and is projected to represent all chains and independents.''

[22] The present discounted value of monetary values was calculated using a 2 percent discount rate in accordance with OMB *Circular A–4 Chapter 12,* available at *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.*

[23] All costs in this proposal are provided in 2023 dollars.

required by the proposed Allergen rule. The marginal additional cost of the Allergen rule above the cost of the proposed Alcohol Facts rule is, therefore, negligible if the two rules have the same compliance date. This cost savings arises because alcohol beverage bottlers and importers would generally have to make a major label change to comply with the Alcohol Facts rule, and industry members that were additionally affected by any new allergen disclosure requirements arising out of this rulemaking would be able to undertake just one label change to comply with the requirements of the two rules.

VII. Public Participation

A. Comments Sought

TTB requests comments from the public and all interested parties on the regulatory proposals contained in this document. TTB seeks comments on the proposed rule as well as other approaches also discussed in this document. TTB has posed specific questions on various issues throughout this preamble and also seeks comments in response to those questions. In developing the final rule, TTB will carefully evaluate the proposed regulations considering all comments and suggested alternative approaches and will adopt the most appropriate approach. Where TTB has specifically solicited comments on alternatives to proposed amendments, it may consider adopting such alternatives in lieu of the proposed amendments based on its review of the comments.

TTB also seeks comments on the impact that the proposed changes will have on consumers and on industry members and any suggestions as to how to minimize any costs or regulatory burdens associated with the proposed regulations, including the following issues:

1. Are there alternative ways of providing a major food allergen disclosure, for example, by allowing information to be provided through a website using a quick response code (QR code) or website address on the label? Will such an alternative method still provide adequate information to the consumer?

2. Does the proposed compliance date suffice to reduce overall costs of compliance, and specifically the costs to small businesses, while ensuring that consumers are protected?

3. Is there a shorter compliance period that would provide more benefits to consumers while still limiting costs and potential impacts on small businesses? Specifically, would a 2-, 3-, or 3.5-year compliance period suffice?

4. If a final rule is issued, will industry members begin implementation of the labeling changes in advance of the compliance date? If yes, how might consumers benefit from early compliance by industry?

5. Are there any ongoing costs of compliance with the proposed rule that TTB has not addressed in this document?

6. How many small businesses would be impacted by the proposed rule, and what would be the economic impact of the proposal on these small businesses? How, if at all, does the length of the compliance period affect the impact on small businesses? Please explain in detail and provide specific cost data.

We welcome comments on all other issues presented in this document.

B. Submitting Comments

You may submit comments on this proposal as an individual or on behalf of a business or other organization via the *Regulations.gov* website or via postal mail, as described in the **ADDRESSES** section of this document. Your comment must reference Notice No. 238 and must be submitted or postmarked by the closing date shown in the **DATES** section of this document. You may upload or include attachments with your comment. You also may submit a comment requesting a public hearing on this proposal. The TTB Administrator reserves the right to determine whether to hold a public hearing. If TTB schedules a public hearing, it will publish a notice of the date, time, and place for the hearing in the **Federal Register**.

C. Confidentiality and Disclosure of Comments

All submitted comments and attachments are part of the rulemaking record and are subject to public disclosure. Do not enclose any material in your comments that you consider confidential or that is inappropriate for disclosure.

TTB will post, and you may view, copies of this document, its supporting materials, and any comments TTB receives about this proposal within the related *Regulations.gov* docket. In general, TTB will post comments as submitted, and it will not redact any identifying or contact information from the body of a comment or attachment.

Please contact TTB's Regulations and Rulings Division by email using the web form available at *https://www.ttb.gov/contact-rrd,* or by telephone at 202–453–2265, if you have any questions regarding comments on this proposal or to request copies of this document, its supporting materials, or the comments received in response.

VIII. Regulatory Analysis and Notices

The impacts of this proposed rule have been examined in accordance with Executive Order 12866, as supplemented by Executive Order 13563 and amended by Executive Order 14094, and the Regulatory Flexibility Act (5 U.S.C. 601–612).

