information in sections 605 and 610 of the FD&C Act have been approved under 0910–0599.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01159 Filed 1–21–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–3942]

Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Petition for rulemaking; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) received a citizen petition from Celiac Journey requesting that we act to protect consumers with celiac disease by requiring that all ingredients with gluten be listed by name in the ingredient list and by requiring cross-contact controls with gluten-containing grains. We are issuing this document to request comment on the issues raised in the petition and on specific questions related to these issues.

DATES: Submit either electronic or written comments and scientific data and information by March 23, 2026.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–P–3942 for ''Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Carol D'Lima, Office of Nutrition and Food Labeling (HFS–800), Nutrition Center of Excellence, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

A. Citizen Petition

In September 2023, Celiac Journey submitted a citizen petition (Docket No. FDA–2023–P–3942) requesting that FDA act to protect consumers with celiac disease (CD) by better enabling them to identify, through labeling, whether a food includes gluten-containing grains (GCGs), and to address cross-contact with GCGs. For purposes of this document, GCGs refers to the cultivated crops that have naturally occurring gluten protein. These include wheat (*Triticum*), rye (*Secale*), barley (*Hordeum*), and crossbreeds like triticale (crossbreed of rye and wheat). Celiac Journey's petition, in part, asks that FDA: (1) issue a rule to require that all ingredients with gluten be listed by name in the ingredient lists of all foods, and (2) add gluten to the list of allergens

in Sec. 555.250 of FDA's Compliance Policy Guide (CPG) entitled ''Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens'' to address both labeling and cross-contact issues related to food manufacturing practices. The petition also makes additional requests, such as asking that oats be included as GCGs because they often contain gluten due to cross-contact. Under FDA's citizen petition regulations, when reviewing a petition, we may publish a notice in the **Federal Register** requesting information and views (21 CFR 10.30(h)(3)).

We note that, in May 2023, FDA issued a draft CPG entitled ''Sec 555.250: Major Food Allergen Labeling and Cross-contact'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact*). This draft CPG, if finalized, would replace the existing CPG Sec 555.250, entitled ''Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-statement-policy-labeling-and-preventing-cross-contact-common-food-allergens*) and serve as a guidance for FDA staff on FDA's enforcement policy regarding major food allergen labeling and cross-contact. Celiac Journey's petition extends its requested revision of Sec. 555.250 to the potential updated version. Although the petition was not submitted specifically in response to the draft CPG, we are also considering this petition as we finalize the CPG.

We are issuing this request for information (RFI) to request comments about the issues presented in Celiac Journey's petition and on specific questions related to these issues. In addition, consistent with the Make Our Children Healthy Again Strategy [1] issued by the Make America Healthy Again (MAHA) Commission, publishing this RFI is the first step in making recommendations about providing more transparency in disclosures of ingredients that impact certain health conditions, such as gluten for those with CD, and other established food allergens.

B. Health Conditions Associated With Consumption of GCGs

Consumption of GCGs has been associated with a number of different immune-mediated food allergies, including Immunoglobulin E (IgE)-mediated anaphylaxis and CD, and can cause allergic reactions and other adverse health consequences in consumers who have these conditions. Among the GCGs, self-reported IgE-mediated allergy to wheat with ''confirmed'' signs or symptoms and doctor diagnosis has a prevalence of up to 0.3% of children and 0.5% of the adult population (Ref. 1, Ref. 2, and Ref. 3 Table 3). If sufficient amounts of glutens or other proteins are consumed, individuals with an IgE-mediated allergy to GCGs can experience acute allergic reactions of variable severity from limited symptoms of itching, hives, or abdominal cramps to vomiting, diarrhea, wheezing, and the possibility for life-threatening anaphylaxis.

