(b) *Determination of claims*—(1) *Delegation of authority to determine claims.* The General Counsel, and such employees of the Legal Division as the General Counsel may designate are authorized to consider, ascertain, adjust, determine, compromise, and settle claims pursuant to the FTCA, as amended, and the regulations contained in 28 CFR part 14 and in this section.

(2) *Disallowance of claims.* If the General Counsel, or the General Counsel's designee, denies a claim, the General Counsel or designee shall notify the claimant, or the claimant's duly authorized agent or legal representative.

Dated: July 11, 2013.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2013–18844 Filed 8–2–13; 8:45 am]

BILLING CODE 4810–AM–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 37

RIN 3038–AD18

Core Principles and Other Requirements for Swap Execution Facilities; Correction

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule; correction.

SUMMARY: The Commodity Futures Trading Commission is correcting a final rule that appeared in the **Federal Register** of June 4, 2013 (78 FR 33476). The final rule applies to the registration and operation of a new type of regulated entity named a swap execution facility, and implements provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

DATES: The effective date of this correction is August 5, 2013.

FOR FURTHER INFORMATION CONTACT: Amir Zaidi, Special Counsel, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street NW., Washington, DC 20581; 202–418–6770; *azaidi@cftc.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2013–12242 appearing on page 33476 in the **Federal Register** of Tuesday, June 4, 2013, the following corrections are made:

§ 37.702 [Corrected]

1. On page 33591, in the second column, in § 37.702 General financial integrity, paragraph (b) is corrected to read as follows:

(b) For transactions cleared by a derivatives clearing organization:

(1) By ensuring that the swap execution facility has the capacity to route transactions to the derivatives clearing organization in a manner acceptable to the derivatives clearing organization for purposes of clearing; and

(2) By coordinating with each derivatives clearing organization to which it submits transactions for clearing, in the development of rules and procedures to facilitate prompt and efficient transaction processing in accordance with the requirements of § 39.12(b)(7) of this chapter.

Appendix B to Part 37—Guidance on, and Acceptable Practices in, Compliance With Core Principles [Corrected]

2. On page 33600, in the second column, under the heading Core Principle 3 of Section 5h of the Act—Swaps Not Readily Susceptible to Manipulation, in paragraph (a)(3), correct the reference to ''section c(5)'' to read ''section c(4).''

Dated: July 31, 2013.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

[FR Doc. 2013–18773 Filed 8–2–13; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2005–N–0404]

RIN 0910–AG84

Food Labeling; Gluten-Free Labeling of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to define the term ''gluten-free'' for voluntary use in the labeling of foods. The final rule defines the term ''gluten-free'' to mean that the food bearing the claim does not contain an ingredient that is a gluten-containing grain (e.g., spelt wheat); an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or inherently does not contain gluten; and that any unavoidable presence of gluten in the food is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food). A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements for a ''gluten-free'' claim will be deemed to be misbranded. In addition, a food whose labeling includes the term ''wheat'' in the ingredient list or in a separate ''Contains wheat'' statement as required by a section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and also bears the claim ''gluten-free'' will be deemed to be misbranded unless its labeling also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for a ''gluten-free'' claim. Establishing a definition of the term ''gluten-free'' and uniform conditions for its use in food labeling will help ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled. We are issuing the final rule under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

DATES: *Effective date:* The final rule becomes effective on September 4, 2013. *Compliance date:* The compliance date of this final rule is August 5, 2014. See section II.B.4 (comment 35 and response 35) for an additional explanation of the compliance date and implementation of this final rule.

FOR FURTHER INFORMATION CONTACT: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, FAX: 301–436–2636, email: *GlutenFreeFinalRule Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Rule

Need for the rule: Celiac disease is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain storage proteins referred to as gluten occurring in wheat, rye, barley, and crossbreeds of these grains. Celiac disease has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease. Many manufacturers currently label their food with a

''gluten-free'' labeling claim. However, there is no current regulatory definition for the ''gluten-free'' claim in the United States. Establishing in this final rule a regulatory definition of the food labeling term ''gluten-free'' and uniform conditions for its use in the labeling of foods is necessary to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled; this final rule is also necessary to respond to a directive of FALCPA (title II of Pub. L. 108–282).

Legal authority: Consistent with section 206 of FALCPA and sections 403(a)(1), 201(n), and 701(a) of the FD&C Act (21 U.S.C. 343(a)(1), 321(n), and 371(a), respectively), we are issuing requirements for the use of the term ''gluten free'' for voluntary use in the labeling of foods.

Major Provisions of the Rule

The final rule defines and sets conditions on the use of the term ''gluten-free'' in foods, including:

- Foods that inherently do not contain gluten (e.g., raw carrots or grapefruit juice) may use the ''gluten-free'' claim.
- Foods with any whole, gluten-containing grains (e.g., spelt wheat) as ingredients may not use the claim;
- Foods with ingredients that are gluten-containing grains that are refined but still contain gluten (e.g., wheat flour) may not use the claim;
- Foods with ingredients that are gluten-containing grains that have been refined in such a way to remove the gluten may use the claim, so long as the food contains less than 20 ppm gluten/has less than 20 mg gluten per kg (e.g. wheat starch);
- Foods may not use the claim if they contain 20 ppm or more gluten as a result of cross-contact with gluten containing grains.

For reasons discussed in more detail in this document, under limited circumstances we intend to exercise enforcement discretion with respect to the requirements for ''gluten-free'' labeling for FDA-regulated beers that currently make a ''gluten-free'' claim and that are: (1) Made from a non-gluten-containing grain or (2) made from a gluten-containing grain, where the beer has been subject to processing that the manufacturer has determined will remove gluten below a 20 ppm threshold. We plan to issue a proposed rule to address our compliance approach to fermented or hydrolyzed products.

In addition, the final rule provides that:

- A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements for a ''gluten-free'' claim will be deemed to be misbranded.
- A food whose labeling includes the term ''wheat'' in the ingredient list or in a separate ''Contains wheat'' statement as required by FALCPA and also bears the claim ''gluten-free'' will be deemed to be misbranded unless its labeling also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for a ''gluten-free'' claim.

By defining ''gluten-free'' and the conditions under which a ''gluten-free'' claim can be used, the final rule makes it easier for individuals with celiac disease to make informed purchasing decisions. This will enable them to adhere to a diet they can tolerate without causing adverse health effects and to select from a variety of available gluten-free foods.

Costs and Benefits

Full compliance with the final rule would have annualized costs of about $7 million per year and annual health benefits of about $110 million per year:

ANNUAL BENEFIT AND COST OVERVIEW

Benefits	Health Gains for Individuals With Celiac Disease	$110,000,000.
	Search Cost Reduction	Unknown.
Costs	Relabeling of Foods	$1,000,000.
	Testing of Foods	$5,800,000.
Net Benefits		>$103,000,000.

Table of Contents

I. Background

A. What is celiac disease?

Celiac disease (also known as celiac sprue and gluten-sensitive enteropathy) is a chronic inflammatory disorder of the small intestine in genetically susceptible individuals. It is triggered by ingesting certain storage proteins, commonly referred to as ''gluten,'' that naturally occur in some cereal grains (Refs. 1 through 3). In such individuals, the consumption of gluten stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response, which damages the tiny, fingerlike protrusions called ''villi,'' that line the small intestine and function to absorb nutrients from food (Ref. 4). Over time, continued dietary exposure to gluten can destroy the intestinal villi of individuals with celiac disease, leading to a lack of absorption of nutrients and a wide variety of other serious health problems (Ref. 4).

The symptoms and clinical manifestations of celiac disease are highly variable among affected individuals and differ in severity. The reasons for this variability are unknown, but may depend upon the individual's age and immunological status, the amount, duration or timing of the exposure to gluten, and the specific area and extent of the gastrointestinal tract involved in the disease (Ref. 5). Symptoms of celiac disease may be: (1) ''Classical,'' affecting the digestive tract (e.g., abdominal bloating; cramping and pain; chronic diarrhea; vomiting; constipation) and resulting in gastrointestinal malabsorption; or (2) ''atypical,'' affecting mainly other parts of the body (e.g., fatigue; irritability; behavior changes; bone or joint pain; tingling numbness in the legs; ulcers in

the mouth; tooth discoloration or loss of enamel; itchy skin rash with blisters called dermatitis herpetiformis) (Refs. 1, 4, 6, and 7).

A large portion of the subpopulation that has celiac disease may not experience any symptoms at all, and these individuals are classified as having either the ''silent'' or ''latent'' form of celiac disease (Refs. 1 and 8). Persons who have the silent form of celiac disease have most of the diagnostic features commonly seen in individuals with classical or atypical celiac disease, such as specific serum antibodies and evidence of damaged intestinal villi. Those who have the latent form of celiac disease have specific serum antibodies, but no evidence of damaged intestinal villi (Ref. 1).

In addition to the aforementioned clinical symptoms and ailments, celiac disease is associated with a number of significant health problems and disorders, including iron-deficiency anemia, vitamin deficiencies, protein-calorie malnutrition, weight loss, short stature, growth retardation in children, delayed puberty, infertility, miscarriage, and osteoporosis (Refs. 1, 6, 9, and 10). Individuals with unmanaged celiac disease are at an increased risk of developing other serious medical conditions, such as Type I diabetes mellitus, intestinal cancers, and both intestinal and extraintestinal non-Hodgkin's lymphomas (Refs. 7, 11, 12, and 13).

Celiac disease has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet (Refs. 1 and 6). Over time, strictly avoiding consumption of gluten can resolve the symptoms, mitigate and possibly reverse the damage, and reduce the associated health risks of celiac disease (Ref. 14). For some individuals with celiac disease, failure to avoid consumption of gluten can lead to severe and sometimes life-threatening complications that can affect multiple organs of the body (Refs. 5, 6, and 15).

B. How prevalent is celiac disease in the United States?

Precise prevalence data for celiac disease are not available. In the January 23, 2007, proposed rule (72 FR 2795 at 2797), we cited estimates regarding the overall prevalence of celiac disease in the United States ranging from about 0.4 percent to about 1 percent of the general population, or approximately 1.5 to 3 million Americans (Refs. 1 and 16). According to the National Health and Nutrition Examination Survey (NHANES) 2009–2010 survey data on medical conditions, 0.14 percent of the civilian, non-institutionalized population of the United States reported having been told by a medical professional that they have celiac disease (Ref. 17). Researchers examining serological data from a subset of the NHANES 2009–2010 study population for evidence of celiac disease estimated the prevalence of celiac disease at 0.71 percent (Ref. 18).

The discrepancy between estimated prevalence and diagnosed cases has been linked primarily to the fact that celiac disease can be silent or latent, as described in section I.A. Silent and latent forms of celiac disease may go undetected in an individual for years before the person develops symptoms causing him or her to seek medical attention. In addition, celiac disease is often mistaken for other gastrointestinal malabsorption disorders that have similar diarrheal symptoms (e.g., irritable bowel syndrome), which further delays its diagnosis (Ref. 19). Only recently has the medical community become more aware of the need to screen for celiac disease when patients experience health problems that may be associated with the disease or when patients have family members, especially first- and second-degree relatives, who have celiac disease (Ref. 1).

C. What did the Food Allergen Labeling and Consumer Protection Act of 2004 do with respect to celiac disease? What other activities did we conduct for this rulemaking?

FALCPA, Title II of Public Law 108–282, was enacted on August 2, 2004. Section 206 of FALCPA directs the Secretary of Health and Human Services (HHS) (the Secretary), in consultation with appropriate experts and stakeholders, to issue a rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. This rulemaking implements section 206 of FALCPA.

FALCPA does not require that we establish a threshold level for gluten. Nonetheless, an important scientific issue associated with the issuance of this rule is the potential existence of a threshold level below which it is unlikely that an individual with celiac disease will have an adverse health effect.

To address this issue, among others, we established an internal, interdisciplinary group (the Threshold Working Group) to review the scientific literature on the issue of a threshold level for gluten. The Threshold Working Group's report, ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food'' (issued in draft and later revised, referred to herein as the ''Thresholds Report'' except where noted) (Ref. 20), summarized the current state of scientific knowledge with respect to a dose-response relationship for gluten, and presented the following four potential approaches that we might consider in establishing such a threshold level, if we chose to do so (Ref. 20, pp. 2 and 38–41; Ref. 21 at pp. 2 and 42–45):

- Analytical methods-based—thresholds are determined by the sensitivity of the analytical method(s) used to verify compliance.
- Safety assessment-based—''safe'' level is calculated using the No Observed Adverse Effect Level (NOAEL) from available human challenge studies, applying an appropriate ''uncertainty factor'' multiplier to account for knowledge gaps.
- Risk assessment-based—examines known or potential adverse health effects resulting from human exposure to a hazard; quantifies the levels of risk associated with specific exposures and the degree of uncertainty inherent in the risk estimate.
- Statutorily derived—uses an exemption articulated in an applicable law and extrapolates from that to other potentially similar situations.

As the Thresholds Report explained, the term ''threshold'' has multiple meanings, including toxicological and statutory (or regulatory) (see Ref. 20 at p. 10). The Threshold Working Group noted that ''[u]nderstanding thresholds for gluten will help FDA develop a definition of 'gluten-free' and identify appropriate uses of the term.'' The Threshold Working Group recognized that setting such a regulatory threshold likely would require consideration of additional factors not addressed in the Thresholds Report, such as ease of compliance and enforcement, concerns of stakeholders (i.e., industry, consumers, and other interested parties), economics (e.g., cost/benefit analysis), trade issues, and legal authorities (Ref. 20 at p. 41).

The Thresholds Report concluded that it was not possible for us to use the quantitative risk assessment-based approach due to the lack of sufficient data from human clinical trials and the lack of sufficient data on exposure, and that the statutorily derived approach is not viable in the absence of applicable statutory provisions (Ref. 20 at pp. 4, 60, and 61). Thus, the two approaches identified in that report as viable for establishing a threshold for gluten were the analytical methods-based approach and the safety assessment-based approach.

In the **Federal Register** of June 17, 2005 (70 FR 35258), we published a notice announcing the availability of the draft version of the Thresholds Report. We invited interested persons to submit comments and any scientific data or other information to the docket during a 60-day comment period that ended on August 16, 2005. The Threshold Working Group considered the comments, data, and information submitted, and made appropriate revisions to the draft Thresholds Report. On May 25, 2006, we posted our response (Ref. 22) to the comments, data, and other information that we received. We also posted the revised Thresholds Report (Ref. 21). Both documents are dated March 2006.

Additionally, in the **Federal Register** of May 23, 2005 (70 FR 29528), we announced that our Food Advisory Committee (FAC) would hold a public meeting on July 13 through 15, 2005, to evaluate the draft version of the Thresholds Report. One purpose of the meeting was for the FAC to determine whether the four approaches considered in the Thresholds Report for establishing a threshold level for gluten were scientifically sound. We invited experts to address a number of specific issues related to sensitivities to gluten. In addition, we invited interested persons to submit comments and any scientific data or other information relevant to the issues pending before the FAC.

During the public meeting, the FAC heard presentations from invited experts on the diagnosis and treatment of celiac disease, the quality of life issues faced by those who have celiac disease and their families, the relationship between gluten proteins in various grains and celiac disease, analytical methods for detecting and measuring the levels of gluten in food, the value and use of prospective and retrospective gluten tolerance studies, and a summary of existing national and international definitions of ''gluten-free'' for food labeling. Further, members of the general public, including those representing trade associations, industry, consumers, and other stakeholders, gave brief presentations before the FAC to share their perspectives on some of the same topics addressed by the invited experts. The speaker presentations, public comments, FAC discussions, and the FAC responses to a set of specific questions and the charge to the FAC posed by FDA's Center for Food Safety and Applied Nutrition (CFSAN) are recorded in the transcript of the meeting, which is available through the FDA Docket No. 2005N–0231 and is posted at CFSAN's Web site (*http://www.fda.gov/ohrms/dockets/ac/cfsan05.html*). Copies of the transcript materials that specifically address the topics of celiac disease and a gluten threshold level are also available through the docket for this rulemaking. A summary of the FAC responses to the questions is provided in the Summary Minutes (Ref. 23).

The FAC concluded that the Thresholds Report ''includes a comprehensive evaluation of the currently available data and descriptions of all relevant approaches that could be used to establish [a] threshold . . . for gluten in food'' (Ref. 23, p. 1). The FAC also identified the risk-assessment approach as the strongest of the four approaches proposed in the Thresholds Report, assuming the availability of sufficient data (Ref. 23, p. 1).

In the **Federal Register** of July 19, 2005 (70 FR 41356), we announced that we would hold a public meeting on August 19, 2005, to discuss the topic of gluten-free food labeling. We gave interested persons until September 19, 2005, to comment on a list of specific questions concerning food manufacturing, analytical methods, and consumer purchasing practices and views about gluten-free foods (70 FR 41356 at 41357). In addition, we invited experts to address these issues at the meeting, and invited members of the general public, including individuals with celiac disease and their caregivers, to share their views about foods produced and labeled as ''gluten-free.'' We received more than 2,400 comments about the public meeting or the list of questions cited in the notice announcing the meeting. The vast majority of these comments were from individuals with celiac disease, their caregivers, and celiac disease associations; we also received comments from the food industry. Most consumers said that they appreciate and use ''gluten-free'' labeling claims to identify packaged foods they can eat when trying to avoid gluten. Many consumers stated that a ''gluten-free'' labeling claim makes it easier to shop for groceries, saving the consumers both time and the frustration experienced when reading often lengthy and complicated ingredients lists that the consumers did not understand. Many consumers also stated that they primarily purchase packaged foods bearing a ''gluten-free'' labeling claim and that a standardized definition of the term ''gluten-free'' for foods marketed in the United States would give them more assurance that foods bearing this claim are appropriate for individuals trying to avoid gluten. The comments reflected a consensus of opinion among individuals with celiac disease, and the organizations which represent them, that wheat, rye, and barley should be excluded from any products labeled as ''gluten-free.'' However, comments from these individuals and organizations varied with respect to whether we should exclude oats from any products labeled as ''gluten-free.''

