Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2005N–0279]

RIN 0910–ZA26

Food Labeling; Gluten-Free Labeling of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to 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 (all noted grains are collectively referred to 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 parts per million (ppm) or more gluten in the food; or 20 ppm or more gluten. A food 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'' would be deemed misbranded. FDA also is proposing to deem misbranded a food bearing 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''). In addition, a food made from oats that bears a gluten-free claim in its labeling would be deemed misbranded if the claim suggests that all such foods are gluten-free or if 20 ppm or more gluten is present in the food. Establishing a definition of the term ''gluten-free'' and uniform conditions for its use in the labeling of foods is needed 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 proposed action is in response to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

DATES: Submit written or electronic comments by April 23, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0279, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rhonda R. Kane, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2371, FAX: 301–436–2636, e-mail: *rhonda.kane@fda.hhs.gov*.

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I. Background

A. 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 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 who have celiac disease, leading to a lack of absorption of nutrients and 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 age and immunological status of the individual, the amount, duration or timing of the exposure to gluten, and the specific area and extent of the gastrointestinal tract involved by 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 are classified as having ''silent'' or ''latent'' forms 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 but not limited to: 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 and 11 through 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 all sources 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. Prevalence of Celiac Disease in the United States

Precise prevalence data for celiac disease are not available. The overall prevalence of celiac disease in the U.S. is currently estimated to range 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). However, the number of Americans with physician-diagnosed celiac disease is estimated at between 40,000 (Ref. 17) and 60,000 (Ref. 18).

This discrepancy between estimated prevalence and diagnosed cases has been linked primarily to the fact that celiac disease can be silent or latent. Some researchers have suggested that the true prevalence is underreported (Ref. 8). Silent and latent forms of celiac disease may go undetected in individuals for years before they develop symptoms causing them to seek medical attention (Ref. 13). 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. Gluten and the Grains of Concern for Individuals with Celiac Disease

1. Meaning of the Term ''Gluten''

There is no single definition of the term ''gluten.'' Technically, the term ''gluten'' refers to a specific complex of proteins that forms when wheat flour is mixed with a liquid and physically manipulated, such as in the kneading of a bread (Ref. 20). This complex of proteins is composed of both ''gliadins'' and ''glutenins,'' which are found in approximately equal proportions in most wheat varieties (Refs. 21 through 23). The gliadins belong to a category of proteins called ''prolamins'' and the glutenins belong to a category of proteins called ''glutelins'' (Refs. 20 and 24).

Although, strictly speaking, ''gluten'' pertains only to wheat proteins, this term is frequently used to refer to the combination of prolamin and glutelin proteins naturally occurring in other grains, including those that have not been demonstrated to cause harmful effects in individuals with celiac disease (e.g., ''corn gluten'' and ''rice gluten'') (Ref. 25). However, in discussions of celiac disease in the medical literature, the term ''gluten'' is used to refer to either gluten in wheat or collectively to the proteins (e.g., prolamins and glutelins) in just those grains that have been demonstrated to cause harmful health effects in individuals who have celiac disease (Refs. 3 and 25).

2. Grains of Concern to Individuals With Celiac Disease

The grains that are reported to contain gluten that can cause harmful health effects in individuals with celiac disease and should be avoided by them are as follows: Wheat (including durum wheat, spelt wheat, and kamut), rye, barley, and crossbred hybrids of these grains (e.g., triticale, which is a cross between wheat and rye), and possibly oats (Refs. 26 through 30). Rye, barley, and triticale are taxonomically very closely related to wheat and contain peptides structurally similar to those found in wheat (Refs. 30 and 31). Although oats are not as closely related to wheat (Ref. 30), they are reported to contain some peptides similar to those found in wheat, which may help to explain why some individuals with celiac disease are sensitive to oats (Ref. 32). In contrast, the cereal grains believed to be well tolerated by individuals with celiac disease and which are not taxonomically as closely related to wheat and are not reported to contain similar peptides to those found in wheat include: Amaranth, buckwheat, corn (maize), Indian ricegrass, Job's tears, millet, quinoa, ragi, rice, sorghum, teff (tef), and wild rice (Refs. 26, 27, 29 through 31, 33, and 34).

There is evidence that both the prolamins (i.e., gliadins) and glutelins (i.e., glutenins) in wheat adversely affect individuals with celiac disease (Refs. 2, 27, and 35 through 37). Wheat gliadin subtypes alpha, beta, gamma, and omega have been shown to cause damage to the intestinal tract of individuals with celiac disease (Refs. 38, 39, and 40, p. 41). Moreover, it is also believed that the prolamins in rye (i.e., secalins) and the prolamins in barley (i.e., hordeums) are responsible for causing adverse health effects in individuals with celiac disease (Refs. 13, 23, 28, 41, and 42). Oats also have prolamins (i.e., avenins) that have some amino acid sequences similar to those occurring in wheat and are believed to be harmful to a small subset of individuals with celiac disease (Ref. 32). Although the prolamins of the aforementioned grains and the wheat glutelins are recognized to cause adverse health effects in individuals with celiac disease, all cereal grains contain other types of proteins, including albumins and globulins, which are not currently associated with celiac disease (Refs. 20 and 21). There is still much unknown about all the specific proteins in the different grains that can affect individuals with celiac disease (Ref. 43).

3. Uncertainty About Including Oats in the Diet of Individuals With Celiac Disease

Currently, there is no general agreement among experts about the extent to which oats present a hazard for individuals with celiac disease. Whether oats should or should not be consumed by individuals with celiac disease has been the subject of controversy for more than 50 years (Ref. 44). There are inconclusive and conflicting results from research on the effects of oat consumption on individuals with celiac disease.

Some of this research, in particular early research, suggests that oat consumption is harmful to individuals with celiac disease (Refs. 26 and 28). More recent studies found that 1 of 19 study participants (Ref. 45) and 4 of 9 participants (Ref. 32) could not tolerate an average of about 50 grams dry weight of oats. The oats used in both studies

were tested to ensure that they did not contain gluten proteins from wheat, rye, or barley.

However, multiple studies in the last 10 years have shown that the ingestion of oats in the diet of individuals who have celiac disease, in both children and adults, does not necessarily lead to increased intestinal or skin symptoms or to altered intestinal pathology, and appears to be preferred to a diet without oats (Refs. 46 through 51). The average amount of oats consumed by participants in each of these studies differed, ranging from about 15 grams to 60 grams dry weight per day. A long-term study that lasted 5 years concluded that individuals with celiac disease prefer and can tolerate without harmful effects a daily average consumption of 34 grams dry weight of oats (Ref. 49).

Although the total number of individuals with celiac disease who are sensitive to oats is unknown, the findings of many of the contemporary studies suggest that the proportion of individuals with celiac disease who cannot tolerate oats in daily amounts of about 50 or less grams dry weight is probably very low. One celiac expert suggests that the size of this subpopulation is likely to be less than one percent of individuals with celiac disease (Ref. 52).

Despite the evidence that the consumption of oats does not present a risk for most individuals with celiac disease, a major obstacle impeding general acceptance of oats in the diet of individuals with celiac disease is the concern about the commingling[1] of oats with wheat, rye or barley that can occur during grain production, transport, storage, or processing (Refs. 44 and 53). Due to this concern, Farrell and Kelly (Ref. 7) advise individuals with newly diagnosed celiac disease not to consume oats until their disease is in remission (e.g., intestinal tract has healed). Some celiac disease treatment or research centers in the United States report that they do not support the inclusion of oats in the diet of individuals with celiac disease, whereas other centers do, stating that oats can enhance the nutrient density and fiber content of a diet that avoids all sources of gluten and possibly improve compliance with this very restrictive diet (Refs. 54 through 56).

Thompson (Ref. 57) conducted a small, non-randomized mail survey using a questionnaire about the acceptability of several foods in diets that do not contain gluten. Thirty seven questionnaires, completed by celiac disease organizations (United States and foreign), physicians, and dietitians/nutritionists, were submitted in response to the survey. Only five (i.e., 1 foreign celiac association and 4 physicians) of the 33 respondents who answered the question about oats considered oats to be an acceptable food, and none of the four U.S. celiac disease associations that responded to the survey considered oats to be an acceptable food for individuals with celiac disease. The reasons given by respondents for their lack of acceptance of oats included concerns about the possibility that oats may cause adverse health effects in individuals with celiac disease either directly or due to the presence of gluten from another grain (e.g., wheat, rye, or barley), and about the insufficiency of long-term research that identifies the amount of oats that can be tolerated by individuals with celiac disease.

According to more recent position statements of 3 of the 4 major celiac associations in the United States that responded to the earlier survey conducted by Thompson (Ref. 57), one of these associations continues to take the position that oats are not an acceptable food for individuals with celiac disease; but, the other two of these associations are not opposed to the inclusion of oats in the diets of individuals with celiac disease, provided that the oats do not contain gluten from other grains and that the daily amount of oats consumed is limited to 1 cup cooked (Ref. 56). Both of the latter associations state that oats can add soluble fiber and nutrients to a diet that avoids all sources of gluten; but, direct individuals with celiac disease to consult with their health care providers before introducing oats into their diet. Also, both of these associations recommend that individuals with celiac disease who consume oats should have their levels of antibodies specific to celiac disease monitored periodically.

The recent *National Institutes of Health Consensus Conference Statement on Celiac Disease* (Ref. 1) does not identify oats as being one of the grains that individuals with celiac disease should avoid. Instead, this statement indicates that it appears that most individuals with celiac disease can include oats in their diet without harmful health effects, but that it may not be practical to do so because oats may contain gluten from other grains due to commingling during their processing. Similarly, the 2006 edition of the American Dietetic Association (ADA) *Nutrition Care Manual (ADA Manual)* recommends that individuals with celiac disease avoid wheat (including wheat in all of its varieties, such as spelt, and in all of its forms, such as wheat starch), rye, barley and their crossbred hybrid varieties (e.g., triticale), but does not advise individuals with celiac disease to presumptively exclude oats from their diet (Ref 58). Instead, the *ADA Manual* states: ''* * *Findings from *in vivo* research on the safety of oats suggest that most persons with celiac disease can safely consume moderate amounts of uncontaminated oats without adversely affecting the intestinal mucosa * * *.'' (Ref. 59). However, the *ADA Manual* acknowledges that ''* * *limited evidence suggests that in some persons with celiac disease, the consumption of uncontaminated oats may result in mucosal inflammation* * *.'' Further, the *ADA Manual* advises that individuals with celiac disease consult with their physicians and dietitians before deciding to consume oats and that any daily intake should be limited to about 50 grams of dry oats that ideally have been tested to ensure that they do not contain gluten from wheat, rye, or barley. The *ADA Manual* also reports that some oat millers have established comprehensive clean-out procedures and control programs to address the problem of commingling of oats with wheat, rye, and barley. In addition, in a letter submitted in response to FDA's 2005 public meeting on gluten-free (see section I.E.4 of this document for details about this meeting), ADA expressed support for FDA establishing a definition of gluten-free for oats that is tied to testing that ensures that those oats do not contain gluten from other grains, so that those oats could bear a gluten-free labeling claim (Ref. 60).

The commingling of oats with wheat, rye, barley or their crossbred hybrids or with the grains generally considered to be acceptable for individuals with celiac disease (e.g., corn and rice) can occur at any step in the farm-to-table continuum. This is due to the common practices of growing crops in rotation and in close proximity to one another as well as using the same equipment and storage bins to harvest and hold different grains (Ref. 53). Accordingly, the official U.S. standard for a given grain typically allows for the presence of a small percentage of other grains (Ref. 61).

It is believed that most oat products commercially available in the United States contain some gluten from wheat, rye, or barley as a result of commingling during the oats' growth, harvesting,

[1]The cited references use the term ''contamination,'' but other references use the term ''commingling.'' For purposes of this proposed rule, FDA has opted to use the term ''commingling,'' and considers that term to mean ''the process of mixing.''

transport, storage, or processing (Refs. 43, 44, 53, 62, and 63). In 2004, Thompson reported that in a recent study 4 samples of each of 3 brands of oat products marketed in the United States were analyzed in duplicate for gluten from wheat, rye, and barley using an enzyme-linked immunosorbent assay (ELISA)-based method (Ref. 63). Ten of the 12 samples, representing all 3 brands of oat products, were reported to contain an amount of gluten ranging from 12 to 1861 ppm, depending upon the individual sample and brand tested. Thompson concluded that none of these brands could be considered a reliable source of oats free of potentially harmful gluten from other grains.

In another study, Hernando and colleagues (Ref. 64) collected 108 samples of commercial oat products (e.g., rolled oats, oat flakes, and oat flours) from Europe, the United States and Canada. The samples were analyzed for gluten from wheat, rye, and barley using an ELISA-based method. In addition, analysis of the samples by polymerase chain reaction (PCR) was used to identify the particular grains present. Consistent with the previous findings of Thompson, the presence of gluten from other grains was found to be widespread. Seventy-nine percent of the oat samples were reported to contain gluten from wheat, rye, and/or barley at a level ranging from less than 3 to 8,000 ppm gluten (Ref. 64). Sixty-one percent of the samples contained more than 200 ppm gluten. Hernando and colleagues also reported barley to be the predominant grain present.

Although there appears to be widespread commingling of oats with other grains, it appears that this commingling is preventable. Two manufacturers who submitted written responses to FDA's 2005 public meeting on gluten-free food labeling report that the oats they market in the United States do not contain gluten from wheat, rye, and barley (Refs. 65 and 66). Examples of the types of special measures reported by one or both manufacturers to ensure that their oats do not contain gluten from wheat, rye, and barley are as follows: (1) Contracting with farmers who are experienced with growing crops to ensure their purity; (2) using only oat seed certified to be pure; (3) planting oats only in fields that have not produced wheat, rye, or barley in either 2 or 3 years; (4) establishing a 25- or 30–foot buffer zone separating their oat crops from other crops; (5) conducting periodic inspections to remove any stray wheat, rye, or barley plants growing in their fields; (6) using only dedicated or thoroughly cleaned equipment and facilities to harvest, transfer, store, and process their oats; (7) having an independent lab test samples of their freshly harvested and milled oats, using an ELISA-based method designed to detect gluten naturally occurring in wheat, rye, and barley; and (8) milling their oats in dedicated facilities that either only mill oats or only mill oats and soy.

