CHAPTER 21 – Food Composition, Standards, Labeling, and Economics

SUBJECT:	GENERAL FOOD LABELING REQUIREMENTS AND LABELING-RELATED SAMPLE ANALYSIS – DOMESTIC AND IMPORT
IMPLEMENTATION DATE:	05/09/2025
PRODUCT CODES:	Industry Codes: 02-41
PRODUCT/ASSIGNMENT CODES (PACs)	21005: General Food Labeling Requirements and Labeling-Related Sample Analysis – Domestic and Import 03803E: Food Safety Program - Allergens

FIELD REPORTING REQUIREMENTS:

PAC 21005 (General Food Labeling Requirements and Labeling-Related Sample Analysis – Domestic and Import) – Use this PAC to report (1) label reviews for the labeling requirements under the Federal Food, Drug, and Cosmetic (FD&C Act), the Fair Packaging and Labeling Act (FPLA), and its implementing regulations; and (2) domestic and import samples collected and analyzed for nutrient content as instructed in this compliance program.

PAC 03803E (Food Safety Program – Allergens) – Use this PAC to report domestic and import samples collected and analyzed for food allergens and gluten.

DO NOT REPORT economic adulteration work under this Compliance Program. Instead, please see *Resource Instructions*.

Refer to *PARTS III Inspectional*, *IV Analytical*, and *V Regulatory/Administrative Strategy* for specific FACTS data reporting instructions.

Contents

Change History

Item	Change	Date
Update	• Sesame added as the 9th major food allergen per the FASTER Act of 2021 • Gluten Free labeling-related instructions and information • The 2016 changes to the nutrition facts label requirements • Area of Emphases redefined • Expanded lists of Import Alerts & interacting Compliance Programs • Updated instructions in all PARTS • Sample Collection Guide added for Area of Emphasis 1 • Clarified sampling priorities • Allergen and Gluten Analyses • Updated data reporting instructions, including PACs and PAFs • Updated references to the LST and labs • Tables clarifying possible charges and evidence needed and potential regulatory actions • References added, Attachments removed • Food Labeling Compliance Program Resource Page created on FDA intranet for FDA staff	05/09/2025

PART I – BACKGROUND

This Compliance Program (CP) was developed to replace the previous CP entitled "DOMESTIC AND IMPORT NLEA, NUTRIENT SAMPLE ANALYSIS, AND GENERAL FOOD LABELING REQUIREMENTS PROGRAM." The title is updated to "GENERAL FOOD LABELING REQUIREMENTS AND LABELING-RELATED SAMPLE ANALYSIS - DOMESTIC AND IMPORT" to capture the content of this CP more accurately. The previous CP was developed to address the requirements of the 1990 Nutrition Labeling and Education Act (NLEA). However, labeling requirements that were preexisting or unrelated to NLEA were also incorporated into the previous CP[1]. Updates in this CP include gluten-free labeling requirements, the 2016 changes to the Nutrition Facts label requirements, and the addition of sesame as the ninth major food allergen per the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, effective January 1, 2023. This updated CP provides instructions to the field concerning inspections and label reviews to determine compliance with food labeling laws and regulations for domestic and imported food products.

Food labeling is an important tool consumers rely on to make informed choices. For example, consumers use the ingredient list to make purchasing decisions and determine whether a food contains an ingredient they want (e.g., whole grains) or an ingredient they need to avoid (e.g., a major food allergen). Consumers need to be able to trust the information on the food label for both nutrition and safety. It is industry's responsibility to make sure that information on food labels is truthful and not misleading. The FDA monitors industry compliance and takes appropriate regulatory actions when warranted.

1. Summary of Requirements

This CP focuses on (1) the labeling requirements under the FD&C Act and Title 21 of the Code of Federal Regulations (21 CFR) and (2) compliance with nutrient declarations, claims, and other labeling requirements based on the analysis of samples of foods and/or recordkeeping, if applicable. Associated requirements include:

- Declaration of major food allergens under section 403(w) of the FD&C Act
- Gluten-free labeling of food (21 CFR 101.91)
- Ingredient declaration (21 CFR 101.4) and labeling associated with safe use in food (for example, 21 CFR 101.17)
- Nutrition labeling (21 CFR 101.9)
- Nutrient content claims and health claims (general: 21 CFR 101.13 and 101.14; more in *PART III Inspectional*)
- Other labeling requirements include, but are not limited to:
  - statement of identity (21 CFR 101.3)
  - statement of the net quantity of contents (21 CFR 101.7)
  - the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5), and
  - the percent juice declaration (21 CFR 101.30).

[1] It is not accurate to refer to any labeling requirement as "NLEA." Many labeling requirements were implemented before the NLEA and other labeling requirements, such as major food allergen and gluten-free labeling requirements, are unrelated to the NLEA.

A. Major Food Allergen Declarations

All packaged foods regulated under the FD&C Act must comply with food allergen labeling requirements of the FD&C Act. Under the FD&C Act, "major food allergen" is defined in section 201(qq) (21 U.S.C. 321(qq)) as an ingredient that is one of the following major foods/food groups or is an ingredient that contains protein derived from one of the following:

- Milk
- Egg
- Fish (e.g., bass, flounder, and cod)
- Crustacean shellfish (e.g., lobster, crabs, and shrimp)
- Tree nuts (e.g., almonds, pecans, and walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame

Definitions and examples of more tree nuts, milk, and eggs considered to be major food allergens can be found in the Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5) | FDA. Check the FDA website for the most recent information.

For more information, refer to Food Allergens/Gluten-Free Guidance Documents & Regulatory Information. See *PART III Inspectional* and the *Allergen Labeling Requirements* document on the Food Labeling Compliance Program Resource Page.

B. Gluten-free Labeling of Food

In 2013, the FDA issued a final rule defining the term "gluten-free" for voluntary use in the labeling of foods. As defined under 21 CFR 101.91, "gluten-free" means:

- (1) That the food bearing the claim in its labeling:
  - Does NOT contain any one of the following:
    - An ingredient that is a gluten-containing grain[2] (e.g., spelt wheat);
    - An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten[3] (e.g., wheat flour); OR
    - An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); OR
  - The food inherently does not contain gluten (e.g., orange juice) AND
- (2) Any unavoidable presence of gluten in the food bearing the claim is below 20 parts per million (ppm) gluten (i.e., below 20 mg gluten per kg of food).

[2] Gluten-containing grain refers to: wheat and any species belonging to the genus Triticum, rye and any species belonging to the genus Secale, barley and any species belonging to the genus Hordeum, and any crossbred hybrids (e.g., triticale (cross between wheat and rye))

[3] The term "gluten" refers to certain storage proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (21CFR101.91(a)(2)).

In 2020, the FDA issued another final rule and amended 21 CFR 101.91. The 2020 final rule established compliance requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, bearing the "gluten-free" claim.

For more information, refer to Food Allergens/Gluten-Free Guidance Documents & Regulatory Information. See *PART III Inspectional*, Gluten-free labeling of food (21 CFR 101.91), and Gluten-Free Labeling of Foods.

C. Ingredients Declaration and Labeling Associated with the Safe Use in Food

Ingredient labeling: Section 403(i)(2) of the FD&C Act requires that the label of a food that is fabricated from two or more ingredients declare each ingredient by its common or usual name (except that spices, flavoring, and colors could be declared as a class (21 CFR 101.22)). In addition, there are specific labeling requirements for the following ingredients (also see the major food allergens discussion above):

- FD&C Yellow No. 5, FD&C Yellow No. 6, and sulfiting agents are ingredients to which some people may be sensitive. Refer to 21 CFR 101.22(j) and (k) for ingredient declaration requirements for colors and chemical preservatives.
- Aspartame (21 CFR 172.804) and sorbitol (21 CFR 184.1835) have statements associated with their safe use in food. Also refer to 21 CFR 101.17 for required warning, notice, and safe handling statements for the safe use of certain foods.
- Cochineal Extract and Carmine may be safely used for coloring foods in accordance with 21 CFR 73.100(d)(2), which states that the label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine must specifically declare the presence of the color additive by listing its respective common or usual name, "cochineal extract" or "carmine," in the statement of ingredients.

D. Nutrition Labeling

The FDA works to help empower consumers to build nutritious diets that support health and wellness. The Nutrition Facts label (NFL) on food packages is used by consumers to make informed choices.

In 2016, the FDA amended its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The updated information is consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States and corresponds to new information on consumer understanding and consumption patterns.

The Food Labeling: Revision of the Nutrition and Supplements Facts Labels Final Rule:

- revised the list of nutrients that are required or permitted to be declared, for example Added Sugars,
- updated Daily Reference Values (DRVs) and Reference Daily Intake (RDI) values that are based on current dietary recommendations from consensus reports,

- amended requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and established nutrient reference values specifically for these population subgroups,
- revised the format and appearance of the Nutrition Facts label and,
- required manufacturers to make and keep certain written records to verify the declaration of specific nutrients and use scientifically valid methods that reliably detect nutrient content in various food matrices, when appropriate.

Refer to the following for more information on the final rule:

- Changes to the Nutrition Facts Label
- Small Entity Compliance Guide: Revision of the Nutrition and Supplement Facts Labels

Additional information on added sugar requirements and the FDA's enforcement discretion guidances:

- Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels
- Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals
- Guidance for Industry: Policy Related to Cranberry Products with Added Flavorings
- Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products

Also in 2016, the FDA issued the Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed (RACC); Serving Size for Breath Mints; and Technical Amendments Final Rule to provide consumers with more accurate and up-to-date information on serving sizes which:

- defines a single-serving container;
- requires dual-column labeling for certain containers;
- updates, modifies, and establishes several RACCs;
- amends the label serving size for breath mints; and
- makes technical amendments to various aspects of the serving size regulations.

Refer to the following for more information on the final rule: Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics

On December 21, 2018, the FDA issued Food Labeling; Revision of the Nutrition and Supplement Facts Labels; Technical Amendments.

PART II - IMPLEMENTATION

1. Objective

- To determine industry compliance with labeling requirements for domestic and imported foods, especially foods known to cause adverse health effects, including food allergens, gluten, and other ingredients known to cause sensitivities (e.g., sulfites). FDA requirements include the proper declaration of ingredients and the proper use of required label statements associated with the safe use in food.
- To collect and evaluate labels of domestic and imported food products to determine compliance with food labeling requirements (including, but not limited to, nutrition labeling, ingredient declarations, claims, net quantity of contents, major food allergens, gluten-free claims, and percent juice).
- To collect and analyze samples of domestic and imported food products to assure that nutrients are present at levels declared on the label.
- To take appropriate regulatory action when product labels are not compliant with the FD&C Act and the implementing regulations.

Note: This CP covers conventional food only. Dietary supplements are not covered under this CP. For dietary supplements, see CP 7321.008 Dietary Supplements - Foreign and Domestic Inspections, Sampling, and Imports, found on the FDA's website Food Compliance Programs (public access) or intranet site Office of Compliance and Enforcement's Compliance Programs (FDA access).