Industry comments submitted in response to the 2005 public meeting or to the list of questions cited in the notice announcing the meeting indicated that currently there is no universal understanding among manufacturers of what the term ''gluten-free'' means and there is no uniform industry standard for producing foods bearing this labeling claim. Several industry comments expressed the opinion that a standardized definition for ''gluten-free'' could help promote fair competition among packaged foods marketed as gluten-free in the United States, because all manufacturers would have to adhere to the same requirements if they label their products ''gluten-free.''

D. What did we propose to do?

In the **Federal Register** of January 23, 2007 (72 FR 2795), we published a proposed rule to define the term ''gluten-free'' and allow its voluntary use in the labeling of foods. In brief, the proposed rule would:

- Define the term ''gluten-free'' for voluntary use in the labeling of foods, to mean that the food does not contain any of the following: An ingredient that is any species of the grains wheat, rye, barley, or a crossbred hybrid of these grains (collectively referred to in the proposed rule as ''prohibited grains''); an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten (e.g., wheat flour); an ingredient that is derived from a prohibited grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 ppm or more gluten in the food; or 20 ppm or more gluten.
- Deem a food to be misbranded that bears the claim ''gluten-free'' or similar claim in its labeling and fails to meet the conditions specified in the proposed definition of ''gluten-free.''
- Deem a food to be misbranded if it bears a ''gluten-free'' claim in its labeling if the food is inherently free of gluten and if the claim does not refer to all foods of that same type (e.g., ''milk, a gluten-free food'' or ''all milk is gluten-free'').

• Deem a food made from oats that bears a ''gluten-free'' claim in its labeling to be misbranded if the claim suggests that all such foods are ''gluten-free'' or if 20 ppm or more gluten is present in the food.

The proposed rule would create a new § 101.91 entitled ''Gluten-free labeling of food.'' In the preamble to the proposed rule (72 FR 2795 at 2803), we stated that, after publication of the proposed rule, we would conduct a safety assessment for gluten exposure consistent with the safety assessment-based approach described in the Thresholds Report. We requested comments providing data relevant to the safety assessment. We stated that we would publish a notice in the **Federal Register** seeking comment on the draft safety assessment and its potential use in the final rule and that we would consider public and peer-review comments in revising the safety assessment, as appropriate. Under the safety assessment-based approach, the labeling threshold would be determined at least in part on the basis of a ''safe'' level or ''tolerable daily intake'' (TDI) of a substance as calculated using the NOAELs and the Lowest Observed Adverse Effect Levels from available dose-response data in animals or humans and applying one or more appropriate ''uncertainty factors'' to account for gaps, limitations, and uncertainty in the data and for inter-individual difference (i.e., variability among individuals within the target population).

We subsequently completed a health hazard assessment of the adverse health effects of gluten exposure in individuals with celiac disease that included a safety assessment for gluten, and we submitted a report on this health hazard assessment, the ''Gluten Report,'' to scientific experts for peer review. In the preamble to this final rule, we generally use the term ''safety assessment'' to mean the entire analysis reported in the ''Gluten Report'', because this language is consistent with the Thresholds Report's use of the term ''safety assessment-based approach.'' We revised the ''Gluten Report'' after considering the experts' comments and made a report concerning the peer review available at our Web site at *http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM264152.pdf.*

In the **Federal Register** of August 3, 2011 (76 FR 46671), we published a notice (2011 notice) that reopened the comment period for the proposed rule, in part, to announce the availability of the ''Gluten Report'' and to invite comments on the report. We also asked whether and if so, how, the safety assessment should affect FDA's proposed definition of ''gluten-free'' in the final rule. Finally, we sought comment on our tentative conclusion that the safety assessment-based approach may lead to a conservative, highly uncertain estimation of risk to individuals with celiac disease associated with very low levels of gluten exposure, and that the final rule should adopt the proposed rule's approach to defining the term ''gluten-free.'' We also sought comment on a few other matters unrelated to the questions about the safety assessment and its potential use in the final rule.

We received a number of comments concerning our safety assessment. To the extent those comments address the potential use of the safety assessment in the final rule, we describe and respond to them in part II. We discuss and respond to comments that focused on the safety assessment's methodology in ''FDA's Responses to Comments on the Report Titled 'Health Hazard Assessment for Gluten Exposure in Individuals With Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten,' '' (Ref. 24) which is available at *http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM362401.pdf.* We received nearly 2,000 submissions in response to both the proposed rule and to the 2011 notice announcing the reopening of the comment period. Most submissions came from individuals, and we also received comments from industry and trade associations, consumer and advocacy groups, academic organizations, and foreign government agencies. For example, many comments from consumers stated that they currently must search the list of ingredients on each product and that it is difficult to do so because the presence of gluten is not always evident to a layperson from the information on the label. Some comments noted that consumers often contact the manufacturer to confirm if the food contains gluten and that this task requires significant time and effort. The comments stated that foods labeled ''gluten-free'' according to a standard definition would provide an easier and faster way to identify such foods. Despite the apparent broad consensus among comments about the need for a standard definition of ''gluten-free,'' the comments raised many distinct issues about how such a definition should be developed and implemented.

We discuss the issues raised in the comments on the proposed rule as well as the 2011 notice, and also describe the final rule, in section II. For ease of reading, we preface each comment discussion with a numbered ''Comment,'' and each response by a corresponding numbered ''Response.'' We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

II. What issues did the comments raise? What are FDA's responses to the comments? What does the final rule say?

A. What general comments did we receive? What regulatory approach should we take?

As explained in sections I.C and I.D, the Thresholds Report summarized the current state of scientific knowledge with respect to a dose-response relationship for gluten, and presented four potential approaches that we might consider in establishing such a threshold level. We decided to issue a proposed rule that used one of those approaches, an analytical methods-based approach, under which the thresholds are determined by the sensitivity of the analytical method(s) used to verify compliance. However, we also conducted a safety assessment in which we reviewed available human challenge studies, exposure data, and other information, applying certain specified assumptions and appropriate ''uncertainty factor'' multipliers to account for knowledge gaps, to arrive at an estimation of risk to individuals with celiac disease associated with very low levels of gluten exposure. In the safety assessment we estimated level of concern (LOC) values for individuals with celiac disease, depending upon the corresponding age group and whether the adverse health effects are clinical or morphological and/or physiological in nature, at the 90th percentile level of intake of ''all celiac disease grain foods.'' As described in the ''Gluten Report,'' the estimated gluten LOC values for individuals with celiac disease range from 0.01 to 0.06 ppm. However, as we noted in the 2011 notice, this estimation of risk to individuals with celiac disease associated with very low levels of gluten exposure may be conservative and highly uncertain.

Many comments supported our tentative conclusion to use the analytical method-based approach, rather than the safety assessment-based approach, and supported our proposed

criteria for defining the term ''gluten-free,'' including the proposed requirement that food bearing a ''gluten-free'' claim not contain 20 ppm or more gluten. Some comments argued that the safety assessment-based approach should be followed. The comments on our approach raised four primary points concerning which approach to use in the final rule, addressed in more detail in the following bulleted list. These were:

- The potential impact of the choice of approach on the availability of foods that could be labeled ''gluten-free'';
- The potential impact on the health of individuals with celiac disease of the choice of approach for establishing a regulatory definition of ''gluten-free'';
- The availability of analytical methods to evaluate compliance and to enforce a regulatory definition of ''gluten-free'' at different levels; and
- The relationship between FDA's definition of ''gluten-free'' and that of international bodies.

1. How would the choice of approach affect the availability of gluten-free foods?

(Comment 1) Several comments stated that using an extremely low level of gluten, such as those estimated in the safety assessment, to define ''gluten-free'' could cause some manufacturers to stop identifying food as gluten-free. The comments explained that, under the safety assessment-based approach, a manufacturer might stop identifying a food as gluten-free because the food could not meet a very low gluten threshold (e.g., 0.01 ppm gluten) for reasons such as an ingredient's cross-contact with gluten-containing grain during agricultural production or supply stages or difficulty separating gluten-containing and gluten-free products in mixed-use processing facilities.

Many comments from individuals with celiac disease stated that they rely on products labeled ''gluten-free'' to reduce the time spent reading ingredient lists on products to determine if the foods are safe for them to eat. These comments expressed concern that if we establish a gluten content that is lower than < 20 ppm gluten for purposes of defining the term ''gluten-free,'' manufacturers might find it difficult to manufacture foods that consistently met the lower gluten content. The comments stated that this may result in fewer foods labeled ''gluten-free.'' The comments suggested that a decrease in the number and variety of foods labeled ''gluten-free'' would mean that individuals with celiac disease would have to invest more time and effort to identify appropriate foods, and could reduce compliance with a gluten-free diet, with potential adverse health consequences for them.

One comment stated that, even if an analytical method were available to test for the presence of gluten at levels below 1 ppm, ''it would become increasingly costly for food companies, despite thorough adherence to good manufacturing practices, either to clean equipment adequately or to invest in dedicated equipment in order to meet the increasingly lower gluten threshold. This in turn would lead to more expensive food products developed for celiac consumers, or to companies stopping the production of 'gluten free' food products, thus reducing the food choices available for gluten sensitive consumers.'' Other comments echoed that the result of adopting the safety assessment-based approach would be more costly food or fewer food options for individuals who have celiac disease.

(Response 1) We agree with the comments that the food industry may be unable to consistently meet a standard limiting the presence of gluten in foods labeled ''gluten-free'' to < 1 ppm, and that such a low level cannot, as of the date of this final rule, be verified through scientifically valid analytical methods. We also agree that such an approach would result in the removal from the market of many products that currently meet the criterion of < 20 ppm gluten in the definition of ''gluten-free'' and bear the claim, or discourage the introduction of new foods labeled as ''gluten-free,'' because manufacturers could not meet a gluten limit much lower than < 20 ppm. Limiting the availability of the number and variety of foods labeled ''gluten-free'' would be detrimental to individuals with celiac disease who are already challenged by the complexities of adhering long term to a gluten-free diet.

As for the comment's claim that an analytical method to detect very low gluten levels would be cost prohibitive, in the absence of such methods, we decline to speculate about their cost and whether manufacturers would be willing to incur such costs.

(Comment 2) Several comments indicated that consumers are uncertain about how much gluten 20 ppm represents and its relevance to the total amount of gluten that most individuals with celiac disease can tolerate.

(Response 2) Twenty ppm gluten is a concentration level rather than an absolute quantity of gluten in a food. Twenty ppm is the same as 0.002 percent. For example, at a concentration level of 20 ppm gluten, a 28.35 gram (g) or 1-ounce portion of food would contain 0.567 mg gluten (20 mg/kg × 28.35 g × 1 kg/1000 g = 0.567 mg). Because 20 ppm refers to a concentration and not an absolute quantity of gluten, if the ingredients of a food are all below 20 ppm, the end product cannot have a concentration that exceeds 20 ppm. The amount of gluten to which a person with celiac disease would be exposed in consuming food labeled ''gluten-free'' would depend upon the total quantity/weight of food consumed and the actual concentration of gluten in the product. On our own initiative, we have revised the final rule to describe the equivalent concentration of 20 mg gluten per kg of food to further harmonize our rule with international standards, such as those used in Codex Standard 118–1979 and European Commission Regulation No 41/2009.

2. How might the choice of approach affect the health of individuals with celiac disease?

(Comment 3) Several comments supported the proposed < 20 ppm gluten level as a criterion for labeling food as ''gluten-free.'' The comments asserted that individuals with celiac disease have for many years been consuming food products with levels of 20 ppm or more without adverse effect, and that products whose gluten levels are < 20 ppm should be safe for most individuals with celiac disease. The comments did not provide data to support these assertions.

Other comments expressed the belief that adopting a gluten level well below 20 ppm would reduce the risk of adverse health outcomes that individuals with celiac disease might experience at the proposed level of < 20 ppm gluten.

(Response 3) The final rule adopts a gluten content of < 20 ppm for parts of the definition of the ''gluten-free'' labeling claim, using the analytical methods-based approach. The scientific research conducted thus far and the information presented in our Gluten Report support a conclusion that most individuals with celiac disease can tolerate food that contains variable trace amounts and concentrations of gluten (see 76 FR 46671 at 46674 through 46675).

As we stated in the 2011 notice: ''To the extent it is possible to do so and protect public health, we believe that we should set a gluten threshold level for 'gluten free' labeling that best assists most individuals with celiac disease in adhering life-long to a 'gluten-free' diet without causing adverse health consequences. If the prevalence of persons with celiac disease not

following a 'gluten-free' diet increases because there are fewer foods labeled 'gluten-free' to choose from (because the criteria for making 'gluten-free' labeling claims are too stringent for most food manufacturers to meet) or such foods become more expensive (because any changes made by manufacturers to enable them to meet more stringent criteria to make foods labeled 'gluten-free' may increase their production costs), then these individuals could be at a higher risk of developing serious health complications and other diseases associated with celiac disease. In other words, moving to a definition of 'gluten-free' that adopts a criterion that is much lower than < 20 ppm gluten could have an adverse impact on the health of Americans with celiac disease.'' (See 76 FR 46671 at 46675).

Thus, while we disagree with the comments to the extent that they suggest that there is clear evidence that individuals with celiac disease have been consuming food with gluten content at or above 20 ppm without adverse effect, we believe that the available data and information support a determination that retaining the < 20 ppm part of the criteria for defining ''gluten-free'' is protective of public health.

For similar reasons, we also disagree with the comments suggesting that adopting a gluten level well below 20 ppm would reduce the risks of adverse health outcomes for individuals with celiac disease. Although the safety assessment estimated that highly sensitive individuals with celiac disease may not be fully protected if they consume foods containing a trace level of gluten above 0.01 ppm but below 20 ppm (see 76 FR 46671 at 46675), statements by some celiac disease researchers, based on their experience and epidemiological evidence, suggest that variable trace amounts and concentrations of gluten in foods can be tolerated by most individuals with celiac disease without causing adverse health effects (id. at 46674–46675). Thus, revising the proposed threshold gluten content for defining ''gluten-free'' to lower than 20 ppm (as per the safety assessment results) would not offer additional protection or clinical benefits to individuals with celiac disease. Moreover, other comments about the methodology used and studies chosen in the safety assessment suggest that the conclusions based on this information have led to highly conservative tolerance estimates for gluten. As such, although clearly defined gluten thresholds cannot be determined at this time of this final rule, there is no evidence that consumption of food products containing less than 20 ppm gluten would pose a risk of adverse health effects for the large majority of individuals with celiac disease. Future research and improved data on defining gluten thresholds may lead us to revisit our conclusion.

The varying needs of individuals with celiac disease may be best addressed by focused education and outreach. We acknowledge the offers of assistance we received in comments from several health care professionals, celiac disease organizations, and others to provide educational materials and conduct seminars that may help individuals to fully understand how the labeling can be used in their adherence to a gluten-free diet.

Although many comments focused on the < 20 ppm part of the criteria, under the final rule there are other criteria for when a food can and cannot be labeled ''gluten-free.'' These other criteria also are intended to reduce exposure to gluten in products labeled ''gluten-free.'' In essence, the definition of ''gluten-free'' is structured in such a way that manufacturers who wish to use a ''gluten-free'' claim cannot use as ingredients in their foods gluten-containing grains, or ingredients derived from those grains that have not been processed to remove gluten, regardless of the ultimate presence of gluten in the food.

Finally, we note that some comments indicated that some manufacturers of foods that may contain gluten—either because they contain ingredients that have been processed to remove gluten but retain some amount of gluten, or due to cross-contact—are able to produce foods that contain well below 20 ppm gluten, through the selection of ingredients, the use of facilities dedicated to only producing gluten-free foods, and the use of additional specific manufacturing controls that can prevent gluten cross-contact situations. We encourage the development and implementation of manufacturing practices that will ensure foods bearing the claim ''gluten-free'' meet the requirements in this final rule.

(Comment 4) One comment asserted that the results of the safety assessment demonstrate that there is no specific level of gluten that typically produces an adverse response in those sensitive to gluten and supported FDA's proposed approach as protective of most people with celiac disease based on currently available data and methodologies. The comment suggested that, if the proposed approach is used, manufacturers of products bearing a ''gluten-free'' claim also should be required to disclose the products' actual gluten content level (in mg per serving) on the label. The comment explained that disclosing the products' actual gluten content level will help individuals determine if a product is appropriate for their individual health needs and better control their gluten consumption. The comment also stated that, if the final rule adopts a < 20 ppm gluten limit, we should amend it quickly as new data become available concerning gluten tolerance or analytical methods.