D. FDA's Prior Statements on Gluten-Free Food Labeling

Currently, there is no FDA regulation that specifically defines the term ''gluten-free.'' In the preamble to a final rule on the declaration of ingredients on food packaging published in the **Federal Register** of January 6, 1993 (58 FR 2850 at 2864), FDA advised that the term ''gluten-free'' can be used in the labeling of foods, provided that when such claim is used, it is truthful and not misleading. Generally, and absent regulations to the contrary, FDA would regard a claim that a food is ''free'' of a substance as false or misleading if the food contains that substance. FDA also noted that the term ''gluten-free'' may be misleading when the food ordinarily does not contain gluten. Although FDA did not define the term ''gluten,'' FDA referred to the grains wheat, barley, rye, oats and millet as those ''which commonly contain gluten'' (FR 2850 at 2863).

FDA's view that the term ''gluten-free'' may be misleading when a food is inherently free of gluten is consistent with FDA regulations governing the use other ''free'' claims. FDA has issued regulations that establish requirements for a ''free'' labeling claim made about a food inherently free of calories (§ 101.60(e)(ii) (21 CFR 101.60(e)(ii)), of nutrients (e.g., sodium, § 101.61(b)(1)(iii) (21 CFR 101.61(b)(1)(iii)) and fat, § 101.62(b)(1)(iii) (21 CFR 101.62(b)(1)(iii)), and of other food components (e.g., cholesterol, § 101.62(d)(1)(ii)(E)). FDA considers ''calorie-free,'' ''sodium-free,'' ''fat-free,'' and ''cholesterol-free'' labeling claims made for a food that inherently does not contain these substances to be misleading to consumers without additional clarifying wording indicating that all foods of the same type, not just the brand of food bearing that ''free'' labeling claim, are also free of the stated substance. Consistent with how FDA has regulated other ''free'' claims, the agency would consider a gluten-free labeling claim made for a food that inherently does not contain gluten to be misleading if it is not accompanied by additional wording to clarify that all foods of the same type, not just the brand of food bearing the gluten-free claim, are also free of gluten.

As discussed elsewhere in this preamble, FDA proposes to define prohibited grain to include all species of wheat, rye, barley, and their crossbred hybrids. FDA's proposed definition of prohibited grain would exclude all other grains, including oats and millet.

E. Food Allergen Labeling and Consumer Protection Act of 2004 and Related Activities

1. Food Allergen Labeling and Consumer Protection Act of 2004

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), 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. FALCPA directs the issuance of a proposed rule by no later than 2 years after the law's enactment date, and a final rule by no later than 4 years after the law's enactment date. FDA is publishing this proposed rule in response to this directive.

2. FDA's Threshold Working Group and Its Report on Approaches to Establish Thresholds

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

To address this issue, among others, FDA 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 draft report, *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food* (the draft Thresholds Report) (Ref. 67), summarized the current state of scientific knowledge with respect to a dose-response relationship for gluten, and presented the following four potential approaches that FDA might consider in establishing such a threshold level, if the agency chose to do so (Ref. 67, pp. 2 and 38 through 41):

- *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 heath 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.

The report also noted that any decisions on approaches to establish a threshold for gluten likely would require consideration of additional factors not addressed in the 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.

A notice of availability for the draft Thresholds Report was published in the **Federal Register** (70 FR 35258, June 17, 2005) and the report was made available through FDA Docket No. 2005N–0231 and the Center for Food Safety and Applied Nutrition (CFSAN) Web site (*http://www.cfsan.fda.gov/~dms/alrgn.html*). FDA requested that interested persons submit comments and any scientific data or other information relevant to the draft Thresholds Report to the docket during a 60-day comment period ending August 16, 2005. The Threshold Working Group considered the comments, data, and information submitted, and made appropriate revisions to the Thresholds Report. On May 25, 2006, FDA posted its response (Ref. 68) to the comments, data, and other information that the agency received on its draft Thresholds Report (*http://www.cfsan.fda.gov/~dms/alrgcom.html*). FDA also posted the revised Thresholds Report (Ref. 69) (*http://www.cfsan.fda.gov/~dms/alrgn2.html*). Both of these documents are dated March 2006.

3. Food Advisory Committee Meeting of July 13 through 15, 2005

In the **Federal Register** of May 23, 2005 (70 FR 29528), FDA announced that FDA's Food Advisory Committee (FAC) would be holding a public meeting on July 13 through 15, 2005, to evaluate the draft Thresholds Report. One purpose of the meeting was for the FAC to determine whether the four approaches considered in the draft Thresholds Report for establishing a threshold level for gluten were scientifically sound. FDA invited experts to address a number of specific issues related to sensitivities to gluten. In addition, FDA invited interested members of the general public to present their 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 standards 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.

Approximately 140 persons attended the FAC meeting. 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 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 FDA Docket No. 2005N–0279 pertaining to this rulemaking. A summary of the FAC responses to the questions is provided in the Summary Minutes (Ref. 70).

The FAC concluded that the draft 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. 70, p. 1). The FAC also identified the risk-assessment approach as the strongest of the four approaches proposed in the draft Thresholds Report, assuming the availability of sufficient data (Ref. 70, p. 1).

FDA received about 20 public responses, each containing one or more comments, to the FAC meeting and to the notice of availability and request for comments on the draft Thresholds Report. (Some of these responses concerned food allergens and are not relevant to this proposal.) Approximately half of the total number of responses mentioned wheat or gluten, and the majority of the responses submitted about gluten addressed issues or provided data directly related to the report's suggested approaches to establishing a threshold level for gluten. Pertinent comments were considered by FDA in the development of this proposed rule. All written responses submitted to FDA about the FAC meeting and the draft Thresholds Report are available through FDA Docket No. 2005N–0231, and copies of those responses that specifically mentioned wheat or gluten are also available through FDA Docket No. 2005N–0279.

4. Gluten-Free Food Labeling Public Meeting of August 19, 2005

In the **Federal Register** of July 19, 2005 (70 FR 41356), FDA announced that it would be holding a public meeting on August 19, 2005, to discuss the topic of gluten-free food labeling. Interested persons were given 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, FDA 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.''

More than 80 persons attended the public meeting on gluten-free food labeling. In response to the notice and public meeting, FDA received more than 2,400 responses, each containing one or more comments, about the public meeting or the list of questions cited in the notice announcing the meeting. The vast majority of these responses were from individuals with celiac disease, their caregivers, and celiac disease associations, with a much smaller number of responses being from the food industry. All written responses submitted to FDA in response to the gluten-free public meeting and the questions posed in the corresponding **Federal Register** meeting notice are available through the FDA Docket No. 2005N–0279.

Most of the consumers' comments 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 grocery shop, saving the consumers both time and the frustration

experienced when reading often lengthy and complicated ingredients lists that they stated they do not understand. Many consumers also stated that they currently purchase only or primarily 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 provide them with 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, opinions expressed in comments from these individuals and organizations varied with respect to whether oats should be excluded from any products labeled as gluten-free.

Industry comments 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 assist industry by promoting 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.

Based upon comments that FDA received during this public meeting or that were submitted in writing to the related FDA Docket No. 2005N–0279, FDA believes that a uniform definition of the term gluten-free would prevent confusion and uncertainty among both consumers and food manufacturers about what this food labeling claim means.

II. Proposed Rule

A. Legal Basis

Section 206 of FALCPA directs the Secretary of HHS, in consultation with appropriate experts and stakeholders, to issue a proposed rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. FDA has authority to issue this proposed rule under sections 403(a)(1), 201(n), and 701(a) of the act (21 U.S.C. 343(a)(1), 321(n), and 371(a). Section 403(a)(1) of the act states that, ''A food shall be deemed to be misbranded if its labeling is false or misleading in any particular.'' In determining whether food labeling is misleading, section 201(n) explicitly provides for consideration of the extent to which the labeling fails to reveal facts ''material with respect to the consequences which may result from the use of the [food] to which the labeling * * *relates under * * *such conditions of use as are customary or usual.'' Section 701(a) of the act vests the Secretary (and by delegation, FDA) with authority to issue regulations for the efficient enforcement of the act.

As directed by FALCPA, FDA is proposing to define the term ''gluten-free'' for voluntary use in the labeling of foods. FDA is also proposing to define various terms corresponding to certain specified grains and proteins that would be prohibited from use as ingredients or sources of ingredients used to make a food bearing a ''gluten-free'' labeling claim. Further, FDA is proposing to specify how a voluntary gluten-free labeling claim must be worded for oats and for other foods that inherently do not contain any gluten. Any use of the term ''gluten-free'' in the labeling of food that does not conform to the proposed regulatory definitions and requirements would render that food misbranded.

In enacting FALCPA, Congress recognized the importance to individuals with celiac disease of avoiding gluten (FALCPA, section 202(6)(B)). To address this issue, section 206 of FALCPA directs FDA to issue a regulation to define and permit use of the term ''gluten-free.'' As discussed elsewhere in this preamble, currently there is neither a regulatory definition of the term ''gluten-free,'' nor is there agreement among manufacturers or consumers as to what this term means. In the course of consulting with experts and stakeholders, FDA has learned that different manufacturers have different and inconsistent definitions of the term ''gluten-free.'' Consumers with celiac disease and their caregivers, who rely on ''gluten-free'' labeling claims to make purchasing decisions, believe that a standardized definition of the term is needed to ensure that those consumers know what to expect when purchasing foods labeled as gluten-free. Therefore, FDA believes that establishing a definition of the term ''gluten-free'' and uniform conditions for its use in the labeling of foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled.

B. Definitions and Criteria for the Use of the Term Gluten-Free in Food Labeling

1. Definitions of the Terms ''Prohibited Grains'' and ''Gluten''

To facilitate proposing a definition of the term ''gluten-free,'' FDA proposes to also define the terms ''gluten'' and ''prohibited grains.'' FDA proposes in § 101.91(a)(2) to define the term ''gluten'' to mean 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). FDA proposes in § 101.91(a)(1) to define the term ''prohibited grain'' to mean any of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye): (1) Wheat, meaning any species belonging to the genus *Triticum*; (2) rye, meaning any species belonging to the genus *Secale*; and (3) barley, meaning any species belonging to the genus *Hordeum*. As discussed in section I.C of this document, the scientific literature reports general agreement among celiac disease experts that naturally occurring prolamins or glutelins in wheat, rye, barley, and their crossbred hybrids can cause serious adverse health effects in individuals with celiac disease and should be excluded from their diet.

FDA is not proposing to include oats in the definition of a prohibited grain. As discussed in section I.C.3 of this document, the unconditional exclusion of oats from the diet of individuals with celiac disease is not supported by the *National Institutes of Health Conference Development Conference Statement on Celiac Disease* (Ref. 1) or by the American Dietetic Association (Ref. 58). FDA recognizes that a small percentage of individuals with celiac disease may not be able to tolerate some of the proteins that naturally occur in oats. However, it appears that a great majority of individuals with celiac disease can tolerate a daily intake of a limited amount (e.g., 50 grams) of oats that are free of gluten from wheat, rye, barley or their crossbred hybrids. Oats are reported to add variety, taste, satiety, dietary fiber, and other essential nutrients to the diet of individuals with celiac disease; thereby making their diet more nutritious and appealing (Refs. 44, 51, 56, and 71). Inclusion of oats in the diet of individuals with celiac disease who can tolerate oats may therefore result in the improved nutritional and health status of those individuals (Refs. 55 and 71).

According to comments FDA received in response to its August 2005 public meeting on gluten-free labeling, at least two food manufacturers can produce

oats that do not contain gluten from wheat, rye, barley, or any of their cross-bred hybrids. Allowing such oats to bear a gluten-free labeling claim would make them easier to identify and perhaps would encourage other manufacturers to produce such oats. Conversely, including oats in the definition of prohibited grain could eliminate any incentive for manufacturers to produce oats free of gluten from other grains because those manufacturers would have no way of distinguishing their products in the marketplace. FDA requests comments on whether the agency should include oats in the definition of a prohibited grain.

2. Definition of the Term ''Gluten-Free''

FDA proposes in § 101.91(a)(3) to define the claim ''gluten-free'' to mean that a 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 that has not been processed to remove gluten; (3) an ingredient that is derived from a prohibited grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food (i.e., 20 micrograms or more gluten per gram of food); or (4) 20 ppm or more gluten.

Examples of a prohibited grain include, but are not limited to, barley, common wheat, durum wheat, einkorn wheat, emmer wheat, kamut, rye, spelt wheat, and triticale. Examples of ingredients that are derived from a prohibited grain and that have not been processed to remove gluten include, but are not limited to:

- Farina, flour made from any of the proposed prohibited grains, graham, and semolina;
- Hydrolyzed wheat protein, vital gluten, wheat bran, and wheat germ; and
- Barley malt extract or flavoring and malt vinegar.

Because these ingredients are derived from a prohibited grain and have not been processed to remove gluten, they are presumed to contain gluten.

Examples of ingredients that are or are sometimes derived from a prohibited grain and processed to remove gluten include, but are not limited to:

- Food starch—modified (modified food starch); and
- Wheat starch.

Although these ingredients have been processed to remove gluten, FDA recognizes that there may be different methods of deriving these ingredients, and that some methods may remove less gluten than others. Therefore, FDA proposes to prohibit a food that contains one of these ingredients from bearing a gluten-free labeling claim if the use of the ingredient results in the presence of 20 ppm or more gluten in the food.

A food may contain 20 ppm or more gluten even though the food does not contain an ingredient derived from a prohibited grain. For example, a food that contains an ingredient derived from oats may contain 20 ppm or more gluten if the oats were commingled with a prohibited grain during their harvest, transport, or storage. FDA believes that manufacturers who elect to use the labeling claim ''gluten-free'' should make certain that foods so labeled do not contain 20 ppm or more gluten, regardless of whether or not those foods contain an ingredient that is derived from a prohibited grain. Under proposed § 101.91(b)(1), a food 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'' would be deemed misbranded.