According to the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), an estimated 2 million people (about 0.7%) in the United States have CD (Ref. 4), a chronic inflammatory disorder of the small intestine triggered by the ingestion of certain storage proteins referred to as gluten, occurring in wheat, rye, barley, and crossbreeds of these grains (*e.g.,* triticale). In people with CD, foods that contain gluten trigger the production of antibodies that attack and damage the lining of the small intestine. This can lead to a wide variety of acute health consequences affecting the digestive tract (*e.g.,* abdominal bloating, cramping and pain, chronic diarrhea) or more atypical symptoms such as fatigue, irritability, bone or joint pain, or blistering skin rash. For people with CD, chronic exposure to GCGs can also lead to nutrient deficiencies, autoimmune disease, and intestinal cancers.

Other health conditions triggered by consumption of GCGs include eosinophilic esophagitis, food protein-induced enterocolitis syndrome, and non-celiac gluten sensitivity (NCGS, also called gluten intolerance, and not considered an immune-mediated food allergy). Individuals with IgE-mediated and/or non-IgE-mediated reactions due to GCGs generally are advised to follow a gluten-free diet. They are also typically advised to check labels for information on GCGs to which they are allergic so that potential allergen hazards can be avoided.

C. Legal Framework Related to GCGs

Several existing statutory and regulatory provisions are relevant to GCGs. The following is a brief overview of some such provisions that are relevant to Celiac Journey's petition and questions presented in this RFI. In general, labeling on packaged foods must include the common or usual name of each ingredient (if there is more than one) (see section 403(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(i))). For example, the label of a food made with rye flour must declare this ingredient by its common or usual name, ''rye flour,'' rather than simply ''flour'' (''flour,'' declared unqualified, refers to flour from ''wheat'' (21 CFR 137.105, 101.4(b)(15))).

Additionally, specific labeling provisions apply to the declaration of some food ingredients. For example, spices, natural flavor, and artificial flavor may be declared using a collective term (*e.g.,* ''spice,'' ''natural flavor,'' or ''artificial flavor,'' respectively) (21 CFR 101.22(h)(1)). Likewise, some color additives may be declared as ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added'' (21 CFR 101.22(k)(2)). Also, incidental additives are generally exempt from the ingredient declaration requirements (see 21 CFR 101.100(a)(3)). Further, some ingredients may be derived from GCGs, but the presence of the GCG may not be apparent to consumers based on the common or usual name (*e.g.,* ''malt extract'' and ''malt syrup'' derived from barley) (see CPG Sec 515.200 ''Malt Extract; Malt Syrup; Malted Cereal Syrup; Liquid Malt; Dried Malt,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-515200-malt-extract-malt-syrup-malted-cereal-syrup-liquid-malt-dried-malt*).

The label of a food that contains an ingredient that is or contains a ''major food allergen'' must declare the presence of the allergen in a manner described by the law (section 403(w) of the FD&C Act (21 U.S.C. 343(w))). The ''major food allergens'' are milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame, as well as food ingredients that contain protein derived from such foods (with certain exceptions) (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))). Major food allergens used as ingredients in packaged foods and regulated under the FD&C Act must be declared by the name of the food source from which the major food allergen is derived either in the ingredient list or the ''Contains'' statement (section 403(w) of the FD&C Act). Unlike other ingredients, major food allergens do not fall under the labeling exceptions for certain food components, such as flavoring, coloring, or incidental additives (section 403(w)(4) of the FD&C Act). Congress established the list of ''major food allergens,'' and FDA does not have the authority to alter the list. However, we

[1] Strategy Report: Make Our Children Healthy Again, available at: *https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf.*

may issue regulations regarding the disclosure of a food allergen (other than a major food allergen) in a spice, flavoring, coloring, or incidental additive (section 403(x) of the FD&C Act (21 U.S.C. 343(x))) and may issue other regulations for non-major food allergens (see 21 U.S.C. 343 note).

Among the GCGs, wheat is a major food allergen and, thus, any ingredient derived from wheat must also be declared as ''wheat'' either in the ''Contains'' statement or in the ingredient list or both (section 403(w) of the FD&C Act). For example, if wheat is a formulated component of a flavoring, coloring, or incidental additive, ''wheat'' must be declared either in the ingredient statement or the ''Contains'' statement (section 403(w)(4) of the FD&C Act).