(Response 4) We agree that the research described in the safety assessment and other data suggest that there is considerable human variability in response (in both kind and degree) to dietary gluten, and we took this inter-individual variability into account in the safety assessment by using a multiplier of 10 as one of the 2 uncertainty factors used to reduce the estimated TDI gluten levels. However, because of this variability and other uncertainties, as we noted in the 2011 notice, the safety assessment-based approach would lead to a conservative, highly uncertain estimate of risk to individuals with celiac disease associated with very low levels of gluten exposure. We also agree with the comment that we will need to continue to evaluate newer scientific knowledge and clinical findings, particularly on the long-term needs of those with celiac disease, and scientifically valid analytical methods for quantifying lower gluten content, as they become available. If those findings change our consideration of the various factors that we have applied in this rulemaking, we may, as suggested by the comment, consider reviewing the standard for ''gluten-free'' labeling. In the meantime, we encourage manufacturers of gluten-free foods to produce such foods with as little gluten as possible and to continue research in processing methods to reduce levels further.

We disagree with the comment's suggestion that we require manufacturers of gluten-free products to disclose their products' actual gluten content level on the labels. First, requiring a gluten-free product's label to disclose the product's actual gluten content level would be impractical because there might be variability in gluten content of a particular food due to natural variation in ingredients, minor modifications in the food's formulation, or changes in other manufacturing practices. Manufacturers also might change ingredient suppliers to reduce their manufacturing costs or buy ingredients from different suppliers if a particular ingredient were in short supply; in these situations, the gluten content of an ingredient also might

change. Thus, if we were to require manufacturers to disclose a product's actual gluten content, we would, in effect, be requiring manufacturers to test each batch of a food product that is already eligible to bear a ''gluten-free'' claim (e.g., did not contain 20 ppm or more gluten) and to reprint labels any time there was a slight variation in the gluten content of that food. This requirement would discourage manufacturers from marketing foods with a ''gluten-free'' label, and this, in turn, would limit the availability and variety of gluten-free foods for individuals with celiac disease.

Second, 20 ppm is currently the lowest level at which analytical methods have been scientifically validated to reliably and consistently detect gluten across a range of food matrices. Therefore, we are not in a position to identify a specific analytical method that a firm could use to identify the actual level of gluten in a food below 20 ppm.

We are aware that some independent third-party organizations currently certify products with respect to their gluten content, and that manufacturers of gluten-free products that obtain such certification may currently include information regarding the certified status of their products on their labels. We will evaluate such labeling to ensure such information is truthful and not misleading and meets other applicable FDA requirements.

3. What analytical methods are available to evaluate compliance and to enforce a regulatory definition of ''gluten-free'' at very low levels?

(Comment 5) Some comments stated that there is no analytical method to measure gluten at the levels identified in the safety assessment (0.01 to 0.6 ppm).

(Response 5) We agree with the comments that it is currently not possible to reliably and consistently test for gluten at the very low levels identified in the safety assessment. There are methods with limits of detection that are lower than the level at which they have been validated. Thus far, the reliability of those methods at these lower limits has not been demonstrated. Twenty ppm remains the level of gluten that can reliably and consistently be detected in a variety of food matrices.

(Comment 6) Numerous comments concurred with the proposed level of < 20 ppm as among the criteria for a ''gluten-free'' definition based on the analytical methods-based approach, but stated that we should reduce the gluten content used as part of the criteria to define the term ''gluten-free'' when validated analytical methods become available to reliably detect gluten in foods at lower levels. In contrast, other comments said that more sensitive analytical methods should not be the determining factor in lowering the gluten threshold level unless there is scientific evidence (e.g., evidence-based, peer-reviewed published studies) demonstrating that 20 ppm gluten in foods labeled ''gluten-free'' is ''toxic'' to those with celiac disease.

(Response 6) We agree, in part, with the comments. If future data indicate that the gluten content of < 20 ppm is not sufficiently protective of the health of individuals with celiac disease and analytical methods become available that can reliably detect gluten in a range of food matrices at levels below 20 ppm, we will reevaluate the < 20 ppm gluten level that we have included as part of the criteria for the definition of ''gluten-free.'' We agree that any changes to this gluten level should be supported by all available data, including data on analytical methods as well as epidemiological and clinical data on the impact of any change on the health of individuals with celiac disease.

In sum, defining the term ''gluten-free'' for use in the voluntary labeling of food involves the consideration of multiple factors, including currently available analytical methods and the needs of individuals with celiac disease, as well as factors such as ease of compliance and enforcement, stakeholder concerns, economics, trade issues, and legal authorities. An important consideration is that, as the comments suggest, lowering the gluten level below 20 ppm will make it far more difficult for manufacturers to make food products that could be labeled as ''gluten-free,'' thereby reducing food choices for individuals with celiac disease. While the safety assessment results suggest that there may be some individuals with celiac disease who are highly sensitive to gluten exposure even at very low levels, the safety assessment, by its nature, may lead to a conservative, highly uncertain estimation of risk for these individuals. Given the various factors we have to consider and the data available to us, we decline to revise the rule to adopt a safety assessment-based approach at this time. However, if new data and information become available in the future that affect the factors we considered in defining ''gluten-free,'' we may consider whether further refinement of the ''gluten-free'' definition would be appropriate.

4. Is the rule consistent with international standards?

(Comment 7) A few comments asked how our proposed definition of ''gluten-free'' differed from those used in other countries. Many comments focused on the < 20 ppm gluten content as the only element of our proposed rule that would apply to international products. Other comments questioned how differences would affect the United States in international trade negotiations, considering the World Trade Organization Agreements on Technical Barriers to Trade (TBT Agreement) and Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Several comments supported the proposed definition of ''gluten-free'' as an opportunity to harmonize international standards for this term. Some comments cautioned against using a lower gluten content value, stating that a lower level would not allow harmonization with international trading partners such as Canada and the European Union, which use a standard of no greater than 20 ppm gluten.

Many comments commented on a definition of ''low gluten'' as allowed in Australia and New Zealand. Most comments stated that ''low-gluten'' labeling is meaningless for individuals who wish to avoid gluten, but other comments supported ''low-gluten'' claims to allow for differences in individual gluten tolerance or personal preference.

(Response 7) The 2011 notice indicated that the < 20 ppm part of the criteria consistent with approaches taken by the Codex Alimentarius Commission's revised ''Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Standard 118–1979)'' and also with the European Commission's Commission Regulation (EC) No 41/2009, concerning ''the composition and labeling of foodstuffs suitable for people intolerant to gluten'' (76 FR 46671 at 46674). The Codex Standard established a threshold of 20 mg gluten per kg of product (which is equivalent to 20 ppm gluten) for foods labeled ''gluten-free,'' and the European Commission regulation requires that foods labeled as ''gluten free'' not contain more than 20 ppm gluten (Refs. 25 and 26).

The final rule's definition of ''gluten-free'' is similar, but not identical, to requirements or positions by the Codex Alimentarius Commission, the European Commission, and Canada. For example, although our final rule, Codex Standard 118–1979, and European Commission Regulation No 41/2009

(Ref. 26) identify wheat, rye, and barley as gluten-containing grains, and allow foods containing ingredients made from wheat, rye, barley, or their crossbred varieties to be labeled ''gluten-free'' if the ingredients have been processed so that the gluten content in the food is reduced, the requirements differ in the amount of reduction required. Codex Standard 118–1979 and European Commission Regulation No 41/2009) require gluten in these ingredients not exceed 20 mg/kg, whereas our final rule requires the use of ingredients processed to remove gluten does not result in the presence of 20 ppm or more gluten in the finished food (§ 101.91(a)(3)(i)(A)(*3*)). In addition, our final rule also requires that any unavoidable presence of gluten in the food be below 20 ppm (see § 101.91(a)(3)(i)(A)(*3*) and (a)(3)(ii)). Codex Standard 118–1979 and European Commission Regulation No 41/2009, in general, require that the gluten content ''not exceed'' 20 mg/kg in the food.''

We also note that, in June 2012, Health Canada described its position on gluten-free claims. Canadian regulations had previously defined ''gluten,'' in part, as any gluten protein from the grain of, or the grain of a hybridized strain created from, barley, oats, rye, triticale, or wheat, kamut, or spelt. In June 2012, however, Health Canada stated that: ''Based on the available scientific evidence, Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of [Health Canada regulation] B.24.018 when a gluten-free claim is made.'' ''Based on the enhanced labeling regulations for allergens and gluten sources, any intentionally added gluten sources, even at low levels (e.g. wheat flour as a component in a seasoning mixture which makes up a small proportion of the final food), must be declared either in the list of ingredients or in a 'Contains' statement. In these cases, a gluten-free claim would be considered false and misleading. If, however, a manufacturer using a cereal-derived ingredient includes additional processing steps which are demonstrated to be effective in removing gluten, then the food may be represented as gluten-free'' (Ref. 27). The Health Canada position that food labeled ''gluten-free'' not contain more than 20 ppm gluten is comparable to the final rule's criterion that foods labeled ''gluten-free'' cannot contain 20 ppm gluten or more gluten.

However, we recognize that our final rule differs in certain respects from requirements or positions taken by Health Canada and other countries or entities. For example, Codex Standard 118–1979, European Commission Regulation No 41/2009, Australia New Zealand Food Standards Code standard 1.2.8 (Ref. 28), and Health Canada include oats as gluten-containing grains, whereas our final rule does not. (We discuss oats in our response to comment 9.) Codex Standard 118–1979 and European Commission Regulation No 41/2009 also state that a gluten-free food is one whose ''gluten level does not exceed'' 20 mg/kg, and Health Canada's position is that a gluten-free food has a gluten content ''not exceeding 20 ppm,'' whereas our final rule defines ''gluten-free'' with respect to a gluten content of < 20 ppm. We do not consider the difference between ''does not exceed 20 mg/kg or 20 ppm,'' compared to our ''< 20 ppm'' gluten content criterion, to be significant because, as indicated in our discussion of comment 19, many foods labeled as ''gluten-free'' have a gluten content well below 20 ppm.

As another difference, we recognize that European Commission Regulation No 41/2009 requires foods for those intolerant to gluten to not contain gluten exceeding 100 mg/kg and to bear the term ''very low gluten,'' and Australia New Zealand Food Standards Code standard 1.2.8 requires that a food have ''no detectable gluten'' if it claims to be ''gluten free.'' The Australia New Zealand Food Standards Code also states that a food can be ''low gluten'' if the detectable gluten content is no more than 20 mg per 100 g of food, which is equivalent to no more than 200 ppm. Our final rule does not define the use of ''low gluten'' or ''very low gluten'' claims. If such claims were used in labeling, we would evaluate such claims on a case-by-case basis as to whether the claim was truthful and not misleading. We discourage the use of statements in labeling about the gluten content in foods other than ''gluten-free.'' (We discuss ''low gluten'' claims in our response to comment 25.)

Based on our review of products currently on the market, we do not believe that the differences between our final rule and standards, requirements, or positions taken by other countries or entities will adversely affect the ability of manufacturers to voluntarily use the ''gluten-free'' claim, as appropriate, on many foods.

B. What comments did we receive on the proposed rule?

1. Definitions (§ 101.91(a))

a. *Prohibited grains (§ 101.91(a)(1)).* The proposed rule would define three terms. Proposed § 101.91(a)(1) would define ''prohibited grain'' as any one of three specific grains (wheat, rye, and barley) ''or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye).''

(Comment 8) Several comments disagreed with or would revise the term ''prohibited grain.'' Some comments stated that the term is misleading because it implies that all consumers, rather than consumers with celiac disease or consumers who are allergic to those grains, should avoid the grains. Some comments suggested alternative terminology; for example, one comment suggested replacing the term ''prohibited grain'' with ''specific grain.''

(Response 8) We agree in part and disagree in part with the comments. We agree that the word ''prohibited'' could create the misimpression that all consumers (rather than solely those individuals with celiac disease) should avoid these grains. We decline, however, to use the term ''specific grains'' because it does not provide any information as to what the term ''specific'' refers. Instead, we have revised § 101.91(a)(1) and corresponding language elsewhere in § 101.91(a) to refer to ''gluten-containing grain'' rather than ''prohibited grain.'' The term ''gluten-containing grain'' is simple, informative, and tied to the rule's definition of ''gluten.'' In addition, ''gluten-containing grain'' may avoid any misinterpretation of the rule's intent with respect to the consumption of gluten by individuals without celiac disease or other medical need to avoid gluten.

(Comment 9) Many comments addressed the use of oats as an ingredient that could be used in a food labeled ''gluten-free.'' Most comments supported the inclusion of oats as an ingredient in ''gluten-free''-labeled foods. The comments stated that the scientific evidence indicates that the majority of individuals who have celiac disease can tolerate eating oats. The comments added that oats are a whole grain and contribute essential nutrients and fiber to a gluten-free diet and that oats add more dietary variety and appeal to following a gluten-free diet. Many comments favored the use of ''gluten-free'' labeling for food containing oats only if the food contains less than 20 ppm gluten. These comments stated that limiting the use of

the ''gluten-free'' claim on these foods would make it easier for consumers to distinguish these oats from other commercially available oats that could contain higher levels of gluten due to cross-contact situations with gluten-containing grains. The comments stated that oats in food labeled ''gluten-free'' would provide individuals who have celiac disease and who are oat-tolerant more assurance that the product has been grown, processed, stored, and handled in a way to prevent incorporation of gluten.

Other comments opposed permitting oats in a food labeled ''gluten-free.'' These comments argued that not all individuals with celiac disease can tolerate oats and that FDA's definition of ''gluten-free'' should accommodate the needs of everyone who has celiac disease. Some comments stated that more research is needed to determine whether individuals with celiac disease should consume oats. Other comments stated that persons newly diagnosed with celiac disease and elderly persons with celiac disease are commonly advised not to introduce oats into their gluten-free diet until their small intestine has fully healed or that some individuals with celiac disease who are asymptomatic may be sensitive to oats and not know it. Finally, some comments said that if we do not prohibit oats in food labeled ''gluten-free,'' then the label should indicate if the food does or does not contain oats.

(Response 9) We agree with the comments that oats may be used as an ingredient in a food labeled as ''gluten-free'' provided that the food meets the definition of ''gluten-free.'' In other words, oats that contain 20 ppm or more gluten due to cross-contact may not bear a ''gluten-free'' claim. While oats are inherently gluten-free, we recognize that some oats may come in contact with gluten-containing grains during their production, processing, storage, or other handling practices. However, as we noted in the preamble to the proposed rule (72 FR 2795 at 2798), the commingling of oats with other grains appears to be preventable. At least two manufacturers who submitted written responses to our 2005 public meeting on gluten-free food labeling reported that the oats they market in the United States do not contain gluten from wheat, rye, and barley (Refs. 29 and 30). Other comments indicated that five brands of gluten-free oats are now commercially available in the United States.

We decline to prohibit the use of oats as an ingredient in foods labeled ''gluten-free.'' As we noted in the proposed rule, data suggest that the proportion of individuals with celiac disease who cannot tolerate oats in daily amounts of about 50 g or less dry weight is probably very low, possibly below 1 percent of the population of individuals with celiac disease, and there is no general agreement among experts about the extent to which oats present a hazard for individuals with celiac disease (72 FR 2795 at 2797 through 2798). Thus, for most individuals with celiac disease, oats can add whole grain options, nutrient enrichment, and dietary variety and appeal to a gluten-free diet. Individuals with celiac disease who cannot tolerate oats can use food label information to avoid eating foods labeled ''gluten-free'' that are made with oats or oat-derived ingredients. Examples of oat-derived ingredients include whole oats, rolled oats (also called oatmeal and oat flakes), steel-cut oats, oat flour, oat bran, and oat fiber. The term ''oat'' or ''oats'' is a part of the common or usual name for each of these ingredients and can be found in the food's ingredient list. For the reasons stated previously in this document, we also decline to revise the rule to require that foods labeled ''gluten-free'' bear additional language indicating that the food does or does not contain oats.

We recognize that there may be instances in which products could contain an oat-derived ingredient without ''oats'' in the name, but we did not receive any data or information on this possibility, and we are aware of only one such ingredient, a non-starch polysaccharide called ''beta glucan,'' which can be derived from multiple sources, including oats, and which is used in certain dietary supplements and to a much lesser extent in conventional foods (Ref. 31).

Because individuals with celiac disease who are sensitive to oats may wish to avoid all oat-derived ingredients, we encourage manufacturers of foods labeled ''gluten-free'' that use an oat-derived ingredient where the word ''oat'' does not appear in the ingredient list as part of any ingredient's name (e.g., beta glucans) to indicate in their labeling that an oat-derived ingredient is present.

(We understand that beta glucan may also be derived from barley, which, unlike oats, is a ''gluten-containing grain'' under § 101.91(a)(1). Similar to wheat starch, we consider beta glucan derived from barley to be an ingredient that has been processed to remove gluten because the process of deriving this ingredient is designed to selectively yield the desired polysaccharide and exclude other naturally occurring components, including protein.)

b. *Gluten (§ 101.91(a)(2)).* Proposed § 101.91(a)(2) would define ''gluten'' as ''the proteins that naturally occur in a prohibited grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).''

(Comment 10) Several comments suggested that FDA revise the definition of ''gluten'' to mean ''specific amino acid sequences'' that naturally occur in a prohibited grain and that cause harmful effects by eliciting an immune response.