3. Use of the Term Gluten-Free in the Labeling of Foods That Inherently Do Not Contain Gluten

FDA proposes in § 101.91(b)(2) to deem misbranded any food, with the exception of a food made from oats, that does not inherently contain any gluten from a prohibited grain and that bears the claim ''gluten-free'' in its labeling, unless the food complies with the following two requirements: (1) The wording of the claim in the labeling of the food clearly indicates that all foods of the same type, not just the brand bearing this labeling claim, are gluten-free (e.g., ''milk, a gluten-free food,'' ''all milk is gluten-free'') and (2) the food does not contain 20 ppm or more gluten. Examples of foods that inherently do not contain gluten include, but are not limited to:

- Different types of milk not flavored with ingredients that contain gluten (e.g., fresh fluid whole, low fat and nonfat milks; evaporated milk; nonfat dry milk; sweetened condensed milk);
- 100 percent fruit or vegetable juices; fresh fruits and vegetables that are not coated with a wax or resin that contains gluten; and frozen or canned fruits and vegetables not made with added ingredients that contain gluten; and
- A variety of single ingredient foods, e.g., butter; eggs; lentils; legumes like dried beans and peas, peanuts, and soybeans; seeds like flax, poppy and sesame; tree nuts like almonds, pecans, and walnuts; non-gluten containing grains like corn, millet and rice; fresh fish like cod, flounder and haddock; fresh shellfish like clams, lobster, and octopus; honey; and water, including bottled waters like distilled and spring.

FDA's proposed requirement for the labeling of foods, other than foods made from oats, that inherently do not contain gluten is consistent with the general principles established at § 101.13(e)(2) (21 CFR 101.13(e)(2)) for existing FDA regulations on ''free'' labeling claims made for foods inherently free of calories, nutrients (e.g., sodium, fat), and other food substances (e.g., cholesterol). If 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 that 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 a ''free'' labeling claim are also free of the substance (Ref. 72). Therefore, FDA views the use of a gluten-free labeling claim for a food inherently free of gluten to be potentially misleading without the inclusion of additional qualifying language.

Although oats are inherently free of gluten as defined in this proposed rule, FDA proposes in § 101.91(b)(3) to deem misbranded a food made from oats that bears a gluten-free labeling claim if the claim refers to all such foods as being gluten-free or if it contains 20 ppm or more gluten. By ''food made from oats,'' FDA means oats, any food that contains oats, and any food that contains any ingredient derived from oats. The proposed gluten-free labeling claim restriction in § 101.91(b)(3) is based on evidence of the presence of gluten from prohibited grains in a number of commercially available brands of foods made from oats, as discussed in section I.C.3 of this document. In light of that evidence, FDA believes that a gluten-free labeling claim that suggests that all foods made from oats are gluten-free would be misleading.

The agency is interested in receiving comments and scientific information on whether a gluten-free claim on an inherently gluten-free food, other than foods made from oats, would be misleading in the absence of additional qualifying language. In addition, FDA is interested in receiving comments and scientific information on whether the proposed examples of how a claim should be worded in the labeling of a food inherently free of gluten (e.g., ''milk, a gluten-free food,'' ''all milk is gluten-free'') would effectively inform consumers that all brands of the same type of food are also free of gluten, or whether there are more appropriate ways to communicate this message to

consumers. Further, FDA requests comments on the agency's proposal to restrict the types of gluten-free labeling claims that can be made for oats.

4. Use of the Analytical Methods-Based Approach in This Proposed Rule to Set a Threshold Level of 20 ppm to Define the Term Gluten-Free

As discussed in section I.E.2 of this document, the draft Thresholds Report describes four approaches FDA could use to establish a threshold level for gluten that could be the basis for decisions on whether to use the term ''gluten-free'' on product labels (Refs. 67, pp. 2, 38 through 41, and 54 through 61). The draft Thresholds Report concludes that it currently is not possible for FDA 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 (Refs. 67, pp. 4, 60, and 61). The draft Thresholds Report concludes that two approaches are viable for FDA to establish a threshold level for gluten: (1) The safety assessment-based approach and (2) the analytical methods-based approach (Ref. 67, pp. 4 and 57 through 60). The revised Thresholds Report identifies the same four approaches and conclusions (Ref. 69, pp. 2, 4, 42 through 45, and 61 through 65).

FDA is planning to conduct a safety assessment for gluten that is consistent with the safety assessment-based approach described in the draft and revised Thresholds Reports (Ref. 67, pp. 38, 39, and 58 through 60 and Ref. 69, pp. 42, 43, and 62 through 64). FDA requests comments providing data relevant to the planned safety assessment, including in particular clinical research and studies designed to measure chronic exposure, that satisfy the data quality criteria discussed in the revised Thresholds Report. We intend to publish a notice in the **Federal Register** seeking comment on the draft safety assessment and its potential use in the final rule, and will consider public and peer-review comments in revising the safety assessment, as appropriate. In developing a final rule on gluten-free labeling, we intend to consider the safety assessment as well as comments received in response to this proposed rule and the notice concerning the safety assessment. Further, as noted in both the draft and revised Thresholds Reports, FDA's establishment of a threshold level for gluten may require consideration of other factors not addressed in that report, such as ease of compliance and enforcement, stakeholder concerns, economics, trade issues, and legal authorities (Ref. 67, p. 41 and Ref. 69, p. 45). This may be true regardless of which approach FDA uses to establish a threshold level for gluten in the final rule (e.g., an analytical methods-based approach or a safety assessment-based approach).

Pending the receipt of comments submitted in response to this rulemaking and the outcome of the planned safety assessment, FDA is currently proposing to use the analytical methods-based approach to establish a threshold level of 20 ppm gluten (i.e., a food labeled gluten-free cannot contain 20 ppm or more gluten) as one of the criteria for defining the term ''gluten-free.'' Given the current unavailability of appropriate test methods that can reliably and consistently detect gluten at levels below 20 ppm,[2] FDA tentatively concludes 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 other pertinent requirements of this proposed rule.

Based upon the current state of technology concerning available and appropriate analytical methods that can detect one or more gluten proteins naturally occurring in wheat, rye, and barley, FDA has tentatively determined that ELISA-based methods can be used to reliably and consistently detect gluten at a level of 20 ppm in a variety of food matrices, including both raw and cooked or baked foods (Ref. 73). ELISA-based methods detect the prolamins in wheat, rye, and barley, which can serve as a biomarker for the presence of those grains, their cross-bred hybrids, or their other naturally occurring proteins. FDA is tentatively considering using an ELISA-based method that has been validated in Europe at the 20 ppm gluten detection level and has been published in the peer-reviewed scientific literature (Ref. 74). FDA has been advised that this method is currently under review by AOAC INTERNATIONAL (Ref. 75). In addition, we are aware that an evaluation of other ELISA-based methods that detect gliadin, a gluten protein, was recently published in the peer-reviewed scientific literature (Ref. 76). FDA requests comments on the appropriateness of 20 ppm gluten as the proposed threshold level as determined using an ELISA-based method.

As new, more sensitive methods of detection are developed, use of a methods-based approach, if not tempered by consideration of other factors, could result in a threshold level that is lower than the proposed threshold level of 20 ppm gluten. For example, the manufacturer of a test kit that uses an ELISA-based method that has been validated at the 160 ppm gluten detection level (Ref. 77) is seeking validation of that method at the 5 ppm gluten detection level (Ref. 78).

Given the possibility that new, more sensitive methods of detection will be developed in the near future, FDA requests comments on what effects the adoption of a lower threshold level would have on individuals with celiac disease and on industry. FDA is interested in receiving scientific data or other information that addresses the question of whether the adoption of a lower threshold level would be of benefit to individuals with celiac disease. FDA is also interested in receiving comments and supporting data on whether the use of a lower threshold level could reduce the commercial availability in the United States of foods labeled gluten-free and whether that reduced availability could negatively impact individuals with celiac disease (e.g., by making it more difficult for them to comply with dietary restrictions, perhaps leading to increased health risks).

In addition, FDA requests comments on whether a safety assessment or risk assessment that addresses gluten threshold levels for individuals with celiac disease has been conducted by other entities. FDA also requests information on any gluten tolerance studies that have been published in the scientific literature since March 2006 when FDA posted the revised Thresholds Report.

FDA recognizes that even those foods that comply with the proposed threshold level of 20 ppm gluten nonetheless may contain some gluten up to 20 ppm. FDA questions whether the potential presence of some gluten up to 20 ppm would be a material fact that, if omitted, would make a ''gluten-free'' claim potentially misleading. FDA requests 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

[2]The revised Thresholds Report (Ref. 69, pp. 59 and 60) identifies specific criteria for evaluating gluten detection analytical methods that are appropriate for establishing a gluten threshold level based upon an analytical methods-based approach. In reviewing the available methods that meet all of the stated criteria (Ref. 73), FDA has tentatively concluded that currently there are no available and appropriate test methods that can reliably and consistently detect gluten in a variety of food matrices at levels below 20 ppm.

whatever threshold level is established in the final rule.

FDA is aware that at least one other regulatory body outside the United States has developed a two-tiered approach to gluten-related food labeling. Australia and New Zealand have established standards for ''gluten-free'' (meaning no detectable gluten) and ''low-gluten'' (meaning no more than 20 milligrams gluten per 100 grams of the food, which is equivalent to no more than 200 ppm gluten in the food) (Ref. 79). As discussed in section III.C.6 of this document, one regulatory option (Option Six) was to develop a 2–tiered approach to a gluten-related food labeling in the United States. However, it is unclear what the scientific basis for such an approach would be; a safety assessment could provide a basis for a threshold, as described in the draft and revised Thresholds Reports, but would not provide a basis for a two-level approach. Thus, FDA tentatively concludes that this approach is not feasible because we do not have sufficient scientific data to recommend a specified level of gluten to define the term ''low gluten.'' In the absence of such information, use of the term ''low gluten'' in the labeling of food could make that labeling potentially misleading. FDA requests comment on this tentative conclusion, including comment on a possible scientific basis for setting a level of gluten to be defined as ''low gluten.''

Also, in the absence of a regulatory definition of ''low-gluten,'' FDA is concerned that different and inconsistent definitions of that term may be developed and used by industry, and that use of the term under such circumstances could mislead consumers. Therefore, FDA is considering whether it is necessary to prohibit use of the claim ''low-gluten'' and similar claims in the labeling of foods. FDA requests comment on this potential prohibition.

C. Compliance and Enforcement of an FDA Gluten-Free Food Labeling Claim

As previously discussed, FDA has identified 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. However, determinations of compliance with the proposed regulation need not be based on analysis of a food. In the enforcement of FDA-regulated food labeling claims, the agency routinely uses a variety of techniques, such as label reviews, onsite inspections of food manufacturers, and analysis of food samples. FDA does not necessarily analyze a food when other information or evidence exists that would enable the agency to determine that the food is misbranded. For example, if flour derived from spelt or kamut, which are species of wheat, is declared in the ingredient list for a bread labeled gluten-free, FDA would not have to analyze the product to deem it misbranded. This is because all flours made from cereal grains contain those grains' naturally occurring proteins. Likewise, if an FDA inspector were to observe the manufacturing of such a bread with spelt or kamut flour, the agency would not have to analyze the product to deem it misbranded.

There are circumstances when FDA may seek to analyze a food to determine if it is misbranded, such as in cases when FDA investigates complaints from consumers who report experiencing adverse health effects after eating a product, and an FDA label review or onsite inspection of the manufacturing facility is insufficient to identify whether there is a problem with the food. For example, an ingredient may not have been declared on the food label or a declared ingredient may inadvertently contain an undeclared substance. In such cases, an analysis of the food may be the only way to identify the presence of the substance that is the subject of the ''free'' labeling claim.

III. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs 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 believe that this proposed rule is not a significant regulatory action under the Executive Order.

A. Need for This Regulation

FALCPA directs the Secretary of HHS to issue, in consultation with appropriate experts and stakeholders, a rule to define and permit use of the term ''gluten-free'' on the labeling of foods.

B. Proposed Regulatory Options

We considered several regulatory options or alternatives: (1) Take no action; (2) take the proposed action—i.e., do not permit firms to make gluten-free claims on foods containing (a) the prohibited grains; (b) ingredients derived from the prohibited grains that have not been processed to remove the gluten; (c) ingredients derived from the prohibited grains that have been processed to remove gluten, if the use of such ingredients results in the presence of gluten in the food at a level of 20 ppm or more; or (d) 20 ppm or more gluten from any source. We are also proposing as part of this option to restrict the wording of gluten-free claims on foods that inherently do not contain gluten; (3) take the proposed action, except enforce the prohibition when the level of gluten exceeds some specified level other than 20 ppm in situations in which the gluten that is present in the food is (a) from ingredients derived from a prohibited grain that have not been processed to remove the gluten or (b) from commingling; (4) do not permit firms to make gluten-free claims on foods containing 20 ppm or more gluten, regardless of the ingredients they use to make them, and restrict the wording of gluten-free claims on foods that inherently do not contain gluten; (5) take the proposed action, except delete the wording requirements for gluten-free claims on foods that inherently do not contain gluten; (6) take the proposed action, but also define the food labeling claim ''low gluten;'' and (7) take the proposed action, except include oats in the list of grains that we propose to prohibit in foods that firms label as gluten-free. We request comments on these options as well as suggestions for other regulatory policy options that we should consider. We will address any significant comments or suggestions in the analysis of the final rule.

C. Impacts of the Proposed Regulatory Option

The primary impacts of the regulatory alternatives that we discuss in the following analysis are costs for firms to make any necessary changes to food labels and the impact of any label changes on consumer search costs. A decrease in search costs is a benefit; an increase in search costs is a cost.

1. Option One: Take No Action

We can only define costs and benefits relative to a baseline. We usually select the option of taking no action as the baseline because it helps readers identify the costs and benefits of actions that change the status quo. By definition, the baseline itself has no costs or benefits. This does not mean that we ignore the costs and benefits of taking no action. Instead, it means that we express the costs and benefits of

taking no action in the costs and benefits of the other regulatory options.