A. Purpose of the Rule

The overall purpose of this proposed rule is to provide consumers who are allergic to one or more major food allergens with more information about the identity and quality of alcohol beverage products. Since the effective date of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), major food allergen labeling has been required for foods subject to the labeling regulations of the FDA (subject to certain exceptions), and the Department of Agriculture has similarly adopted regulations for foods subject to its labeling regulations. Alcohol beverages subject to the labeling regulations of the FAA Act are the only type of packaged beverage category without any requirement for major food allergen labeling.

Accordingly, TTB proposes to require the disclosure of major food allergens used in the production of alcohol beverages subject to the FAA Act.[24] TTB believes this proposal would provide consumers who are allergic to one or more of the nine major food allergens with the information they need to avoid exposure and the health risks posed by these ingredients.

B. Benefits

According to the FDA, food allergies and other food hypersensitivities affect millions of Americans.[25] A food allergy is an immune response to certain proteins in food, which may cause mild symptoms, but may also result in a severe, life-threatening allergic reaction called anaphylaxis. Because food allergies currently cannot be cured, early recognition of which foods cause individuals to have an allergic reaction, and learning how to avoid such foods, are important ways to prevent serious health risks.

TTB does not possess data that would enable it to quantify the monetary benefits of the proposed rule. However, TTB believes that a labeling statement

[24] Further information on the specifics of TTB's proposal and its authority to implement the proposal are in Section II.

[25] See *https://www.fda.gov/food/food-labeling-nutrition/food-allergies.*

with information about the presence of major food allergens in the production of an alcohol beverage will provide significant benefits. Consumers with these food allergies will be able to make an informed decision as to whether consumption of a particular alcohol beverage may pose a risk of an allergic reaction. This proposal will also promote consistency in major food allergen disclosure across all types of food product labels, removing ambiguity about whether a product contains a major food allergen or not. TTB invites comments on its conclusion that consumers would benefit from having this information available on product labels.

C. Costs of Compliance

As set forth in Section VI of this preamble, based on its use of the FDA Labeling Cost Model and assuming a 5-year coordinated compliance period with the Alcohol Facts rule, TTB estimates that the marginal additional cost of the Allergen rule above the cost of the proposed Alcohol Facts rule is negligible. This is because industry members would generally have to make a major label change to comply with the Alcohol Facts rule, and industry members that were additionally affected by any new allergen labeling requirements from this rulemaking would be able to undertake just one label change to comply with the requirements of the two rules.

TTB notes that this proposal does not require additional analytical testing, as it generally requires labeling of major food allergens used as an ingredient, and ingredients are expected to be known by the producer.

D. Executive Orders 12866, 13563, and 14094

This proposed rule is a ''significant regulatory action'' for purposes of Executive Order 12866, as supplemented by Executive Order 13563 and amended by Executive Order 14094, and has been reviewed by the Office of Management and Budget.

E. Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), TTB has analyzed the potential economic effects of this action on small entities. In lieu of the initial regulatory flexibility analysis required to accompany proposed rules under 5 U.S.C. 603, section 605 allows the head of an agency to certify that a rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

TTB certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposed rule is not expected to have significant secondary or incidental effects on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. Pursuant to 26 U.S.C. 7805(f), TTB will submit the proposed regulations to the Chief Counsel for Advocacy of the Small Business Administration (SBA) for comment on the impact of the proposed regulations on small businesses.

The following analysis provides the factual basis for TTB's certification under section 605.