2. Program Management Instructions

A. Inspection Priorities

The inspection priorities for the CPs listed below in *Section C Interactions Between Compliance Programs* are covered within each CP. However, specific instructions for label review during inspections are provided in this CP (see *PART III Inspectional*). Label reviews conducted during inspections of firms under the interacting CPs in the *Interactions Between Compliance Programs* section should be reported under the 21005 PAC.

B. Planning Instructions

(1) Domestic and Foreign Inspections

- Label reviews, also known as label exams, should focus on the products covered under the CPs listed below in *Section C Interactions between Compliance Programs*.
- Focus of label reviews should be on the Areas of Emphasis listed in *PART III.1.A*
- The outcome of label reviews may warrant the collection of samples. Note: Sample collections are not typically performed during foreign inspections, unless specifically directed.

(2) Domestic Sample Collection

- This CP includes domestic surveillance sampling for general nutrient analyses. Sampling should focus on the products listed in *PART III Inspectional*, Table 5 "*Collection Schedule for Product Sampling for Nutrient Analysis*."

- Surveillance samples should preferentially be collected during domestic inspections conducted under the CPs listed below in *Section C Interactions Between Compliance Programs*. If a division needs to collect more samples to meet its sampling obligations, the division can collect samples at wholesale or distribution centers. If there are no other options available, the division can collect samples at the retail level.

(3) Imports

- Focus label examinations on Areas of Emphasis listed in *PART III Inspectional*.
- Import surveillance sampling is not indicated per this compliance program.
- Whenever possible, label examinations and collection of samples for general nutrient analyses should be conducted in conjunction with regularly scheduled import work under other food compliance programs and assignments.
- Import Alerts (IAs) - All IAs are available through the public FDA.gov Import Alerts page. The most relevant IAs to this CP are listed below:

Table 1: Import Alerts Relevant to the Food Labeling Compliance Program

IA 99-39	Detention Without Physical Examination (DWPE) of Imported Food Products That Appear to Be Misbranded
IA 99-22	Detention Without Physical Examination Of Foods Containing Undeclared Major Food Allergens Or Foods That Fail To Properly Label Major Food Allergens
IA 99-21	Detention Without Physical Examination of Food Products Containing Undeclared Added Sulfiting Agents

This is not an all-inclusive list of Import Alerts related to this CP. A list of all Import Alerts by Number can be found here.

- The import enforcement strategy (see *PART V Regulatory/Administrative Strategy*) focuses on the importance of efficient use of compliance resources based on risk. Please note that importers:
  - Are responsible for the compliance of the foods they offer for importation.
  - Might purchase foods without altering the existing labeling prior to importation.
  - Might provide labeling specifications or the labeling itself to the foreign manufacturer for use.
  - Might submit a request to the detaining FDA field office for authorization to relabel a product (Form FDA 766).
  - Might respond to detention, refusal, or detention without physical exam (DWPE) by changing suppliers of the product but not ensuring the new source has compliant labeling; as a result, the importer continues to offer the same or similar product from an alternative source but with the same or similar labeling violations.

C. Interactions Between Compliance Programs

This CP may interact with the following CPs. In addition to PAC 21005, also use the appropriate PAC from the below CPs when warranted. To access the CPs listed below, visit

The FDA's website Food Compliance Programs (public access) or intranet site Office of Compliance and Enforcement's Compliance Programs (FDA access).

Table 2: Compliance Programs That May Interact with this Food Labeling Compliance Program

7303.040	Preventive Controls and Sanitary Human Food Operations
7303.050	Sampling for Foodborne Biological Hazards, and Filth – Domestic and Import
7303.070	Acidified and Low Acid Canned Foods Program – Import & Domestic
7303.819	Import Foods – General
7303.842	Seafood Processor, Products, and Importer Inspection Program
7303.847	Juice HACCP Inspection Program
7303.878	Foreign Supplier Verification Programs Inspections
7304.004	Pesticides and Industrial Chemicals in Domestic and Imported Foods
7304.019	Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic
7309.006	Domestic and Import Food Additives and Color Additives
7318.003	National Conference on Interstate Milk Shipments (NCIMS) Milk Safety Program
7321.002	Medical Foods Program – Import and Domestic
7321.006	Infant Formula Program – Inspection, Sample Collection, and Examination

D. Resource Instructions

- Resources for label review (domestic), import label exams, sample collections, and analyses are provided in the OII Field Workplan.
- Currently, surveillance of economic adulteration is implemented through assignments rather than through this CP. If ad hoc samples need to be taken, the division should consult with the HFP/OCE contact (see *PART VI References, Attachments, and Program Contacts*) to ensure Human Foods Program (HFP) support. Time expended for activities related to economic adulteration should be reported under PAC 21003 (Domestic Food Economics and Standards) or PAC 21004 (Import Food Economics and Standards).

E. Interactions with other Federal Agencies, State and Local Counterparts, and Foreign Authorities

- Investigations Operations Manual (IOM) subchapter 3.2 Federal Agency Interaction lists Memorandums of Understanding (MOUs), some of which may also be applicable to the activities conducted under this CP. For example, Memorandum of Understanding (MOU) 225-18-003 exists between the FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB, formerly the Bureau of Alcohol, Tobacco, and Firearms) for labeling of distilled spirits, wine, and malt beverages. Please see FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration. A complete list of MOUs can be found at FDA Memoranda of Understanding.
- Divisions will collaborate with commissioned state agencies to make them aware of the requirements of this program.

- States may share product labels and/or analytical data with the FDA. After reviewing the results, the FDA may follow-up as appropriate.

PART III - INSPECTIONAL

1. Operations

This part includes the instructions investigators should follow during inspectional activities, import activities, and sample collections to evaluate industry compliance with labeling requirements outlined in *PART I Background* of this program. Inspections of food facilities will not be conducted under this CP and instead will be conducted under CPs such as those included under *PART II 2. C. Interactions Between Compliance Programs* of this program.

Investigator Training Requirement

Investigators should ensure that they have taken the most updated conventional food labeling training course available. A link to this training is posted on the Food Labeling Compliance Program Resource Page. As of the 2025 revision of this CP, the 2022 *CC8003W: Food Labeling* course in the Office of Training Education and Development (OTED) LearnED system is the current version.

A. Areas of Emphasis

The activities conducted under this CP should be based on the following Areas of Emphasis (AoE):

(1) Area of Emphasis 1: Labeling Violations Related to Major Food Allergens, Gluten, and Labeling Associated with the Safe Use of Foods

Product labels that fail to declare major allergens in accordance with the food allergen labeling requirements in the FD&C Act, product labels that fail to comply with the gluten-free requirements, and product labels that lack other label information associated with safe use in food.

This AoE includes any product that, based on the label exam and associated record review:

- fails to declare a major food allergen as required under section 403(w) of the FD&C Act;
- includes a gluten-free claim but fails to meet the regulatory requirements in 21 CFR 101.91;
- fails to declare sulfiting agents (e.g., sulfur dioxide, sodium sulfite, sodium bisulfate, potassium bisulfate, sodium metabisulfite, and potassium metabisulfite), FD&C Yellow No.5 (tartrazine), carmine and cochineal extract; or
- lacks required label statements associated with safe use of foods such as warning or safe handling statements.

(2) Area of Emphasis 2: Lack of Nutrition Labeling

Product labels that fail to bear nutrition labeling and are not covered by an exemption.

(3) Area of Emphasis 3: Nutrition Labeling Deficiencies

Product labels that bear significant nutrition labeling deficiencies (e.g., absence of mandatory nutrients in nutrition labeling), incorrect serving size (e.g., serving size not based on the appropriate RACC), and/or labeling that misrepresents the number of calories, or other nutrient declarations.

(4) Area of Emphasis 4: Nutrient Content Claims and Health Claims Violations

Product labels that fail to meet the requirements for nutrient content claims and/or health claims, specifically:

- Product labels that bear unauthorized nutrient content claims or unauthorized health claims, or
- Product labels that bear authorized nutrient content claims/health claims, but the products do not qualify for making the claims, or
- Product labels that bear qualified health claims subject to enforcement discretion but do not qualify for making such claims.

(5) Area of Emphasis 5: Food Standards Violations

Products that are represented as a food for which a definition and standard of identity have been prescribed by regulations and the food does not appear to conform to such definition and standard in the regulations.

(6) Area of Emphasis 6: Other Labeling Violations

Product labels that bear significant deficiencies from other labeling requirements.

B. Inspections

During each domestic and foreign surveillance inspection of firms that are manufacturing and/or labeling, or re-labeling food products, investigators are to perform label exams to cover all the labeling for at least 3 food products (including labels of ingredients for consistency with the finished product label), focusing on the AoE noted below. This CP coverage may also apply to investigations and remote regulatory assessments (RRA), as appropriate. Deficiencies must be fully documented in the Establishment Inspection Report (EIR).

(1) Evidence Collection

In all instances, when a violation of the nature described in an Area of Emphasis is known or suspected, documentary and/or photographic evidence to support the violation must be collected. Depending on the circumstance, the supporting evidence might include the product label, photos of all sides of the container, product formulations or batch records, raw material ingredient label photos and/or specifications, Certificate of Analysis (COA), affidavits, interstate records, or physical sample.

Collect original, physical labels during domestic and foreign inspections when possible. When not practical, take legible photos or scans of product labels. Photos of product labels are permitted for imports operations, but these photos must be completely legible. Furthermore, these photos must be taken of each side of the package, including when the package has no labeling. Identify which panel is the subject of the photo or scan (i.e., Principal Display Panel (PDP), right of PDP (information panel), left of PDP, Back, Top, Bottom).

Legibility of photos should be confirmed before the inspection is closed out. During domestic and foreign establishment inspections, if legible photos cannot be taken, physical labels should be collected.

For domestic inspections, submission of the evidence can be added to the EIR as an Exhibit or Attachment, as appropriate, with an explanation of the label deficiencies in the EIR.

Documentary (DOC) samples may be collected and submitted in accordance with IOM, Chapter 4. If you take a domestic physical official sample, these documents are attached to the physical sample Collection Report (C/R).

For foreign inspections, submission of the evidence can be added to the EIR as an Exhibit or Attachment, as appropriate, with an explanation of the label deficiencies in the EIR. During foreign inspections, do not collect documentary or physical product samples, unless directed.

During an inspection of a firm at which physical samples or DOC samples of labels are collected for post inspectional review, investigators should inform firm management:

> "The collection of product labels does not obligate the agency to provide you with written feedback on the labels. This lack of correspondence should not be construed as indicating that the labels are in compliance. Your firm is responsible for assuring compliance of product labels."

Document the information was relayed to the firm in the EIR. Potential labeling deficiencies should be discussed with firm management.