2. Option Two: Take the Proposed Action—Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing the Prohibited Grains or Ingredients That Have Been Derived From Those Grains and Have Not Been Processed to Remove the Gluten; Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing Ingredients Derived From the Prohibited Grains That Have Been Processed to Remove the Gluten, if the Level of Gluten Is 20 ppm or Greater; Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing 20 ppm or More Gluten, Regardless of How the Gluten Got Into the Food; and Restrict Wording of Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

a. *Overview*. We are proposing to prohibit firms from making gluten-free claims on the labels of foods that contain any of the following: (1) Ingredients that are any of the species of the grains wheat, rye, barley, or a crossbred hybrid of these grains (e.g., triticale) (these grains are collectively referred to as ''prohibited grains,'' a term we propose to define in this rule); (2) ingredients that have been derived from a prohibited grain and have not been processed to remove the gluten; (3) ingredients that have been derived from a prohibited grain and have been processed to remove the gluten, if the use of such ingredients results in the presence of gluten in the food at a level of 20 ppm or more; and (4) 20 ppm or more gluten from any source. We do not specify a particular level for the first two categories of substances because we would not need to test such products to determine the presence of gluten. Instead, we would be able to determine the presence of gluten by (1) reading the labels of the foods bearing gluten-free claims to determine if firms declared any of the prohibited grains or ingredients derived from the prohibited grains that have not been processed to remove the gluten in the ingredient list or (2) by conducting onsite inspections of manufacturing facilities to observe if firms were using any of the prohibited grains or ingredients derived from the prohibited grains that have not been processed to remove the gluten to make a food labeled gluten-free. Specifying a level of 20 ppm for the third and fourth categories of substances enables us to test food containing those substances to determine if they contained gluten. The third category of substances refers to ingredients that have been derived from a prohibited grain but have been processed to remove the gluten. Some common examples from among the many ingredients in this category are wheat starch, malt extract, and malt vinegar. Depending on the effectiveness of the procedures used, people may be able to remove all the gluten from those ingredients. Thus, we would not be able to determine if food that firms made using those ingredients contained gluten by simply reading the ingredient list. The fourth category of substances refers to gluten from any source including commingling with any of the prohibited grains. We would not be able to determine if food contained gluten due to commingling by reading the ingredient list.

Not permitting gluten-free claims on foods that firms make using the prohibited grains and ingredients that have been derived from them and have not been processed to remove the gluten would have no impact on current labeling because we already do not permit firms to make gluten-free claims on foods that contain gluten, and any product that firms make using prohibited grains and ingredients that have been derived from them and have not been processed to remove the gluten would contain gluten. Similarly, specifying 20 ppm or more gluten as the amount of gluten that would cause a food bearing a gluten-free labeling claim to be misbranded, if the gluten that is present in the food is from ingredients that have been derived from a prohibited grain and have been processed to remove the gluten or from any other source, would have no impact on current food labeling. Although to date we have not identified a maximum level of gluten that would be permissible in a food bearing a gluten-free claim, we generally would regard a claim that a food is ''free'' of a substance as false or misleading if the food actually contains that substance. As we discussed earlier in this preamble, a method exists that can reliably and consistently detect the presence of gluten at a level of 20 ppm. If we were to take enforcement action against a product with a gluten-free claim under our existing regulations and policies, we would use this test to determine whether a food bearing a gluten-free claim is misbranded. Therefore, these two elements of the proposed rule do not change the status quo and cannot generate costs or benefits.

We recognize that some firms may currently be making gluten-free claims on the labels of products that contain gluten at levels of 20 ppm or more. Any costs to these firms from changing product labels are not costs of this rule but of the existing statute that prohibits false or misleading labeling. We are also proposing to restrict how firms may word gluten-free claims that appear on inherently gluten-free food. In addition to the requirement that such food not contain 20 ppm or more gluten from any source, we also propose that if a food, other than a food made from oats, that inherently does not contain gluten bears a gluten-free labeling claim, then the wording of the claim must clearly indicate that all foods of the same type, not just the brand bearing this labeling claim, are gluten-free. Two examples of the wording of a claim that would meet both criteria are ''milk, a gluten-free food'' and ''all milk is gluten-free.'' Currently, we determine whether a gluten-free claim on an inherently gluten-free product is misleading on a case-by-case basis. Therefore, this element could generate both costs and benefits. We also propose that a food made from oats can bear a gluten-free labeling claim if the wording of the claim does not refer to all foods of the same type as gluten-free. This element could also generate both costs and benefits.

b. *Costs*. Restricting the wording of gluten-free claims on inherently gluten-free foods could generate compliance costs because it would require firms to remove or change current gluten-free claims on inherently gluten-free foods that use wording that does not meet our proposed requirements. We searched the Food Labeling and Packaging Survey 2000 (FLAPS 2000) database for foods bearing gluten-free claims and found the following types of foods: Yeast, enriched rice drink, pad Thai noodles (rice noodles and sauce), and rice pudding. In addition, we found ''wheat gluten-free'' claims on yeast and a soy protein shake. We would not classify as inherently gluten-free any of the foods that we identified in FLAPS as bearing gluten-free claims because firms could formulate or manufacture those types of foods to contain gluten. Based on this information, we estimate that this element of the proposed rule would generate minimal or no relabeling costs.

In addition, this element might generate increased search costs for some consumers by suppressing the use of gluten-free claims on inherently gluten-free food other than foods made from oats. The incentive for firms to use these claims increases with the ability of the claims to increase profits. Gluten-free claims that consumers interpret to refer to a particular brand probably increase that particular firm's profits more than gluten-free claims that consumers interpret to refer to general product types because such brand-specific claims provide consumers a reason to buy a particular brand of product while

product-type claims only provide consumers a reason to buy any product within a given product-type category. Therefore, requiring firms to use wording that refers to general product types would reduce to some degree the incentives for firms to use gluten-free claims and, therefore, would probably reduce the number of such claims appearing on inherently gluten-free food. However, some firms may still use gluten-free claims to influence consumers choosing between general product-type categories. The cost generated by this potential reduction in the use of gluten-free claims on inherently gluten-free food depends on the usefulness of such claims for consumers. Reducing the use of gluten-free claims would not generate costs for consumers who are already aware of inherently gluten-free foods because they would not need such claims to identify those foods. However, reducing the use of gluten-free claims could generate costs for consumers who are not aware that some inherently gluten-free foods are gluten-free because they might currently use such claims to help identify those foods as foods they can eat when following a diet that does not include gluten. We do not have sufficient information to estimate this potential cost.

c. *Benefits*. Restricting the wording of gluten-free claims on inherently gluten-free foods other than foods made from oats might generate benefits for some consumers by making any gluten-free claims that do appear on inherently gluten-free food more informative. These benefits would depend on the usefulness of such information for consumers. The wording restrictions would not benefit consumers who already know that inherently gluten-free foods are gluten-free either from prior knowledge or because they infer it from the existence of gluten-free claims on multiple foods within a given product category. However, the wording restrictions would benefit consumers who are unaware that certain inherently gluten-free foods are inherently free of gluten. The optimal level of informative labeling would balance the countervailing impacts of the potential reduction in the number of gluten-free claims and the increase in the information content of each gluten-free claim. We do not have sufficient information on consumers' knowledge of inherently gluten-free food or on the number of such foods that firms might choose to identify as inherently gluten-free in the future to estimate these benefits.

Restricting the wording of gluten-free claims on foods made from oats might generate benefits for some consumers by making any gluten-free claim that does appear on those foods less likely to mislead consumers by implying that those foods cannot contain gluten via commingling with the prohibited grains. We do not have sufficient information on the impact on consumers of avoiding potential confusion about the possibility that foods made from oats may contain gluten via contact with the prohibited grains or on the number of foods made from oats that firms might choose to label as gluten-free in the future to estimate these benefits.

d. *Summary*. Not permitting gluten-free claims on foods that firms make using the prohibited grains or ingredients that have been derived from them and have not been processed to remove the gluten would not generate costs or benefits. Similarly, not permitting gluten-free claims on foods that firms make using ingredients that have been derived from prohibited grains and have been processed to remove the gluten and on foods that contain gluten from any other source, if those foods contain 20 ppm or more gluten, would also not generate costs or benefits. Both of these proposed requirements are consistent with how we would currently enforce our existing statute that prohibits false or misleading labeling statements. Restricting the wording of gluten-free claims on foods that inherently do not contain gluten might require some firms to change product labels. However, we were unable to identify any such foods. Therefore, we estimate that these costs would be minimal. Restricting the wording of gluten-free claims on inherently gluten-free foods may also generate future costs and benefits by changing the incentives to use such claims and changing the information content of gluten-free claims on affected foods. We do not have sufficient information to quantify these potential costs and benefits.

3. Option Three: Take the Proposed Action, Except Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing Ingredients Derived From the Prohibited Grains That Have Been Processed to Remove The Gluten, if The Level of Gluten Is Some Specified Level Other Than 20 ppm, and Do Not Permit Firms to Make Gluten-Free Claims on Foods If the Level Of Gluten Is Some Specified Level Other Than 20 ppm, Regardless of How the Gluten Got Into the Food

a. *Overview*. Under this option, we could specify a threshold level that was either higher or lower than 20 ppm gluten for deeming a food labeled gluten-free to be misbranded, when the gluten that is present in that food is from ingredients that have been derived from the prohibited grains and have been processed to remove the gluten or from any other source. However, we have chosen to analyze alternative levels higher than 20 ppm gluten because we do not know of any currently available and appropriate test methods that can reliably and consistently detect gluten at levels below 20 ppm. Specifying a level higher than the proposed level of 20 ppm gluten would expand the number of foods that would be eligible to bear gluten-free claims and would generate both costs and benefits. We do not need to specify precisely a level above the proposed level of 20 ppm in order to analyze this option. We note that if we were to choose this option, then we would need additional scientific data to analyze the costs and benefits of whatever level we chose.

Specifying a level higher than 20 ppm gluten would not generate compliance costs for industry because gluten-free claims are voluntary and no firms would need to remove existing labeling claims that are appropriate under the statute. However, it could generate search costs for some consumers. As we discussed in section I.A of this document, the symptoms of celiac disease are highly variable among affected individuals. We don't know the reasons for this variability. Some individuals with celiac disease may be unable to tolerate whatever level of gluten we might specify. Individuals who cannot tolerate whatever level of gluten we might specify might nevertheless continue to rely on gluten-free claims to identify appropriate foods and might suffer adverse health consequences from doing so. However, we assume that most consumers who use gluten-free claims to identify appropriate foods will have been diagnosed with celiac disease and will be under a physician's care for that condition. Therefore, sensitivity to whatever level of gluten we might allow would probably be detected within a short time and these individuals would probably not continue to rely on gluten-free claims to identify appropriate foods. The more likely consequence, and the consequence that we base the remainder of our analysis upon, is that consumers who are sensitive to gluten at this higher level would no longer be able to rely on gluten-free claims to identify foods that are safe for them to eat and would need to take other steps to identify these foods. This would increase the cost for these consumers to

find appropriate foods. The increased search costs might cause these consumers to conduct fewer searches for appropriate foods, which could lead them to reduce their compliance with a diet that does not include gluten and increase their risk of various adverse health effects. In addition, increased search costs for some consumers would tend to discourage firms from continuing to produce or develop new foods that contain no gluten because it could reduce their ability to inform consumers of such foods using gluten-free labeling claims, although they could continue to inform consumers about these foods in other ways. This might further reduce the compliance of these consumers with a diet that does not include gluten and generate additional adverse health effects.

Under this option, the potential benefits of specifying a level greater than 20 ppm gluten, when the gluten that is present in the food is from ingredients that have been derived from a prohibited grain and have been processed to remove the gluten or from any other source, are similar in nature but opposite in effect to the costs and would accrue to different consumers. Consumers who can tolerate whatever level we specify would value our adopting that level because it might allow them to use gluten-free claims to identify a greater range of appropriate foods. This reduction in search costs could lead these consumers to conduct additional searches for appropriate foods, which could lead to them to increase their compliance with diets that do not include gluten and lower their risk of adverse health effects. In addition, the decreased search costs for these consumers would tend to encourage firms to produce or develop foods with up to the specified level of gluten, which could increase these consumers' compliance with a diet that does not include gluten and further reduce their risk of adverse health effects.

We do not know how much some consumers and firms would value our specifying a level higher than 20 ppm gluten. The potential value for consumers who would benefit from this option is probably lower on a per-person basis than the corresponding potential loss for consumers who would be unable to tolerate the level of gluten allowed under the specified level because the incremental effect on a given individual's search costs of gluten-free claims appearing on some additional foods is smaller than the incremental effect of losing the use of gluten-free claims on all foods. However, we do not know how many consumers can and cannot tolerate particular levels of gluten. Therefore, we cannot draw any conclusions on the net benefits of specifying different levels.

This option would include the provisions restricting the wording of gluten-free claims on inherently gluten-free food. Therefore, it would also generate the costs and benefits that we associated with those provisions in our discussion of Option Two (the proposed action) previously discussed.

b. *Costs.* As we discussed in the preceding overview, this option would increase search costs for consumers who are unable to tolerate the specified level of gluten. However, as we discussed in section I of this document, accurately estimating the prevalence of celiac disease in the United States is difficult for a variety of factors. These factors also demonstrate that individuals vary for many reasons in their sensitivity to gluten. One researcher who did attempt to identify a level that all celiac patients can tolerate was Fasano (Ref. 80), who, based on data from Catassi, et al., (Ref. 81) and Collin, et al., (Ref. 82), suggested that all individuals with celiac disease may be able to tolerate between 20 and 100 ppm. (See Ref. 69 at pp. 39 and 40 for further discussion of this literature.) Some researchers address this issue in the context of wheat starch because wheat starch is a common ingredient that contains varying and sometimes very low levels of gluten (Refs. 41, 82, and 83). In general, as we discussed in both the draft and revised Thresholds Reports (Ref. 67, pp. 35 and 36 and Ref. 69, pp. 39 and 40) , the studies are inconclusive about the safety and subjective acceptability of foods that contain 20 ppm or more gluten for individuals with celiac disease. To reflect this uncertainty, we assume that 0 percent to 100 percent of consumers with celiac disease are unable or unwilling to tolerate 20 ppm or more gluten over the long term and, therefore, would be unable to continue to use gluten-free claims to identify appropriate foods under this option.

Physicians have diagnosed approximately 40,000 to 60,000 people as having celiac disease in the United States (Refs. 17 and 18). We assume that physicians have prescribed a diet that does not include gluten for all consumers they have diagnosed with celiac disease. If 0 to 100 percent of these consumers cannot tolerate 20 ppm or more gluten, and if all of these consumers currently use gluten-free claims to identify appropriate foods, then 0 to 60,000 people who currently use gluten-free claims would be unable to continue to do so.