In FY 2022, TTB collected $8.3 billion in taxes from the alcohol industry.[26] With regard to the total number of authorized producers of alcohol beverages, there are 17,649 wineries and bonded wine cellars; 14,185 brewers; and 4,494 distillers.[27] However, the number of authorized producers and importers who obtain certificates of label approval (COLAs) in any given year, and who therefore could be affected by this proposed rule, is much lower. For example, in FY 2022, TTB received 192,954 label applications and 26,922 formula applications for alcohol beverages.[28] Internal data from TTB's COLAs Online system shows that, on average, fewer than 12,000 permittees or brewers applied for label approval in each of Fiscal Years 2020–2022. The data also shows that most of these COLA applications come from the same set of permittees and brewers every year. During the 3-year period of Fiscal Years 2020–2022, fewer than 18,000 unique permittees or brewers applied for label approval.

The value of the U.S. import trade in alcohol beverages in 2021 totaled $23.9 billion.[29] According to data published on the website of the Distilled Spirits Council of the United States,[30] the total economic contribution of the alcohol beverage industry to the U.S. economy in 2019 included 2,514,000 ''direct'' jobs and 5,630,000 ''total'' jobs; $67.9 billion in direct wages and $160.3 billion in total wages; and $242.6 billion in direct economic activity and $572.3 billion in total economic activity.

TTB recognizes that most producers, bottlers, and importers of alcohol beverages are small entities. The SBA sets out size standards based on the North American Industry Classification System (NAICS), under which an entity can be considered small for the purposes of Regulatory Flexibility Act analysis.[31] Breweries are considered small if they have fewer than 1,250 employees; wineries are considered small if they have fewer than 1,000 employees; and distilleries are considered small if they have fewer than 1,100 employees.[32]

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) data include information on employment among establishments within NAICS codes. The most recent data are from 2019.[33] The SUSB data did not include employment at the 1,000, 1,100, or 1,250 employee threshold; however, it does include the number of firms within each NAICS code that have at least 500 employees. Based on those numbers, approximately 99% of the firms in these three NAICS codes are small entities. The percentage may be greater, depending on how many firms have at least 500 employees and fewer than 1,000 employees (for wineries), 1,100 employees (for distilleries), or 1,250 employees (for breweries). There is no NAICS code for importers of alcohol beverages.

[26] Alcohol and Tobacco Tax and Trade Bureau Annual Report Fiscal Year 2022 (FY 2022 TTB Annual Report), available at *https://www.ttb.gov/images/pdfs/ttbar2022.pdf,* page 5.

[27] Id. at page 10.

[28] Id. at page 16. It should be noted that the number of label applications does not necessarily correlate to the number of brands and UPCs in the marketplace for several reasons. TTB cannot determine whether approved labels appear in the marketplace, or how long those labels may remain in use. For example, there may be malt beverage labels authorized for a particular sporting event that are no longer found in the marketplace a few months after the event has taken place. On the other hand, some labels may be revised to reflect different net contents or alcohol content statements without submission of a new label to TTB. Industry members may decide not to use labels for which they have obtained approval. Thus, TTB does not use the number of COLA applications as an estimate of how many brands or UPCs are in the marketplace at any given time.

[29] Id. at page 30.

[30] Economic Contributions of Alcohol Beverage Industry 2019, Distilled Spirits Council of the United States, available at *https://www.distilledspirits.org/wp-content/uploads/2021/10/Economic-Contributions-2019.pdf.* See Annual Economic Briefing (February 9, 2023), Distilled Spirits Council of the United States, available *at https://www.distilledspirits.org/wp-content/uploads/2023/02/FINAL-2022-AEB-Slide-Deck-2.9.23-941am.pdf.*

[31] See Size Standards, U.S. Small Business Administration, available at *http://www.sba.gov/content/small-business-size-standards.*

[32] 13 CFR 121.201.