FDA regulations allow for the voluntary labeling of foods as ''gluten-free'' and establish criteria that must be met to use such labeling (see 21 CFR 101.91(a)). For purposes of such labeling, a ''gluten-containing grain'' means wheat, rye, barley, or their crossbred hybrids (21 CFR 101.91(a)(1)). A ''gluten-free'' claim may only be made if the food does not contain an ingredient that is: (1) a GCG; (2) derived from a GCG that has not been processed to remove gluten; or (3) derived from a GCG that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (*i.e.,* 20 milligrams (mg) or more gluten per kilogram (kg) of food). In the case of fermented or hydrolyzed foods or ingredients, any GCGs must be processed to remove gluten prior to the fermentation or hydrolysis. A ''gluten-free'' claim is also permissible when the food inherently does not contain gluten. In addition to these criteria, a gluten-free claim may only be made if any unavoidable presence of gluten in the food bearing the claim is below 20 ppm (21 CFR 101.91(a)(3)).[2] Also, oats, which contain proteins called avenins, are not considered GCGs under this gluten-free rule. Thus, a food bearing a ''gluten-free'' claim can include oats as long as the oats meet the standards for the unavoidable presence of gluten in the definition of ''gluten-free.''

FDA regulations also address food allergen cross-contact. Under 21 CFR part 117, a ''food allergen'' means a ''major food allergen'' as defined in section 201(qq) of the FD&C Act, and ''allergen cross-contact'' means the unintentional incorporation of a food allergen into food (21 CFR 117.3). Our regulations also include current good manufacturing practice (CGMP) requirements and preventive controls requirements to significantly minimize or prevent allergen cross-contact (see 21 CFR part 117). In addition, juice and seafood processors should also consider allergen cross-contact under sanitation standard operating procedures or in their Hazard Analysis and Critical Control Point (HACCP) plan under 21 CFR parts 120 and 123, respectively.

D. FDA's Allergen Evaluation Framework

In January 2025, FDA issued a final guidance titled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Interested Parties'' (Allergen Evaluation Guidance) (Ref. 3). The Allergen Evaluation Guidance identifies the scientific factors and other information relevant to evaluating the public health importance of food allergens other than one of the major food allergens listed in the FD&C Act (hereafter referred to as non-listed food allergens) and discusses how FDA generally intends to evaluate the total body of evidence.

The Allergen Evaluation Guidance describes four scientific factors that FDA intends to consider when evaluating the public health importance of non-listed food allergens: (1) evidence of IgE-mediated food allergy; (2) the prevalence of an IgE-mediated food allergy in the U.S. population; (3) the severity of IgE-mediated food allergic reactions; and (4) allergenic potency (the amount of food allergenic protein required to elicit an IgE-mediated food allergic reaction in a sensitized individual). While the Allergen Evaluation Guidance focuses on IgE-mediated food allergies, FDA has acknowledged that because some foods can cause both IgE-mediated and non-IgE-mediated reactions, evidence of non-IgE-mediated reactions and allergies associated with the food can be useful information in an evaluation of the public health importance of such a food allergen. The Allergen Evaluation Guidance affirms that food allergens causing non-IgE-mediated allergies may also raise public health concerns, and FDA intends to evaluate the public health importance of these allergens on a case-by-case basis. Beyond the four scientific factors, the Allergen Evaluation Guidance also states that to evaluate whether a non-listed food allergen is of public health importance, FDA may seek or request data and other information relevant to the labeling and production of food containing the food allergen.

Examples of such data and other information are:

- Data and other information relevant to the prevalence in the United States of food allergic reactions that could be attributed to exposure to the food allergen that is not disclosed on the label of food products;
- Prevalence and amounts of the undisclosed food allergen, such as situations in which source information about a non-listed food allergen used as an ingredient is not required to be included in the food label; examples of this include spice, color, flavoring, or when the common or usual name of the food ingredient does not include the source (*e.g.,* malt extract does not disclose ''barley'' as the source);
- Characteristics of food products and food production practices;
- Data from patient-centered studies or other patient-centered information (*e.g.,* food allergy quality-of-life questionnaires) regarding patients' experiences, perspectives, needs, and priorities regarding avoidance of foods that are or contain food allergens; and
- Data on clinically cross-reactive food allergies to the food and, if relevant, whether potential cross-reactivity to the food allergen would not be well-recognized in the U.S. allergic population.