(Response 10) We decline to revise the definition as suggested by the comments. The comments did not explain how the definition would be improved by replacing ''proteins'' with ''specific amino acid sequences'' or by replacing ''may cause adverse health effects'' with ''cause harmful effects by eliciting an immune response.'' We also note that our definition of ''gluten'' is comparable to those used by Codex Standard 118–1979 and European Commission Regulation No 41/2009; both define ''gluten'' as ''a protein fraction from wheat, rye, barley, oats, or their crossbred varieties and derivatives thereof, to which some [people] are intolerant and [that] is insoluble in water and 0.5M'' sodium chloride solution. Consequently, except for replacing ''prohibited grain'' with ''gluten-containing grain'' (as we explained in our response to comment 8), we have finalized the definition of ''gluten'' without change.

c. ''*Gluten-free'' (§ 101.91(a)(3)).* Proposed § 101.91(a)(3) would define the labeling claim ''gluten-free'' or similar claims as meaning that the food bearing the claim in its labeling does not contain any of the following: (1) An ingredient that is a prohibited grain; (2) an ingredient that is derived from a prohibited grain and has not been processed to remove gluten (e.g., wheat flour); (3) an ingredient that is derived from a prohibited grain and has been processed to remove gluten if use of that ingredient results in a presence of 20 parts per million (ppm) or more gluten in the food; and (4) 20 ppm or more gluten. The proposal also cited examples of similar claims, such as ''free of gluten,'' ''without gluten,'' and ''no gluten'' that would have to meet the same definition as the term ''gluten-free.''

(Comment 11) Many comments asked us to develop a clear and consistent definition for the ''gluten-free'' labeling claim. However, one comment from a national organization committed to serving the celiac community noted that it had dietitians with expertise in the gluten-free diet develop a 15-question online consumer survey designed to obtain consumer input on the various

questions posed by FDA as they related to consumers and their decisions and choices related to gluten-free products. The organization executed the online survey, open to consumers for 45 days, and collected over 5,000 responses. The comment indicated that 95 percent of the respondents preferred the term ''gluten-free'' to indicate that a product meets FDA's definition for ''gluten-free,'' as set forth in the proposed rule. The comment also noted that voluntary label statements, such as ''may contain'' or ''processed in a plant with,'' currently restrict consumer use of some foods. The comment said that these types of voluntary label statements would be unnecessary if consumers could rely on a ''gluten-free'' label that indicated a product had been tested to below 20 ppm. The comment suggested that we strive for ''clarity'' in all aspects of the regulation. Another comment suggested that any definition of ''gluten-free'' should facilitate a reasonable level of consistency among various products labeled as ''gluten-free'' and should ensure that individuals who are sensitive to or cannot tolerate gluten can rely on gluten-free products meeting the same minimum definition.

Several comments recommended a single labeling definition for ''gluten-free'' foods and believed multiple labels would be too confusing to the public. As one comment stated, ''only one simple, clear standard claim like 'gluten free' may simplify the identification of gluten-free products (with a gluten level below 20 ppm).''

One comment stated that we should expressly prohibit ambiguous statements, such as ''No Gluten Added'' or ''Made from Gluten Free Ingredients.'' Other comments expressed similar sentiments about variations of similarly worded claims. One comment said that manufacturers use such statements to suggest that the product is suitable for individuals with celiac disease, while simultaneously attempting to avoid liability for any gluten in the product that could result from cross-contact or cross-contamination during the manufacturing process. Similarly, other comments urged us to prohibit other claims about the presence or absence of gluten ingredients unless the food meets FDA requirements for a ''gluten-free'' claim.

(Response 11) We agree that the final rule should clearly define the term ''gluten-free.'' Section 206 of FALCPA directs the Secretary to define and permit use of the term ''gluten-free'' in the labeling of foods. Although proposed § 101.91(a)(3) would have defined ''gluten-free'' and include ''or similar claim,'' we have revised the final rule to define the term ''gluten-free'' without referring to ''similar claims.'' A single definition should help individuals with celiac disease identify foods that they can tolerate, without having to wonder whether foods bearing different label claims present different risks, and thus manage their diets more easily. Furthermore, as the comments suggest, it may be confusing to define ''gluten-free'' in a manner that also attempts to capture ''similar claims.'' For example, as the comments indicate, a claim such as ''no gluten added'' might not be similar to ''gluten-free;'' instead, a ''no gluten added'' claim could mean that the manufacturer did not increase the food's gluten content during the manufacturing process beyond whatever level of gluten the food contained before manufacturing. While another comment suggested that we prohibit other claims, our experience with lists of examples, such as listing the products subject to a rule, indicates that it may be impractical to list more examples of ''similar'' claims. (See, e.g., 66 FR 59138 at 59144 (November 27, 2001) (''FDA's experience demonstrates that, despite FDA's intentions to provide advice or clarity, whenever the agency attempts to provide complete descriptions of the products that are subject to a particular regulation or part, the descriptions are either misconstrued as being exhaustive or definitive (so that persons whose products are not identified or even slightly different from the products mentioned in the description claim that they are exempt from the rule) or must be constantly revised to add new products and to remove old products'').

Nevertheless, we recognize that some companies use claims that are similar to our definition of ''gluten-free.'' Our experience with other content claims on foods suggests that claims that a food contains ''no gluten,'' is ''free of gluten,'' or is ''without gluten'' (the examples of ''similar claims'' in proposed § 101.91(a)(3)) would be misleading if the food does not meet the definition for ''gluten-free'' specified in § 101.91(a)(3) (Ref. 32). Consequently, we have revised § 101.91(b)(2) to state that, ''A food that bears the claim 'no gluten,' 'free of gluten,' or 'without gluten,' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.'' In essence, we consider the statements ''no gluten,'' ''free of gluten,'' and ''without gluten,'' to be equivalent to a ''gluten-free'' claim. We use the term ''requirements'' to accurately describe the list of items in this paragraph. We discourage the use of statements in labeling about the gluten content of foods other than ''gluten-free'' and would evaluate any such statements under sections 403(a)(1) and 201(n) of the FD&C Act.

(Comment 12) Many comments requested that we establish a universal symbol/logo and/or a standardized print format for all manufacturers who wish to make a ''gluten-free'' claim on their food labels. The comments said that symbols, logos, or standardized print formats would make it easier for consumers to identify gluten-free foods, to reduce their time shopping, and to reduce possible confusion by having the same symbol appear in the same place using the same print format on foods bearing a ''gluten-free'' labeling claim. Comments from certification organizations suggested that consumers, particularly the most gluten-sensitive individuals, look for those symbols and understand what they mean.

Other comments opposed the use of a universal ''gluten-free'' symbol/logo. Some comments said that some manufacturers and grocery store chains have designed their own unique symbols/logos for identifying gluten-free foods and should be able to continue using these symbols/logos for labeling gluten-free foods or to use these symbols/logos on printed cards or other signs to call attention to gluten-free products sold in their stores. Still other comments noted several third party gluten-free certification programs that have developed their own specific ''gluten-free'' symbols/logos to identify foods that comply with particular criteria for a gluten-free food. One comment noted that some food companies seek independent, third-party certification for their gluten-free products. The comment urged us to not restrict the companies' use of certification programs or symbols. The comment said that inclusion of multiple ''gluten-free'' symbols on the same food or any restriction against continued use of third-party ''gluten-free'' certification program symbols/logos could make it more confusing or difficult for consumers to identify foods that met the criteria of those third-party ''gluten-free'' certification programs.

(Response 12) The proposed rule did not address the use of a universal symbol/logo, and we do not have any data indicating that mandating a universal symbol/logo is necessary to ensure that the claim is not false or misleading.

We are aware that some companies or organizations have developed specific phrases or symbols to indicate adherence to their own standards or to

the standards of an independent gluten-free certification program for foods that meet specific criteria. We would review the use of any gluten-related claim not addressed in the final rule under sections 403(a)(1) and 201(n) of the FD&C Act.

(Comment 13) One comment noted that the proposed rule would allow a food to be labeled ''gluten-free'' if it uses an ingredient derived from a prohibited grain that has been processed to remove gluten, but would not allow a food to be labeled ''gluten-free'' if it used a prohibited grain or used an ingredient derived from a prohibited grain, if the processing of the food (instead of the ingredient) results in the removal of gluten to below 20 ppm in the final product. The comment said that processes exist that remove gluten from foods produced with gluten containing ingredients, and suggested that because the processes that remove gluten can occur at any stage in production, from the preparation of the ingredients to the finished product, the final rule should allow the use of the term ''gluten-free'' regardless of when the gluten removing process occurs.

(Response 13) Comments indicate that individuals with celiac disease search for ''gluten-free'' claims and also review the ingredient statement for specific ingredients. The final rule limits the use of gluten-containing ingredients to ensure the food, as consumed, contains as little gluten as possible. Allowing the ''gluten-free'' label claim on food whose ingredients have been processed to remove gluten, but not on food that has been processed to remove gluten helps ensure that the finished product has the lowest amount of gluten that is reasonably possible, and consistent with the use of specific manufacturing practices that can prevent gluten cross-contact situations. We plan to issue a proposed rule to address our compliance approach to foods that are, or contain ingredients that are, fermented or hydrolyzed, as discussed in response to comment 14. We anticipate that the proposed rule will include a discussion related to the whether it is feasible, and if so, under what circumstances, to process food to remove gluten.

(Comment 14) Several comments responded to analytical methods-related issues raised in our 2011 notice regarding a scientifically valid method that can be used to accurately determine if foods that are or contain ingredients that are fermented or hydrolyzed (i.e., in which chemical components are decomposed by reaction with water) contain < 20 ppm gluten to support ''gluten-free'' claims. Other comments discussed whether we also should require these manufacturers to maintain records on test methods, protocols, and results and to make these records available to FDA upon inspection.

Some comments, primarily from manufacturers of gluten detection test kits or the food industry, asserted that there are some competitive enzyme-linked immunosorbent assay (ELISA)-based methods that can accurately detect and measure gluten concentration levels in fermented and hydrolyzed foods as low as 0.24 mg/100 g or 2.4 ppm. These comments also maintained that these methods were validated to ensure that they perform reliably and can report test results in terms of intact gluten concentration or ppm gluten. Several other comments, particularly from those with celiac disease, celiac disease associations, or health professionals, wanted FDA to require records of test methods, protocols, and results to permit ''gluten-free'' claims on fermented or hydrolyzed foods. Some comments wanted the recordkeeping requirements to apply to all foods bearing a ''gluten-free'' claim.

(Response 14) We routinely rely upon scientifically valid methods [1] in our enforcement programs on food labeling. However, we are aware that currently available sandwich ELISA-based methods are not effective in detecting and quantifying intact gluten proteins in fermented and hydrolyzed foods. The sandwich ELISA-based methods designed to detect gluten require the presence of two antigenic epitopes and are not appropriate for fermented and hydrolyzed products.

In comparison to sandwich ELISA-based methods, competitive ELISA-based methods need the presence of a single antigenic epitope. However, without an appropriate reference standard to gauge the response, one cannot interpret the results on a quantitative basis that equates the response to intact gluten. Evidence in the scientific literature is currently lacking about a scientifically valid competitive ELISA method which confirms that any gluten peptides detected in a food sample can be accurately quantified in terms of ppm intact gluten protein. Therefore, we do not consider these methods scientifically valid for the purposes of analyzing fermented or hydrolyzed foods to determine compliance with this rule under § 101.91(c). We intend to issue a proposed rule to address how FDA will evaluate compliance with § 101.91(b) when an evaluation of compliance based on an analysis of the food using a scientifically valid method under § 101.91(c) is not available because the food is fermented or hydrolyzed or contains fermented or hydrolyzed ingredients. We intend to consider the need for issuing guidance for these foods to the extent the proposed rule does not issue before the compliance date for this final rule.

A ''gluten-free'' claim will be permitted on fermented and hydrolyzed foods or foods containing fermented or hydrolyzed ingredients that meet all of the requirements for bearing a ''gluten-free'' claim even though the gluten content of the food cannot be reliably measured pursuant to § 101.91(c). Until we establish provisions specifically for these foods, through further rulemaking, as is true for all food manufacturers who wish to use ''gluten-free'' labeling on their food, manufacturers of fermented or hydrolyzed foods or foods that use fermented or hydrolyzed ingredients are responsible for ensuring that the food bearing a ''gluten-free'' claim is not misbranded for failure to meet all of the requirements of the final rule. Manufacturers can implement measures that are necessary to prevent the introduction of gluten into the food during the manufacturing process to ensure that the finished product will comply with the provisions in § 101.91.

(Comment 15) Several comments concerned ''gluten-free'' labeling claims on beers. Some comments wanted FDA to allow beers to be labeled ''gluten-free'' if the beers contained less than 20 ppm gluten. One comment stated that, in some European countries, the traditional brewing processes for barley malt-based beers have been modified to ensure that beers labeled as ''gluten-free'' contain significantly less than 20 ppm of gluten.

In contrast, other comments favored prohibiting the use of a ''gluten-free'' claim on the label of beers made from gluten containing ingredients but were later ''reduced'' in gluten due to the processing methods.

(Response 15) The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the issuance and enforcement of regulations with respect to the labeling of beers that are malt beverages under the Federal Alcohol Administration Act (FAA Act). Certain beers do not meet the definition of a malt beverage under the FAA Act (27

[1] As noted in the 2011 notice, a scientifically valid method for purposes of substantiating a ''gluten-free'' claim for foods matrices where formally validated methods (e.g., that underwent a multi-laboratory performance evaluation) do not exist is one that is accurate, precise, and specific for its intended purpose and where the results of the method evaluation are published in the peer-reviewed scientific literature. In other words, a scientifically valid test is one that consistently and reliably does what it is intended to do.

U.S.C. 211(a)(7)). These beers are not subject to the labeling requirements under the FAA Act and are subject to the labeling requirements administered by FDA (Ref. 33).

On May 24, 2012, TTB issued an interim policy on gluten content statements in the labeling and advertising of beverages or beers they regulate. The ''Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages'' allows the use of the following qualifying statement to inform consumers: ''Product fermented from grains containing gluten and [processed or treated or crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten,'' or ''This product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten.'' (TTB Ruling No. 2012–2, May 24, 2012, available at *http://www.ttb.gov/rulings/2012-2.pdf*)

Beers subject to FDA's labeling requirements are those beers that are not made from both malted barley and hops but are instead made from either malted barley and no hops or with substitutes for malted barley (for example sorghum, millet, rice or buckwheat) with or without hops. Other beers subject to FDA's labeling requirements not brewed from gluten-containing grains may contain gluten through cross-contact with gluten-containing grains or ingredients during processing. (We also note that, for purposes of this discussion, we do not consider saké and similar products to be ''beers.'' Saké and similar products are treated as wine under the FAA Act and are subject to FDA's labeling requirements only if they contain less than 7 percent alcohol by volume.)

Beers are among the foods subject to fermentation during manufacturing. As discussed in our response to comment 14, we intend to issue a proposed rule to address how FDA will evaluate compliance with § 101.91(b) when an evaluation of compliance based on an analysis of the food using a scientifically valid method under § 101.91(c) is not available because the food is fermented or hydrolyzed or contains fermented or hydrolyzed ingredients.

We intend to address the ''gluten-free'' labeling of beers subject to FDA's labeling requirements in that proposed rule. However, the issues with respect to the labeling of FDA-regulated beers as gluten-free go beyond the question of how compliance can be verified. First, we note that consumers might not distinguish between those beers subject to FDA's labeling requirements and those beers subject to TTB's labeling requirements. Second, some comments have claimed that beers made from gluten-containing grains can be processed in a way that removes gluten. We are aware of a limited number of such products in the market. As with other fermented foods, we are not aware of any scientifically valid way to evaluate these claims, and there is inadequate evidence in the record concerning the effectiveness of the commenters' gluten removal process. We want to avoid any changes to labels that may cause further confusion with regard to ''gluten-free'' beer until we issue the separate rule on gluten-free labeling of hydrolyzed and fermented foods.

In light of these considerations, we intend to exercise enforcement discretion with respect to the requirements for ''gluten-free'' labeling for beers subject to FDA labeling requirements. Our consideration for enforcement discretion would extend to beers that currently make a ''gluten-free'' claim and that are: (1) Made from a non-gluten-containing grain or (2) made from a gluten-containing grain, where the beer has been subject to processing that the manufacturer has determined will remove gluten. This enforcement discretion pertains only to these beers subject to our labeling requirements that make a ''gluten-free'' claim as of August 5, 2013 pending completion of the rulemaking process with respect to fermented or hydrolyzed products. To the extent that a beer manufacturer wants to make a new gluten-free claim that is not present on a label as of August 5, 2013, they should contact FDA regarding the possible expansion of FDA's consideration for the exercise of enforcement discretion related to such labeling.

FDA expects beer manufacturers using a ''gluten-free'' claim to take appropriate measures to prevent cross-contact with gluten-containing grains during production, processing, storage, or other handling practices. We note that beer manufacturers, whose beers are subject to FDA's labeling requirements, that make beer from a gluten-containing grain or from non-gluten-containing grains are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB guidance, about processing of beers to reduce gluten. However, such statements must be truthful and not misleading. Beers bearing a ''gluten-free'' claim, or other statements related to the gluten processing or content other than ''gluten free,'' are still subject to sections 403(a)(1) and 201(n) of the FD&C Act.

(Comment 16) Several comments claimed that individuals with celiac disease are concerned that gluten-containing ingredients used in food products may not be readily identifiable in the list of ingredients on food packages. The comments suggested that ingredients declared as ''flavoring'' or ''modified food starch'' could contain gluten or ingredients derived from gluten-containing grains. Some comments suggested that we require the source of these ingredients be declared on the label for foods bearing the ''gluten-free'' labeling claim.