(2) Areas of Emphasis

(a) **Area of Emphasis 1:** Labeling Violations Related to Major Food Allergens, Gluten, and Labeling Associated with the Safe Use of Foods

i. Requirements for Major Food Allergen Labeling

During the course of the inspection, the investigator should utilize the information in the *Allergen Labeling Requirements* document on the Food Labeling Compliance Program Resource Page to determine if the firm's finished product labels comply with requirements of section 403(w) of the FD&C Act. Review formulations, raw material labels (especially multicomponent ingredients), flavors, spices, colors, and incidental additives (21 CFR 101.100(a)(3)) for ingredients that are/or contain one or more of the major food allergens. Review finished products made with these raw materials to determine if the major food allergens are appropriately declared on the label as required.

If the investigator observes that the firm's labels do not identify major food allergens as required by section 403(w) of the FD&C Act, document the deficiencies in the EIR. See the *Evidence Collection* section above for evidence to be collected. Document the firm's corrective action plan for meeting the allergen labeling requirements of the FD&C Act.

ii. Requirements for Gluten-Free Claims

During the course of the inspection, when gluten-free claims are made on product labels, the investigator should utilize the information below and in *Field Alert 58 Gluten-Free Labeling of Food* (found on the Food Labeling Compliance Program Resource Page) to determine if the firm's gluten-free claims comply with requirements of 21 CFR 101.91.

Gluten-free claims are voluntary; labels may include a "gluten-free" claim or one of the following claims defined in 21 CFR 101.91 to be synonymous with "gluten-

free:" "free of gluten," "no gluten," or "without gluten." There may be other terms that could imply gluten-free; however, these terms are not defined in 21 CFR 101.91 and are reviewed on a case–by-case basis.

As defined under 21 CFR 101.91, "gluten-free" means:

- (1) That the food bearing the claim in its labeling:
  - Does NOT contain any one of the following:
    - An ingredient that is a gluten-containing grain[4] (e.g., spelt wheat);
    - An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten[5] (e.g., wheat flour); or
    - An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); OR
  - The food inherently does not contain gluten (e.g., orange juice) AND
- (2) Any unavoidable presence of gluten in the food bearing the claim is below 20 parts per million (ppm) gluten (i.e., below 20 mg gluten per kg of food).

If a product is found with a "gluten-free" claim during an inspection, the investigator should determine if the firm's finished product complies with the requirements in 21 CFR 101.91 by reviewing formulations, material labels (especially multicomponent ingredients, flavors, spices, and colors for ingredients that are, or contain, a gluten-containing grain), records for fermented and hydrolyzed ingredients/foods, or the distillation process for distilled foods, as applicable. The investigator should also look for sources of potential cross-contact with gluten-containing ingredients. If evidence of the potential presence of a gluten-containing ingredient from cross-contact is found in a food that bears a "gluten-free" claim the investigator should contact the HFP/Office of Compliance and Enforcement (OCE)/Office of Enforcement (OE) contact (see *PART VI References, Attachments, and Program Contacts*) to determine if product sampling and analytical testing for the presence of gluten is warranted (see sample collection instructions below in the section *Sample Size for Compliance (Physical Product Samples)* under "Area of Emphasis 1" for additional instructions).

For fermented and hydrolyzed products/ingredients (e.g., yogurt, sauerkraut, pickles, cheese, green olives, alcoholic beverages under the FDA's labeling jurisdiction, and hydrolyzed plant proteins), compliance with the a "gluten-free" claim is based on records (not gluten analysis) that are made and kept by the manufacturer (see 21 CFR 101.91(c)(2)-(4)).

[4] Gluten-containing grain refers to: wheat and any species belonging to the genus Triticum, rye and any species belonging to the genus Secale, barley and any species belonging to the genus Hordeum, and any crossbred hybrids (e.g., triticale (cross between wheat and rye))

[5] The term "gluten" refers to certain storage proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (21CFR101.91(a)(2)).

For distilled products (e.g., some vinegars and distilled water), compliance is evaluated by verifying the absence of protein (and thus gluten) in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food (see 21 CFR 101.91(c)(5)).

For additional information, see the following resources:

- *Field Bulletin #50 Gluten-Free Final Rule* found on the Food Labeling Compliance Program Resource Page
- Small Entity Compliance Guide: Gluten-Free Labeling of Foods
- Gluten-Free Labeling of Foods
- Questions and Answers on the Gluten-Free Food Labeling Final Rule
- Federal Register: Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

iii. Requirements for Declaration of Certain Colors, Sulfiting Agents, Warning Statements, and Labeling Associated with Safe Use in Food

Document the absence in finished product labels of any required declarations for color additives or chemical preservatives or required label statements associated with the safe use in food. See the following CFR sections for examples of specific requirements:

- For information on the declaration of Yellow No. 5, see (21 CFR 74.705)
- For information on the declaration of Carmine and Cochineal extract requirements, see 21 CFR 73.100
- For information on the declaration of sulfiting agents, see 21 CFR 101.100(a)(4)
- For information on warning, notice, and safe handling statements, see 21 CFR 101.17
- Examples of required label statements associated with the safe use in food required by some food additive regulations in 21 CFR Parts 172, 179 and 180; for example, quinine (21 CFR 172.575), saccharin (21 CFR 180.37), aspartame (21 CFR 172.804), and sorbitol (21 CFR 184.1835), etc.[6] ; this is not an all-inclusive list. See Food Additive regulations starting at 21 CFR 170. If there are questions about other labeling for food additives contact CFSAN-OC-LDSCBInquiries@fda.hhs.gov

For DOC and physical sampling instructions, see the sections *Documentary Samples for Compliance* and *Sample Size for Compliance (Physical Product Samples)* "Area of Emphasis 1."

(b) **Area of Emphasis 2:** Lack of Nutrition Labeling

This includes labels that fail to bear a Nutrition Facts label (NFL) that are not exempt from nutrition labeling.

[6] Some food additives have labeling requirements associated with the safe use of the additive. Lack of the required statements should possibly be considered for an unsafe food additive charge.

During the course of the inspection, the investigator should utilize the information below and in the *Nutrition Labeling Requirements Additional Information* document located on the Food Labeling Compliance Program Resource Page to determine if the firm's finished product labels comply with requirements of 21 CFR 101.9.

All labels on food offered for sale are required to include an NFL unless exempt under one of the exemptions provided in 21 CFR 101.9(j).

If the label does not include an NFL, in addition to the labeling evidence listed above in the *Evidence Collection* section, the division should provide sufficient documentation in the EIR to enable HFP/OCE to verify whether the products are covered under an exemption (21 CFR 101.9(j)) from nutrition labeling. For example:

- Retailers may qualify for an exemption based on gross annual income as provided in 21 CFR 101.9(j)(1). Documentation should include either annual gross sales or annual gross sales of food to consumers.
- Small businesses may file annually for a Small Business Nutrition Labeling Exemption (SBNLE) under 21 CFR 101.9(j)(18). Documentation to verify if a firm may qualify for this exemption should include the number of full-time equivalent employees and number of units per product sold annually in the U.S. (21 CFR 101.9(j)(18)(iv)).
    - The annual filing is product specific.
    - See Firms That Have Filed for a Small Business Nutrition Labeling Exemption for a current list of exempt firms. Divisions should refer to this Internet website before conducting label examinations. If the division needs additional information including the specific products covered under the firm's notice, they should contact ONFL's Small Business Coordinator (see *PART VI References, Attachments, and Program Contacts*).
- If the firm is not an importer and has fewer than 10 full-time equivalent employees, that firm does not have to file a SBNLE notice for any food product with annual sales of fewer than 10,000 total units.

Note: A nutrient declaration, nutrient content claim, or health claim on a food product label usually negates the exempt status of the product and triggers the requirement for nutrition labeling. However, such claims do not negate all exemptions; see 21 CFR 101.9(j).

For additional information about nutrition labeling exemptions, see *Nutrition Labeling Requirements Additional Information* document found on the Food Labeling Compliance Program Resource Page.

(c) **Area of Emphasis 3:** Nutrition Labeling Deficiencies

During the course of the inspection, the investigator should utilize the information below and the information in the *Nutrition Labeling Requirements Additional Information* document on the Food Labeling Compliance Program Resource Page to determine if the firm's finished product labels comply with the requirements of 21 CFR 101.9.

There have been several updates to the NFL. For general resources about the changes, see the following with detailed information:

- Details of Key Changes with a side-by-side comparison of the old vs. Current label
- At a Glance: Highlights of the Final Nutrition Facts Label Fact Sheet
- Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints

The nutrition labeling on a food product must be an accurate representation of the nutritional value of the food. For this purpose, compliance criteria has been established (21 CFR 101.9(g)(3),(4),(5), & (6)):

- For **any added vitamin, mineral, protein, or dietary fiber,** the nutrient content of the composite analyzed is at least equal to the value declared on the label for that nutrient;
- For **any naturally occurring vitamin, mineral, protein, total carbohydrate**, **dietary fiber, polyunsaturated or monounsaturated fat**, the nutrient content of the composite analyzed is at least equal to 80% of the value declared on the label for that nutrient; and
- **For calories, total sugars, added sugars, total fat, saturated fat, trans fat, cholesterol, or sodium**, the nutrient content of the composite analyzed is not more than 20% in excess of the value declared on the label for that nutrient.

Please note that all nutrients listed in the NFL are considered "nutrients," including sugars, cholesterol, and sodium.

Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohol, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, total sugars, added sugars, total fat, saturated fats, trans fat, cholesterol, or sodium under labeled amounts are also acceptable within good manufacturing practice.

Whether a food contains "**Added nutrients**" can be determined by several factors, including discussions with the firm, review of the formulation, the ingredient list, the Nutrition Facts label, nutrient content claims which include terms such as "enriched," "added," "fortified", "extra" or similar terms, or health claims which use similar terms. See also 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Human Consumption, Subpart D, Special Dietary and Nutritional Analysis, for ingredients that may be added nutrients for additional information.

Focus on added nutrients that are the subject of any claim or nutrients that are declared in the Nutrition Facts label at greater than 10% Daily Value (DV).

Note: Records are required for certain nutrients. There are no official methods of analysis from the Association of Official Analytical Chemists' (AOAC) or other

reliable or appropriate analytical procedures available to verify the amount of some declared nutrients on the NFL. Therefore, manufacturers are required in 21 CFR 101.9(g)(10), to make and keep written records of the amount of some nutrients.

Records are required for the following nutrients:

- Added sugars when there is both naturally occurring sugars and added sugars in a product.
- Dietary fiber when the fiber in the food is from mixtures of dietary fiber, soluble fiber, or insoluble fiber and added non-digestible carbohydrates that do not meet the definition for dietary fiber. See: FDA Issues Guidance, Science Review, and Citizen Petition Responses on Dietary Fiber. Also see: Questions and Answers on Dietary Fiber.
- All-rac-α-tocopherol added to the food and RRR-α-tocopherol in the finished food when a mixture of both forms of vitamin E are present in a food.
- Folic acid added to the food and the amount of naturally occurring folate in the finished food when a mixture of both forms is present in a food.

See Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Guidance for Industry Small Entity Compliance Guide, specifically Sections V & VI.

During an inspection, if an investigator identifies products that contain nutrients as listed above, ensure the manufacturers have the required records for those nutrients in that product(s). These records must be made available for review and copying if requested.

See also the *Example of Nutrition Label Review for Analysts* on the Food Labeling Compliance Program Resource Page.

(d) **Area of Emphasis 4:** Nutrient Content Claims and Health Claims Violations

i. Nutrient Content Claims

Nutrient content claims are claims that, expressly or implicitly, characterize the level of a nutrient of the type required to be in nutrition labeling (see 21 CFR 101.9) in a food, that are authorized by the FDA and are made in accordance with the FDA's authorizing regulations.

Nutrient content claims describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and light (or lite). An unauthorized or undefined nutrient content claim is one that is not defined by regulation, or it is not authorized under the Food and Drug Administration Modernization Act (FDAMA). An unqualified nutrient content claim is when a product label bears an authorized or defined nutrient content claim, but the product does not meet the criteria for making the claim.

Requirements for nutrient content claims are found in 21 CFR 101.13 and Subpart D (21 CFR 101.13, and 101.54 through 101.67). For example, to make a "fat-free" nutrient content claim, a product must contain less than 0.5 grams of fat per reference amount customarily consumed and per labeled serving. For further

information, refer to Guidance for Industry: Food Labeling Guide and Nutrient Content Claims.

ii. Health Claims

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition.

General requirements for all health claims are found in 21 CFR 101.14. Authorized health claims are those that are defined or otherwise permitted by the FDA through FDAMA or a Letter of Enforcement Discretion. Health claims that are permitted by regulations are found in Subpart E, 21 CFR 101.71 through 101.83. Additional authorized health claims are found on the FDA website Label Claims for Food & Dietary Supplements page. An unauthorized or undefined health claim is one that is not defined by regulation, or it is not authorized under FDAMA, or it is not a qualified health claim where FDA has provided a Letter of Enforcement Discretion.

- An unqualified health claim is when a product label bears an authorized or defined health claim, but the product does not meet the criteria for making the claim.
- An unauthorized health claim may also be considered a disease claim. Disease claims are not permitted on foods.[7]

Individual health claims may have additional specific nutrient requirements including disqualifying levels of nutrients for all health claims. For example, the health claim in 21 CFR 101.74 for sodium and hypertension requires that the food must meet all the nutrient content requirements of 21 CFR 101.61 for a "low sodium" food.

The language used in the health claim on the label must be as required by their respective source that permits the claim.

iii. Types of Label Claims

Table 3: Types of Label Claims

Claims	Reference	Examples
Nutrient Content Claims	See 21 CFR 101.54 through 101.67	"Good source," "high," "more," and "high potency" nutrient content claims (21 CFR 101.54)
Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard	See 21 CFR 101 Subpart E (101.72- 101.83) for list of FDA authorized SSA claims, criteria for making	"Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of

[7] Disease claims on conventional foods may position the food as an unapproved new drug. Such claims are evaluated on a case-by-case basis by HFP/OCE/OE/DCFDSE/CFLEB for potential "unapproved new drug" charges.

Claims	Reference	Examples
	the claim, and language to be used.	osteoporosis in later life." (21 CFR 101.72)
FDA Modernization Act of 1997 (FDAMA) Health and Nutrient Content Claims	See List of FDA Modernization Act (FDAMA) Authorized Claims	"Replacing saturated fat with similar amounts of unsaturated fats may reduce the risk of heart disease. To achieve this benefit, total daily calories should not increase."
Qualified Health Claims	Enforcement Discretion (ED) letters. NOTE that only the claims listed in the ED letters are permitted.	"Eating yogurt regularly, at least 2 cups (3 servings) per week, may reduce the risk of type 2 diabetes. FDA has concluded that there is limited information supporting this claim."
Structure/Function Claims for Conventional Foods	See Structure/Function Claims for Conventional Foods. Reviewed on a case-by-case basis.	"Calcium supports strong bones."
Disease Claims	Claims related to a disease condition not authorized by one of the existing claims above. Reviewed on a case-by-case basis.	"This food (or nutrient)" prevents cancer"

For more information about the various types of health claims and nutrient content claims, visit Questions and Answers: Authorized and Qualified Health Claims in Food Labeling and Label Claims for Conventional Foods and Dietary Supplements.

Appendix C of the Guidance for Industry: Food Labeling Guide contains a summary of those nutrient content and health claims that have been approved for use.

See the section *Areas of Emphasis,* specifically *Area of Emphasis 4,* for more information about Area of Emphasis 4.

Investigators should refer to the specific regulations/requirements listed in the table above to determine if the amount of the nutrients listed in the NFL qualifies the product to make the claim. To make authorized nutrient content claims or health claims, products must meet certain nutritional requirements.

During an inspection, if an investigator observes unauthorized labeling claims or a questionable practice that is clearly related to the nutrient content of a product, the investigator should document the information in the EIR and take a photo of the

label(s) associated with the product. For additional DOC sampling instruction see section *Documentary Samples for Compliance* and for additional physical sampling instructions see section *Sample Size for Compliance (Physical Product Sample)* covering Area of Emphasis 3 and Area of Emphasis 4.

(e) **Area of Emphasis 5:** Food Standards Violations

Food standards are found in 21 CFR Parts 130 through 169. Products that are represented as a food for which a definition and standard of identity have been prescribed by regulations may be violative if the food does not conform to such definition and standard in the regulations. Contact HFP/OCE/OE/DCFDSE/Critical Foods and Labeling Enforcement Branch (see *PART VI References, Attachments, and Program Contacts)* if a violation is suspected.

Some plant-based alternative foods may be using a standardized term as part of their statement of identity, but plant-based alternative foods are not standardized foods and are not covered under this area of emphasis. Also note that plant-based guidances are being developed and will be provided when available.

(f) **Area of Emphasis 6:** Other Labeling Violations

Product labels that bear significant deficiencies from other labeling requirements, such as:

- Failure to include a statement of identity or has an incorrect statement of identity (21 CFR 101.3)
- Mischaracterization of conventional foods as medical foods[8] or dietary supplements: (21 CFR 101.3)

Labels that fail to bear an ingredient list or a complete ingredient list 21 CFR 101.4), such as the label fails to declare the sub ingredients of multicomponent ingredients as required).

- Failure to use the common or usual name of an ingredient (21 CFR 101.4)
- Failure to provide a net quantity of contents statement (21 CFR 101.7)
- Failure to provide the name and place of business information (21 CFR 101.5)
- Foreign language issues, i.e., the label bears one or more foreign languages but fails to bear all required label information in those languages, in addition to English (21 CFR 101.15)
- Failure to declare percentage of juice, when required (e.g., a product labeled as juice or claiming to contain juice must declare the percent juice on the label) (21 CFR 101.30)
- Labels or labeling that bear false or misleading information or claims.

[8] Medical food is defined in section 5(b) of the Orphan Drugs Act (21 USC 360ee (b)(3)). Medical food is exempt from the nutrition labeling, nutrient content claim, and the health claim provisions of the FD&C Act. Products labeled as medical food that do not meet the statutory definition are covered under this program and are subject to the nutrition labeling, nutrient content claim, and the health claim provisions of the FD&C Act. (See Guidance for Industry: Frequently Asked Questions About Medical Foods – Third Edition)

During an inspection, if an investigator observes products that do not meet the labeling requirements listed above, the investigator should document the practice in the EIR and take a photo of all sides of the label(s) associated with the product. For additional DOC and physical sampling instructions, see sections *Documentary Samples for Compliance* and *Sample Size for Compliance (Physical Product Sample)*, respectively.

(3) Educational or Firm Resource Materials

During firm inspections where labeling deficiencies are noted, the following resources, which are readily available, should be provided to the firm, as appropriate, and reported in the EIR in accordance with the IOM.

- Title 21 of the Code of Federal Regulations
- Guidance for Industry: Food Labeling Guide
- Labeling & Nutrition Guidance Documents & Regulatory Information
- Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)
- Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021
- Food Allergens/Gluten-Free Guidance Documents & Regulatory Information
- Label Claims for Food & Dietary Supplements
- Other relevant guidance and information listed in this CP.

C. Investigations

The information listed in *PART III.1.B. Inspections* above also applies for Investigations if appropriate for the investigation being conducted.

D. Sample Collections

Physical product samples and documentary samples may be necessary to support compliance actions.

(1) Foreign Inspections

Samples should not be collected during foreign inspections unless directed.

(2) Domestic Inspections

(a) Compliance Sample Collections

For compliance ("for cause") samples, the Collection Report (C/R) should specify, in the Remarks section, the nutrients for the lab to focus on:

- Nutrient(s) forming the basis for a nutrient content claim or health claim, regardless of the label declaration (% of the DV) for that nutrient.* This includes claims for low/no nutrient (e.g. "fat free"). See Area of Emphasis 4: Nutrient Content Claims and Health Claims Violations for additional information on identifying a nutrient content claim or health claim.
- If there is no claim, then select nutrients found in 21 CFR 101.9, prioritizing those declared as being:
    - present at a low/zero percent for total fat, saturated fat, sodium, or total sugar (if suspected to be inaccurate); OR

- present at or above 10% of the DV for Vitamin D, Potassium, Calcium, or Iron; OR
- present at or above 10% of the DV for any added nutrient.* See Area of Emphasis 3: Nutrition Labeling Deficiencies for additional information on determining whether the food contains added nutrients.

  * Note: Manufacturers must make and keep written records to verify the declaration of certain nutrients, specifically added sugars, dietary fiber, vitamin E, folate and folic acid. See 21 CFR 101.9(g)(10). If you are considering a sample collection to test for one of these nutrients, please contact HFP/OCE before collecting the sample.

i. Documentary Samples for Compliance

- Collect DOC samples per IOM, Chapter 4"Documentary Samples." See *Evidence Collection* section above.
- Some nutrients and claims will require records review rather than collections of physical samples.
- When an investigator identifies a possible violation of labeling regulations, they may submit evidence as Exhibits in the EIR or a DOC sample in accordance with IOM, Chapter 4. Contact HFP/OCE. OCE should review the submitted labels to determine if there is a violation, the extent of such violation, and any follow-up recommendation.
- Label photos should only be sent to the lab when the label is not part of the product packaging. For example, if an investigator collects raw material during an inspection, they should take a photo of the raw material packaging and send both the raw material and label photos to the lab.
- For evidence of incomplete ingredient lists due to failure to declare sub ingredients of a product, legible photos of the multicomponent raw material ingredient list should be taken. In addition, other evidence would include ingredient (raw material) specification sheets, product formulations, observations recorded in the EIR, affidavit, etc.