II. Request for Comment

We invite comments concerning adverse reactions due to ''ingredients of interest'' (*i.e.,* non-wheat GCGs and oats) in the United States. We also invite comments on labeling issues or concerns with identifying ingredients of interest on packaged food products in the United States. We specifically invite comment in response to the questions below. Any party submitting comments need not address all the questions listed in this request. Please provide applicable data and references, if available.

A. Data and information on IgE-mediated and non-IgE-mediated food allergies and adverse reactions to non-wheat GCGs (including prevalence, severity, and potency).

Celiac Journey's petition cites information in reports by the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) expert consultation to support the assertion that ingredients of interest (*i.e.,* rye, barley, and oats) are GCGs that require additional labeling standards in the United States. FDA has reviewed the information in recent

[2] The regulation also addresses the use of the ''gluten-free'' claim for fermented and hydrolyzed food, or foods that contain fermented or hydrolyzed ingredients (21 CFR 101.91(b) and (c)).

FAO/WHO global reports relevant to this petition (see Ref. 5 and Ref. 6). We note that our review of this information indicates that there is limited U.S. data on adverse reactions to ingredients of interest. An FDA summary of the limited data in the FAO/WHO reports for IgE-mediated food allergies to non-wheat GCGs is available in Ref. 7.

As background, in 2019, the Codex Alimentarius Commission (CAC) tasked the FAO/WHO to form an Expert Consultation on Risk Assessment of Food Allergens (hereafter referred to as expert consultation) to develop criteria to determine which foods are priority allergens at a global level, and to validate and update the list of allergenic foods and ingredients in section 4.2.1.4 of the General Standard for the Labelling of Pre-Packaged Foods (GSLPF) based on risk assessment. As highlighted in ''Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment'' (Ref. 5) of the resulting report, the expert consultation identified prevalence, severity, and potency of IgE-mediated allergy and CD as the main criteria. Based on these criteria, the expert consultation recommended modifying the definition for cereals listed as priority allergens to include ''Cereals containing gluten (*e.g.,* wheat and other *Triticum* species, rye and other *Secale* species, barley and other *Hordeum* species and their hybridized strains).'' The expert consultation's report found wheat to have sufficient prevalence, severity, and potency of IgE-mediated food allergies and noted that it is associated with CD toxicity. In contrast, the report stated that there is very limited data on the prevalence, severity, and potency of IgE-mediated food allergies for barley and rye (and crossbreeds of these cereal grains), but included them on the GSLPF priority list because they are foods that have potential to cause CD toxicity. The expert consultation's report also considered that these cereals are IgE-cross-reactive with wheat, thereby posing a risk to wheat-allergic consumers.

Consistent with the expert consultation's report, IgE-mediated reactions causing anaphylaxis are well-described for wheat, which is a major food allergen. However, apart from limited data showing that these cereals may have clinical cross-reactivity with wheat allergy, there is very little data on how frequently non-wheat GCGs cause IgE-mediated allergies and associated life-threatening reactions. Also, there are limited potency data for non-wheat GCGs, including what are dose exposures from undisclosed ingredients in food products that cause adverse allergic reactions. In the absence of such data, community report data (such as abstracts, research queries, patient surveys or registries of adverse reactions or food challenge data, etc.) could provide evidence of IgE-mediated allergies to non-wheat GCGs.

In addition to IgE-mediated allergies, consumption of gluten can cause CD toxicity. There are well-established data on the prevalence and potential severe health consequences of CD in the U.S. population (Ref. 8). As described in the Allergen Evaluation Guidance, FDA will consider evidence of non-IgE-mediated reactions as supplemental information in the evaluation of the public health importance of a food allergen.