(Response 16) We recognize that, in some situations, an ingredient that is a ''flavoring'' or ''modified food starch'' may be derived from a gluten-containing grain but nonetheless be present in a food bearing a ''gluten-free'' label. We note that the use of the ''gluten-free'' claim on a food label is voluntary and does not replace or eliminate any other labeling requirements. Wheat is a major food allergen under FALCPA and any food that is, or contains an ingredient that bears or contains, a major food allergen under section 201(qq) of the FD&C Act must declare either the word ''Contains'' followed by the name of the food source from which the major food allergen is derived, or the common or usual name of the major food allergen in the list of ingredients followed in parentheses by the name of the food source unless subject to an exception (section 403(w)(1) of the FD&C Act). A flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen is subject to the labeling requirements of section 403(w)(4) of the FD&C Act. Section 101.91(b)(1) of the final rule states that we will consider a food bearing the claim ''gluten-free'' in its labeling to be misbranded if it fails to meet the requirements of paragraph (a)(3) of this section, which includes the requirement that any ingredient derived from a gluten-containing grain be processed to remove gluten such that its use in the finished product does not result in 20 ppm or more gluten in the food. Therefore, this final rule does not change the current labeling requirements for major food allergens, including wheat. To the extent the comment requests that we require that *all* ingredients in flavorings be listed in the ingredient statement, the request is outside the scope of this rulemaking.

(Comment 17) A few comments suggested that we establish a gluten limit for ingredients derived from gluten-containing grains that have been

processed to remove gluten. One comment suggested 20 ppm as a reasonable limit to set for safety and ease of testing. Another comment suggested that if ingredients derived from gluten-containing grains must be used, and if the food complies with the maximum gluten content of 20 ppm, market practice will impose the same requirement at the ingredient level.

(Response 17) We decline to revise the rule to establish a specific gluten limit for ingredients derived from a gluten-containing grain that have been processed to remove gluten. As we discussed in the preamble to the proposed rule (72 FR 2795 at 2802), although ingredients such as wheat starch, are processed to remove gluten, there may be different methods of deriving these ingredients, and some methods may remove less gluten than others. The final rule provides that the use of such ingredients must not result in the presence of 20 ppm or more gluten in the finished food (i.e., 20 mg or more gluten per kg of food). To use additional adjectives to indicate that these ingredients have been ''significantly'' or ''substantially'' reduced in gluten would have little meaning given the variability in the gluten levels in the starting materials and the various processes used. Likewise, to establish gluten thresholds for these specific ingredients would add criteria to the definition of ''gluten-free'' that do not offer additional benefit to the protection of public health beyond those provided by the definition of ''gluten-free.''

We agree that, as more manufacturers use ingredients derived from gluten-containing grains that have been processed to remove gluten, the market may respond by producing more ingredients that have been processed to reduce the gluten content even further and supporting the use of such ingredients in food products that meet the definition of ''gluten-free.'' Thus, we encourage suppliers of ingredients derived from a gluten-containing grain to process those ingredients using appropriate controls to achieve gluten content below 20 ppm. Manufacturers that are producing ''gluten-free'' foods may be more inclined to buy ingredients from suppliers that can produce ingredients with gluten content levels below 20 ppm. We would expect such manufacturers, as part of good manufacturing practice, to test the ingredient itself to ensure the gluten level in the ingredient is below 20 ppm. Alternatively, we would expect such manufacturers, as part of good manufacturing practice, to rely on a certificate of analysis for the ingredient, and to verify the accuracy and reliability of the certificate of analysis ensuring that the ingredient contains less than 20 ppm gluten. Such a certificate of analysis would be based on initial qualification and periodic re-qualification of the supplier through testing of the ingredient with sufficient frequency or at least once per year.

(Comment 18) One comment suggested that any commingling or cross-contact that may occur should not be evaluated under the < 20 ppm element of the definition, at least until such time as a safety-based threshold is established that would justify such inclusion. The comment asked that the final rule not condition voluntary use of the term ''gluten-free'' on whether a food contains 20 ppm or more gluten ''for any reason'' or on whether the product does not contain 20 ppm or more gluten if the product is made from oats.

(Response 18) The 20 ppm gluten threshold level is just part of the criteria used to define ''gluten free.'' The < 20 ppm part of the criteria for the definition of ''gluten-free'' is based on an analytical methods-based approach, not a safety-assessment-based approach. We recognize that gluten may be present in a food either because it is a component of an ingredient used to produce that food or through cross-contact during production, processing, storage, or other handling practices. Therefore, it is appropriate to use the same definition both for foods that have been formulated or processed not to contain 20 ppm or more gluten and for the presence of gluten in foods that do not inherently contain gluten, such as oats.

(Comment 19) Some comments expressed concern about some foods currently labeled as ''gluten-free'' having gluten content at or above 20 ppm or that many foods labeled ''gluten-free'' would contain the maximum permissible level of gluten near but still below 20 ppm.

(Response 19) Under the final rule, foods can no longer be labeled ''gluten-free'' if they contain 20 ppm or more gluten. The final rule uses an analytical methods-based approach to establish a gluten content of < 20 ppm as part of the criteria for defining the term ''gluten-free.'' Given the current unavailability of test methods that can reliably detect gluten at levels below 20 ppm, we conclude that ''gluten-free'' labeling on a food that contains less than 20 ppm gluten would be neither false nor misleading, so long as it conforms to all aspects of the final rule.

As for the comments expressing concern about some foods currently labeled as ''gluten-free'' having gluten content at or above 20 ppm, data submitted in comments to the proposed rule indicate that many products that are currently labeled as ''gluten-free'' have gluten content well below 20 ppm gluten. In addition we note that in surveys that have been conducted for foods labeled as gluten-free, available for sale in Canada, most samples contained less than 20 ppm of gluten (Ref. 27 at p. 4).

2. Requirements (§ 101.91(b))

Proposed § 101.91(b) would establish three different requirements relating to the use of a ''gluten-free'' labeling claims.

a. *Use of the ''gluten-free'' claim or similar claims.* Proposed § 101.91(b)(1) would state that ''A food that bears a ''gluten-free'' claim or similar claim in its labeling and fails to meet the conditions specified in paragraph (a)(3) of this section will be deemed misbranded.''

As we discussed earlier in our response to comment 11, the final rule now defines the term ''gluten-free'' without referring to ''similar claims'' or providing examples of similar claims. Section 101.91(b)(2) of the final rule states: ''A food that bears the claim 'no gluten,' 'free of gluten,' or 'without gluten' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.'' In essence, we consider the statements ''no gluten,'' ''free of gluten,'' and ''without gluten'' to be equivalent to a gluten-free claim. We are planning educational efforts to help consumers learn that when they see foods labeled as being ''gluten-free,'' the term will have a consistent meaning and, therefore, be a reliable tool when planning a gluten-free diet.

On our own initiative, we also have revised § 101.9(b)(1) to refer to ''the requirements of paragraph (a)(3) of this section'' instead of ''the conditions specified in paragraph (a)(3) of this section.'' This change corresponds to the language used in § 101.91(b)(2) of the final rule.

b. *Foods that do not inherently contain any gluten.* Proposed § 101.91(b)(2) would apply to foods that do not inherently contain any gluten from a prohibited grain (now referred to as a gluten-containing grain in the final rule), but would exclude foods made from oats. In brief, proposed § 101.91(b)(2) would consider such foods that bear a ''gluten-free'' claim to be misbranded unless the claim ''refers to all foods of that same type (e.g., 'milk, a gluten-free food,' 'all milk is gluten-

free')'' and the food does not contain 20 ppm or more gluten.

We invited comments and scientific information on whether a ''gluten-free'' claim on an inherently gluten-free food would be misleading in the absence of additional qualifying language.

(Comment 20) While a few comments supported proposed § 101.91(b)(2) as written, most comments expressed significant confusion as to the requirements for labeling foods inherently free of gluten. Numerous comments expressed concern that the rule would result in foods inherently free of gluten being deemed misbranded or ''illegal'' if they claimed to be ''gluten-free.'' The comments did not appear to understand that the proposed rule would find these foods misbranded only if they omitted the qualifying language when they claimed to be ''gluten-free'' (assuming they met the other criteria for a ''gluten-free'' labeling claim).

Other comments discussed the proposed qualifying language. The comments expressed concern that, in many instances, it would be misleading to suggest that a particular food or food category is always gluten-free. Some comments referred to the issues discussed in our analysis of oats in the proposed rule (72 FR 2795 at 2801), noting that cross-contact with gluten-containing ingredients can and does occur in virtually any facility where gluten-containing ingredients are present. One comment stated that ''requiring that inherently gluten-free foods electively labeled 'gluten-free,' declare that all such foods are gluten-free, is to deny the cross-contact risks to which many inherently gluten-free foods are regularly exposed. Furthermore, requiring such a statement devalues the efforts of manufacturers who employ exhaustive measures to remedy those risks of cross-contact. That type of reference, in effect, tells the consumer that foods labeled 'gluten-free'—and subject to federal regulations—are no more safe than those bearing no claim at all. Enforcing a requirement of such an advisory will perpetuate the confusion and risks to individuals with celiac disease that FALCPA is expected to undo.''

Other comments noted that certain foods of the same type may be available in flavored and unflavored forms or with additional ingredients that may contain traces of gluten. Many comments cautioned that, if one product used a ''gluten-free'' claim with the qualifying language (i.e., a statement that all foods of that type are gluten-free), some consumers may pick a flavored or formulated, gluten-containing version of the product and mistakenly believe that it also is inherently free of gluten. A few comments suggested that the proposed qualifying language for foods that inherently do not contain gluten would only be appropriate for single ingredient foods which are not flavored nor have added ingredients. Several comments urged us to allow an unqualified ''gluten-free'' claim if the food meets the definition of ''gluten-free.'' They emphasized that this unqualified labeling would be useful to consumers who are seeking gluten-free products.

Other comments explained that the proposed additional clarifying wording indicating that all foods of the same type, not just the brand bearing ''gluten-free'' labeling claim, also are free of gluten could compel manufacturers to make representations about all products in a given category, including products that the manufacturer does not make or cannot control. Some comments explained that companies are willing to support that their own products may bear a ''gluten-free'' claim (< 20 ppm gluten), but do not wish to make a statement suggesting that other companies have made the same determination or have the same controls or manufacturing practices to minimize or prevent contact with gluten.

Many comments suggested that we establish a simple ''gluten-free'' claim, regardless of whether the product is inherently gluten-free or formulated to be gluten-free. To minimize consumer confusion, many comments suggested that the final rule allow a ''gluten-free'' claim on products that have been processed in a manner that ensures the products meet the definition of ''gluten-free'' and contain less than 20 ppm gluten. The comments also suggested that consumers seeking to avoid gluten do not care if the food is inherently (or ''naturally'') gluten-free or processed to remove gluten by formulation or ingredient substitution.

Other comments explained that the proposed requirements for qualifying language could have an unintended consequence as it could cause companies to stop labeling their products as ''gluten-free,'' rather than deal with misbranding issues. The comments indicated that such a result would frustrate consumers because there would be fewer foods labeled as ''gluten-free.''

(Response 20) We understand how the proposal's additional clarifying language for foods inherently free of gluten could cause confusion and concern for the consumers seeking foods with a ''gluten-free'' labeling claim. We agree with the comments stating the requirement for qualifying language on foods that inherently do not contain gluten could be interpreted as saying that it is the nature of the food, rather than the care provided by the company making the ''gluten-free'' claim, that ensures the product meets the definition of ''gluten-free.'' Likewise, we agree with the comments suggesting that, in this situation, requiring companies using the ''gluten-free'' claim to add the qualifying language that all foods of the same type are also gluten-free would, in effect, require the companies to make representations as to the gluten-free status of products outside of their control. We agree that such qualified labeling on one brand of food that inherently does not contain gluten could mislead consumers into assuming that a flavored or formulated gluten-containing version of that product is also gluten-free, and could result in an individual with celiac disease consuming gluten and possibly suffering negative health consequences as a result.

Consequently, we conclude that a ''gluten-free'' claim, without qualifying language, on a food that is inherently free of gluten is not misleading. We have revised the final rule so that a food labeled as ''gluten-free'' must meet the definition of ''gluten-free'' in § 101.91(a)(3), but will not require additional qualifying language. This final rule will allow us to determine whether specific ''gluten-free'' labeling claims are misleading on a case-by-case basis. A food bearing a ''gluten-free'' label must meet each of the relevant criteria in the ''gluten-free'' definition, and qualifying language would not be necessary for consumers to understand the meaning of the term ''gluten-free'' with respect to other foods, including those that may also be inherently free of gluten. There may be inherently gluten-free foods that still may not meet the definition of ''gluten-free'' due to cross-contact with gluten that leads to gluten content in the food that are at or above 20 ppm. There also may be inherently gluten-free foods that have some cross-contact with gluten-containing products, but are still able to bear the ''gluten-free'' claim because the presence of gluten in the food due to cross-contact is less than 20 ppm. Thus, the approach we have taken in the final rule should result in labeling that is easier for consumers to understand. We note that, in changing our approach to ''gluten-free'' claims on inherently gluten free foods we are making a determination that, in many situations ''gluten-free'' labeling is unlike the ''free'' labeling claims (nutrient content

claims) made for foods inherently free of calories, nutrients such as sodium or fat, and other food substances such as cholesterol (see 21 CFR 101.13(e)(2) and 72 FR 2795 at 2802). The general rationale behind the labeling of ''free'' claims is that, as we explained in the preamble to the proposed rule, ''[i]f a single brand of food inherently free of the substance that is the subject of its 'free' labeling claim does not also include additional qualifying language, consumers may mistakenly assume that only the particular brand of the food is free of the substance and may not understand that other brands of the same type of food that do not make the 'free' labeling claim are also free of the substance'' (See id.). As noted previously, some comments challenged the logic of that rationale in the context of gluten-free labeling and indicated that firms did not want to make representations as to the gluten-free status of products outside of their control, because it could result in adverse health consequences to consumers. We concur with these comments.

We have removed proposed § 101.91(b)(2) and its subparagraphs (i) and (ii), and we reorganized the final rule to include § 101.91(a)(3)(i)(B) stating that the definition applies if the food inherently does not contain gluten and, as stated in § 101.91(a)(3)(ii), any unavoidable presence of gluten in the food is below 20 ppm gluten.

3. Compliance (§ 101.91(c))

Proposed § 101.91(c) would indicate that, when compliance is based on an analysis of a food, we would ''use a method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.'' In the 2011 notice, we stated our tentative conclusion that the analytical methods we would use to assess compliance with the < 20 ppm gluten content ''should be specified in codified language'' (76 FR 46671 at 46673). However, the 2011 notice also stated that we recognized that some food matrices, such as fermented or hydrolyzed foods, may lack currently available scientifically valid methods that can be used to accurately determine if these foods contain < 20 ppm gluten (id.). In such cases, we indicated that we were considering whether to require manufacturers of such foods to have a scientifically valid method that will reliably detect gluten at 20 ppm or less before including a ''gluten-free'' claim in the labeling of their foods.

(Comment 21) Several comments addressed whether the final rule should specify the analytical methods we would use to assess compliance. In general, the comments advised against specifying analytical methods in the rule. One comment, for example, said that a number of adverse effects could result, including:

- The possibility that the analytical methods we chose would become outdated quickly. The comment indicated that there are two or more additional commercially available test kits that offer peer reviewed performance that is at least equivalent to the analytical methods (the ELISA R5-Mendez Method and the Morinaga method) we had identified in the 2011 notice (76 FR 46671 at 46672).
- Limiting the testing options for food manufacturers and regulatory and commercial laboratories. The comment expressed concern that identifying specific analytical methods in the final rule could result in problems when a specific kit becomes unavailable on a temporary basis or if the kit was changed or removed from market for any reason.
- Limiting our flexibility to use improved technology as it becomes available and dissuading test kit manufacturers from developing improved methods.

Another comment supported our selection of the ELISA R5-Mendez Method, but stated that ''analysts should be free to use any method that provides comparable results'' and that ''other methods may be equivalent.'' Another comment urged us to ''remain flexible as to the method of test validation'' and added that not specifying analytical methods would ''permit a more rapid development of dependable and affordable technologies for testing gluten.'' Additional comments recommended that FDA develop performance criteria rather than identify particular analytical methods to enable the widest choice among gluten-detection methods that the Agency and other entities could consider using to determine compliance with a ''gluten-free'' claim. However, the comments did not provide any data or information on performance criteria that FDA should consider.

(Response 21) Upon further consideration, we agree that specifying the analytical methods in the final rule could limit our flexibility and possibly deter the development of new and better analytical methods. We also note that specifying the analytical methods we would use for compliance purposes, as part of the final rule, would not be binding on food manufacturers because neither the proposed rule nor this final rule requires them to use the same analytical methods to determine the gluten content. To the extent that food manufacturers or other interested parties want to know the specific scientifically valid method we intend to consider using when determining compliance, we can identify this method through other means (such as through a guidance document).

If we were to specify analytical methods in the final rule that FDA is to use to determine compliance with the final rule, and the methods are revised, we would have to, by regulation, change the methods specified in the rule. The revisions to the methods may be more than a technical change and require notice and comment rulemaking. As one comment recognized, if we had to engage in rulemaking to revise or update analytical methods, we would run the risk that the analytical methods specified by regulation would become outdated or obsolete quickly (especially if the methods were revised or updated frequently) and that we would deter the development of better test methods. We have, however, revised § 101.91(c) by inserting ''scientifically valid'' before ''method'' to make clear that we will use a scientifically valid method for purposes of compliance testing.

As for the comments regarding the use of performance criteria, the comments did not provide any data and information on which the Agency could rely to support such an approach. Therefore, we are not making changes in response to this comment.

(Comment 22) Many comments discussed how manufacturers might comply with the rule. The comments asked that we require foods (including oats) to be ''certified'' or verified that they do not contain 20 ppm or more gluten and to meet all other FDA requirements for a gluten-free food before being labeled ''gluten-free.'' The comments argued that certification would provide assurance that foods bearing this claim do not contain levels of gluten at or above 20 ppm. Many comments expressed the concern that cross-contact with gluten-containing ingredients could result in the inadvertent presence of gluten in a food labeled ''gluten-free.''