[33] 2019 SUSB Annual Data Tables by Establishment Industry, U.S. Census Bureau, available at *https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html.*

TABLE 1—NUMBER OF FIRMS WITH AT LEAST 500 EMPLOYEES

Small-entity size standards for potentially affected industries and number of firms with at least 500 employees				Total employment
Industry (NAICS code)	Small-entity size standard	Total number of firms	Number of firms with at least 500 employees	
Breweries (NAICS 312120)	Fewer than 1,250 employees	4,217	23 (approximately 0.5 percent)	84,503
Wineries (NAICS 312130)	Fewer than 1,000 employees	3,944	19 (approximately 0.48 percent)	59,587
Distilleries (NAICS 312140)	Fewer than 1,100 employees	1,004	10 (approximately 1%)	16,828

Data on revenues by firm size and industry are also available in the SUSB, but are published less frequently. The most recent data available is from 2017.[34] Based on this data, with the revenues adjusted for inflation, 2,609 of the total number of firms (3,214) listed as breweries under NAICS Code 312120 have fewer than 20 employees.[35] This category accounts for $3,314,362,000 of the total inflation-adjusted receipts of $36,032,713,000, or roughly 9.2 percent of the total receipts. With regard to wineries, 2,975 of the 3,576 firms under NAICS Code 31230 have fewer than 20 employees. This category accounts for $2,907,606,000 of the total inflation-adjusted receipts of $24,891,833,000, or roughly 12 percent of the total receipts. With regard to distilleries, 659 of the 760 firms under NAICS Code 31240 have fewer than 20 employees. This category accounts for $1,060,898,000 of the total inflation-adjusted receipts of $14,590,615,000 or roughly 7 percent of the total receipts.

As noted above, not all alcohol beverage producers would be impacted by the requirements of this proposed rule. Some alcohol beverages, while subject to permitting and excise tax requirements, are not required to be labeled under the FAA Act. These include wines with less than 7 percent alcohol by volume and beer produced without both malted barley and hops. Additionally, most alcohol beverages do not contain major food allergens. Some examples of alcohol beverages that use ingredients in the production process that contain major food allergens are malt beverages that contain wheat, and wines and malt beverages that use eggs or fish as processing aids. Some specialty products that are currently labeled as containing ''natural flavors'' may also have to include new labels disclosing the use of major food allergens.

While most businesses subject to the proposed rule are small businesses, the changes proposed in this document will not have a significant impact on those small entities. The production, bottling, importation, and distribution of alcohol beverages is an industry subject to extensive Federal, State, and local regulation. The labeling and advertising regulations under the FAA Act have been in place since 1936. TTB believes that adding a disclosure requirement for major food allergens, the presence of which industry members already track in the usual course of business, will not have a significant impact on the regulated industry.

TTB cannot estimate the exact cost per small entity because we do not know how many product brands (covered by different UPCs) on average are owned by small entities as defined by the SBA. However, as discussed in Section VI, above, TTB estimates that the marginal additional cost of the Allergen rule above the cost of the proposed Alcohol Facts rule is negligible. This is because industry members would generally have to make a major label change to comply with the Alcohol Facts rule, and industry members that were additionally affected by any new allergen labeling requirements from this rulemaking would be able to undertake just one label change to comply with the requirements of the two rules.

This proposal differs from the proposed rule on mandatory allergen statements in 2006 in that allergen labeling requirements will not apply to distilled spirits products where no protein from major food allergens remains in the product after distillation. See Section V, above, and Notice No. 62, 71 FR 42329, July 26, 2006. This will reduce the number of products subject to major allergen disclosure, and thus the compliance burden for small distillers. Additionally, TTB is proposing to reduce the costs associated with the label redesign by not requiring industry members to submit new applications for label approval when the only change is the inclusion, deletion, or revision of a major food allergen statement.