Because there is well-documented information on the prevalence and severity of GCGs causing CD and on IgE-mediated allergies specifically to wheat, for this RFI, we are particularly interested in data that can quantify and characterize IgE- and non-IgE-mediated reactions to non-wheat GCGs in U.S. food products. FDA is particularly interested in data and information regarding prevalence, severity, and/or potency relating to:

1. Non-wheat GCGs causing IgE-mediated allergies or reactions, including anaphylaxis, in the United States. This could include published or unpublished clinical study data, community reports, or other data, such as food challenge data. Please provide units of measure, where available (*e.g.,* for prevalence information, 1 in 10,000 adults; for severity information, percent of reactions characterized as anaphylaxis, number of emergency visits, etc.).

2. Clinically cross-reactive food allergies between wheat and any of the non-wheat GCGs. This could include study data, community reports, or other relevant information.

3. Non-wheat GCGs causing non-IgE-mediated reactions in individuals with CD or other food allergic conditions (*e.g.,* eosinophilic gastrointestinal disorders).

B. Data and information on gluten in oats (including frequency and amounts of gluten in oats), and the prevalence, severity, and potency of IgE-mediated and non-IgE-mediated allergy and adverse reactions to oats.

Celiac Journey's petition requests that we include oats as a GCG because they often contain gluten due to cross-contact. Although FDA does not consider oats to be a GCG (21 CFR 101.91(a)(1)), we recognize that a major concern underlying the use of oats is cross-contact with wheat and cereals like barley or rye, resulting in concentrations of gluten that are potentially significant in the context of exacerbation of CD or IgE-mediated reactions (Ref. 9). Recent work conducted by the FAO/WHO expert consultation provides information related to the extent of gluten presence in oats due to cross-contact (Ref. 5). The expert consultation did not consider oats to be a cereal priority allergen because this food poses a low public health risk of causing IgE-mediated allergy or CD toxicity. Nevertheless, the consultation recognized that oats can have potentially significant levels of GCGs due to cross-contact.

Because oats may have gluten, due to cross-contact, and because the citizen petition asks FDA to consider oats as a GCG, FDA requests the following information:

4. To what extent do oat food products contain GCGs as a result of cross-contact? What amounts of GCGs are usually present? What other grains or ingredients contain GCGs due to cross-contact (and how do amounts compare to amounts in oats)?

5. What is the prevalence, severity, and potency of IgE- or non-IgE-mediated adverse reactions due to consumption of the following oat-containing ingredients?

a. Pure or gluten-free oats alone?

b. Oats having cross-contact with GCGs, and, in particular, non-wheat GCGs?

Please provide relevant studies or data and provide the unit of measure (*e.g.,* 1 in 10,000 adults).

6. To what extent are oat products labeled in a way to indicate/not indicate the presence of GCGs (*e.g.,* ''may contain gluten'')? If specific products or product categories are identified, please provide labels or photos and provide information about the type of food (*e.g.,* packaged food product or food from a retail food establishment or elsewhere).

7. What potential challenges might there be if there were requirements to eliminate, minimize, or label the presence of non-wheat GCGs in food products containing oats?

C. Data and information on undisclosed ingredients of interest (including their prevalence and usage amounts in food products and adverse events resulting from consumption of these food products).

As explained in the background section, in general, an ingredient must be declared by the common or usual name on the label or labeling of packaged foods (see section 403(i) of the FD&C Act). Wheat is also a major food allergen and, thus, when used as an ingredient, wheat must be declared as ''wheat'' either in the ''Contains''

statement or in the ingredient list (section 403(w) of the FD&C Act). However, the ingredients of interest are not major food allergens, so, under certain circumstances, it may be permissible for a packaged food that contains an ingredient of interest not to explicitly name the food source (*e.g.,* rye, barley, oats) on the label or labeling. For example, if the ingredient of interest falls under the regulatory provisions described above for incidental additives, spices, flavoring, or coloring, the presence of rye, barley, or oats might not be declared on the label. Also, there are instances when the common or usual name of an ingredient does not reflect that it is derived from an ingredient of interest. For example, malt extract, which is derived from barley, may be labeled as ''barley malt,'' but it can also be referred to as ''malt extract'' or ''malt syrup,'' which do not disclose the barley source of the ingredient to consumers.