We assume that only consumers who have been diagnosed with celiac disease, or those who buy food for such consumers, are currently using gluten-free claims to find appropriate foods. However, some consumers who have not been diagnosed as having celiac disease may also follow a diet that does not include gluten on their own initiative if they are experiencing symptoms of gluten intolerance. We consider this group to illustrate the consequences of our assumption that only those consumers who have been diagnosed with celiac disease use gluten-free claims on product labels.

As we explained in section I.B of this document, the prevalence of celiac disease in the United States, including both symptomatic and asymptomatic individuals, ranges from about 0.4 percent to about 1.0 percent (Refs. 1 and 16), although the actual prevalence may be higher or lower. Based on this information, we assume that 0.4 percent to 1.0 percent of the United States population may have celiac disease. One study found that 40 percent of children and 60 percent of adults who were newly diagnosed with celiac disease were symptomatic (Ref. 84). Therefore, we assume the overall rate of new celiac patients who are symptomatic is between 40 percent and 60 percent.

The U.S. population in August 2005 was approximately 297 million (Ref. 85). If the overall prevalence of celiac disease is between 0.4 percent and 1 percent, then approximately 1.2 million to 3.0 million people in the United States have celiac disease. If 40 percent to 60 percent of people with celiac disease have symptoms of that disease, then between 500,000 and 1.8 million people in the United States have symptoms associated with celiac disease. Earlier we noted that only 40,000 to 60,000 people in the United States have been diagnosed with celiac disease. Subtracting this number of people from the estimated number of people in the United States who have symptoms associated with celiac disease and rounding to the nearest tenth of one million implies that approximately 0.4 million to 1.8 million people have undiagnosed celiac disease and exhibit some symptoms of that disease. If some of these consumers, or those who buy food for these consumers, are currently using gluten-free claims to identify appropriate foods, then the consequences of revising the criteria for using those claims would be much greater than we have estimated based only on consumers who have been diagnosed with celiac disease.

Any consumers who currently rely on gluten-free claims to identify appropriate foods and who would be unable to continue to use those claims because they cannot tolerate the level of gluten allowed under the specified level would probably need to spend additional time identifying appropriate foods. In the comments that we received during the public meeting on gluten-free food labeling, some comments said they spent up to an extra 10 hours per week shopping, while other comments said they spent five times as much time shopping as they did before they started a diet that does not include gluten. One consumer group reported that some consumers on a diet that does not include gluten said they spent an extra 30 minutes per week shopping, while other consumers said they spent twice as much time shopping as they did before they started a diet that does not include gluten (Ref. 86). This group did not report how much time the consumers spent shopping before they started a diet that does not include gluten. However, in the analysis of a previous and unrelated rule, we estimated that the average shopping time for all grocery store purchases was 46.2 minutes per week (68 FR 51738 at 51744, August 28, 2003). This average would have included those on special diets such as diets that do not include gluten. However, most people are not on special diets. Therefore, we interpret the information from this consumer group to mean that some consumers on a diet that does not include gluten who reported spending twice as much time shopping spent about 90 minutes shopping per week. This group did not report on the smallest amount of extra time that these consumers spent shopping; but, we assume that all consumers on a diet that does not include gluten would spend at least some extra time shopping. We have chosen 10 minutes per week as a reasonable estimate of this minimum amount of extra shopping time. We assume that the results reported by the consumer group are more representative of the average consumer on a diet that does not include gluten than the results reported by these individual consumers, who might not be typical of the average consumer on a diet that does not include gluten. Based on this information, we assume that being on a diet that does not include gluten increases food shopping time by 10 to 46 minutes per week.

We do not know the difference in search times for those who can use gluten-free labels and those who cannot. The range in search costs that we reported previously probably includes consumers who make considerable use of gluten-free claims to identify foods and consumers who do not. Many consumers who can make considerable use of gluten-free claims probably still need to expend at least some additional time searching for foods relative to the average consumer because relatively few foods bear gluten-free claims. In addition, some consumers who use gluten-free claims to identify acceptable foods may also read ingredient lists to confirm the absence of gluten (Ref. 87). Therefore, the ability to use gluten-free claims probably leads to a relatively small reduction in extra shopping time for consumers on diets that do not include gluten. We do not have sufficient information to estimate the time savings associated with being able to use existing gluten-free claims; but, we have chosen a range of 10 to 50 percent of the difference between the low end and the high end of the range of total extra shopping time, or 0 minute to 18 minutes per week, as the extra shopping time that the ability to use gluten-free claims could reasonably be expected to eliminate. We request comments on this assumption.

Consumers who cannot rely on gluten-free claims and who buy foods in conventional grocery stores probably expend the most extra time shopping because they would have to rely on ingredient lists or take other approaches to identifying appropriate foods. These consumers might need to learn more about food ingredients or use references on food ingredients. In addition, some of these consumers may call or write manufacturers to ask about ingredients. Some consumers may look up information on foods on the Internet. Finally, some of these consumers may refer to reference lists of gluten-free foods that some celiac organizations publish for this purpose. Consumers who cannot rely on gluten-free claims and who buy gluten-free foods in specialty stores or from mail order firms probably have lower search costs because some of these sources may identify foods that do not contain gluten. However, gluten-free foods are typically more expensive when purchased in specialty stores or from mail order firms than when purchased in conventional grocery stores; so, the reduction in search cost is offset by increased product prices.

Based on this information, we assume that losing the ability to rely on the relatively small number of existing gluten-free labels may increase search costs by 0 to 18 minutes per week. Multiplying this range by the number of consumers who we estimated might lose the use of gluten-free labeling, 0 to 60,000, results in a potential increase in search costs of 0 to 18,000 hours per week. The average value of 1 hour of leisure time should be similar to the average value of 1 hour of working time, which was $26.05 in September 2005 for nonfarm private and State and local Government workers in the United States (Ref. 88). Therefore, we estimate the cost associated with potential increases in search costs for some consumers to be $0 to $24 million per year.

If specifying a level higher than 20 ppm gluten increases product search costs for some consumers, then it may also lead those consumers to conduct fewer searches for appropriate foods, which could reduce their compliance with diets that do not include gluten. Some consumers already have difficulty following a diet that does not include gluten. One recent study said that the literature suggests that only 17 percent to 65 percent of patients who are prescribed a diet that does not include gluten manage to adhere to that diet (Ref. 89). An earlier study found that only 2 percent of 130 patients who had been diagnosed with celiac disease managed to adhere to a diet that does not include gluten (Ref. 90). One article said that poor compliance with diets that do not include gluten was at least partially due to the inconvenience of purchasing and preparing gluten-free food and the higher prices of gluten-free foods (Ref. 46). Search costs are one measure of the inconvenience of purchasing gluten-free food and probably also play a role in the higher cost of such foods.

Some studies have found relatively high compliance rates for diets that do not include gluten that allow ingredients that may have trace amounts of gluten, such as wheat starch. This suggests that compliance with diets that do not include gluten that allow such ingredients may be higher than compliance with diets that do not include gluten that do not allow such ingredients. One article noted that 85 percent of celiac patients in Finland manage to adhere over the long-term to a diet that does not include gluten that allows wheat starch (Ref. 82). Similarly, one study that was conducted in Finland found that 88 percent of the patients in that study adhered to a diet that does not include gluten that allowed wheat starch (Ref. 89). These percentages are higher than the 2 percent to 65 percent compliance rates for diets that do not include gluten that we mentioned in the preceding paragraph, which were from articles that appear to have interpreted any gluten

intake as a failure to comply with a diet that does not include gluten. If there is a difference in compliance rates, then part of this difference may be because gluten-intolerant consumers who can tolerate foods made with ingredients that may contain trace amounts of gluten, such as wheat starch, can more easily find appropriate and acceptable foods. For example, one study found that 13 of the 17 consumers in that study preferred a product made with wheat starch containing approximately 15 ppm gluten to foods made with rice flour or cornstarch that were entirely gluten-free (Ref. 83). On the other hand, Thompson (Ref. 41) contended that there is no evidence that compliance is higher among patients following diets that do not include gluten that allow foods made with wheat starch than among those following diets that do not include gluten that do not allow foods made with wheat starch. For example, some of the differences in the compliance rates that appear in different articles may be due to differences in the usual diets of various countries or other factors that are unrelated to whether the diet includes products that contain trace amounts of gluten such as wheat starch.

Of course, factors other than search costs and product costs may affect compliance with a diet that does not include gluten. For example, one article that looked at 55 cases of persisting celiac disease caused by non-compliance with a diet that does not include gluten found that 73 percent of those patients were not aware of the continuing nature of the disease and thought they had recovered from a temporary illness, while 27 percent were aware of the continuing nature of the disease but were unable to maintain compliance without additional dietary counseling (Ref. 90). The authors suggested that the principal reason for non-compliance with a diet that does not include gluten might be the lack of morbidity associated with chronic untreated celiac disease. They noted that although a few patients had experienced lassitude, abdominal discomfort, or occasional diarrhea, the symptoms were not compelling. Another study also suggested that one potential reason for intentional non-compliance with a diet that does not include gluten is that many non-compliant patients have no symptoms and normal hematological and biochemical profiles despite notable mucosal villous atrophy and inflammation (Ref. 83).

Based on this information, we assume that if this option raised search costs for some consumers, then it could lead them to decrease their compliance with a diet that does not include gluten. However, we do not have sufficient information to estimate the incremental change in compliance rates.

If this option reduced some consumers' compliance with a diet that does not include gluten, then it could generate adverse health effects for those consumers. The adverse health effects associated with celiac disease are highly variable among affected individuals. We do not know the reasons for this variability, but it may depend on the age and immunological status of the individual; the amount, duration, or timing of the exposure to gluten; and the specific area and extent of the gastrointestinal tract involved by disease (Ref. 5). We discussed the adverse health effects associated with gluten consumption by celiac patients in section I.A of this document. Although decreased compliance with a diet that does not include gluten would probably generate some adverse health effects, the literature is not clear on the effect of changes in compliance on health outcomes. Based on this information, we conclude that any decrease in compliance with a diet that does not include gluten could generate additional cases of various adverse health effects. However, we cannot estimate the number of cases from this effect because we do not have sufficient information on the impact of this option on product search costs, the impact of product search costs on compliance rates, or the impact of changes in compliance rates on the risk of various adverse health effects.

Finally, any reduction in the usefulness of gluten-free claims for some consumers might discourage firms from continuing to produce or developing foods with a level of gluten below the specified level. Firms could use other truthful and not misleading wording on food labels to inform consumers that a product was not made with gluten-containing ingredients or contained less than the specified level of gluten. However, these other types of label statements might not be as effective as gluten-free claims. This potential reduction in the number of foods with a level of gluten below the specified level might further increase search costs for consumers who desire such foods and might further reduce their compliance with diets that do not include gluten. We do not have sufficient information to estimate these potential costs.

This option would also generate the costs that we associated with restricting the wording of gluten-free claims on inherently gluten-free food in our discussion of Option Two. We do not have sufficient information to estimate these costs.

c. *Benefits.* As we discussed in the preceding overview, specifying a level higher than 20 ppm gluten might generate benefits because it would enable firms to use gluten-free claims on additional foods. Consumers who can tolerate the specified level of gluten could use gluten-free claims to more easily identify appropriate foods.

We do not know how many existing foods contain particular levels higher than 20 ppm because no information is available on the amount of gluten in different grain-derived food ingredients or finished food (Ref. 69, p. 37). However, the gluten in many foods that contain trace amounts of gluten comes from ingredients such as wheat starch, malt extract, or malt vinegar. The level of gluten in wheat starch varies between 14 ppm and 740 ppm (i.e. 7 ppm to 370 ppm prolamin, which corresponds to 14 ppm to 740 ppm gluten) (Ref. 41). One small survey of 24 wheat-starch derived flours in Finland found levels of less than 20 ppm up to 160 ppm gluten (Ref. 82). The gluten levels in these products were distributed approximately as follows: 58 percent had 20 ppm or less, 13 percent had more than 20 ppm up to 40 ppm, 13 percent had more than 40 ppm up to 60 ppm, 0 percent had more than 60 ppm up to 80 ppm, 8 percent had more than 80 ppm up to 100 ppm, 0 percent had more than 100 ppm up to 140 ppm, and 8 percent had more than 140 ppm up to 160 ppm. One study analyzed gluten levels in 2 brands of wheat starch and found levels of approximately 15 ppm (0.75mg/100g) and 560 ppm (28mg/100g) (Ref. 83). One article noted that improved gluten detection techniques have demonstrated that some food made with wheat starch contains more gluten than the current Codex standard for gluten-free foods would allow (Ref. 91). Codex Standard 118–1981 (amended 1983) for gluten-free foods that is in effect today defines ''gluten-free'' to mean that the total nitrogen content of gluten-containing cereal grains used to make a product cannot exceed 0.05 gram nitrogen per 100 grams dry cereal grain (Ref. 92). However, some authors have attempted to estimate what this Codex restriction means in terms of ppm of gluten. One study estimates that the current Codex standard allows gluten-free products to contain up to 500 ppm (50 mg/100 g) (Ref. 93). Other studies estimate that the current Codex standard allows gluten-free products to contain up to 600 ppm gluten (60 mg/100 g) (Refs. 94 and 89). Based on this information, we assume wheat starch contains between 14 ppm and 740 ppm gluten. The level of gluten

in products made with wheat starch would be significantly lower, depending upon the amount of wheat starch used in proportion to the other ingredients to make the products. However, we do not have data on the level of gluten in products made with wheat starch. Foods made with malt extract may also contain low levels of gluten (Ref. 95). Firms produce malt extract from malt grain derived from barley. Depending on the extraction technique, malt extract may contain residual amounts of gluten. One study tested some foods containing malt extract and found gluten in some samples of chocolate powder, chocolate milk, and chocolate bars, but not in breakfast cereals (Ref. 91). Foods that firms manufacture using other ingredients, such as oats, may also contain gluten if these other ingredients are commingled with grains like wheat, rye, barley, or triticale (Refs. 63 and 64).