TTB considered other options to reduce the regulatory burden and cost for small businesses, but ultimately is not proposing them. One option considered was to exempt small businesses from the requirements of the proposed rule. The primary purpose of this proposed rule is to provide information to consumers who are allergic to one or more of the nine major food allergens. This purpose would be weakened by a permanent exemption for small businesses. Consumers would not be able to rely on alcohol beverage labels to disclose the presence of major food allergens if the requirements did not apply to all such products. Moreover, TTB questions whether a permanent exemption from mandatory labeling requirements would be consistent with the mandate, in the FAA Act, to ensure that labels provide consumers with adequate information about the identity and quality of alcohol beverage products. TTB notes that there is no specific statutory authority for exempting small businesses from the requirements of the FAA Act as there is under the FD&C Act for nutritional labeling regulated by the FDA. Further, the small business exemption under FDA regulations pertains only to nutrition labeling information, and not to any other mandatory information, including allergens. TTB also considered the option of proposing an extended compliance period only for small businesses. However, this would not be administrable for TTB without imposing additional requirements on these businesses. When reviewing applications for label approval, TTB employees do not have access to the number of people employed by each company, and thus it would not be practical to base compliance status on the SBA standards for small businesses. Additionally, reporting such information to TTB with each label

[34] This data is only available from Economic Census years (years ending in 2 and 7). See 2017 SUSB Annual Data Tables by Establishment Industry, U.S. Census Bureau, available at *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[35] A recent study estimates that 28.3% of brewing facilities are brewpubs, with 66.7% of brewing facilities categorized as ''micro'' breweries. The study explains that brewpubs and small micro-brewers ''produce beer for a limited market—sometimes only for their own restaurant or retail establishment.'' See Beer Serves America—A Study of the U.S. Beer Industry's Economic Contribution in 2022,'' prepared for the Beer Institute and National Beer Wholesalers Association, which is available at *https://beerservesamerica.org/wp-content/uploads/2023/05/2022-Beer-Serves-America-Report.pdf.*

application would impose a new burden on all industry members that would be subject to this proposed rule. Instead, TTB is proposing a compliance period of 5 years for all industry members, and is expecting that many industry members, particularly large businesses, will start declaring major food allergens after publication of a final rule, in advance of the compliance date.

As previously noted, the label redesign, printing, and administrative costs associated with making a labeling change are on a per-UPC basis. Under the FDA Labeling Cost Model, the longer the compliance period, the more likely it is that affected industry members can coordinate new labeling requirements with scheduled labeling changes, so cost estimates fall significantly as the time allowed for the new labeling requirements increases. In other words, the longer the period industry is given to comply with the new labeling requirements, the lower the costs. According to the FDA Labeling Cost Model, with a compliance period of 5 years, 100 percent of the labeling changes resulting from a regulatory change can be coordinated with a regularly scheduled labeling change, thus significantly reducing the estimated costs and burdens for small businesses that would be subject to the proposed rule.

TTB specifically solicits comments on the number of small producers, bottlers, and importers of alcohol beverages that may be affected by this proposed rule and the impact of this rule on those small businesses. TTB welcomes data on all these issues.

F. Paperwork Reduction Act

Three of the regulatory sections addressed in this notice of proposed rulemaking contain collections of information that have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). Those regulatory sections are 27 CFR 4.32, 5.63, and 7.63, and they contain existing information collections assigned OMB control numbers 1513–0084 and 1513–0087. OMB No. 1513–0084 concerns the labeling of sulfites in alcohol beverages, and OMB No. 1513–0087 concerns alcohol beverage labeling requirements under the FAA Act.

This proposed rule includes a new collection of information involving the mandatory declaration of major food allergens on the labels of alcohol beverages. This collection of information has been submitted to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995 pending receipt and evaluation of public comments. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The regulatory sections in this proposed rule that contain the new information collection requirement for a declaration of major food allergens are in proposed regulatory sections §§ 4.32 and 4.32a for wine labels, §§ 5.63 and 5.75 for distilled spirits labels, and §§ 7.63 and 7.75 for malt beverage labels. This new collection of information will be mandatory, and the likely respondents are for-profit businesses, including corporations, partnerships, and small businesses. Specifically, the new information collection would require alcohol beverage bottlers and importers to disclose the presence of any of the nine major food allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame), as well as ingredients that contain protein derived from these foods, if used in the production of the alcohol beverage, unless an exception applies. The disclosure would state ''Contains major food allergen(s)'' followed by a colon and the name of the food source from which each major food allergen is derived.