We are aware that there are ingredients derived from ingredients of interest that do not disclose the source. Specifically, we are aware of ''malt,'' ''malt extract,'' and ''malt syrup,'' but note that many of the food products on the market with these ''malt''-type ingredients declare the barley source in the ingredients list. Also, although there are labeling exceptions described above with regard to spices, flavoring, coloring, or incidental additives, it is unclear whether any non-wheat GCG or oat ingredients are ever used as such. Celiac Journey's petition is asking us to require that all ingredients with gluten be listed by name in the ingredient lists of all foods, however, our review indicates that most ingredients appear to already declare the gluten source as described above. Therefore, we pose the following questions:

8. What are instances where ingredients of interest (rye, barley, or oats) would be undisclosed on a food package and potentially cause adverse reactions?

9. What is the prevalence and severity of IgE- and non-IgE-mediated adverse reactions to undisclosed ingredients of interest in food products. Please provide relevant studies or data and provide the unit of measure (*e.g.,* 1 in 10,000 adults) to the extent it is available.

a. If possible, please provide information on the symptoms and severity of reactions. Additionally, please specify the suspected food or ingredient and whether the reaction was from consumption of rye, barley, a crossbreed, or oats. If available, please provide pictures of product labels.

b. Please specify if reactions were from a packaged food product or food from a retail establishment or elsewhere.

10. We would like information about undisclosed ingredients of interest in packaged foods or in restaurant foods. Please specify the types of ingredients, frequency, and amounts of undisclosed ingredients of interest in foods. We are particularly interested in data, but specific examples and pictures of packages or labels may be helpful to illustrate the issue. For amounts, please provide a unit measure (*e.g.,* ''5 grams of gluten per kilogram (ppm) of packaged food product'' or ''50 milligrams of total gluten protein per serving''). Please specify whether the ingredients of interest are undisclosed for any of the following reasons:

a. Because the common or usual name of an ingredient does not list the GCG source in a way that it is apparent that GCG is present (*e.g.,* malt extract). Specify the types of ingredients, prevalence, and usage amounts in foods.

b. Because they are used as processing aids or incidental additives.

c. Because they are part of a spice mix, flavoring, or coloring.

d. Because they are present due to cross-contact.

11. What potential challenges might there be if there were requirements to label the presence of non-wheat GCGs and oats in foods that do not currently require their disclosure in the ingredient statement for one of the reasons described above?

D. Data and information related to ingredients of interest, including potential consumer perspectives and experiences.

12. Please provide data from patient-centered studies or information (*e.g.,* food allergy quality-of-life questionnaires) regarding patients' experiences, perspectives, needs, and priorities regarding avoidance of foods that are or contain ingredients of interest.

13. We are interested in information and studies on consumer purchasing and consumption choices related to GCGs, including cost considerations, labeling information (*e.g.,* gluten-free, undisclosed ingredients), and consumption of oats. Specifically, we are interested in the following information:

a. How heavily do consumers rely on purchasing foods voluntarily labeled as ''gluten-free'' versus purchasing foods that do not declare a GCG in the ingredient statement?

b. For foods that are not voluntarily labeled as ''gluten-free'' and do not declare a GCG in their ingredient statement, do consumers avoid foods that contain certain ingredients because they may contain undisclosed gluten (for example, foods labeled as containing ''flavors,'' ''colors,'' or ''spices'')? Please provide specific examples and labels, if available.

c. Do consumers generally avoid oats or other ingredients that may contain gluten due to cross-contact even when no GCGs or gluten terms are listed? If so, please provide specific examples and labels, if available.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. Gupta, R.S., Warren, C.M., Smith, B.M., Jiang, J., Blumenstock, J.A., Davis, M.M., Schleimer, R.P., Nadeau, K.C., 2019. ''Prevalence and Severity of Food Allergies Among US Adults,'' JAMA network open 2, e185630-e185630. Doi: 10.1001/jamanetworkopen.2018.5630. Available at: *https://doi.org/10.1001/jamanetworkopen.2018.5630.*