Some individuals with celiac disease may be able to tolerate levels of gluten higher than 20 ppm in ingredients such as wheat starch, malt extract, and malt vinegar. These consumers may be able to use current ingredient labeling to identify appropriate foods if firms list these types of ingredients on product labels and no other potential sources of gluten appear on the ingredient lists. However, these consumers would not always be able to use ingredient lists to determine whether a product contains gluten because some ingredients' common or usual names do not identify their food sources and some ingredients can be derived from grains that contain gluten or from grains that do not contain gluten. In some cases, firms may include ingredients containing trace amounts of gluten in other listed ingredients that have collective names such as flavors and colors. Other consumers may be able to tolerate the lower but not the higher levels of gluten that might occur in foods that contain these ingredients. These consumers would not be able to rely on current ingredient labeling because some foods that contain these ingredients could contain more than whatever amount of gluten higher than 20 ppm those consumers can tolerate. These consumers would need to take additional steps to identify foods that contain gluten at the levels they can tolerate. These additional steps might involve using references on gluten levels in different foods, calling manufacturers, or buying foods through specialty vendors that select appropriate foods or provide advice on acceptable foods. Using a level higher than 20 ppm gluten could decrease search costs for both groups of consumers, but the effect would be larger for consumers who cannot use the ingredient list to identify appropriate foods.

We do not know how many consumers can tolerate any particular level of gluten. In the preceding discussion of costs, we estimated that 0 to 100 percent of the 40,000 to 60,000 consumers who we estimated to be currently on a diet that does not include gluten cannot tolerate an amount of gluten higher than 20 ppm. The corresponding estimate of the percentage of consumers who can tolerate a level of gluten higher than 20 ppm also ranges from 0 percent to 100 percent, which corresponds to 0 to 60,000 consumers.

We also do not know the impact on search costs for these consumers. In the preceding cost discussion, we estimated that being on a diet that does not include gluten increases product search time by 10 to 46 minutes per week. We do not know how much of this increased time cost comes from reading ingredient labels to identify ingredients that may contain low levels of gluten or taking other steps to determine the gluten levels of foods that have these ingredients as the only sources of gluten. However, a reasonable estimate of the increased time cost is 10 to 50 percent of the difference between the low end and high end of the range of total extra shopping time, or 0 minute to 18 minutes per week after rounding. Therefore, we assume that allowing gluten-free claims to appear on foods with levels of gluten higher than 20 ppm could reduce consumers' search costs by 0 to 18 minutes per week. We request comments on this assumption. Multiplying the estimated number of consumers who have been diagnosed with celiac disease by the number of minutes results in a potential search cost savings of 0 to 18,000 hours per week. The average value of one hour of leisure time should be similar to the average value of 1 hour of working time, which was $26.05 in September 2005 (Ref. 88). Therefore, we estimate the potential benefit of reduced product search costs to be $0 to $18 million per year.

Any decrease in search costs for some consumers could lead those consumers to conduct additional searches for appropriate foods, which might increase their compliance with a diet that does not include gluten. If these consumers increased their compliance with a diet that does not include gluten, then they may reduce their risk of adverse health effects. This option might also encourage firms to develop new foods with the specified level of gluten because it would improve the ability of firms to signal to consumers through the use of gluten-free labeling claims that a given product contains less than the level of gluten. The development of new foods might also further facilitate compliance with a diet that does not include gluten for consumers who can tolerate the specified level of gluten, which could lead to additional health benefits. We do not have sufficient information to estimate these benefits.

This option would also generate the benefits that we associated with restricting the wording of gluten-free claims on inherently gluten-free food in our discussion of Option Two. We do not have sufficient information to estimate these benefits.

d. *Summary*. The element of this option that specifies a level higher than 20 ppm gluten, when the gluten that is present in the food is from ingredients that have been derived from a prohibited grain and have been processed to remove the gluten or from any other source, would allow firms to make gluten-free claims on the labels of some foods that contain less than this level of gluten and would generate both costs and benefits. The costs would accrue to consumers who cannot tolerate the specified level of gluten and the benefits would accrue to consumers who can tolerate the specified level of gluten. We do not have sufficient information to compare the impact of this option on these two groups of consumers. Using the full range of 0 percent to 100 percent of consumers diagnosed with celiac disease as potentially falling into either group gives countervailing search costs and benefits of $0 to $18 million per year. Changes in search costs could also generate countervailing health effects for these two groups of consumers. The optimal rule from a cost-benefit perspective would balance the cost of reducing the usefulness of gluten-free claims for consumers who have a relatively high degree of sensitivity to gluten with the benefit of making gluten-free claims as useful as possible for consumers who are attempting to control their intake of gluten but are relatively less sensitive to gluten. However, we do not have sufficient information to quantify these effects or to estimate the optimal level of gluten.

The element of this option that would restrict the wording of gluten-free claims on inherently gluten-free food could also generate costs and benefits. Costs would result from a potential reduction in the likelihood that firms will use gluten-free claims on inherently gluten-free food, while the benefits would result from the greater information content or the reduced potential for misleading consumers of

any such claims that do appear on these foods. We do not have sufficient information to determine the net effect of these countervailing influences.

4. Option Four: Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing 20 ppm or More Gluten, Regardless of the Ingredients They Use to Make Them, and Restrict the Wording of Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

Under this option, we would allow firms to make gluten-free claims on food that they make from any type of ingredient if the food does not contain 20 ppm or more gluten. This option would generate the same costs and benefits as Option Two except that applying the 20 ppm level to food that contains one or more of the prohibited grains or that contains ingredients that have been derived from them and have not been processed to remove the gluten would represent a change from our current approach to such claims. Our current approach to claims of the form ''substance X-free'' is that a product that bears such a claim on its label cannot contain any level of substance X. Applying this approach to gluten-free claims implies that we do not allow firms to use gluten-free claims on foods they make from these substances regardless of the level of gluten in that food. Option Two maintains our current approach for these foods. Therefore, applying the level of 20 ppm to this food would generate costs and benefits that we did not discuss under Option Two.

As a practical matter, any product that firms make from one or more of the prohibited grains will contain 20 ppm or more gluten. Therefore, the impact of applying the level to food that contains one or more of the prohibited grains is the same as the impact of our current position of prohibiting gluten-free claims on the labels of food containing these grains. Therefore, this change will not generate costs or benefits relative to the baseline.

In contrast, a food that contains ingredients that have been derived from a prohibited grain and have not been processed to remove the gluten may contain less than 20 ppm gluten. Therefore, applying the level to this category of food would result in costs and benefits relative to the baseline of our current position. These costs and benefits would be in addition to the costs and benefits that we discussed under Option Two.

The cost of applying the level to food that contains ingredients that have been derived from a prohibited grain and have not been processed to remove the gluten is that we would need to test the food to determine if it can bear a gluten-free claim. Enforcement actions that require testing are significantly more costly for us than enforcement actions that only require us to read ingredient lists on food labels. However, we have not analyzed the difference in costs for enforcement actions that require testing and those that do not. In addition, we cannot estimate how many times we would need to take enforcement actions against this type of food. Therefore, we cannot estimate this additional cost.

This provision would not generate costs for consumers because consumers who cannot tolerate 20 ppm gluten are unable to rely on gluten-free claims to identify acceptable products under our current approach and would also be unable to do so under the proposed requirements of Option Two. This is because both our current approach to claims of the general form ''substance X-free'' and the approach expressed in Option Two allow firms to make gluten-free claims on products that contain less than 20 ppm gluten if the gluten that is present in the food is from a source other than an ingredient that is a prohibited grain or that has been derived from a prohibited grain and has not been processed to remove the gluten.

The benefit of applying the level of 20 ppm to food that contains ingredients that have been derived from a prohibited grain and have not been processed to remove the gluten is that firms would be able to begin using gluten-free claims on this type of food, provided that the food did not contain 20 ppm or more gluten. This would generate benefits for consumers who can tolerate up to 20 ppm gluten because they would be able to rely on gluten-free claims to identify additional products. We do not have sufficient information to estimate this benefit.

In summary, this option would have the same costs and benefits as Option Two except for the costs and benefits of applying the level of 20 ppm to food that contains ingredients that have been derived from a prohibited grain and have not been processed to remove the gluten. We do not have sufficient information to quantify these countervailing costs and benefits. Therefore, we cannot compare the net benefits of this option to the net benefits of Option Two.

5. Option Five: Take the Proposed Action, Except Delete Wording Requirements for Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

We could take the proposed action but delete the requirements relating to the wording of gluten-free claims on foods that inherently do not contain gluten. In that case, we would continue the status quo approach of determining whether such claims are misleading on a case-by-case basis. This would eliminate the costs and benefits of the proposed requirements that we discussed under Option Two. Therefore, this option would not generate any costs or benefits.

6. Option Six: Take the Proposed Action, But Also Define the Food Labeling Claim ''Low Gluten''

Under this option, we would specify requirements for a ''gluten-free'' labeling claim as directed by FALCPA and also specify requirements for a less restrictive ''low gluten'' labeling claim that firms could use on foods that contained a relatively low level of gluten at some specified level higher than 20 ppm. Firms can already use ''low gluten'' claims if those claims are truthful and not misleading. However, we currently do not have a position on the level of gluten that renders a ''low gluten'' claim truthful and not misleading. Determining an appropriate level of gluten to use in defining ''low gluten'' on a cost benefit basis would require, among other things, dose-response data on the health impacts of various levels of gluten on those with celiac disease. We do not have sufficient scientific data to recommend a specified level of gluten to define the term ''low gluten.'' Nevertheless, we address significant regulatory options in regulatory impact analyses irrespective of their feasibility.

This two-tier approach could generate higher benefits than Option Two in two ways. First, by establishing explicit criteria for using ''low gluten'' claims, we might encourage firms to use such claims. Second, by basing the use of ''low gluten'' claims on a particular level of gluten, we would standardize the meaning of ''low gluten'' claims and make them more useful for consumers. Encouraging the use of ''low gluten'' claims and standardizing the level of gluten in foods bearing such claims might generate benefits because a combination of ''gluten-free'' claims and ''low gluten'' claims would provide claims that might be useful for both more sensitive and less sensitive consumers, which would increase the

number of consumers who find such claims useful and decrease the number of consumers who might be unable to continue to use these claims to identify appropriate foods.

However, this option may also generate costs beyond those we discussed under Option Two. First, some firms may already be using ''low gluten'' claims. If we define that term relative to a particular level of gluten, then some of these firms may need to change product labels. We were unable to identify any foods bearing ''low gluten'' labels in the FLAPS database. Therefore, we estimate that any labeling costs would be minimal. Second, the presence of two claims corresponding to different levels of gluten might confuse some consumers and lead them to consume foods with more gluten than they intend to consume. Encouraging the use of ''low gluten'' claims might exacerbate this potential problem. While many consumers may be familiar with ''free'' and ''low'' content claims in the context of nutrients, we have not previously defined ''low'' claims for other food substances that some consumers may need to totally avoid. We do not have sufficient information to estimate the costs and benefits of this option.

7. Option Seven: Take Proposed Action, Except Include Oats in the List of Grains That We Propose to Prohibit in Foods That Firms Label as Gluten-Free

We could also expand the list of prohibited grains to include oats. Some consumers with celiac disease may be unable to tolerate some of the proteins that naturally occur in oats and may prefer to avoid oats in addition to avoiding the proposed prohibited grains and ingredients people make from those grains discussed in Option Two. However, other consumers with celiac disease may be able to tolerate the proteins that naturally occur in oats and, therefore, may wish to consume oats when following a diet that does not include gluten. This option could generate some relabeling costs because we currently allow firms to use gluten-free claims on foods that contain oats but do not contain gluten from commingling with a prohibited grain. These firms would need to remove the gluten-free claims from foods made from oats if we were to include oats in the list of prohibited grains. We do not know how many foods are made from oats and do not contain gluten, nor do we know the percentage of such foods that bear gluten-free claims. We searched the FLAPS 2000 database and did not find any foods that contained oats and had a gluten-free claim. Therefore, we estimate that any labeling costs would be minimal.

In addition, if we included oats in the list of prohibited grains, then we would reduce the usefulness of those claims for consumers who wish to avoid gluten but can tolerate the naturally occurring proteins in oats. The increase in search costs for these consumers could be considerable because oats are a common food ingredient that can be particularly important for celiac patients who wish to avoid wheat, rye, barley, and their crossbred hybrids. An increase in search costs for these consumers may decrease their compliance with a diet that does not include gluten and possibly increase their risk of adverse health effects.

However, this option would generate benefits for consumers who wish to avoid gluten and also wish to avoid oats because, if we include oats in the list of prohibited grains, then these consumers would be able to use gluten-free claims to identify appropriate foods. Expanding the usefulness of gluten-free claims for these consumers would reduce their search costs, possibly increase their compliance with a diet that does not include gluten, and possibly reduce their risk of adverse health effects.

As we discussed in detail at section I.C.3 of this document, the literature is divided on the percentage of consumers with celiac disease who can tolerate oats, even when steps have been taken to prevent commingling with prohibited grains such as wheat and rye. Based on this information, we assume that some consumers with celiac disease may wish to avoid oats and that the usefulness of gluten-free claims for these consumers could depend on whether or not we include oats in the list of proposed prohibited grains. However, we do not have sufficient information to estimate the number of such consumers or the net impact of including oats in the proposed prohibited list of grains.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We are not proposing to change our current position with respect to the grains or proteins that we associate with gluten or the level of gluten that we would use to determine compliance with the requirements for using gluten-free claims. Further, we know of no foods that inherently do not contain gluten and that bear gluten-free claims that do not meet our proposed wording restrictions and that are produced by small entities. Therefore, the agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

A. Proposed Regulatory Options

We considered the following regulatory options: (1) Take no action; (2) take the proposed action—do not permit firms to make gluten-free claims on foods containing the prohibited grains or ingredients that have been derived from them and have not been processed to remove the gluten; do not permit firms to make gluten-free claims on foods containing ingredients derived from the prohibited grains that have been processed to remove the gluten, if the level of gluten is 20 ppm or greater; do not permit firms to make gluten-free claims on foods containing 20 ppm or more gluten, regardless of how the gluten got into the food (i.e. declared ingredient, undeclared ingredient, contaminant, etc.); and restrict the wording of gluten-free claims on foods that inherently do not contain any gluten; (3) take the proposed action, except do not permit firms to make gluten-free claims on foods containing ingredients derived from the prohibited grains that have been processed to remove the gluten, if the level of gluten is greater than some specified level higher than 20 ppm, and do not permit firms to make gluten-free claims on foods if the level of gluten is greater than some specified level higher than 20 ppm, regardless of how the gluten got into the food; (4) do not permit firms to make gluten-free claims on foods containing 20 ppm or more gluten, regardless of the ingredients they use to make them, and restrict the wording of gluten-free claims on foods that inherently do not contain gluten; (5) take the proposed action, except delete the wording requirements for gluten-free claims on foods that inherently do not contain gluten; (6) take the proposed action, but also define the food labeling claim ''low gluten;'' and (7) take the proposed action, except include oats in the list of grains that we propose to prohibit in foods that firms label as gluten-free.