(Response 22) We decline to revise the rule to require certification that foods comply with the definition and requirements regarding a ''gluten-free'' claim. Under sections 403(a)(1) and 201(n) of the FD&C Act, manufacturers must ensure that all statements they include on their food labels are truthful and not misleading. The final rule defines the term ''gluten-free,'' but does not require manufacturers to use a

particular test methodology or to certify their products.

Additionally, given the range of food products and methods of manufacturing, it would be impractical and an inefficient use of our resources for us to require, through regulation, a precise manner in which manufacturers must or should certify or verify the gluten content of their products. Manufacturers are free to develop their own methods that best suits their particular needs to determine the gluten content of their products. In addition, other methods may be used for quality control, specifications, contracts, surveys, and similar non-regulatory functions. Some companies may choose, but are not required, to have third parties certify or verify the gluten content of their product to ensure their products labeled as ''gluten-free'' are within the definition of ''gluten-free.''

4. Miscellaneous Comments

Several comments addressed matters that were not specific to a particular provision in the proposed rule or issues not covered by the rule. We address those comments here.

(Comment 23) In the preamble to the proposed rule, we recognized that even those foods that comply with the proposed definition of ''gluten-free'' nonetheless could contain some amount of gluten up to 20 ppm (72 FR 2795 at 2803). We questioned whether the potential presence of some gluten below 20 ppm would be a material fact that would make a ''gluten-free'' claim potentially misleading. We invited comments on whether the use of additional qualifying language (e.g., ''does not contain 20 ppm or more gluten per gram of food'') would be necessary to inform individuals with celiac disease that a food labeled as ''gluten-free'' nonetheless may contain the amount of gluten permitted under whatever threshold level is established in the final rule. The 2011 notice repeated the invitation for comments and provided an example of such qualifying language in the form of ''a possible asterisk after the term 'gluten-free' and an associated statement that says, e.g., 'does not contain 20 ppm or more gluten' '' (76 FR 46671 at 46675).

We received comments both supporting and opposing the addition of language to indicate that foods labeled ''gluten-free'' could have the potential presence of less than 20 ppm gluten in the product. Comments supporting the inclusion of this language on the label explained that this would inform consumers about the meaning of the ''gluten-free'' claim. Many comments indicated that the public should receive truth in labeling and therefore the label should indicate the presence of even trace amounts of gluten.

In contrast, comments opposing the additional qualifying language stated that it would likely confuse consumers without providing any additional benefits. One comment noted that there appears to be no other health-related claims (e.g., fat-free, sugar-free, low-sodium) that define or further qualify the regulatory definition via additional labeling statements and that ''a good labeling regulation does not distort a valid, established public health standard.'' In addition, some comments suggested the additional language could discourage manufacturers from making a ''gluten-free'' claim on products that are inherently gluten-free and produced under cGMPs. The comments said that manufacturers whose foods had gluten content well below 20 ppm could refrain from labeling their food as ''gluten-free'' because the qualifying language could mislead consumers into assuming most products contain the maximum levels of gluten.

(Response 23) We agree with the comments opposing the use of qualifying language to inform individuals with celiac disease that a food labeled as ''gluten-free'' nonetheless may contain less than 20 ppm of gluten because the final rule defines the criteria and requirements for the ''gluten-free'' labeling claim. The lawful use of the federally defined term ''gluten-free'' on a food label will inform both consumers and industry of the fact that the food bearing the ''gluten-free'' claim may not contain 20 ppm or more gluten. Education and outreach programs will be important to ensure that individuals with celiac disease and other consumers understand the definition and the changes set forth by these regulations.

We also agree with the comment that additional qualifying language that would, in effect, restate § 101.91(a)(3) would be inconsistent with other FDA regulated labeling claims (e.g., fat-free, sugar-free) that define the term without the need to further qualify that regulatory definition elsewhere on the label.

We also agree with the comments suggesting that additional qualifying language could create a disincentive for manufacturers to make a ''gluten-free'' claim. For example, if a manufacturer's food had less than 5 ppm gluten, but the final rule would require the manufacturer to state ''does not contain 20 ppm or more gluten'' in addition to the ''gluten-free'' claim, the manufacturer might decide to remove the ''gluten-free'' claim rather than risk creating the misimpression that its food contained up to 20 ppm gluten. Additionally, if a manufacturer could improve its manufacturing or processing operations to create a food with less than 5 ppm gluten, but the final rule would require the statement of ''does not contain 20 ppm or more gluten,'' the manufacturer might decide to forego those improvements because the statement would only refer to ''20 ppm or more gluten.'' Requiring the additional qualifying language, therefore, could result in fewer ''gluten-free''-labeled foods being available and limit the ability of individuals with celiac disease to follow a gluten-free diet.

We do not agree with the comments supporting the additional qualifying language. While we acknowledge the desire of some consumers to know the exact gluten content of foods, we adopted an analytical methods-based approach, with a threshold level of 20 ppm gluten, because we determined that this level is appropriate, enforceable, and practical after considering multiple types of information, including the scientific literature on the sensitivity of consumers with celiac disease and information on the methods available to reliably detect and quantify gluten in a wide variety of foods.

Therefore, the final rule does not require the use of additional qualifying language (e.g., ''does not contain 20 ppm or more gluten'') to inform individuals with celiac disease that a food labeled as ''gluten-free'' nonetheless may contain less than 20 ppm gluten.

(Comment 24) A few comments asked about the inclusion of wheat starch in foods labeled ''gluten-free.'' Proposed § 101.91(a)(3)(iii) would allow a food to bear a ''gluten-free'' claim provided that any ingredient that is derived from a prohibited grain has been processed to remove gluten (e.g., wheat starch), if the use of the ingredient does not result in the presence of 20 ppm or more gluten in the finished food. Wheat starch is an ingredient derived from wheat (a gluten containing grain) that has been processed to remove gluten. As discussed in our response to comment 17 (regarding a < 20 ppm gluten content level applied to individual ingredients), a comment suggested that if ingredients derived from gluten-containing grains must be used, and if the food complies with the maximum gluten content of < 20 ppm, market practice will impose the same requirement at the ingredient level (in other words, ingredient purchasers will require that the ingredients contain less than 20 ppm gluten). Several comments submitted by

individuals with celiac disease indicated that they would not purchase a product that included the term ''wheat'' within the ingredient list. The comments noted that because wheat is considered a ''major food allergen'' under FALCPA the term wheat could appear either in the list of ingredients or in a separate ''Contains wheat'' statement near the list of ingredients. One comment said that if wheat must be identified on the label of a food that also bears a ''gluten-free'' claim, consumers will not be able to determine whether the food is appropriate for them to consume and will have to avoid the food. The comment suggested that the result would be an unnecessary restriction in an already restrictive diet and also suggested that individuals with celiac disease will receive a confusing message that wheat starch in food labeled ''gluten-free'' is acceptable, but wheat starch in other foods must be avoided.

(Response 24) We agree that individuals with celiac disease would receive a confusing message if foods bearing a ''gluten-free'' claim also include the term ''wheat'' in the ingredient list or in a ''Contains'' statement, as required by FALCPA (Ref. 34). Although we were unable to identify many products bearing a ''gluten-free'' claim that also have the term ''wheat'' appearing in the ingredient list, a food may bear both a ''Contains wheat'' statement under § 101.91(b)(3) of the final rule and a ''gluten-free'' claim or a claim identified in § 101.91(b)(2) of the final rule and be in compliance with both section 203 of FALCPA (regarding food labeling for allergenic substances) and the ''gluten-free'' label regulation arising from section 206 of FALCPA. In such situations, § 101.91(b)(3) requires that the labeling also bear the statement that ''The wheat has been processed to allow this food to meet FDA requirements for gluten-free foods,'' preceded by an asterisk (*) or other symbol that links this statement to the word ''wheat,'' either in the ingredient list or the ''Contains wheat'' statement, depending on how the allergen declaration is made. Without this statement, a food that identifies the presence of wheat either in the ingredient statement or in a ''Contains wheat'' statement under § 101.91(b)(3) and bears a ''gluten-free'' claim under § 101.91(a)(3)(i)(A)(*3*) will be deemed misbranded.

We also included ''or a claim identified in paragraph (b)(2) of this section'' in § 101.91(b)(3) to clarify that this disclaimer is also needed when a food bears the term ''wheat'' in the ingredient list or a separate ''Contains wheat'' statement and also contains a ''no gluten,'' ''free of gluten,'' or ''without gluten'' claim.

(Comment 25) The preamble to the proposed rule acknowledged that at least one other regulatory body outside the United States has developed a two-tiered approach to gluten-related food labeling (72 FR 2795 at 2804). Australia and New Zealand have established standards for ''gluten-free'' (meaning no detectable gluten) and a less restrictive standard for ''low-gluten'' (meaning no more than 20 mg gluten per 100 g of the food, which is equivalent to no more than 200 ppm gluten in the food) (Ref. 28). The preamble to the proposed rule also discussed the possible development of a similar 2-tiered approach to gluten-related food labeling in the United States (72 FR 2795 at 2811 through 2812). At the time we issued the proposed rule, we tentatively had concluded that a two-tiered approach was not feasible because we do not have sufficient scientific data to recommend a specified level of gluten to define the term ''low gluten.'' We invited comments on this tentative conclusion, including comments on a possible scientific basis for setting a level of gluten to be defined as ''low gluten.''

Several comments addressed the issue of ''low-gluten,'' ''very low-gluten'' or other tiered gluten labeling claims. Most comments opposed tiered gluten labeling claims. The comments agreed with us that there is no scientific basis for these claims and such claims would not benefit individuals with celiac disease. For example, many comments noted a preference for a single definition of ''gluten-free,'' stating that a dual definition of ''gluten-free'' and ''low-gluten'' would be confusing. The comments suggested that terms implying various gluten content levels may confuse individuals with celiac disease who are advised to follow a gluten-free diet rather than one that is low in gluten or gluten-reduced. Comments opposed to the use of ''low-gluten'' claims or tiered gluten labeling also expressed concerns that these other claims may influence individuals with celiac disease to substitute such foods for foods labeled ''gluten-free'' and thereby jeopardize their health.

Other comments said we should establish a tiered gluten labeling system allowing individuals with celiac disease, especially those very sensitive to gluten, to distinguish between foods that do not have any gluten and those that contain a trace amount of gluten. Most comments expressing this opinion favored defining ''gluten-free'' to mean either zero, no detectible, or < 5 ppm gluten and defining the term ''low-gluten'' to mean a greater amount of gluten than allowed for a ''gluten-free'' food, but no more than 20 ppm (e.g., < 5 ppm or < 10 ppm for a ''low-gluten'' claim). Some comments said we should consider allowing ''low-gluten'' claims consistent with those used in other countries. Several comments expressed support for the two-tiered gluten labeling system in effect in Australia and New Zealand. One comment suggested the term ''celiac safe'' to mean < 20 ppm and another comment suggested the terms ''Gluten-0'' for no gluten, ''Gluten-5'' or ''Lo Gluten 5'' for no more than 5 ppm gluten, and ''Gluten-20'' or ''Lo Gluten 20'' for no more than 20 ppm gluten).

(Response 25) We decline to define the terms ''low-gluten,'' ''very-low gluten,'' or other terms mentioned by the comments or to adopt a tiered gluten labeling system. We agree with comments that stated that tiered labeling claims would likely be confusing to those with celiac disease if there was a proliferation of ''low-gluten'' or ''very-low-gluten'' claims on food labels. With respect to the other terms suggested by the comments, we continue to lack a scientific foundation for developing definitions for these terms. We also decline to define terms for gluten content below 20 ppm because, as of the date of this final rule, given the current unavailability of appropriate test methods that can reliably and consistently detect gluten at levels below 20 ppm.

Because it is currently not known what amount of gluten would be appropriate for foods bearing a ''low-gluten'' or a ''very-low-gluten'' claim, we have decided only to define ''gluten-free'' as described in § 101.91(a)(3).

(Comment 26) Many comments asked that we require the labels of food bearing a ''gluten-free'' claim to state on the label the total amount of gluten contained in the food (e.g., based upon a gluten analysis of the food). Some comments suggested that we require food labels to declare the amount of gluten present per serving of food in the Nutrition Facts label. Some comments asserted that consumers want to be able to compare ''gluten-free''-labeled foods and choose those with the lowest gluten content to reduce their potential health risks or to estimate their total daily cumulative gluten intake as a way to manage their gluten-free diet. Some comments stated that many consumers do not understand the meaning of a < 20 ppm gluten criterion for a ''gluten-free'' food. Other comments argued that this information is necessary for the label to be truthful and not misleading, or that consumers view the declaration

of gluten within the Nutrition Facts label to be consistent with the manner in which we require nutrients to be declared on food labels.

(Response 26) We decline to require an analysis of the food and resulting declaration on the label of the total amount of gluten contained in a food bearing a ''gluten-free'' claim as discussed in our response to comment 4. Declaring the results of such testing would not be consistent with the purpose of developing a consistent definition of the term ''gluten-free'' to mean that the food contains < 20 ppm gluten and conforms to the final rule's other elements.

To the extent comments seek to add a gluten declaration as part of the Nutrition Facts label, such a request is outside the scope of this rule. However, whether or not a ''gluten-free'' labeling claim is made, we will not object if manufacturers voluntarily provide the amount of gluten present in their food elsewhere on the food label, as long as such a statement is truthful and not misleading. Such voluntary information must comply with all other rules regarding labeling.

(Comment 27) Several comments requested that we permit ''gluten-free'' claims on foods in the form in which they are consumed rather than foods as packaged. The comments noted that certain foods (e.g., dried soup mixes), when prepared according to package directions (e.g., prepared with water), would meet the definition of a ''gluten-free'' food.

In contrast, other comments stated that a ''gluten-free'' claim should apply to the food ''as packaged'' instead of the food ''as prepared.'' The comments said that individuals with celiac disease might consume a food bearing a ''gluten-free'' claim in ways other than those specified in the preparation directions. The comments wanted the assurance that foods, ''as packaged'' and bearing a ''gluten-free'' claim, meet all FDA requirements for a ''gluten-free'' food.

(Response 27) The ''gluten-free'' claim applies to foods ''as packaged'' and not ''as prepared'' according to package directions. This requirement is consistent with our other statutory labeling requirements and implementing regulations. While we understand that setting the criteria for ''gluten free'' claims based on a food ''as packaged'' may not allow certain foods to bear a ''gluten-free'' claim, we agree that some individuals with celiac disease who purchase ''gluten-free'' labeled foods may wish to consume those foods in ways other than those stated in the package directions. For example, instead of reconstituting a dried soup mix according to instructions, a consumer may wish to use that mix in a concentrated form to flavor other foods or to prepare a vegetable dip. If a food sold in a concentrated form were dependent upon food preparation using package directions to ensure the prepared food conforms to this final rule and contains less than 20 ppm gluten, errors in preparation or alternative use of the packaged food product could result in persons with celiac disease consuming foods with gluten content higher than that permitted by our definition of ''gluten-free.''

(Comment 28) Some comments expressed concern that individuals with celiac disease also are exposed to gluten in drugs, dietary supplements, or cosmetics. A few comments wanted us to develop a rule that would be applicable to the labeling of drugs, dietary supplements, and cosmetics in addition to foods.

(Response 28) The final rule does apply to dietary supplements. We are issuing the final rule under FALCPA. FALCPA's requirements apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. Section 201(ff) of the FD&C Act states that ''Except for purposes of section 201(g) [definition of drug], a dietary supplement shall be deemed to be a food within the meaning of this Act.'' Accordingly, the final rule applies to dietary supplements. The use of a ''gluten-free'' claim in food labeling including the labeling of dietary supplements is voluntary and does not replace or eliminate any other labeling requirements.

Requirements related to ''gluten-free'' labeling on drugs and cosmetics are outside the scope of this rule. We note that, in the **Federal Register** of December 21, 2011, we published a notice inviting information and comments about ways to help individuals with celiac disease avoid the presence of gluten in drug products (76 FR 79196). The notice also invited information on ingredients in human drug products that are currently derived from wheat, barley, or rye. The comment period closed on March 20, 2012, and FDA's Center for Drug Evaluation and Research is reviewing those comments. As for cosmetics, should we receive data or information indicating that cosmetics present a concern for individuals with celiac disease, we may consider whether further action is warranted.

Additionally, we wish to clarify that this rule pertains to food intended for human use. Although we are aware of gluten claims with respect to food intended for animals, our rulemaking activities have focused on defining the term ''gluten-free'' in a manner that would help humans concerned about managing the gluten in their diet.

(Comment 29) A few comments asked how our definition of ''gluten-free'' would apply to individuals who have an immunoglobulin E-mediated (IgE-mediated) food allergy to wheat, or other non-celiac disease conditions related to consumption of gluten. The comments asked us to consider their needs in defining ''gluten-free.''

(Response 29) We considered a number of factors, including the needs of individuals who have a food allergy to wheat or are sensitive to gluten, in developing this final rule. We are issuing the final rule under, in part, section 206 of FALCPA. In general, FALCPA's requirements apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. Additionally, section 203 of FALCPA requires food manufacturers to declare, on the label, if a product contains an ingredient that is one of the eight major food allergens or that contains protein from a major food allergen.