Area of Emphasis 1: Labeling Violations Related to Major Food Allergens, Gluten, and Labeling Associated with the Safe Use of Foods

Please see Table 4 below for information related to physical sample collection associated with the various scenarios.

Table 4: Sample Collection Guide for Area of Emphasis 1

Scenarios	Physical Sample Needed?
Allergens	
(1) For allergen source labeling (domestic and foreign inspections) when evidence, such as observation of the use of allergenic ingredients or the formulation for the product,	No

Scenarios	Physical Sample Needed?
indicates that finished product labeling fails to declare a major food allergen as required under sections 403(w) and 403(i)(2) of the Act, the investigator should collect appropriate evidence related to the finished product and raw materials, including relevant labels. Take legible photos of the product package with the label and collect other appropriate evidence.	
(2) If the product is *suspected* to contain a major food allergen, which is not declared in the ingredient list or Contains statement (or both), i.e., an undeclared allergen. (3) If the product is *suspected* to have the presence of a major food allergen due to cross-contact, i.e., unintended allergen presence. Note, allergen cross-contact falls under the CGMP, Preventive Controls (PC), or HACCP requirements, not labeling requirements.	Possibly; contact HFP/OCE consistent with IOM 8.2.3.4.3 – Allergen Samples
(4) When a product label bears a claim that it is free of a major food allergen but is suspected to contain that allergen due to inspectional observations or review of the formulation, raw material ingredients, or finished product labeling (such as an allergen advisory statement that mentions the same allergen).	Possibly; this may also be a CGMP/PC/HACCP issue. Contact HFP/OCE and refer to IOM 8.2.3.4.3 - Allergen Samples If this is due to an undeclared major food allergen, see scenario (1) above.
Gluten	
(1) When a label bears a gluten-free claim and the ingredient list includes a gluten-containing grain (i.e., wheat, rye, barley, or their crossbred hybrid), the investigator should collect appropriate evidence related to the finished product and raw materials, including relevant labels. Take legible photos of the product package with the label and collect other appropriate evidence.	No
(2) When a label bears a gluten-free claim and bears the term “wheat” in the ingredient list or in a separate “Contains wheat” statement and does not bear a statement that the wheat has been processed to meet FDA requirements for gluten-free ("The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."). Take legible photos of the product package with the label and collect other appropriate evidence.	No

Scenarios	Physical Sample Needed?
When gluten cross-contact is suspected.	Yes, but first consult with HFP/OCE
If the product is a hydrolyzed or fermented food (or contains such ingredients) such as soy sauce. Take legible photos of the product package with the label and collect other appropriate evidence. Contact HFP/OCE/OE/DCFDSE for guidance on the need for record collection.	No (not for gluten analysis)
If the product is a distilled food (or contains such ingredient), such as vinegar. Take legible photos of the product package with the label and collect other appropriate evidence.	It depends. Consult with HFP/OCE for appropriate next steps.
Other Allergen and Gluten Free Priorities - for example complaints	As directed by OCE, HFP Program Office
Colors and Food Additives	
When the label exam or inspectional observations determines that a product may contain an undeclared color or food additive that must be labeled as a condition of safe use, physical samples may be required under the Domestic and Import Food Additive and Color Additive Compliance Program (CP 7309.006). Review CP 7309.006 for additional sampling instructions.	Yes; review CP 7309.006 for sampling instructions

ii. Sample Size for Compliance (Physical Product Samples)

General

Area of Emphasis 1: Labeling Violations Related to Major Food Allergens, Gluten, and Labeling Associated with the Safe Use of Foods

At this time, do not collect a physical sample if the product is suspected to contain undeclared major food allergens or unintended presence of major food allergens due to cross-contact (not covered under this CP), or if it is labeled with a gluten-free claim on a hydrolyzed or fermented food or foods that contain fermented or hydrolyzed ingredients, unless directed by the HFP/OCE/Office of Enforcement contact. However, labels should be collected as instructed above. See Table 4 for more information.

If directed by HFP/OCE/OE/DCFDSE/Critical Foods and Labeling Enforcement Branch to support a gluten-free claim on a non-hydrolyzed or non-fermented food/ingredient, or allergen-free claim: a sample should consist of five (5) subs; each sub containing a minimum of 100 g (approximately 4 oz). If a retail unit weighs less than 100 g, obtain multiple units from the same lot totaling at least 100 g per sub. For granulated/powdered dry products, a sample consists of 10 subs (each sub containing a minimum of 100g). For domestic sample collections, a separate 702(b) portion is

required. Exemptions from collecting the 702(b) portion are found in the IOM, Chapter 4.

For sampling of colors or food additives associated with the safe use of foods, please see instructions found in CP 7309.006.

Area of Emphasis 2 and 3: Lack of Nutrition Labeling and Nutrition Labeling Deficiencies

Collect evidence as exhibits in the EIR or DOC sample in accordance with IOM Chapter 4 of any product that appears, based on the field exam or inspection, to be deficient in one or more of these areas as described above. For imports, the labeling would be collected by taking photos during a field or label exam.

For Area of Emphasis 3: Analysis of a physical sample may be necessary to verify the level of a nutrient in the product; contact the HFP/OCE for further instruction. For example, if the ingredient list includes a fat or oil as one of the most predominant ingredients; however, the "Total Fat" in the NFL is declared as 0g, it would be appropriate to submit the sample for analysis for "Total Fat" because the level declared in the NFL may be incorrect.

Area of Emphasis 4: Nutrient Content Claims and Health Claims Violations

Physical samples for nutrient analysis may be required to support regulatory action under this area of emphasis. However, a physical sample may not be required if the levels of nutrients declared on the label clearly do not meet the requirements of claims (e.g., if the product is labeled as "low sodium" but declares 300 mg of sodium per serving).

Specify the nutrient forming the basis for the health claim or nutrient content claim in the remarks section of the Collection Report (C/R).

Domestic samples to support nutrient values declared in the Nutrition Facts label[9] for health claims or nutrient content claims

A sample will consist of twenty-four (24) intact consumer-size retail packages, two (2) packages from each of twelve (12) randomly selected shipping cases. The sample should be collected from a lot of twelve or more cases with the same manufacturing lot code. This sample size includes the 702(b) portion. Exemptions from collecting the 702(b) portion are found in the IOM, Chapter 4. Flag as a compliance sample for analysis.

Area of Emphasis 5: Food Standards Violations

[9] Except nutrients where no valid testing method exists as noted in AoE 3 above where records must be kept to support the amount of the nutrient declared in the NFL.

Many of these violations will be based on label or formulation review and some food standards also have enrichment requirements, such as noodles. Physical samples may be considered on a case-by-case basis with HFP concurrence.

Area of Emphasis 6: Other Labeling Violations

In all instances when it is known or suspected that the product labels bear significant deficiencies from other labeling requirements, documentary and/or photographic evidence to support the violation must be collected.

Attention should be given to labels with information in foreign languages. Labels should be reviewed for accuracy in the translation of ingredients from the foreign language to English to determine if the translation correctly describes all ingredients, particularly with regard to the declaration of major food allergens, FD&C Yellow No. 5 (tartrazine), other names for certified colors or E-numbers, and sulfites. If the division does not have a staff member who can translate, please contact the General Program contact person for assistance.

If there is any foreign language present on the label, it would likely trigger all required label statements to be present in that foreign language as required by 21 CFR 101.15(c)(2). See also CPG Sec 562.400 Foreign Language Declarations on Food Labels.

Depending on the circumstance, the supporting evidence might include the product label, photos of the container, raw material ingredient label photos, COA, formulation or batch records, affidavits, interstate records, and so on.

For domestic inspections, submission of the evidence in the form of a DOC sample is recommended. For foreign inspections, submission of the evidence can be added to the EIR as an Exhibit or Attachment, as appropriate, with an explanation of the label deficiencies in the EIR.

(b) Surveillance Sample Collections

i. Workplan Sampling Obligations

See the current OII Field Workplan for domestic or import sampling obligations for each division. The planned physical sample collections include both compliance ("for cause") sampling and surveillance sampling. The field should attempt to collect sufficient surveillance samples during the year, that, when added to the compliance samples, meets their full workplan obligation. Surveillance samples should be collected only if sufficient compliance samples requiring analysis do not materialize (see section *Sample Size for Compliance (Physical Product Samples)* AoE 3 above). Coordinate with the lab as needed.

Each division should attempt to provide import or domestic routine surveillance samples to the appropriate lab for nutritional analysis, in line with division sample collection obligations and the lab's sample analysis obligations.

Surveillance samples (to meet the division's sampling obligations) of domestic or imported foods may be collected of any product from the list below in Table 5.

- Products should be manufactured within the collecting division if it's a domestic sample.
- Divisions should give higher priority to the product category listed first in each quarter (based on the fiscal year, not calendar year).
- Divisions should also give high priority to products with nutrient content claims and make sure that the nutrient that is the subject of the claim is analyzed by requesting the specific analysis in the C/R.
- Use of the collection schedule in Table 5 helps the laboratory by grouping analyses.

Table 5: Collection Schedule for Product Sampling for Nutrient Analysis

Quarter	Product	Group I.D.
First (Oct. – Dec.)	Canned/frozen/dried: Vegetables and fruits Fruit and vegetable juices	A
First (Oct. – Dec.)	Beverages (soft drinks, energy drinks, bottled coffees/teas etc.)	E
First (Oct. – Dec.)	Gelatins/puddings Candy Syrups/jam/honey	J
Second (Jan. – March)	Milk/milk products Cheese/cheese foods Frozen dairy products Dairy substitutes/alternatives	D
Second (Jan. – March)	Dressing Butter/margarine Other oil/fat products	K
Second (Jan. – March)	Peanut butter/other nut products	L
Third (Apr. – June)	Baked goods/baking mixes Noodles/noodle products/pastas Grains/grain products Corn flour products	B
Third (Apr. – June)	Soups	H
Third (Apr. – June)	Snack chips/crackers	I
Fourth (July – Sept.)	Cold/hot breakfast cereals Vegetable protein products Multicomponent seafood products (e.g., seafood patties, meals) Meal replacements (e.g., protein bars, protein powders, low/reduced calorie foods)	C
Fourth (July – Sept.)	Infant foods (other than infant formulas, see CP 7321.006)	F

Quarter	Product	Group I.D.
Fourth (July – Sept.)	Gravies/sauces/ketchup	M

NOTES:

- Further guidance may be posted on the Food Labeling Compliance Program Resource Page.
- The product group identifications (Group I.D.) are the same as those assigned to the products in previous fiscal years; this will assure consistency when comparing analytical data for product groups over multiple years.
- Investigators have flexibility to collect samples outside of a Group I.D.'s designated quarter if warranted. For example, if an investigator is collecting samples for products listed for collection in the first quarter but finds samples that warrant collection that are listed in the second quarter, they may collect them at the same time. Or, if an investigator can collect a sample during an inspection of a manufacturer, the investigator may collect that sample regardless of the quarter listed in Table 5 for that product.