As discussed in Section VI, Cost Analysis, above, the FDA Labeling Cost Model projects a ''mean'' internal recordkeeping burden of 1 hour per UPC for labeling changes that are coordinated, and 2 hours per UPC for labeling changes that are not coordinated. As noted above, TTB is proposing a 5-year compliance date, which means that 100 percent of the labeling changes will be ''coordinated.'' TTB believes that a significant proportion of the alcohol beverage industry already collects and maintains information regarding the presence of major food allergens in their products in the usual course of business. Furthermore, TTB does not propose to require industry members to submit new COLA applications for the sole purpose of adding, deleting, or revising major food allergen statements. Thus, the proposed rule would not increase recordkeeping requirements regarding certificates of label approval, which are covered by OMB Control Number 1513–0020.

Accordingly, TTB is estimating an annual burden of 1 hour per respondent for the new major food allergen disclosures proposed under the FAA Act labeling regulations. TTB estimates its annual burden as follows:

- *Number of Respondents:* 10,000.
- *Number of Responses:* 30,000.
- *Average per-Response Burden:* 1 hour per respondent.
- *Total Annual Burden:* 10,000 hours.

TTB has submitted the major allergen disclosure statement information collection requirements and the revised collection requirements under the FAA Act to OMB for review. Please send any comments on these new and revised collection requirements to OMB at Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, or by email to *OIRA_submissions@omb.eop.gov.* Please also send a copy of any such comments to TTB by any of the comment submission methods described in the **ADDRESSES** section of this document. Comments should be submitted no later than April 17, 2025.

TTB specifically requests comments concerning:

- The accuracy of the estimated burden associated with the proposed collections of information (see below);
- Whether a unified compliance date for labeling changes that may arise from this rulemaking, along with separate rulemakings on ingredient labeling and ''Alcohol Facts'' labeling, would result in lowering the combined burden hours for the three rulemakings;
- Whether the proposed labeling requirements are necessary to provide consumers with adequate information as to the identity and quality of alcohol beverages, including whether the information will have practical utility;
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the collections of information; and;
- Estimates of capital and start-up costs and costs of operation, maintenance, and purchase of services to maintain records and substantiate label claims.

List of Subjects

27 CFR Part 4

Advertising, Alcohol and alcoholic beverages, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Trade practices, Treaties, Wine.

27 CFR Part 5

Advertising, Alcohol and alcoholic beverages, Customs duties and inspection, Distilled spirits, Food additives, Grains, Imports, International

agreements, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Trade practices.

27 CFR Part 7

Advertising, Alcohol and alcoholic beverages, Beer, Customs duties and inspection, Food additives, Imports, Labeling, Malt Beverages, Packaging and containers, Reporting and recordkeeping requirements, Trade practices.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR parts 4, 5, and 7 as set forth below:

PART 4—LABELING AND ADVERTISING OF WINE

■ 1. The authority citation for 27 CFR part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

■ 2. Amend § 4.32 by adding paragraph (f) to read as follows:

§ 4.32 Mandatory label information.

* * * * *

(f) *Declaration of major food allergens.* If any major food allergen as defined in § 4.32a is used in the production of a wine, the label must include a statement as required by that section.

* * * * *

■ 3. Amend § 4.32a by revising the section heading and paragraphs (a)(1)(i), (b), and (c) to read as follows:

§ 4.32a Mandatory labeling of major food allergens.