The use of ''gluten-free'' on a food label is voluntary and does not replace or eliminate any other labeling requirements. Therefore, any food containing an ingredient that is a major food allergen under section 201(qq) of the FD&C Act must declare the presence of that ingredient as described in section 403(w)(1) of the FD&C Act.

As we discussed in our response to comment 24, the labeling of wheat as a major food allergen would present the potential for confusion with the ''gluten-free'' claim. Rather than prohibit the use of the ''gluten-free'' claim on products that have used ingredients derived from wheat that have been processed to remove gluten and comply with the definition of ''gluten-free,'' and considering the potential for individuals with an IgE-mediated wheat food allergy to experience adverse health effects in response to servings of food containing residual wheat protein levels below 20 ppm, we have added another requirement for additional qualifying language in § 101.91(b)(3) of the final rule. Section 101.91(b)(3) provides that a food that bears the term ''wheat'' in the ingredient list or in a separate ''Contains wheat'' statement in its labeling as required by section 403(w)(1)(A) of the FD&C Act and also bears the claim ''gluten-free'' will be deemed misbranded unless its labeling

also bears additional language (set forth in the rule) clarifying that the food complies with FDA requirements for a ''gluten-free'' claim.

(Comment 30) A few comments addressed farmers, food companies, and restaurants making ''gluten-free'' claims about their grains/crops, food products, or menu items, respectively. The comments were concerned that these foods could contain gluten due to common cross-contact situations. Other comments expressed the concern that food service personnel may not be thoroughly trained and knowledgeable about the need to segregate gluten-free and non- gluten-free products, and the dietary needs of the celiac population.

(Response 30) Under the final rule, manufacturers making a ''gluten-free'' claim on their labeling must ensure that such foods, in addition to meeting the other criteria, do not contain 20 ppm or more gluten, including the unavoidable presence of gluten due to gluten cross-contact situations or migration from packaging materials.

With respect to restaurants, FDA guidance suggests that any use of an FDA-defined food labeling claim (e.g., ''fat free'' or ''low cholesterol'') on restaurant menus should be consistent with the respective regulatory definitions (Ref. 35).

As for food service personnel, issues regarding the training of food service personnel are beyond the scope of this rulemaking.

(Comment 31) A few comments asked if we intend to issue guidance to industry regarding ''gluten-free'' labeling.

(Response 31) Section 206 of FALCPA directs us to engage in rulemaking to define and permit the use of the term ''gluten-free'' on the labeling of foods. We anticipate that manufacturers wishing to label their products as ''gluten-free'' will be able to understand and comply with the final rule without difficulty. We intend to issue guidance about the ELISA-based methods (Refs. 36 and 37) FDA will use when analysis of a food would be necessary in order to determine regulatory compliance with FDA's definition of ''gluten-free'' for a food bearing such a labeling claim. If, upon further experience with the rule, we find that it would be helpful to issue additional guidance, whether such guidance would be directed at industry or at FDA itself (such as discussion of a new test method), we will consider developing such guidance.

(Comment 32) Some comments urged that we fund research to learn more about potential treatment for celiac disease beyond the avoidance of gluten or about oat sensitivity in some people with celiac disease. Other comments suggested we also support research to determine the impact of low levels of gluten in gluten-sensitive individuals.

(Response 32) Although we agree that these issues are of interest to FDA, the funding of any research activities is beyond the scope of this rulemaking. The final rule is limited to defining the term ''gluten-free'' and to describing how such a claim is permitted in the labeling of foods.

(Comment 33) Several comments expressed concerns about foods containing some level of gluten due to contact with gluten sources (i.e., through cross-contact), and suggested that we require specific manufacturing conditions for foods bearing a ''gluten-free'' claim. In the context of this rule, cross-contact occurs when a food without gluten comes in contact with a gluten-containing food or ingredient, resulting in the presence of gluten in the food not intended to contain gluten. The comments suggested that multi-product facilities do not have sufficient means to minimize the introduction of gluten in products and therefore believed that these foods could not be without gluten. The comments suggested the use of dedicated facilities or dedicated production lines to exclude the unavoidable contact with gluten with foods bearing a ''gluten-free'' claim.

Some comments were particularly concerned that foods inherently free of gluten (e.g., rice or dried fruits) could be processed in facilities or on equipment that also manufacture gluten-containing foods. Because of cross-contact concerns, these comments requested that we require foods bearing a ''gluten-free'' claim to be manufactured on equipment or in facilities that only produce foods that are inherently free of gluten. Some comments asked that we require, when appropriate, that foods labeled ''gluten-free'' also disclose on the label that they were not produced in dedicated facilities (i.e. ''this food manufactured in a facility that also processes foods containing gluten''). However, many other comments said these additional label declarations would be useless and frustrating to individuals with celiac disease who are seeking foods for their gluten-free diets. Still other comments noted that products can be produced in mixed product facilities and still comply with the final rule's definitions and requirements through the use of controls designed to avoid cross-contact of foods with gluten sources during food manufacturing.

(Response 33) We agree with the comments stating that manufacturers that adhere to specific manufacturing practices that can prevent gluten cross-contact situations can produce foods that meet the final rule's definition of ''gluten-free.'' The < 20 ppm level is only one of the criteria used to define ''gluten free.'' We determined that this level is appropriate, enforceable, practical, and protective of the public health. We expect foods bearing the ''gluten-free'' claim to be manufactured using whatever controls are necessary to prevent cross-contact with all gluten sources and to ensure that any amount of gluten that may be present in the food from cross-contact is as low as possible and that the food has less than 20 ppm gluten.

We disagree with comments asking us to require labels to disclose whether foods are not produced in dedicated facilities or on dedicated equipment because such a disclosure would suggest that those foods have necessarily come in contact with gluten and do not comply with the definition of ''gluten-free.'' Nevertheless, manufacturers may disclose voluntarily whether their foods are produced in dedicated facilities or on dedicated equipment, provided that such statements are truthful and non-misleading.

We also disagree with comments requesting that we require foods bearing a ''gluten-free'' claim be manufactured on dedicated equipment or in dedicated facilities because limitations due to cost, equipment utilization needs, and space would make it impractical for many manufacturers to produce gluten-free foods. Some data show that large companies are more likely than their medium-size or small-size counterparts to dedicate facilities to avoid cross-contact (Ref. 38). Facilities should be able to avoid cross-contact during production by using, for example, physical barriers (such as walls, curtains, or distance) or air handling as a means of isolating the production line and by cleaning and sanitation of equipment between production runs. Also, the requirement sought by the comments likely would discourage manufacturers from labeling their products as ''gluten-free'' and result in fewer foods labeled ''gluten-free'' available for persons with celiac disease.

Accordingly, the final rule does not require foods bearing a ''gluten-free'' claim to be manufactured in dedicated facilities or on dedicated equipment, or require any form of disclosure on the label that the foods were not produced in dedicated facilities or on dedicated equipment. We expect these facilities to take proper precautions to reduce the potential for cross-contact of food, food ingredients, food-contact surfaces,

finished foods, or food-packaging materials from gluten sources. The potential for this cross-contact may be reduced by adequate controls and operating practices, effective design, and the separation of operations in which such contact is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, cleaning and sanitation, or other effective means.

(Comment 34) Several comments urged us to strictly enforce our rule to ensure that foods bearing a ''gluten-free'' claim comply with the final rule.

(Response 34) We enforce our regulations primarily through inspections of food processing facilities, examination of imports, collection and testing of food products on the market, and imposition of enforcement measures as required to protect consumers. Manufacturers are responsible for ensuring that food bearing a ''gluten-free'' claim is not misbranded for failure to meet the final rule.

(Comment 35) One comment asked how we will enforce the rule against foods already in the marketplace. The comment explained the concern that the consumer will not be able to trust the labeling initially and the rule will be less effective than anticipated.

(Response 35) The final rule becomes effective on September 4, 2013. We recognize that manufacturers of foods currently bearing a ''gluten-free'' claim may need time to review their products to ensure that these foods comply with this final rule, or to remove ''gluten-free'' or similar claims from the label if their foods do not comply. Consequently, we are establishing a compliance date of August 5, 2014.

Although we are issuing the final rule after January 1, 2013, there is sufficient justification for establishing the compliance date of August 5, 2014, to enforce the provisions of this final rule, rather than January 1, 2016, which FDA established as the next uniform compliance date for other food labeling changes for food labeling regulations issued between January 1, 2013, and December 31, 2014 (77 FR 70885; November 28, 2012).

We believe that 12 months from the date of publication is sufficient time for manufacturers to review their products to ensure that these foods comply with this final rule, or to remove ''gluten-free'' or similar claims from the label if their foods do not comply. This period of 12 months is consistent with what FDA has used in the past for compliance with the requirements of voluntary food labeling claims. We believe that waiting until FDA's next uniform compliance date of January 1, 2016, would create an unnecessary delay in the enforcement of this final rule, as foods bearing the voluntary label claim ''gluten-free'' that do not comply with FDA's regulatory definition of ''gluten-free'' could have an adverse public health impact on persons with celiac disease who may be consuming those foods.

Therefore, we are establishing the compliance date to enforce the provisions of this final rule at August 5, 2014. By that time, manufacturers of foods labeled with the ''gluten-free'' claim must comply with the requirements of the final rule.

In the interim, if manufacturers want to use stickers as a short-term measure to amend their labels, we would not object provided that the stickered products are in compliance with all of FDA's labeling requirements. If a manufacturer chooses this option, the sticker should adhere to the package under customary storage conditions throughout the shelf life of the product, and the corrected label must comply with all applicable laws and regulations.

(Comment 36) Some comments expressed concern that distilled vinegar, as a food product or ingredient, could contain gluten. The comments said we should not allow distilled vinegar to be labeled as ''gluten-free.'' Other comments expressed concern about gluten in malt vinegar and malt extract. One comment stated that information contained in the preamble to the proposed rule is contradictory regarding malt vinegar and malt extract. The comment noted that, in some places, the preamble to the proposed rule listed these foods together with wheat starch. The comment said that listing malt vinegar and malt extract with wheat starch could create the misimpression that malt vinegar and malt extract have been processed to remove gluten.

(Response 36) As the comments suggest, there are different types of vinegars. For example, there is distilled vinegar (also known as spirit vinegar or grain vinegar) and other vinegars that are not distilled like cider vinegar (also known as apple vinegar or simply ''vinegar''), wine vinegar (also known as grape vinegar), malt vinegar, sugar vinegar, and glucose vinegar to mention a few. All vinegars undergo a fermentation process during their production, but can be derived from different substances. For example, cider vinegar is made by the alcoholic and subsequent acetous fermentations of the juice of apples; whereas, wine vinegar is made by the alcoholic and subsequent acetous fermentations of the juice of grapes. In addition, as the comments noted, some vinegars may be made from gluten-containing grains, such as malt vinegar, which is the product made by the alcoholic and subsequent acetous fermentations, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt. For a fuller discussion see Food and Drug Administration, Compliance Policy Guide Sec. 525.825, ''Vinegar, Definitions—Adulteration With Vinegar Eels'' (available at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074471.htm*).

As we indicated in our response to comment 14, we intend to issue a proposed rule to address how FDA will evaluate compliance with § 101.91(b) when an evaluation of compliance based on an analysis of the food using a scientifically valid method under § 101.91(c) is not available because the food is fermented or hydrolyzed or contains fermented or hydrolyzed ingredients.

We intend to consider the comments received on vinegars, including distilled vinegar, in that proposed rule.

(Comment 37) Many comments urged FDA to coordinate with the U.S. Department of Agriculture (USDA) so that FDA and USDA have the same standard for foods labeled ''gluten-free.'' Other comments indicated that the same definition of ''gluten-free'' should apply to all foods and that ''gluten-free'' labeling of foods should be mandatory and not voluntary to be protective of individuals with celiac disease.

(Response 37) We have been in contact with both the Food Safety and Inspection Service (FSIS, which is an Agency within USDA) and TTB concerning our gluten-free rulemaking and related issues. USDA regulates the labeling of all poultry, most meats, and certain egg products, and TTB regulates the labeling of most alcoholic beverages. We expect to continue working with both FSIS and TTB on matters relating to use of the term ''gluten-free.''

Regarding the comments to make gluten-free labeling ''mandatory,'' section 206 of FALCPA directed us to establish a definition for the term ''gluten-free'' and ''permit'' use of this term in the labeling of food. We consider the use of the word ''permit'' instead of ''require,'' to mean that manufacturers may, but are not required to, label their food products ''gluten-free'' provided that they comply with our rule.

III. What is the legal authority for this rule?

We received no comments on the legal basis, as set forth in the proposed

rule, to define the term ''gluten free'' for voluntary use in the labeling of foods.

Consistent with section 206 of FALCPA and sections 403(a)(1), 201(n), and 701(a) of the FD&C Act, we are issuing requirements for the use of the term ''gluten free'' for voluntary use in the labeling of foods. A food bearing the claim ''gluten-free'' that does not conform to the requirements in the final rule would result in the food being misbranded within the meaning of sections 403(a)(1) and 201(n) of the FD&C Act.

We include requirements in § 101.91(b)(2) of the final rule for the use of the terms ''no gluten,'' ''free of gluten,'' and ''without gluten'' in the labeling of food in order for such food to not be misbranded under sections 403(a)(1) and 201(n) of the FD&C Act. Specifically, food that bears such a claim in labeling must meet the requirements for the use of the ''gluten-free'' claim because the use of ''no,'' ''free of,'' and ''without'' gluten connote the same meaning to consumers as ''gluten-free'' (Ref. 32). Thus, it would be misleading to consumers to use such terms if the food bearing the claim did not meet the same requirements as a food bearing a ''gluten-free'' claim.

In addition, § 101.91(b)(3) of the final rule requires a food that bears a ''gluten-free'' claim (as well as a ''no gluten,'' ''free of gluten,'' or ''without gluten'' claim) in addition to a statement regarding wheat content on the label required by section 403(w) of the FD&C Act, to also bear additional language to clarify that the wheat has been processed to allow this food to meet FDA requirements for a gluten-free food in order for the food not to be misbranded under sections 403(a)(1) and 201(n) of the FD&C Act. Because consumers would see two seemingly contradictory terms in the labeling based on separate statutory and regulatory requirements for each, this additional language is necessary to prevent consumers from being misled (Ref. 32).

The legal basis for federal preemption is discussed in the Federalism section, section VII.

IV. Analysis of Impacts—Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 39) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2005–N–0404). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available at *http://www.regulations.gov.* We believe that the final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity of this final rule are small, but not negligible, and as a result we conclude that the final rule could have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The analyses that we have performed to examine the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 39).

V. How does the Paperwork Reduction Act of 1995 apply to this final rule?

We conclude that the labeling provisions of this final rule set forth in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the ''gluten-free'' labeling claims are ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. What is the environmental impact of this rule?

We have determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. What are the federalism impacts of this rule?

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of Executive Order 13132 requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Here, we have determined that certain narrow exercises of State authority would conflict with the exercise of Federal authority under the FD&C Act.

In section 206 of FALCPA, Congress directed us to issue a proposed rule to define and permit use of the term ''gluten-free'' on the labeling of foods, in consultation with appropriate experts and stakeholders, to be followed by a final rule for the use of such term in labeling. In the preamble to the proposed rule (72 FR 2795 at 2813 through 2814), we proposed preemption of State requirements and indicated that we had consulted with numerous experts and stakeholders in the proposed rule's development. Different and inconsistent amounts of gluten in foods with ''gluten-free'' labeling result in the inability of those individuals with celiac disease who adhere to a gluten-free diet to avoid exposure to gluten at levels that may result in adverse health effects. There is a need for national uniformity in the meaning of the term ''gluten-free'' so that most individuals with celiac disease can make informed purchasing decisions that will enable them to adhere to a diet they can tolerate without causing adverse health effects and can select from a variety of available gluten-free foods. If States were able to establish different definitions of the term ''gluten-free,'' then individuals with celiac disease would not be able to rely on that term to understand the amount of gluten the food may contain and thereby use the

term to identify appropriate dietary selections. As a result, individuals with celiac disease may unnecessarily limit their food choices, or conversely, select foods with levels of gluten that are not tolerated and that may cause adverse health effects. Food manufacturers, if confronted by a State or various State requirements that adopted a different gluten threshold than what the final rule establishes, might decide to remove the ''gluten-free'' label, and such a result would make it more difficult for individuals with celiac disease to identify foods that they can tolerate and achieve a dietary intake from a variety of foods to meet an individual's nutrient needs. Moreover, a consistent definition of ''gluten-free'' enables the Agency to more efficiently enforce the definition across all foods through the use of a reliable scientifically valid method to detect gluten and ensure labels bearing a ''gluten-free'' claim are truthful and not misleading.

Therefore, the objective of this rule is standardizing use of the term ''gluten-free'' in the labeling of foods so that foods with this claim in labeling, and foods with a claim of ''no,'' ''free of,'' and ''without'' gluten, which connote a similar meaning to that of ''gluten free,'' are used in a consistent way and will therefore prevent consumer confusion and assist individuals with celiac disease to make purchasing decisions.

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the ''minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.'' The final rule meets the preceding requirement because it preempts State law narrowly, only to the extent required to achieve uniform national labeling with respect to the requirements related to the use of the term ''gluten-free,'' as well as the terms ''no gluten,'' ''free of gluten,'' or ''without gluten.'' As we explain later in this section, we are preempting State or local requirements only to the extent that they are different from the requirements in this section related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten.'' In addition, we cannot foresee every potential State requirement and preemption may arise if a State requirement is found to obstruct the federal purpose articulated in this rule. We do not intend the final rule to preempt other State or local labeling requirements with respect to other statements or warnings about gluten. For example, a State would not be preempted from requiring a statement about the health effects of gluten consumption on persons with celiac disease or information about how the food was processed.