For surveillance samples, the sample Collection Report (C/R) should specify, in the Remarks section, the nutrients for the lab to focus on:

Please follow directions found in *PART III 1.D.(2)(a) Compliance Sample Collections*.

ii. Sample Size for Surveillance

Samples of the products listed in Table 5, unless otherwise specified, will consist of twenty-four (24) intact consumer-size retail packages consisting of two (2) packages from each of twelve (12) randomly selected shipping cases. The sample should be collected from a lot of twelve or more cases with the same manufacturing lot code. This sample size includes the 702(b) portion. Exemptions from collecting the 702(b) portion are found in the IOM, Chapter 4.

(c) Sample Shipping

Samples should be handled and shipped per IOM 4.7 "Sampling: Preparation, Handling, Shipping."

All physical samples (Domestic and Import) collected for nutrient analysis (under this program) are to be shipped to the appropriate lab for analysis only for the specific nutrients subject to the claim or as identified by the investigator (for surveillance samples only). This includes Special Domestic Import Samples (SDIs). Please see *PART IV 1. Analyzing Laboratories* for Analyzing Laboratories specific to Label Review, Nutrient Analysis, Allergens and Gluten Analysis. Please use the FDA Laboratory Servicing Table (LST) Dashboard.

All physical samples (Domestic and Import) collected for allergen or gluten analysis should be sent to a servicing lab per the FDA Laboratory Servicing Table (LST) Dashboard.

E. Import Activities

Import sample collections and examinations should be reported in the FDA Import System: System for Entry Review and Imports Operations (SERIO).

(1) Import Sample Collections

(a) Compliance Sample Collections

General sample size for import compliance (physical product) samples should follow the instructions listed section *PART III 1.D.(2)(a)(ii) Sample Size for Compliance (Physical Product Samples), General*, except for the 702(b) requirement.

Import samples to support nutrient values declared in the Nutrition Facts label[10] will consist of twelve (12) intact consumer-size units of the product, one unit from each of twelve (12) randomly selected shipping cases. The sample should be collected from a lot of twelve or more cases with the same manufacturing lot code.

For shipping imports compliance samples, follow the instructions listed in *PART III 1.D.(2)(c) Sample Shipping*.

(b) Surveillance Sampling

Imports surveillance sampling should follow instructions listed in section *PART III 1.D.(2)(b) Surveillance Sample Collections*, except for the 702(b) requirement. This includes *Workplan Sampling Obligations*, and *Sample Size for Surveillance*. For shipping imports surveillance samples, follow the instructions listed in *PART III 1.D.(2)(c) Sample Shipping*.

(2) Field Exams and Import Coverage

Label Exams (LEX): Investigators are to perform label exams (LEX/LBL) to cover all product labeling.

Photos of product labels are permitted. All photos collected should be clear and legible (see applicable photography instructions in IOM Chapter 6).

(a) Use PAF LBL for general labeling (LEX/LBL) and NIS (LEX/NIS) for nutrition labeling.

(b) Labels collected for compliance review

The Areas of Emphasis (described above) should be the focus of label exams and conducted under the same instructions listed above under *Inspections, Areas of Emphasis*. Evidence needed to support the appearance of a violation should be collected and attached to the entry line.

Label exams should focus on ensuring that labeling provisions are met and should be conducted per IOM 6.3 “Field Examination.” In addition:

[10] Except nutrients where no valid testing method exists as noted in AoE 3 above where records must be kept to support the amount of the nutrient declared in the NFL.

- Review product labels to ensure that labeling meets allergen source declaration or gluten-free claim requirements.
    - For example, if a product bears a picture of tree nuts on the label, but the common or usual name of the specific type of tree nut is not declared in the list of ingredients or a Contains statement, the line should be detained and refused, and a recommendation to place the firm/product(s) on DWPE (Import Alert (IA) 99-22) should be submitted to the Division of Import Operations, Import Compliance Branch.
    - For example, if the label includes a gluten-free claim; however, the ingredient list includes the term "wheat" or food bears a "Contains wheat" statement, but the label does not include the required statement, "The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods," the line should be detained and refused, and a recommendation to place the firm/product(s) on DWPE (Import Alert (IA) 99-39) should be submitted to the Division of Import Operations, Import Compliance Branch.
- Review labels of various products to ensure that they bear appropriate ingredient declarations.
    - Ingredients that are not declared by common or usual names; for example, foreign terms, E-numbers, incorrect names for colors, brand names, and undeclared sub ingredients of multicomponent ingredients.

(3) Foreign Language Labels

Attention should be given to imported product labels for accuracy in the translation of ingredients from the foreign language to English to determine if the translation correctly describes all ingredients, particularly with regard to declaration of major food allergens, FD&C Yellow No. 5 (tartrazine), other names for certified colors or E-numbers, and sulfites. Import divisions may utilize the translation web tools to review foreign language labels as part of the admissibility process.

If there is any foreign language present on the label it would likely trigger all required label statements to be present in that foreign language as required by 21 CFR 101.15(c)(2). See also CPG Sec 562.400 Foreign Language Declarations on Food Labels.

F. Other

(1) State Collected Labels

States trained in labeling requirements should continue to provide coverage of food labels during contract food safety inspections. If deficiencies are noted during state review, violative labels and/or photographs of the labels should be submitted by the state to their division with the inspection reports, regardless of if the state is taking action or being referred to the division. Some states are taking follow-up action on label deficiencies independently. Latitude given to each state would depend on the division's experience in working with the state concerning labeling issues.

2. **Reporting**

In addition to the *Field Reporting Requirements* on page 1 of this program, the following also apply:

- Imports: Resources for conducting import label exams, collecting physical samples, and DOC samples (including labeling photos) have been allocated in OII's Field Work Plan for this program. Refer to the *Evidence Collection* section for guidance on evidence development.

- Domestics:
  - For each inspection conducted, report the following in the EIR:
    - Number of Labels Reviewed
    - Names of Products Reviewed

    For example: "*Three product labels were reviewed during the inspection. The specific labels reviewed were for "Grandma's Molasses Cookies", "Standard Brand Cinnamon Graham Crackers" and "Specialty Brand Little Fish Cheese-Flavored Crackers".*
  - If any labels are potentially violative, collect a documentary (DOC) sample and complete per Chapter 4 of the IOM. Use PAC 21005.

- Foreign: Report field examinations in the EIR as above per the Domestics directions, except do not collect a documentary (DOC) sample during a foreign inspection unless directed. Submission of the evidence can be added to the EIR as an Exhibit or Attachment, as appropriate, with an explanation of the label deficiencies in the EIR.

- Domestic and Foreign: For inspections where label examinations are conducted under this compliance program, include PAC 21005 in the eNSpect inspectional coverage and provide a recommended inspection classification (NAI, VAI, OAI) based on the outcome of the label examination.

  If deficiencies are noted with labels, they should be discussed with firm management, as appropriate, and the discussion should be reported in the EIR in accordance with the IOM. If no deficiencies are found during the label review, do not explicitly state in the EIR that "no deficiency noted" because a full label review has not been completed.

  Refer to the *Evidence Collection* section for guidance on evidence development.

  In addition, in accordance with the IOM, report:

  - Any samples collected.
  - If physical samples or DOC samples of labels are collected for post inspectional review or for potential compliance action, report if the firm was informed that "The collection of product labels does not obligate the agency to provide you with written feedback on the labels. This lack of correspondence should not be construed as indicating that the labels are in compliance. Your firm is responsible for assuring compliance of product labels."
  - Any guidance materials provided to the firm.

The coding instructions below should be followed when reporting sample collections into the appropriate FDA system. This coding is essential for headquarters to determine whether a sample was collected for label review only or analysis.

- DOC samples (including label photos) - Use PAC 21005, Problem Area Flag (PAF) FDF and, for Domestics/Foreign, also use Results Flag FDL.
- Physical samples for nutrient analysis (Areas of Emphasis 3 and 4) – Use PAC 21005, PAF NIS for nutrient analysis. Additionally, use PAF FDF for label review. For Domestics/Foreign, also use Results Flag FDL for the label review. Indicate whether the physical sample was collected as a surveillance sample or a compliance sample.
- Physical samples for allergen analysis (AoE 1) – Use PAC 03803E and PAF ALG for laboratory analysis in the appropriate FDA system. Indicate whether the physical sample was collected as a surveillance sample or a compliance sample.

Table 6: Reporting for Sample Collections

Reporting	**PAC**	**PAF**	**Results Flag**
Nutrient Analysis – Label Review	21005	FDF	FDL (Domestics/Foreign)
Nutrient Analysis	21005	NIS	--
Allergen/Gluten Analysis	03803E	ALG	--

PART IV - ANALYTICAL

1. Analyzing Laboratories

A. Label Review

An FDA lab will perform a label review of surveillance and compliance samples collected according to the Collection Report (C/R) and other procedures in *PART III Inspectional* of this program. Exclude samples for allergen and gluten, unless otherwise directed.

- See FDA Laboratory Servicing Table (LST) for appropriate laboratory to perform a label review of surveillance and compliance samples collected according to the C/R and other procedures in PART III Inspectional of this program. Exclude label reviews for allergen and gluten samples, unless other directed.

Note: Investigators should consult with the lab prior to sample shipment.

B. Nutrient Analysis

An FDA lab will perform nutrient analyses of surveillance and compliance samples collected according to the C/R and other procedures in *PART III Inspectional* of this program.

- See FDA Laboratory Servicing Table (LST) for appropriate laboratory to perform nutrient analyses of surveillance and compliance samples collected according to the C/R and other procedures in PART III Inspectional of this program.

Note: Investigators should consult with the lab prior to sample shipment.

C. Allergen and Gluten Analysis

Analyses for allergen and gluten will be performed on surveillance and compliance samples collected according to the C/R and other procedures in *PART III Inspectional* of this program by the following servicing labs:

- See FDA Laboratory Servicing Table (LST) for appropriate laboratory to perform allergen or gluten analyses of surveillance and compliance samples collected according to the C/R and other procedures in PART III Inspectional of this program. Exclude label reviews for allergen and gluten samples, unless other directed.

Note: Investigators should consult with the lab prior to sample shipment.

2. Analyses to be Conducted

- Label Review
- Nutrient Analysis
- Allergen Analysis
- Gluten Analysis

3. **Methodology**

A. Label Review

(1) General

The label of each sample will be reviewed for compliance with 21 CFR 101.3, 101.4, 101.5, 101.7, 101.9, 101.13, 101.14, 101.17, 101.22, 101.30, 101.91, and 101.100 where applicable by the analyzing laboratory. Observations will be recorded using FORM FDA 431a. An *Example of Nutrition Label Review for Analysts* can be found on the Food Labeling Compliance Program Resource Page.