(a) * * *

(1) * * *

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; or

* * * * *

(b) *Labeling requirements.* All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine, including major food allergens used as incidental additives, such as processing aids, must be declared on a label affixed to the container, except when covered by a petition for exemption approved by the appropriate TTB officer under § 4.32b. The declaration must consist of the words ''Contains Major Food Allergen(s)'' followed by a colon and the name of the food source from which each major food allergen is derived (for example, ''Contains Major Food Allergen: milk'' or ''Contains Major Food Allergens: egg and milk''), except that the declaration of processing aids (such as clarifying agents) may optionally include the parenthetical explanation (''processing aid'') immediately following the name of the major food allergen (for example, ''Contains Major Food Allergen: egg (processing aid).''

(c) *Cross reference.* For labeling requirements applicable to wines containing FD&C Yellow No. 5, cochineal extract or carmine, and sulfites, see § 4.32(c) through (e).

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

■ 4. The authority citation for 27 CFR part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205 and 207.

■ 5. Amend § 5.63 by redesignating paragraphs (c)(5) through (8) as paragraphs (c)(6) through (9) and adding a new paragraph (c)(5).

The addition reads as follows:

§ 5.63 Mandatory label information.

* * * * *

(c) * * *

(5) *Major food allergens.* If any major food allergen as defined in § 5.75 is used in the production of a distilled spirits product, the label must include a statement as required by that section.

* * * * *

Subpart F—[Amended]

■ 6. Amend subpart F by removing the undesignated center heading ''Food Allergen Labeling'' preceding § 5.82.

§§ 5.82 and 5.83 [Redesignated as §§ 5.75 and 5.76]

■ 7. Redesignate §§ 5.82 and 5.83 as §§ 5.75 and 5.76, respectively, in subpart F.

■ 8. Amend newly redesignated § 5.75 by revising the section heading and paragraphs (a)(1)(i) and (b) and adding paragraph (c) to read as follows:

§ 5.75 Mandatory labeling of major food allergens.

(a) * * *

(1) * * *

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; or

* * * * *

(b) *Labeling requirements.* (1) Except as provided in paragraph (b)(2) of this section, all major food allergens (defined in paragraph (a)(1) of this section) used in the production of a distilled spirits product, including major food allergens used as incidental additives, such as processing aids, must be declared on a label affixed to the container, except when covered by a petition for exemption approved by the appropriate TTB officer as described in § 5.76. The declaration must consist of the words ''Contains Major Food Allergen(s)'' followed by a colon and the name of the food source from which each major food allergen is derived (for example, ''Contains Major Food Allergen: milk'' or ''Contains Major Food Allergens: wheat and milk''), except that the declaration of processing aids (such as clarifying agents) may optionally include the parenthetical explanation (''processing aid'') immediately following the name of the major food allergen (for example, ''Contains Major Food Allergen: egg (processing aid).''

(2) The labeling requirements of this section do not apply to major food allergens used in the production of a distilled spirits product if they have been completely distilled in such a manner that no protein remains in the distilled spirits. TTB will evaluate compliance by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the finished product. If ingredients containing protein are added to the distilled spirits product after distillation, and no major food allergens are listed on the label, industry members must be prepared to substantiate, upon request, the absence of protein in the distillate, the absence of any major food allergens in the added ingredients, and the precautions taken to prevent cross-contact.

(c) *Cross reference.* For labeling requirements applicable to distilled spirits containing FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame, see § 5.63(c)(6) through (9).

§ 5.76 [Amended]

■ 9. Amend newly redesignated § 5.76 in paragraph (a) introductory text by removing ''5.82'' and adding in its place ''5.75'' and in paragraph (a)(2) by removing ''5.82(a)(1)(i)'' and adding in its place ''5.75(a)(1)(i)''.

§§ 5.82 and 5.83 [Reserved]

■ 10. Add reserved §§ 5.82 and 5.83.

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

■ 11. The authority citation for 27 CFR part 7 continues to read as follows:

Authority: 27 U.S.C. 205 and 207.

Subpart E—Mandatory Label Information

■ 12. Amend § 7.63 by adding paragraph (b)(5) to read as follows

§ 7.63 Mandatory label information.