2. Gupta R.S., Warren C.M., Smith B.M., Blumenstock J.A., Jiang J., Davis M.M., Nadeau K.C., ''The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States,'' *Pediatrics,* 142(6):e20181235, 2018. Doi: 10.1542/peds.2018–1235. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC6317772/.*

* 3. FDA. ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Interested Parties.'' January 2025. Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-fda-staff-and-interested-parties-evaluating-public-health-importance-food-allergens-other.*

4. Choung R.S., Unalp-Arida A., Ruhl C.E., Brantner T.L., Everhart J.E., Murray J.A., ''Less hidden celiac disease but increased gluten avoidance without a diagnosis in the USA: Findings from the National Health and Nutrition Examination Surveys from 2009 to 2014,'' *Mayo Clinic Proceedings,* pii:S0025–6196(16)30634–6, 2016. Doi:10.1016/j.mayocp.2016.10.012. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC5459670/.*

* 5. FAO and WHO. 2022. ''Risk Assessment of Food Allergens. Part 1—Review and validation of Codex Alimentarius priority allergen list through risk assessment. Meeting Report.'' Food Safety and Quality Series No. 14. Rome. Available at: *https://doi.org/10.4060/cb9070en*.
* 6. FAO and WHO. 2023. ''Risk Assessment of Food Allergens—Part 5: Review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats. Meeting report.'' Food Safety and Quality Series, No. 23. Rome. Available at: *https://doi.org/10.4060/cc8387en*.
* 7. Memorandum from Ben Remington, Senior Scientist, HFP, *Summary and review of information from FAO/WHO reports and other sources relevant to the citizen petition from Celiac Journey (Docket No. FDA–2023–P–3942),* Aug. 13, 2025.
* 8. Memorandum from Stefano Luccioli, Senior Medical Officer and Allergen Coordinator, HFP, OFCSDSI, DCC, *Data and information reported by the ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens on gluten-containing grains (GCGs) and oats as priority allergenic foods causing celiac disease or other non-IgE-mediated food allergy,* Aug. 24, 2025.
9. Do, A.B., Khuda, SE, Sharma, G.M., 2018. ''Undeclared Food Allergens and Gluten in Commercial Food Products Analyzed by ELISA,'' Journal of AOAC International 101, 1–13. Available at: *https://doi.org/10.5740/jaoacint.17-0384*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0213]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before March 23, 2026.

ADDRESSES: When commenting, please reference the document identifier/OMB control number 0937–0213–60D and title of collection ''Teen Pregnancy Prevention FY2023 performance measures collection.'' You may send your comments electronically to Tara Rice, *tara.rice@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: To obtain copies of supporting material for the proposed collection(s) summarized in this notice, please include the document identifier and project title for reference, and address inquiries to Tara Rice, *tara.rice@hhs.gov* or 240–453–8123.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Teen Pregnancy Prevention FY2023 performance measures collection.

Type of Collection: extension.

OMB No.: 0937–0213.

Abstract: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), requests an extension clearance for the collection of performance measures specifically for FY2023 Teen Pregnancy Prevention (TPP) Program grantees. OPA supports two types of grants through the TPP program: projects that replicate TPP program models that have been shown to be effective through rigorous evaluation (Tier 1), research and demonstration projects that develop and test additional models and innovative strategies to prevent teen pregnancy (Tier 2). Collection of performance measures is a requirement of all TPP awards and is in the NOFOs. The data collection allows OPA to comply with federal accountability and performance requirements, inform stakeholders of grantee progress in meeting TPP program goals, provide OPA with metrics for monitoring FY2023 TPP grantees, and facilitate individual grantees' continuous quality improvement efforts within their projects.

OPA requests clearance for three years.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
TPP Tier 1 & Tier 2 Rigorous Impact grantees.	TPP Tier 1 & Tier 2 Rigorous Impact grantees.	73	2	8	1,168
Supportive Services	Tier 1 Grantees	58	2	0.25	29
Tier 2 Innovation Network	Tier 2 Innovation Network Grantees	6	2	1	12
Total					1,209