(2) Compliance and Surveillance Samples

The laboratory will perform a label review of surveillance and compliance samples collected according to the C/R and other procedures in *PART III Inspectional* of this program. Exclude samples for allergen and gluten, unless otherwise directed.

HFP/OCE will conduct a label review of compliance samples (label photographs) submitted by FDA investigators and on all labels submitted by states to the FDA for deficiencies.

B. Nutrient Analysis

(1) General

Do not perform nutrient analysis of samples containing insufficient units of the same manufacturing lot code (including the 702(b) portion, where applicable). Notify the collecting district to re-sample if this occurs.

(2) Compliance Samples and Surveillance Samples

Analyze only for the nutrient(s) forming the basis for a health claim or nutrient content claim that is not supported by the label declaration, or to verify the level of the nutrient(s) in the Nutrition Facts label (NFL). This nutrient(s) should be specified in the C/R or selected using the order of priority defined in *PART III 1.D.(2)(a) Compliance Sample Collections*.

(3) Perform analyses of compliance and surveillance samples for the selected nutrients as follows:

For compliance samples, use all the "A" or "B" set of sub-samples. Retain the remaining set of sub-samples as the 702(b) portion. Composite 12 sub-samples according to directions from HFP. Samples should be collected with the same manufacturing lot code. Verify samples were appropriately stored and handled. Divide the composite in three separate containers labeled composite 1, 2 and 3.

Sample composites shall be analyzed using a method from the FDA Foods Program Compendium of Analytical Methods, Elemental Analysis Manual (EAM), or an AOAC official method, as available and appropriate. Compendial methods (multi-laboratory validated) are generally preferred over single laboratory validated methods.

All methods must be validated, and samples shall be defined within the scope of the selected method. When required, method extensions must be completed prior to the submission of regulatory sample results following the FDA Foods Program Guidelines for the Validation of Chemical Methods. Any new nutrient analysis method that is developed and validated must be agreed upon in advance by the HFP/Office of Laboratory Operations and Applied Sciences (OLOAS) contacts (*PART VI References, Attachments, and Program Contacts*).

Immediately reanalyze the original composite of an apparently violative sample. Reanalysis should be done by an experienced second analyst using the same method or one approved by HFP/OLOAS contacts. Quality control measurements (e.g., method blanks, fortified analytical portions, reference materials, etc.) shall also be performed to document analytical method performance.

(4) Reporting

The nutrition labeling on a food product must be an accurate representation of the nutritional value of the food. For this purpose, reporting will be based on labeling criteria as defined in 21 CFR 101.9 (g)(3),(4),(5), and (6). Compliance will be based on the metric measure specified in the label statement of serving size.

- For added vitamins, minerals, total protein, or dietary fiber, report the nutrient content of the composite analyzed if found below the value declared on the label for that nutrient;
- For naturally occurring vitamins, minerals, total protein, total carbohydrate, dietary fiber, polyunsaturated or monounsaturated fat, report the nutrient content of the composite analyzed if found to be less than 80% of the value declared on the label for that nutrient; and
- For calories, total sugars, added sugars, total fat, saturated fat, trans fat, cholesterol, or sodium, report the nutrient content of the composite analyzed if found to be more than 20% in excess of the value declared on the label for that nutrient.

Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohol, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, total sugars, added sugars, total fat, saturated fats, trans fat, cholesterol, or sodium under labeled amounts are also acceptable within good manufacturing practice. Regulatory actions may consider the variability generally recognized for the analytical method use in that food at the level involved.

C. Allergen Analysis

(1) General

Analysis for the presence of undeclared allergens will be conducted using established FDA enzyme-linked immunosorbent assay (ELISA) methods for the detection of food allergens following the requirement of "Two Method Confirmation." Sample testing will be performed with two commercially available validated food allergen ELISA test kits for the target allergen(s). One of the two test kits will be used for qualitative screening, while confirmatory

analysis will be conducted using both ELISA test kits. For example, for milk allergen analysis, screening will be conducted using the Veratox Total Milk ELISA kit, and confirmatory analysis will be conducted using both the Veratox Total Milk, and the MIoBS Casein ELISA kits.

For food samples where homogenous distribution of allergens is assumed, a 100 g portion (may vary based on the approximate serving size or oral portion size) from the sample will be ground and mixed to homogeneity. For samples where heterogenous distribution of the allergen is a concern, multiple 100 g portions collected from different sub-samples will be homogenized independently.

(2) Compliance Samples

Qualitative screening of each sample will be performed in triplicate. For samples with an optical density (OD) value less than (<) the kit limit of quantitation (LOQ) during screening, additional testing will be conducted to confirm the negative finding. For this, the sample will be spiked with the target allergen at a level above the LOQ of the two ELISA test kits, analyzed using the two ELISA test kits specific for the target allergen, and recovery will be calculated. If found to be a true negative, a sample can be used to prepare controls.

(3) Surveillance Samples

Qualitative screening of each sample will be performed in triplicate. For samples with an OD value less than (<) the kit LOQ during screening, no additional testing will be conducted. A sample can be used to prepare controls if tested and found to be a true negative.

(4) Perform analyses of compliance and surveillance samples as follows:

The lab will conduct quantitative analysis of samples that test presumptive positive (OD value greater than (>) LOQ during screening) using the quantitative analytical protocols employing two ELISA test kits specific for the target allergen. Samples will be analyzed in triplicate and serially diluted as described in the workbook for each allergen. During the confirmatory analysis, positive and negative controls will be included along with the samples in the analysis. Positive controls consist of a negative control matrix (with similar composition as the sample) and a matrix spike sample prepared with the target allergen fortified at two (or three) concentrations that span the dynamic range of the ELISA test kit used for analysis.

(5) Reporting

The labs will follow the ELISA test kit insert and the allergen specific workbooks for the analysis and data processing. At the completion of the analyses, the labs will submit copies of the completed workbooks to the HFP/OCE. Leftover samples associated with positive analysis will be held until the case is closed.

D. Gluten Analysis

(1) General

All sample analyses for the presence of gluten will be analyzed using established FDA ELISA methods for the detection of gluten following the requirement of “Two Method Confirmation.” Sample testing will be performed with two commercially available validated gluten ELISA test kits. One of the two kits will be used for qualitative screening, while

confirmatory analysis will be conducted using both ELISA test kits. For gluten analysis, screening will be conducted using the MIoBS Wheat Protein ELISA kit, and confirmatory analysis will be conducted using both the MIoBS Wheat protein and RIDASCREEN Gliadin ELISA kits.

For food samples where homogenous distribution of gluten is assumed, a 100 g portion (may vary based on the approximate serving size or oral portion size) from the sample will be ground and mixed to homogeneity. For samples where heterogenous distribution of gluten is a concern, multiple 100 g portions collected from different sub-samples will be homogenized independently.

(2) Compliance Samples

Qualitative screening of each sample will be performed in triplicate as described in the project workbook using the MIoBS Wheat Protein ELISA test kit. For samples with an OD value of less than (<) the kit LOQ during screening, additional testing will be conducted to confirm the negative finding as described in the allergen analysis section. If found to be a true negative, a sample can be used to prepare controls. Samples with OD values greater than (>) the LOQ but below 16 ppm gluten will not be analyzed further.

(3) Surveillance Samples

Qualitative screening of each sample will be performed in triplicate as described in the project workbook using the MIoBS Wheat Protein ELISA test kit. Samples yielding a result of less than (<) 16 ppm gluten during screening will not be analyzed further. A sample can be used to prepare controls if tested and found to be a true negative.

(4) Perform analyses of compliance and surveillance samples as follows:

The lab will conduct quantitative analysis of samples that test presumptive positive (OD value greater than or equal to (≥) 16 ppm gluten using the MIoBS Wheat Protein ELISA during screening) using the quantitative worksheets in the gluten workbook. Samples will be analyzed in triplicate and serially diluted as described in the workbook using both the RIDASCREEN Gliadin ELISA kit and the MIoBS Wheat Protein ELISA kit. During the confirmatory analysis, positive and negative controls will be included along with the samples in the analysis. Positive controls consist of a negative control matrix (with similar composition as the sample) and a matrix spike prepared with gluten fortified at two (or three) concentrations that span the dynamic range of the ELISAs used for the analysis.

(5) Reporting

The labs will follow the gluten ELISA test kit insert and gluten analysis workbook for the analysis and data processing. At the completion of the analyses, the labs will submit copies of the completed workbook to the HFP/OCE. Leftover samples associated with positive analysis for gluten will be held until the case is closed.

4. **Reporting**

The lab will report all Lab Class 2 and Lab Class 3 samples to HFP/OCE at HFPOCESampleResults@fda.hhs.gov for appropriate regulatory follow-up.

Use the following for reporting sample analyses into FACTS:

Table 7: Reporting for Sample Analyses

Reporting	PAC	PAF
Nutrient Analysis – Label Review	21005	FDF
Nutrient Analysis	21005	NIS
Allergen/Gluten Analysis	03803E	ALG

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

The overarching program goals are to monitor industry compliance with labeling requirements, remove misbranded products from the market, and prevent entry of misbranded products into U.S. commerce. When developing a regulatory case, it is imperative to establish JIVR (jurisdiction, interstate commerce, violation, and individual responsibility) and to gather adequate and necessary supporting evidence. If warranted, the instructions provided in this part should be used to assess the significance of the deficiencies found and to recommend appropriate regulatory action(s).

1. **Possible Charges and Evidence**

Table 8: Possible Charges and Evidence

Possible FD&C Act Charge	Evidence Needed for Support
Misbranded, Section 403(a)(1) - The labeling is false or misleading (including violations of gluten-free claims). **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements. • Formulation information, such as ingredient list, photos of raw material ingredient labels, batch record, COA, or other documentation, if applicable and available. • C/R and analytical package if charge is based on nutritional analysis. • A product with an allergen-free claim on the label was analyzed and the presence of a specific allergen is confirmed. If this is due to allergen cross-contact, this issue should also be addressed under PC.

Possible FD&C Act Charge	Evidence Needed for Support
	• Documentation for potential violations of Gluten-Free claims, including records regarding the fermented or hydrolyzed food or ingredients as described in 21 CFR 101.91(c)(2) through (c)(4).
Misbranded, Section 403(b) - The article appears to be offered for sale under the name of another food. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements. • Formulation information, such as ingredient list, photos of raw material ingredient labels, batch record, COA, or other documentation, if relevant and available.
Misbranded, Section 403(e)(1) - Food is in package form and the label fails to bear the name and place of business of the manufacturer, packer, or distributor. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R.