* * * * *

(b) * * *

(5) *Major food allergens.* If any major food allergen as defined in § 7.75 is used in the production of a malt beverage, the label must include a statement as required by that section.

§§ 7.71 through 7.74 [Reserved]

■ 13. Add reserved §§ 7.71 through 7.74.

Subpart F—[Amended]

■ 14. Amend subpart F by removing the undesignated center heading ''Food Allergen Labeling'' preceding § 7.82.

§§ 7.82 and 7.83 [Redesignated as §§ 7.75 and 7.76]

■ 15. Redesignate §§ 7.82 and 7.83 as §§ 7.75 and 7.76, respectively, in subpart F.

■ 16. Amend newly redesignated § 7.75 by revising the section heading and paragraphs (a)(1)(i), (b), and (c) to read as follows:

§ 7.75 Mandatory labeling of major food allergens.

(a) * * *

(1) * * *

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; or

* * * * *

(b) *Labeling requirements.* All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a malt beverage, including major food allergens used as incidental additives, such as processing aids, must be declared on a label affixed to the container, except when covered by a petition for exemption approved by the appropriate TTB officer under § 7.76. The declaration must consist of the words ''Contains Major Food Allergen(s)'' followed by a colon and the name of the food source from which each major food allergen is derived (for example, ''Contains Major Food Allergen: milk'' or ''Contains Major Food Allergens: wheat and milk''), except that the declaration of processing aids (such as clarifying agents) may optionally include the parenthetical explanation (''processing aid'') immediately following the name of the major food allergen (for example, ''Contains Major Food Allergen: egg (processing aid).''

(c) *Cross reference.* For labeling requirements applicable to malt beverages containing FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame, see § 7.63(b)(1) through (4).

§ 7.76 [Amended]

■ 17. Amend newly redesignated § 7.76 in paragraph (a) introductory text by removing ''7.82'' and adding in its place ''7.75'' and in paragraph (a)(2) by removing ''7.82(a)(1)(i)'' and adding in its place ''7.75(a)(1)(i)''.

§§ 7.82 and 7.83 [Reserved]

■ 18. Add reserved §§ 7.82 and 7.83.

Signed: January 10, 2025.

Mary G. Ryan,

Administrator.

Approved: January 10, 2025.

Aviva Aron-Dine,

Deputy Assistant Secretary (Tax Policy).

[FR Doc. 2025–00955 Filed 1–16–25; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED–2025–OSERS–0003]

Rehabilitation Training Program—National Vocational Rehabilitation Technical Assistance Center

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education.

ACTION: Proposed priority, requirements, and definitions.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority, requirements, and definitions under the Rehabilitation Training program. The Assistant Secretary may use the priority, requirements, and definitions for competitions in fiscal year (FY) 2025 and later years. We intend to use the priority, requirements, and definitions to fund a cooperative agreement to establish a national vocational rehabilitation technical assistance center (NVRTAC) to provide training and technical assistance to personnel of State VR agencies and their partners to upgrade and increase their competencies, skills, and knowledge in providing quality services and effective management of the VR program.

DATES: We must receive your comments on or before February 18, 2025.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *www.regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *www.regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Roslyn Thomas, U.S. Department of Education, 400 Maryland Avenue SW, Lyndon Baines Johnson Building, Room 4A10, Washington, DC 20202. Telephone: (202) 987–0105. Email: *84.264L@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

A brief summary of the rule is available at *www.regulations.gov/docket/ED-2025-OSERS-0003.*

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed priority, requirements, and definitions. To ensure that your comments have maximum effect in developing the notice of final priority, requirements, and definitions, we urge you to clearly identify the specific priority, requirement, or definition that each comment addresses.

Specific Requests for Comment: The Department is particularly interested in comments regarding the best way for the NVRTAC to prioritize among VR agencies needing intensive training and technical assistance. We are also interested in comments regarding whether the project requirements and related activities under the proposed priority reflect the greatest needs in the field and can assist the State VR