Section 4(d) of Executive Order 13132 states that when an Agency foresees the possibility of a conflict between State law and federally protected interests within the Agency's area of regulatory responsibility, the Agency ''shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.'' Section 4(e) of Executive Order 13132 provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA's Division of Federal and State Relations invited the States' participation in this rulemaking by providing notice via fax and email transmission to State health commissioners, State agriculture commissioners, and State food program directors as well as FDA field personnel of the publication of the proposed rule. The notice gave the States further opportunity for input on the rule, advised the States of FDA's possible action, and encouraged State and local governments to provide any comments. We did not receive any comments from State or local authorities.

After we had published the proposed rule in the **Federal Register**, the President issued a memorandum entitled ''Preemption'' (74 FR 24693 (May 22, 2009)). The memorandum, among other things, instructs Agencies to ''not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation'' and ''not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132'' (id.).

Because of the May 22, 2009, memorandum and because the final rule differs from the proposed rule in several respects, we explain in detail here the principles underlying our conclusion that the final rule may result in preemption of State and local laws under a narrow set of circumstances and describe the final rule's codified provision regarding preemption.

Under the Supremacy Clause of the Constitution (U.S. Constitution; Art. VI, clause 2), State laws that interfere with or are contrary to Federal law are invalid. (See *Gibbons* v. *Ogden,* 22 U.S. (9 Wheat.) 1, 211 (1824).) Federal preemption can be express (stated by Congress in the statute) or implied. Implied preemption can occur in several ways. For example, Federal preemption may be found where Federal law conflicts with State law. Such conflict may be demonstrated either when ''compliance with both federal and state [law] is a physical impossibility'' (*Florida Lime and Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142–143 (1963)), or when State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'' (*Crosby* v. *Nat'l Foreign Trade Council,* 530 U.S. 363, 372–74 (2000) (citing *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941))). State law is also preempted if it interferes with the methods by which a Federal law is designed to reach its goals. (*See International Paper Co.* v. *Ouellette,* 479 U.S. 481, 494 (1987); *Michigan Canners & Freezers Ass'n* v. *Agricultural Marketing & Bargaining Bd.,* 467 U.S. 461, 477–478 (1984).)

Additionally, '' 'a federal agency acting within the scope of its congressionally delegated authority may preempt state regulation' and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law'' (*City of New York* v. *FCC,* 486 U.S. 57, 63–64 (1988) (quoting *Louisiana Public Service Comm'n* v. *FCC,* 476 U.S. 355, 369 (1986)). ''Federal regulations have no less preemptive effect than federal statutes'' (*Fidelity Federal Savings and Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982)).

When an Agency's intent to preempt is clearly and unambiguously stated, a court's inquiry will be whether the preemptive action is within the scope of that Agency's delegated authority (*Capital Cities Cable, Inc.* v. *Crisp,* 467 U.S. 691, 700 (1984); *Fidelity Federal Savings,* 458 U.S. at 154). If the Agency's choice to preempt ''represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute [the regulation will stand] unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned'' (*United States* v. *Shimer,* 367 U.S. 374, 383 (1961)). In *Hillsborough County,* the Supreme Court stated that FDA possessed the authority to promulgate regulations preempting local laws that compromise the supply of plasma and could do so (*Hillsborough County, Fla.* v. *Automated Medical Laboratories, Inc.,* 471 U.S. 707, 721 (1985)). We believe we have similar authority to preempt State and local laws and regulations to the limited extent that they define and permit use of ''gluten-

free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' differently from our final rule because different State or local requirements would be contrary to the Congressional directive for us to define and permit use of the term ''gluten-free.''

State or local laws or regulations that define and permit use of ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' differently from our final rule could frustrate the ability of most consumers to identify gluten-free foods and avoid adverse health effects and deter manufacturers from applying a ''gluten-free'' label to their foods. As discussed previously, currently, individuals with celiac disease do not know what the term ''gluten-free'' on a product means because there is no consistent or established definition of ''gluten-free'' in the United States. For example, a product currently labeled gluten-free could contain 10 ppm gluten or 100 ppm gluten. Therefore, consumers with celiac disease cannot have confidence to identify and purchase gluten-free products they can tolerate and that can provide a variety of foods in their diets. With a uniform federal definition, consumers throughout the United States can understand what the term ''gluten-free'' means on a packaged food. A uniform definition of gluten-free will also allow the Agency to more efficiently enforce the definition on product labels and manufacturers will be able to comply with a single set of requirements which may lead to greater use of this voluntary labeling. Consequently, we have added a new § 101.91(d) entitled ''Preemption'' to the final rule. Section 101.91(d) declares that a State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in § 101.91 for the definition and use of the term ''gluten-free,'' as well as the terms ''no gluten,'' ''free of gluten,'' or ''without gluten.'' Preemption may also arise with regard to other labeling language regarding gluten if a state requirement is found to obstruct the federal purpose articulated in this rule.

VIII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified all the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. National Institutes of Health (NIH), NIH Consensus Development Conference on Celiac Disease, ''National Institutes of Health Consensus Statement on Celiac Disease,'' NIH, Bethesda, MD, pp. 1–15, June 28–30, 2004, available at *http://consensus.nih.gov/2004/2004CeliacDisease118PDF.pdf.*
2. Shan, L., O. Molberg, I. Parrot, et al., ''Structural Basis for Gluten Intolerance in Celiac Sprue,'' *Science,* 297:2275–2279, 2002.
3. Jabri, B., D.D. Kasarda, and H.R Green, ''Innate and Adaptive Immunity: The Yin and Yang of Celiac Disease,'' *Immunological Reviews,* 206:219–231, 2005.
4. National Digestive Disease Information Clearinghouse, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (NIH), ''Celiac Disease,'' NIH Publication No. 08–4269, September 2008, available at *http://digestive.niddk.nih.gov/ddiseases/pubs/celiac/.*
5. Dewar, D., S.P. Pereira, and P.J. Ciclitira, ''The Pathogenesis of Coeliac Disease,'' *International Journal of Biochemistry and Cell Biology,* 36:17–24, 2004.
6. Fasano, A. and C. Catassi, ''Current Approaches to Diagnosis and Treatment of Celiac Disease: An Evolving Spectrum,'' *Gastroenterology,* 120(3):636–651, 2001.
7. Farrell, R.J. and C.P. Kelly, ''Celiac Sprue,'' *New England Journal of Medicine,* 346(3):180–188, 2002.
8. Mäki, M. and P. Collin, ''Coeliac Disease,'' *Lancet,* 349:1755–1759, 1997.
9. Fasano, A., ''Celiac Disease—How to Handle a Clinical Chameleon,'' *New England Journal of Medicine,* 348:2568–2570, 2003.
10. Catassi, C. and A. Fasano, ''Celiac Disease as a Cause of Growth Retardation in Childhood,'' *Current Opinion in Pediatrics,* 16:445–449, 2004.
11. Catassi, C., E. Fabiani, G. Corrao, et al., ''Risk of Non-Hodgkin Lymphoma in Celiac Disease,'' *Journal of the American Medical Association,* 287(11):1413–1419, 2002.
12. Peters, U., J. Askling, G. Gridley, et al., ''Causes of Death in Patients With Celiac Disease in a Population-Based Swedish Cohort,'' *Archives of Internal Medicine,* 163:1566–1572, 2003.
13. Green, P.H.R. and B. Jabri, ''Coeliac Disease,'' *Lancet,* 362:383–391, 2003.
14. Pietrzak, M.M., C. Catassi, S. Drago, et al., ''Celiac Disease: Going Against the Grains,'' *Nutrition in Clinical Practice,* 16:335–344, December 2001.
15. Corrao, G., G.R. Corazza, V. Bagnardi, et al., ''Mortality in Patients with Coeliac Disease and Their Relatives: A Cohort Study,'' *Lancet,* 358:356–361, 2001.
16. Rostom, A., C. Dubé, A. Cranney, et al., ''Celiac Disease,'' Evidence Report/Technology Assessment Number 104, Prepared by the University of Ottawa Evidence-Based Practice Center Under Contract No. 290–02–0021 for the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services, Rockville, MD, AHRQ Publication No. 04–E029–2, p. 140, September 2004.
17. Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), ''National Health and Nutrition Examination Survey Questionnaire,'' Question MCQ082, Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011, available at *http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/MCQ_F.htm#MCQ082.*
18. Rubio-Tapia, A., J.F. Ludvigsson, T.L. Brantner, et al., ''The Prevalence of Celiac Disease in the United States,'' *Gastroenterology,* 142(5):S181–S182, May 2012.
19. Sanders, D.S., M.J. Carter, D.P. Hurlstone, et al., ''Association of Adult Coeliac Disease With Irritable Bowel Syndrome: A Case-Control Study in Patients Fulfilling ROME II Criteria Referred to Secondary Care,'' *Lancet,* 358:1504–1508, 2001.
20. The Threshold Working Group, ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,'' Draft Report, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, pp. 1–103, June 2005, available at *http://www.fda.gov/ohrms/dockets/dockets/05n0231/05n-0231-rpt0001.pdf.*
21. The Threshold Working Group, ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,'' Revised Report, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, pp. 1–106, March 2006, available at *http://www.fda.gov/downloads/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/UCM192048.pdf.*
22. FDA, ''FDA's Responses to Public Comments on the Draft Report 'Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,' '' March 2006, available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106042.htm.*
23. Food Advisory Committee, CFSAN/FDA, ''Summary Minutes for the Food Advisory Committee Meeting on 'Advice on CFSAN's Draft Report: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,' '' Greenbelt, MD, pp. 1–11, July 13–15, 2005, available at *http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4160m1_summary%20minutes.pdf.*
24. FDA, ''FDA's Responses to Comments on the Report Titled 'Health Hazard Assessment for Gluten Exposure in Individuals With Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten,' '' December 2012, available at *http://www.fda.gov/downloads/Food/*

FoodScienceResearch/RiskSafetyAssessment/UCM362401.pdf.
25. Codex Alimentarius Commission, ''Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Standard 118–1979),'' Rome, Italy, pp. 1–3, 2008; available at *http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf.*
26. The Commission of the European Communities, ''Commission Regulation (EC) No 41/2009,'' *Official Journal of the European Union,* Brussels, Belgium, pp. L 16/3–L 16/5, January 20, 2009; available at *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:016:0003:0005:EN:PDF.*
27. Health Canada, Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch ''Health Canada's Position on Gluten-Free Claims,'' dated June 2012, available at *http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/securit/allerg/cel-coe/gluten-position-eng.pdf.*
28. Government of Australia, ''Australian New Zealand Food Standards Code: Chapter 1—General Food Standards, Part 1.2—Labelling and Other Information Requirements, Standard 1.2.8—Nutrition Information Requirements,'' pp. 2 and 14, 2012, available at *http://www.comlaw.gov.au/Details/F2012C00218.*
29. Armour, B., and T.B. Perry, Cream Hill Estates Ltd., Public comment letter Document ID: FDA–2005–N–0404–0399, submitted on November 19, 2005, to Docket No. 2005N–0279 pertaining to the Center for Food Safety and Applied Nutrition, Food and Drug Administration Public Meeting on Gluten-Free Food Labeling held in College Park, MD, pp. 1–3, August 19, 2005, available at *http://www.regulations.gov/#!documentDetail;D=FDA-2005-N-0404-0399.*
30. Smith, S., Gluten Free Oats LLC, Public comment letter EMC301 submitted on March 20, 2006, to Docket No. 2005N–0279 pertaining to the Center for Food Safety and Applied Nutrition, Food and Drug Administration Public Meeting on Gluten-Free Food held in College Park, MD, pp. 1–2, August 19, 2005.
31. Daou, C. and H. Zhang, ''Oat Beta-Glucan: Its Role in Health Promotion and Prevention of Diseases,'' *Comprehensive Reviews in Food Science and Food Safety,* 11: 355–365, 2012.
32. Verrill, L., Y. Zhang, and C.T.J. Lin, Memorandum, ''Consumer Studies' Comments on Alternative Terms for 'Gluten-Free' on The Food Label,'' Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, July 8, 2013.
33. FDA, ''Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Draft Guidance,'' August 2009, available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm166239.htm.*
34. Verrill, L. and C.-T.J. Lin, Memorandum, ''Consumer Studies' Comments on a Proposed Codicil in the 'Gluten-Free' Labeling Final Rule,'' Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, July 8, 2013.
35. FDA/CFSAN, ''Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods,'' April 2008, available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053455.htm.*
36. AOAC Research Institute, ''Certificate of Performance Tested℠ Status, Certificate No. 120601,'' AOAC International, Gaithersburg, MD, 2013; available at *http://www.aoac.org/iMIS15_Prod/AOAC_Docs/RI/RI_MethodsCert/2013_120601_certificate.pdf.*
37. Morinaga Institute of Biological Science, Inc., ''Product: Food Allergen Kits: Food Allergen ELISA Kits,'' available at *http://www.miobs.com/english/product/food_allergen_elisa_kits/index.html,* and Information Sheet Download ''Wheat Protein ELISA Kit (Gliadin),'' available at *http://www.miobs.com/english/product/food_allergen_elisa_kits/dl/gdrev1.pdf.*
38. FDA/CFSAN, ''Report to The Committee on Health, Education, Labor, and Pensions United States Senate and the Committee on Energy and Commerce United States House of Representatives, Food Allergen Labeling and Consumer Protection Act of 2004 Public Law 108–282,'' available at *http://www.fda.gov/downloads/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/UCM179390.pdf.*
39. FDA/CFSAN, ''Gluten-Free Labeling of Foods, Final Regulatory Impact Analysis and Regulatory Flexibility Analysis,'' 2013.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Food and Drug Administration amends 21 CFR part 101 as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

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

■ 2. Section 101.91 is added to subpart F to read as follows:

§ 101.91 Gluten-free labeling of food.

(a) *Definitions.* (1) The term ''gluten-containing grain'' means any one of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye):

(i) Wheat, including any species belonging to the genus *Triticum;*

(ii) Rye, including any species belonging to the genus *Secale;* or

(iii) Barley, including any species belonging to the genus *Hordeum.*

(2) The term ''gluten'' means the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

(3) The labeling claim ''gluten-free'' means:

(i) That the food bearing the claim in its labeling:

(A) Does not contain any one of the following:

(*1*) An ingredient that is a gluten-containing grain (e.g., spelt wheat);

(*2*) An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or

(*3*) An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or

(B) Inherently does not contain gluten; and

(ii) Any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food).

(b) *Requirements.* (1) A food that bears the claim ''gluten-free'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(2) A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(3) A food that bears the term ''wheat'' in the ingredient list or in a separate ''Contains wheat'' statement in its labeling, as required by 21 U.S.C. 343(w)(1)(A), and also bears the claim ''gluten-free'' or a claim identified in paragraph (b)(2) of this section will be deemed misbranded unless the word ''wheat'' in the ingredient list or in the ''Contains wheat'' statement is followed immediately by an asterisk (or other symbol) that refers to another asterisk (or other symbol) in close proximity to the ingredient statement that immediately precedes the following: ''The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods.''

(c) *Compliance.* When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food

matrices, including both raw and cooked or baked products.

(d) *Preemption.* A State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the definition and use of the claim ''gluten-free,'' as well as the claims ''no gluten,'' ''free of gluten,'' or ''without gluten.''

Dated: July 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 126

RIN 1400–AD41

[Public Notice 8409]

Amendment to the International Traffic in Arms Regulations: Libya and UNSCR 2095

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to update the defense trade policy regarding Libya to reflect resolution 2095 adopted by the United Nations Security Council.

DATES: This rule is effective August 5, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Sarah J. Heidema, Acting Director, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–2809, or email *DDTCResponseTeam@state.gov.* ATTN: Regulatory Change, Libya.

SUPPLEMENTARY INFORMATION: On March 14, 2013, the United Nations Security Council adopted resolution 2095 (''UNSCR 2095''), which further modified the arms embargo against Libya put in place by the adoption in February and March of 2011 of resolutions 1970 and 1973, respectively, and modified by resolutions 2009 and 2016, adopted in September and October of 2011, respectively (for previous ITAR amendments regarding Libya defense trade policy, *see* ''Amendment to the International Traffic in Arms Regulations: Libya,'' RIN 1400–AC83, 76 FR 30001, and ''Amendment to the International Traffic in Arms Regulations: Libya and UNSCR 2009,'' RIN 1400–AC97, 76 FR 68313).

UNSCR 2095 removed the requirement for member states to notify the Committee of the Security Council concerning Libya (''the Committee'') of exports of non-lethal military equipment, and the provision of any technical assistance or training, intended solely for security or disarmament assistance to the Libyan government. It also removed the requirement to seek the approval of the Committee for exports of non-lethal military equipment, and related technical assistance or training, for humanitarian and protective use. The Department of State is amending ITAR § 126.1(k) accordingly.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since the Department is of the opinion that this rule is exempt from 5 U.S.C. 553, it is the view of the Department that the provisions of section 553(d) do not apply to this rulemaking. Therefore, this rule is effective upon publication. The Department also finds that, given the national security issues surrounding U.S. policy towards Libya, notice and public procedure on this rule would be impracticable or unnecessary; for this reason also, this rule is effective upon publication.

Regulatory Flexibility Act

Since the Department is of the opinion that this rule is exempt from the provisions of 5 U.S.C. 553, there is no requirement for an analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rulemaking has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These executive orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

The Department of State has reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.