B. Impacts of the Proposed Regulatory Options on Small Entities

1. Option One: Take No Action

Taking no action would have no impact on small entities.

2. Option Two: Take the Proposed Action—Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing the Prohibited Grains or Ingredients That Have Been Derived From Those Grains and Have Not Been Processed to Remove the Gluten; Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing Ingredients Derived From the Prohibited Grains That Have Been Processed to Remove the Gluten, if the Level of Gluten Is 20 ppm or Greater; Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing 20 ppm or More Gluten, Regardless of How the Gluten Got Into the Food; and Restrict Wording of Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

We are not proposing to change how we currently enforce our existing statute that prohibits false or misleading labeling other than instituting new wording requirements for gluten-free claims on foods that inherently do not contain gluten. This element may generate compliance costs for small entities. However, as we discussed in the preceding regulatory impact analysis, we know of no such foods. Therefore, we estimate that this proposed rule would generate minimal or no costs for small entities. We request information on the impact of the proposed action and all other options on small entities.

3. Option Three: Take the Proposed Action, Except Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing Ingredients Derived From the Prohibited Grains That Have Been Processed to Remove the Gluten, If the Level of Gluten Is Some Specified Level Other Than 20 ppm, and Do Not Permit Firms to Make Gluten-Free Claims on Foods If the Level of Gluten Is Some Specified Level Other Than 20 ppm, Regardless of How the Gluten Got Into the Food

This option would have the same minimal impact on small entities as Option Two. As we discussed in the preceding preliminary regulatory impact analysis, we could analyze levels either higher or lower than 20 ppm, but we have chosen to analyze levels higher than 20 ppm because we do not know of any currently available and appropriate test methods that can reliably and consistently detect gluten at levels below 20 ppm. Under Option Three, specifying a level higher than 20 ppm gluten would not generate additional compliance costs for small entities because gluten-free claims are voluntary and no small firms would need to remove existing labeling claims that complied with our existing position. Therefore, we estimate that this option would also generate minimal or no costs for small entities.

4. Option Four: Do Not Permit Firms to Make Gluten-Free Claims on Foods Containing 20 ppm or More Gluten, Regardless of the Ingredients They Use to Make Them, and Restrict the Wording of Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

This option would have the same minimal impact on small entities as Option Two. Under Option Four, applying the level of 20 ppm to all foods, regardless of the ingredients firms use to make them, would not generate additional compliance costs for small entities because gluten-free claims are voluntary and no small firms would need to remove existing labeling claims that they would not already have had to remove under our existing approach to regulating gluten-free food labeling. Therefore, we estimate that this option would also generate minimal or no costs for small entities.

5. Option Five: Take the Proposed Action, Except Delete Wording Requirements for Gluten-Free Claims on Foods That Inherently Do Not Contain Gluten

Taking the proposed action except deleting the wording requirements for gluten-free claims would eliminate any impact on small entities.

6. Option Six: Take the Proposed Action, but Also Define the Food Labeling Claim ''Low Gluten''

Establishing requirements for ''low gluten'' claims might generate compliance costs for small entities. As we discussed in the preceding regulatory impact analysis, we currently allow ''gluten-free'' claims that are truthful and not misleading. If we define ''low gluten'' based on a particular level of gluten, then some small firms might need to change their product labels. However, we were unable to identify any foods bearing ''low gluten'' claims in the FLAPS database. Therefore, we estimate that any labeling costs associated with this provision would be minimal. In addition, the provision dealing with gluten-free claims on foods that inherently do not contain gluten would have a minimal impact on small entities. Therefore, we estimate that this option would have minimal or no impact on small entities.

7. Option Seven: Take Proposed Action, but Include Oats in the List of Grains That We Propose to Prohibit in Foods That Firms Label as Gluten-Free

Including oats in the list of prohibited grains may generate relabeling costs for some small firms because we currently allow firms to make gluten-free claims on foods that contain oats but do not contain any of the prohibited grains or ingredients derived from those grains provided that any gluten present is less than 20 ppm. We do not know how many small firms produce foods that contain oats but do not contain any of the prohibited grains or ingredients derived from those grains and that bear gluten-free claims. We searched the FLAPS 2000 database and did not find any foods that contained oats and bore gluten-free claims. Therefore, we estimate that any costs that might accrue to small entities from this option would be minimal.

V. Unfunded Mandates

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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Executive Order 13132: Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * 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.''[3] Here, FDA has determined that the exercise of State authority would

[3]Because we have determined that the act preempts State law because the exercise of State authority conflicts with the exercise of Federal authority under that statute, we need not construe our statutory rulemaking authority as required by section 4(b) of the Executive order.

conflict with the proposed exercise of Federal authority under the act.

FDA is the expert Federal agency charged by Congress with ensuring that food labeling is truthful and not misleading. Under section 403(a)(1) of the act, a food is deemed misbranded if its labeling is false or misleading in any particular. In determining whether labeling is misleading, FDA takes into account not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribe in the labeling thereof or under such conditions of use as are customary or usual (section 201(n) of the act).

In section 206 of FALCPA, Congress directs FDA 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. As discussed elsewhere in this preamble, FDA has consulted with numerous experts and stakeholders in the development of this proposed rule. FDA has learned that different manufacturers currently have different and inconsistent definitions of the term ''gluten-free,'' and that individuals with celiac disease need a standardized definition of the term ''gluten-free'' to help them make purchasing decisions that will support their need to avoid consumption of gluten. Therefore, FDA believes that establishing a definition of the term ''gluten-free'' and uniform conditions for its use in the labeling of foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled. If State authorities were permitted to impose labeling requirements that are inconsistent with those proposed in this rule, the federal objective of standardizing use of the term ''gluten-free'' in the labeling of foods to ensure that such labeling is neither false nor misleading would be frustrated.

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.'' This proposed rule would meet the preceding requirement because it would preempt state law only to the extent required to preserve Federal interests. 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 the Executive order 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 intends to invite the States' participation in this rulemaking by providing notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, and food program directors as well as FDA field personnel of FDA's publication of this proposed rule. The notice would provide the States with further opportunity for input on the rule. It would advise the States of FDA's possible action and encourage the States and local governments to review the notice and to provide any comments to the FDA Docket Number 2005N–0279, opened in the [enter date] **Federal Register** by [enter date]. FDA is providing an opportunity for State and local officials to comment on this proposed rule. The agency intends to comply with all of the applicable requirements under Executive Order 13132 to ensure that this proposed rule is consistent with the Executive order.

FDA's Division of Federal-State Relations intends to invite the States' participation in this rulemaking by providing notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, and food program directors as well as FDA field personnel of FDA's publication of this proposed rule. The notice would provide the States with further opportunity for input on the rule. It would advise the States of FDA's possible action and encourage the States and local governments to review the proposed rule and to provide any comments to the FDA Docket No. 2005N–0279, opened in the July 19, 2005, **Federal Register**, by April 23, 2007. FDA is providing an opportunity for State and local officials to comment on this proposed rule.

VII. Environmental Impact Analysis

FDA has tentatively determined under 21 CFR 25.30(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.

VIII. Paperwork Reduction Act of 1995

FDA has tentatively concluded that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified by Docket No. 2005N–0279. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the cited Web site addresses, but is not responsible for subsequent changes to them 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 Development Conference Statement,'' NIH, Bethesda, MD, pp. 1–15, June 28–30, 2004, accessible at *http://consensus.nih.gov/2004/2004CeliacDisease118html.htm* on June 22, 2006.

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. 06–4269, pp. 1–11. October 2005, accessible at *http://digestive.niddk.nih.gov/ddiseases/pubs/celiac/* on June 22, 2006.

5. Dewar, D., S.P. Pereira, and P.J. Ciclitira, ''The Pathogenesis of Coeliac Disease,'' *International Journal of Biochemistry & 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. Hamilton, F., ''Celiac Disease–A Not So Uncommon Disorder,'' Presentation, Transcript of the Center for Food Safety and Applied Nutrition, Food and Drug Administration Public Meeting on Gluten-Free Food Labeling held in College Park, MD, p. 33, August 19, 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-01-vol16.doc* on June 22, 2006. (Also see errata sheet for transcript accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-02-erratta-vol16.doc* on June 22, 2006.)

18. Peterson, T., ''Goodbye to Gluten,'' *The Salt Lake Tribune*, September 12, 2005.

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. Brown, A., *Understanding Food Principles and Preparation*, Second Ed., Wadsworth/Thomson Learning, Belmont, CA, pp. 402–403 and 420–421, 2004.

21. Pomeranz, Y., *Modern Cereal Science and Technology*, VCH Publishers, Inc., New York, NY, pp. 40–42, 44, and 53, 1987.

22. Skerritt, J.H. and A.S. Hill, ''Enzyme Immunoassay for Determination of Gluten in Foods: Collaborative Study,'' *Journal of the Association of Official Analytical Chemists*, 74(2):257–264, 1991.

23. Hischenhuber, C., R. Crevel, B. Jarry, et al., ''Review Article: Safe Amounts of Gluten for Patients With Wheat Allergy or Coeliac Disease,'' *Alimentary Pharmacology & Therapeutics*, 23(5):559–575, March 1, 2006.

24. Shewry, P.R., N.G. Halford, P.S Belton, et al., ''The Structure and Properties of Gluten: An Elastic Protein From Wheat Grain,'' *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences*, 357:133–142, 2002.

25. Kasarda, D.D., Personal Communication, January 22, 2005.

26. Dicke, W.K., H.A. Weijers, and J.H van de Kamer, ''Coeliac Disease. II. The Presence in Wheat of a Factor Having a Deleterious Effect in Cases of Coeliac Disease,'' *Acta Paediatricia*, 42:34–42, January 1953.

27. van de Kamer, J.H., H.A. Weijers, and W.K. Dicke, ''Coeliac Disease. IV. An Investigation Into the Injurious Constituents of Wheat in Connection With Their Action on Patients With Coeliac Disease,'' *Acta Paediatrica*, 42:223–231, May 1953.

28. Baker, P.G. and A.E. Read, ''Oats and Barley Toxicity in Coeliac Patients,'' *Postgraduate Medical Journal*, 52:264–268, May 1976.

29. Anand, B.S., J. Piris, and S.C. Truelove, ''The Role of Various Cereals in Coeliac Disease,'' *Quarterly Journal of Medicine*, New Series 47(185):101–110, 1978.

30. Kasarda, D.D., ''What We Know About Grain Safety,'' Paper Presented at the Columbia University Celiac Disease and Other Food Intolerances Conference, Columbia University Medical Center, New York, NY, Program Description & Objectives, pp. 23–33, October 22, 2004.

31. Kasarda, D.D., ''Grains in Relation to Celiac Disease,'' *Cereal Foods World*, 46(5):209–210, 2001.

32. Arentz-Hansen, H., B. Fleckenstein, O. Molberg, et al., ''The Molecular Basis for Oat Intolerance in Patients With Celiac Disease,'' *PLoS Medicine*, 1:84–92, October 2004.

33. Johnson, D.L., D. Sands, and A. Pilgeram, ''Indian Ricegrass: A Gluten-Free Cereal,'' Presentation Abstract, The Association for the Advancement of Industrial Crops Annual Meeting, Saskatoon, Saskatchewan, Canada, Program and Abstracts, p. 16, August 25–28, 2002, accessible at *http://www.aaic.org/02progrm.htm* on June 22, 2006.

34. Kupper, C., ''Dietary Guidelines for Celiac Disease and Implementation,'' Presentation Abstract, National Institutes of Health (NIH), NIH Consensus Development Conference on Celiac Disease, Bethesda, MD, pp. 91–95, June 28–30, 2004, accessible at *http://consensus.nih.gov/2004/2004CeliacDisease118Program.pdf* on June 22, 2006.

35. van de Wal, Y., Y.M.C. Kooy, P. van Veelen, et al., ''Glutenin Is Involved in the Gluten-Driven Mucosal T Cell Response,'' *European Journal of Immunology*, 29(10):3133–3139, 1999.

36. Vader, W., Y. Kooy, P. van Veelen, et al., ''The Gluten Response in Children With Celiac Disease is Directed Toward Multiple Gliadin and Glutenin Peptides,'' *Gastroenterology*,122(7):1729–1737, 2002.

37. Molberg, O., N.S. Flaete, T. Jensen, et al., ''Intestinal T-Cell Responses to High-Molecular-Weight Glutenins in Celiac Disease,'' *Gastroenterology*, 125(2):337–344, 2003.

38. Ciclitira, P.J., D.J. Evans, N.L.K. Fagg, et al., ''Clinical Testing of Gliadin Fractions in Coeliac Patients,'' *Clinical Science*, 66:357–364, 1984.

39. Ellis, H.J., E.L. Pollock, W. Engel, et al., ''Investigation of the Putative Immunodominant T Cell Epitopes in Coeliac Disease,'' *Gut*, 52:212–217, 2003.

40. European Food Safety Agency (EFSA), ''Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a Request from the Commission Relating to the Evaluation of Allergenic Foods for Labelling Purposes,'' EFSA-Q–2003–016, *EFSA Journal*, 32:40–45, 146, 147, 152, 155–157, 159, 160, 167, 169, 171, 174, 181, 187, 189, 192, 193, and 195, 2004, accessible at *http://www.efsa.europa.eu./en/science/nda/nda_opinions/341.html* on June 27, 2006.

41. Thompson, T., ''Wheat Starch, Gliadin, and the Gluten-Free Diet,'' *Journal of the American Dietetic Association*, 101(12):1456–1459, December 2001.

42. Kagnoff, M.F., ''Overview and Pathogenesis of Celiac Disease,'' *Gastroenterology*, 128:S10–S18, April Supplement, 2005.

43. Kasarda, D.D., ''Celiac Disease and Safe Grains,'' Web page, July 2003, accessible at *http://wheat.pw.usda.gov/ggpages/topics/Celiac.vs.grains.html* on June 22, 2006.

44. Thompson, T., ''Oats and the Gluten-Free Diet,'' *Journal of the American Dietetic Association*, 103(3):376–379, March 2003.

45. Lundin, K.E.A., E.M. Nilsen, H.G. Scott, et al., ''Oats Induced Villous Atrophy in Coeliac Disease,'' *Gut*, 52(11):1649–1652, 2003.

46. Janatuinen, E.K., P.H. Pikkarainen, T.A. Kemppainen, et al., ''A Comparison of Diets With and Without Oats in Adults With Celiac Disease,'' *New England Journal of Medicine*, 333(16):1033–1037, 1995.

47. Hardman, C.M., J.J. Garioch, J.N. Leonard, et al., ''Absence of Toxicity of Oats in Patients With Dermatitis Herpetiformis,'' *New England Journal of Medicine*, 337(26):1884–1887, 1997.

48. Janatuinen, E.K., T.A. Kemppainen, P.H. Pikkarainen, et al., ''Lack of Cellular and Humoral Immunological Responses to Oats in Adults With Coeliac Disease,'' *Gut*, 46(3):327–331, 2000.

49. Janatuinen, E.K., T.A. Kemppainen, R.J. Julkunen, et al., ''No Harm From Five Year Ingestion of Oats in Coeliac Disease,'' *Gut*, 50(3):332–335, 2002.

50. Högberg, L., P. Laurin, K. Faith-Magnusson, K., et al., ''Oats to Children With Newly Diagnosed Celiac Disease: A Randomized Double Blind Study,'' *Gut*, 53:649–654, 2004.

51. Peräaho, M., P. Collin, K. Kaukinen, et al., ''Oats Can Diversify a Gluten-Free Diet in Celiac Disease and Dermatitis Herpetiformis,'' *Journal of the American Dietetic Association*, 104(7):1148–1150, July 2004.

52. Kelly, C., Public comment number EC4 submitted on July 28, 2005 to Docket No. 2005N–0231 pertaining to Center for Food

Safety and Applied Nutrition, Food and Drug Administration Draft Report entitled ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,'' pp. 1–2, June 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0231/05N-0231-EC4.htm* on June 22, 2006.

53. Kasarda, D.D., Agricultural Research Service, Western Regional Research Center, U.S. Department of Agriculture, ''Grains in Relation to Celiac (Coeliac) Disease,'' Web page, updated 1999, accessible at *http://wheat.pw.usda.gov/ggpages/topics/celiac.html* on June 22, 2006.

54. Cureton, P., ''Celiac Consumer: Survey Results,'' Presentation and Remarks During Question and Answer Period, Transcript of 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. 214–215 and 236–237, August 19, 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-01-vol16.doc* on June 22, 2006.. (Also see errata sheet for transcript accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-02-erratta-vol16.doc* on June 22, 2006.)

55. Lee, A., Remarks During Question and Answer Period, Transcript of 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. 237–238, August 19, 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-01-vol16.doc* on June 22, 2006. (Also see errata sheet for transcript accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-02-erratta-vol16.doc* on June 22, 2006.)

56. Case, S., *Gluten-Free Diet: A Comprehensive Guide, Expanded Edition*, Case Nutrition Consulting, Regina, Saskatchewan, Canada, pp. 21–24, 28, and 29, 2006.

57. Thompson, T., ''Questionable Foods and the Gluten-Free Diet,'' *Journal of the American Dietetic Association*, 100(4):463–465, April 2000.

58. American Dietetic Association (ADA), ''Celiac Disease–Nutrition Care–Grains to Avoid,'' *ADA Nutrition Care Manual©*, American Dietetic Association, Chicago, Illinois, 1 electronic page, 2006, accessible at *www.nutritioncaremanual.org* on June 26, 2006.

59. American Dietetic Association (ADA), ''Celiac Disease–Nutrition Care–Oats,'' *ADA Nutrition Care Manual©*, American Dietetic Association, Chicago, Illinois, 2 electronic pages, 2006, accessible at *www.nutritioncaremanual.org* on June 26, 2006.

60. Hager, M., American Dietetic Association, Public comment letter EC–1482 submitted on September 20, 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, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-EC1482-Attach-1.pdf* on June 22, 2006.

61. U.S. Department of Agriculture, ''Official United States Standards for Grain, Subpart A–General Provisions,'' pp. A1–A5, June 1999, accessible at *http://151.121.3.117/reference-library/standards/810101.pdf* on June 2005. [Note standards for specific grains are accessible at *http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous* on June 22, 2006.]

62. American Gastroenterological Association, ''Medical Position Statement: Celiac Sprue,'' *Gastroenterology*, 120:1522–1525, 2001.

63. Thompson, T., ''Gluten Contamination of Commercial Oat Products in the Unites States,'' *New England Journal of Medicine*, 351(19):2021–2022, 2004.

64. Hernando A., J.R. Mujico, D. Juanas, et al., ''Confirmation of the Cereal Type in Oat Products Highly Contaminated With Gluten,'' *Journal of the American Dietetic Association*, 106(5):665, May 2006.

65. Armour, B. and T.B. Perry, Cream Hill Estates Ltd., Public comment letter EMC299 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, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279_emc-000299-03.pdf* on June 22, 2006.

66. 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.

67. 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, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0231/05n-0231-rpt0001.pdf* and *http://www.cfsan.fda.gov/~dms/alrgn.html* on June 22, 2006.

68. Food and Drug Administration, ''FDA's Responses to Public Comments on the Draft Report 'Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,''' Web site posting, March 2006, accessible at *http://www.cfsan.fda.gov/~dms/alrgcom.html* on June 22, 2006.

69. 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, accessible at *http://www.cfsan.fda.gov/~dms/alrgn2.html* on June 22, 2006.

70. Food Advisory Committee, Center for Food Safety and Applied Nutrition, Food and Drug Administration, ''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, accessible at *http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4160m1_summary%20minutes.pdf* and *http://www.fda.gov/ohrms/dockets/ac/cfsan05.html* on June 22, 2006.

71. Størsrud, S., L.R. Hulthén, and R.A. Lenner, et al., ''Beneficial Effects of Oats in the Gluten-Free Diet of Adults With Special Reference to Nutrient Status, Symptoms and Subjective Experiences,'' *British Journal of Nutrition*, 90:101–107, 2003.

72. Burke, S.J., S.J. Milberg, and W.W. Moe, ''Displaying Common but Previously Neglected Health Claims on Product Labels: Understanding Competitive Advantages, Deception, and Education,'' *Journal of Public Policy & Marketing*, 16(2):242–255, Fall 1997.

73. Gendel, S.M., Memorandum to the Administrative Record for the Gluten-Free Food Labeling Proposed Rule, pp. 1–5 (with 31 attachments), May 12, 2006.

74. Méndez, E., V. Carmen, U. Immer, et al., ''Report of a Collaborative Trial to Investigate the Performance of the R5 Enzyme Linked Immunoassay to Determine Gliadin in Gluten-Free Food,'' *European Journal of Gastroenterology & Hepatology*, 17(10):1053–1063, 2005.

75. Johnson, K., Personal Communication, March 16, 2006.

76. Matsuda, R., Y. Yoshioka, H. Akiyama, et al., ''Interlaboratory Evaluation of Two Enzyme-Linked Immunosorbent Assay Kits for the Detection of Egg, Milk, Wheat, Buckwheat, and Peanut in Foods,'' *Journal of AOAC INTERNATIONAL*, 89(6):1600–1608, November/December 2006.

77. AOAC INTERNATIONAL, Official Method 991.19: ''Gliadin as a Measure of Gluten in Foods.'' Chapter 32, Cereal Foods, *Official Methods of Analysis of AOAC INTERNATIONAL*, 18th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, pp. 15–17, 2005.

78. Fielder, R., Personal Communication, May 10, 2006.

79. Food Standards Australian New Zealand, ''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. 1 and 16–17, 2006, accessible at *http://www.foodstandards.gov.au/foodstandardscode* June 27, 2006.

80. Fasano, A., Personal Communication, November 22, 2004.

81. Catassi, C., E. Fabiani, G. Iacono, et al., ''Toxicity of Gluten Traces in Patients on Treatment for Celiac Disease. Results of a Prospective, Placebo-Controlled, Double-Blind, Randomized Study,'' Presentation Abstract No. S1775, *Digestive Disease Week*, May 14–19, 2005, accessible at *http://precis.preciscentral.com/files/source/67/html/45832.htm* on June 22, 2006.

82. Collin, P., L. Thorell, K. Kaukinen, et al., ''The Safe Threshold for Gluten Contamination in Gluten-Free Products. Can Trace Amounts Be Accepted in the Treatment of Coeliac Disease?'' *Alimentary Pharmacology & Therapeutics*, 19(12):1277–1283, June 2004.

83. Chartrand, L.J., P.A. Russo, A.G, DuHaime, et al., ''Wheat Starch Intolerance in Patients With Celiac Disease,'' *Journal of*

the American Dietetic Association, 97(6):612–618, June 1997.

84. Fasano, A., I. Berti, T. Gerarduzzi, et al., ''Prevalence of Celiac Disease in At-Risk and Not-At-Risk Groups in the United States. A Large Multicenter Study,'' *Archives of Internal Medicine*, 163:286–292, 2003.

85. U.S. Census Bureau, Population Division, ''U.S. POPClock Projection,'' Web page, accessible at *http://www.census.gov/population/www/popclockus.html* on August 18, 2005

86. Blast, A., National Foundation for Celiac Awareness, Public Statement, Transcript of the Center for Food Safety and Applied Nutrition, Food and Drug Administration Public Meeting on Gluten-Free Food Labeling held in College Park, MD, p. 287, August 19, 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-01-vol16.doc* June 22, 2006. (Also see errata sheet for transcript accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-02-erratta-vol16.doc* June 22, 2006.)

87. Schluckebier, M., ''Food Labeling Concerns for CD/DH,'' Presentation, Transcript of the Center for Food Safety and Applied Nutrition, Food and Drug Administration Public Meeting on Gluten-Free Food Labeling held in College Park, MD, p. 200, August 19, 2005, accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-01-vol16.doc* on June 22, 2006. (Also see errata sheet for transcript accessible at *http://www.fda.gov/ohrms/dockets/dockets/05n0279/05n-0279-tr00001-02-erratta-vol16.doc* on June 22, 2006.)

88. Bureau of Labor Statistics, U.S. Department of Labor (USDL), ''Employer Costs for Employee Compensation Summary,'' USDL: 05–2279, December 9, 2005.

89. Kaukinen, K., P. Collin, K. Holm, et al., ''Wheat Starch-Containing Gluten-Free Flour Products in the Treatment of Coeliac Disease and Dermatitis Herpetiformis. A Long Term Follow-Up Study,'' *Scandinavian Journal of Gastroenterology*, 34:163–169, 1999.

90. McCrae, W.M., M.A. Eastwood, M.R. Martin, et al., ''Neglected Coeliac Disease,'' *Lancet*, 1:187–190, 1975.

91. Sdepanian V.L., I.C.A. Scaletsky, U. Fagundes-Neto, et al., ''Assessment of Gliadin in Supposedly Gluten-Free Foods Prepared and Purchased by Celiac Patients,'' *Journal of Pediatric Gastroenterology and Nutrition*, 32:65–70, January 2001.

92. Codex Alimentarius Commission, Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO), Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Twenty-fifth Session, ''Proposed Draft Revised Standard for Gluten-Free Food *At Step 7*,'' Comments from Sweden, Finland, AOECS–Association of European Coeliac Societies, IWGA–International Wheat Gluten Association, CX/NFSDU 03/4–Add. 1, pp. 1–11, October 2003.

93. Lohiniemi, S., M. Mäki, K. Kaukinene, et al., ''Gastrointestinal Symptoms Rating Scale in Coeliac Disease Patients on Wheat Starch-Based Gluten-Free Diets,'' *Scandinavian Journal of Gastroenterology*, September, 35(9):947–949, October 2000.

94. Peräaho, M., K. Kaukinen, K. Paasikivi, et al., ''Wheat-Starch-Based Gluten-Free Products in the Treatment of Newly Detected Coeliac Disease: Prospective and Randomized Study,'' *Alimentary Pharmacology & Therapeutics*, 17(4):587–594, February 2003.

95. Faulkner-Hogg, K.B., W.S. Selby, and R.H. Loblay, ''Dietary Analysis in Symptomatic Patients With Coeliac Disease on a Gluten-Free Diet: The Role of Trace Amounts of Gluten and Non-Gluten Products,'' *Scandinavian Journal of Gastroenterology*, 34(38):784–789, August 1999.

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 proposes to amend 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 ''prohibited 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 prohibited grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

(3) The labeling claim ''gluten-free'' or similar claim (e.g., ''free of gluten,'' ''without gluten,'' ''no gluten'') means that the food bearing the claim in its labeling does not contain any of the following:

(i) An ingredient that is a prohibited grain (e.g., spelt wheat);

(ii) An ingredient that is derived from a prohibited grain and that has not been processed to remove gluten (e.g., wheat flour);

(iii) 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 parts per million (ppm) or more gluten in the food (i.e., 20 micrograms or more gluten per gram of food);

(iv) 20 ppm or more gluten.

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

(2) With the exception of foods made from oats, a food that does not inherently contain any gluten from a prohibited grain (e.g., milk, corn, frozen concentrated orange juice) and that bears the claim ''gluten-free'' in its labeling will be deemed misbranded unless:

(i) The claim refers to all foods of that same type (e.g., ''milk, a gluten-free food,'' ''all milk is gluten-free''); and

(ii) The food does not contain 20 ppm or more gluten.

(3) A food made from oats that bears the claim ''gluten-free'' or similar claim in its labeling will be deemed misbranded if the claim refers to all foods of the same type (e.g., ''all oats are gluten-free'') or if the food contains 20 ppm or more gluten.

(c) *Compliance.* When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will 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.

Dated: January 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–843 Filed 1–22–07; 8:45 am]

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DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

28 CFR Part 20

[Docket No. FBI 113; AG Order No. 2855–2007]

RIN 1110–AA24

Carriage of Concealed Weapons Pursuant to Public Law 108–277; the Law Enforcement Officers Safety Act of 2003

AGENCY: Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: Notice of proposed rulemaking with request for comments.

SUMMARY: The Department of Justice (the Department) is amending Title 28 of the Code of Federal Regulations to authorize access to FBI-maintained criminal justice information systems for