Possible FD&C Act Charge	Evidence Needed for Support
	• Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements.
Misbranded, Section 403(e)(2) - Food is in package form and the label fails to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Batch sheets, weight sheets, formulation. • Translation of foreign statements.
Misbranded, Section 403(f) – if any word, statement, or other information required by or under the authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary terms of purchase and use. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has

Possible FD&C Act Charge	Evidence Needed for Support
For example: • the label is not legible due to type size, insufficient contrast, • required information is not in required location on the label, • label contains information in two or more languages but fails to repeat all required information in both languages or the label fails to include all required information in English, except in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English.	been in use since the appropriate date. • Translation of foreign statements.
Misbranded, Section 403(g)(1) - The article purports to be or is represented as a food for which a definition and standard of identity have been prescribed by regulations (Section 401) and the article does not conform to such definition and standard. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements. • Formulation information, such as ingredient list, photos of raw material ingredient labels, batch record, COA, or other documentation, if relevant and available.
Misbranded, Section 403(g)(2) - The article purports to be or is represented as a	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label

Possible FD&C Act Charge	Evidence Needed for Support
food for which a definition and standard of identity have been prescribed by regulations (Section 401) and the article is not labeled with the name specified in the definition and standard, or the label does not bear the common names of optional ingredients (other than spices, flavoring and coloring) present in such food, insofar as may be required by such regulation. **Add Section 801(a)(3)** for import cases.	is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements. • Formulation information, such as ingredient list, batch record, COA, or other documentation, if relevant and available.
Misbranded, Section 403(i)(1) - The label fails to bear the common or usual name of the food, if any there be. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements.
Misbranded, Section 403(i)(2) – if a food is fabricated from two or more ingredients and the label fails to bear the	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label

Possible FD&C Act Charge	Evidence Needed for Support
common or usual name of each such ingredient and if a food purports to be a beverage containing vegetable or fruit juice, but does not bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food. **Add Section 801(a)(3)** for import cases.	is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements. • Formulation information, such as ingredient list, photos of raw material ingredient labels, batch record, COA, or other documentation, if available.
Misbranded, Section 403(k) - the product bears or contains an artificial coloring, flavoring, or a chemical preservative but does not bear labeling stating that fact. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Other labeling involved, such as brochures, web pages, etc., if relevant. • Translation of foreign statements.

Possible FD&C Act Charge	Evidence Needed for Support
	• Formulation information, such as ingredient list, batch record, photos of raw material ingredient labels, COA, or other documentation, if relevant and available. • If applicable, C/R and analytical package.
Misbranded, Section 403(q) – the label fails to bear nutrition labeling when not exempt, or the label bears nutrition labeling with significant deficiencies. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Evidence to establish whether product is exempt from nutrition labeling - record of submitting a SBNLE, number of Full Time Equivalents (FTEs), units of each product annually sold in the US. • Translation of foreign statements. • Formulation information, such as ingredient list, batch record, COA, or other documentation, if relevant and available.
Misbranded, Section 403(r) – the label bears nutrient-content or health-related claims but fails to meet requirements to make the claim, or the claim is not authorized. **Add Section 801(a)(3)** for import cases.	• Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the

Possible FD&C Act Charge	Evidence Needed for Support
	inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Other labeling involved, such as brochures, web pages, etc. • Translation of foreign statements. • Formulation information, such as ingredient list, batch record, COA, or other documentation, if relevant and available. • If applicable, C/R and analytical package.
Misbranded, Section 403(w) - The label fails to identify all major food allergens present in the product. **Add Section 801(a)(3)** for import cases.	Evidence is needed to establish that the allergen was added as an ingredient in the product but was not declared on the label. • Legible views of all label panels, including top and bottom and unlabeled parts of container, if label is examined and photographed on the container. • Legibility of labels should be confirmed before closing out the inspection/examination. If legible photos cannot be obtained, physical labels should be collected. Include a description of how the label is applied to the product in the EIR or C/R. • Note that label proofs are not evidence of use. Obtain statement from the firm that the label proof has been in use since the appropriate date. • Translation of foreign statements.

Possible FD&C Act Charge	Evidence Needed for Support
	• Formulation information, such as ingredient list, photos of raw material ingredient labels, batch record, COA, or other documentation, if relevant and available. • If applicable, C/R and analytical package.

* **NOTE:** For situations that are unique, unusual, or novel, consider submitting a CMS work activity (WA) that is tasked to HFP Critical Foods and Labeling Enforcement Branch (see *PART VI References, Attachments, and Program Contacts* for contact) for review prior to generating a case.

2. **Compliance Activities**

A. Labeling (General labeling requirements, Nutrient, Allergen, and Gluten)

When an investigator identifies a possible violation of labeling regulations, they may submit evidence as Exhibits in the EIR or a DOC sample or label examination in accordance with IOM, Chapter 4 or 6, respectively. Send to HFP/OCE for review and possible action. HFP/OCE should review the submitted labels to determine if there is a violation and the extent of such violation.

B. Analytical (Nutrient, Allergen, and Gluten)

The lab will report all Lab Class 2 and Class 3 samples to HFP/OCE for review and appropriate follow-up action. When HFP/OCE receives the package for review, they should review the package and the section below to determine what action to take/recommend. These labels require evaluation by HFP to determine if significant labeling deficiencies exist.

3. **Actions**

When sufficient evidence has been collected to support misbranding, HFP/OCE/OE should use Table 9 to aid in determining/recommending appropriate regulatory action(s). Actions taken will depend on whether there is an associated public health hazard, a history of non-compliance, and whether the firm makes voluntary corrections. The divisions should also review the Regulatory Procedures Manual (RPM) for procedures and additional factors to consider for regulatory actions, including any applicable Direct Reference Authority (DRA).

Table 9: Potential Regulatory Actions for Labeling and Nutrition Violations

Violation Area	Violation	Potential Actions
Labeling Violations Related to Major Food Allergens, Gluten, and Labeling Associated with the Safe Use of Foods	Area of Emphasis 1, including • Product labels that fail to declare major food allergens that are ingredients in the formulation of the food. • Product labels that declare allergens in the ingredient list or Contains statement that are not ingredients in the formulation. • Labels include a gluten-free claim without meeting the requirements in 21 CFR 101.91. • Product labels lack label information associated with safe use of food (Warning Statements in 21 CFR 101.17, other statements required by certain food additive regulations, e.g. 21 CFR 172.804 Aspartame), and certain color additives, e.g., FD&C Yellow No 5, carmine/cochineal extract. • See Records Requirements at the bottom of the table.	• Warning Letter • Import Detention and Refusal • Recall • Seizure • DWPE (add to Red List of an Import Alert) • Injunction Labels that fail to declare major allergens should be referred to HFP/OCE/OCIC/DREI Recalls Branch for potential immediate follow-up
Lack of Nutrition Labeling	Area of Emphasis 2 • Product label fails to bear nutrition labeling and are not covered by an exemption.	• Warning Letter (DRA) • Import Detention and Refusal • Recall • Seizure • DWPE (add to Red List of an Import Alert) • Injunction
Nutrition Labeling Deficiencies	Area of Emphasis 3, including • Product label bears significant nutrition labeling deficiencies. • Labeling misrepresents the amount of calories or other nutrient declarations.	• Warning Letter • Import Detention and Refusal • Recall • Seizure • DWPE (add to Red List of an Import Alert)

Violation Area	Violation	Potential Actions
	• The sample (domestic or import) contains less than 100% of declared amount of any added vitamin, mineral, protein, dietary fiber, or potassium. • The sample contains less than 80% of the declared amount of any naturally occurring vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat or potassium. • The sample contains more than 120% of the declared amount of calories, sugars, total fat, saturated fat, trans fat, cholesterol, or sodium. • See Records Requirements at the bottom of the table.	• Injunction

Nutrient Content Claims and Health Claims Violations	Area of Emphasis 4, including
	• Product labels bear unauthorized or unqualified nutrient content claims or health claims.
	• Product labels bear an approved nutrient content/health claim, but the product clearly does not meet the criteria or fail to qualify for making the claim (i.e., not supported by nutrient analysis).
	  ○ The sample (domestic or import) contains less than 100% of declared amount of any added vitamin, mineral, protein, dietary fiber, or potassium.
	  ○ The sample contains less than 80% of the
		• Warning Letter
		• Import Detention and Refusal
		• Recall
		• Seizure
		• DWPE (add to Red List of an Import Alert)
		• Injunction

Violation Area	Violation	Potential Actions
	declared amount of any naturally occurring vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat or potassium. ○ The sample contains more than 120% of the declared amount of calories, sugars, total fat, saturated fat, trans fat, cholesterol, or sodium.	
Food Standards Violations	Area of Emphasis 5 • Product does not meet the Standard of Identity applicable to the labeled product.	• Warning Letter • Import Detention and Refusal • DWPE (add to Red List of an Import Alert)
Other Labeling Violations	Area of Emphasis 6 • Product labels that bear significant deficiencies from other labeling requirements.	• Warning Letter • Import Detention and Refusal • DWPE (add to Red List of an Import Alert)
Records Requirements	Areas of Emphasis 1 and 3 Records Requirements • The firm does not have the appropriate records to meet the recordkeeping requirements to support certain gluten-free claims in 21 CFR 101.91(c)(2) or specific nutrients listed in 21 CFR 101.9(g)(10).	• Warning Letter • Import Detention and Refusal • DWPE (add to Red List of an Import Alert)

A. Advisory, Administrative, and Legal Actions

(1) Voluntary Corrections to Achieve Compliance

For non-egregious nutrient declaration violations discovered as a result of sample collection and analysis: When a firm has no previous violations (similar to the current violation) and there is no immediate hazard involved, the HFP/OCE may contact the firm to inform the firm of the results and work with the firm if they voluntarily decide to make the corrections required to be in compliance with FDA regulations. If the firm decides to make voluntary

corrections, the division should follow-up to resample the product or verify corrections as appropriate.

(2) Warning Letter

Warning Letters consideration will be handled by HFP/OCE/OE.

- A Warning Letter consideration should include, as appropriate:
  - legible images of the product label and labeling
  - photos of all sides of the labeled finished product
  - formulation information
  - photos of raw material ingredient labels (to verify sub-ingredients)
  - interstate documentation
  - other relevant records as necessary
  - For violations documented by analytical findings, include the complete analytical work sheets.
- A Warning Letter consideration should be based on no more than three (3) products. If labels from more than three (3) products are collected, HFP/OCE/OC should select three (3) products that best represent the violations in all products to form the basis of the Warning Letter.

  Note: Divisions should contact ONFL Small Business contact (see *PART VI References, Attachments, and Program Contacts)* to verify that a small business notification has not been submitted. Divisions should **ensure** that the product is not associated with a volume and firm size that excludes the firm from submission of a small business notification for that product (21 CFR 101.9(j)(18)(iv)).

(3) Import Detention and Refusal

All detention recommendations (except where DRA has been granted) shall be sent to HFP/OCE/OE/DPIE/Imports Enforcement Branch for review and concurrence and must include a digital copy of the label and all supporting documentation. Please note that if the division has already issued an FDA Notice of Detention (legal charges issued), a detention recommendation should not come to HFP for review, unless technical review of testimony from the firm or legal counsel has been received. If Detention and Refusal is supported, the issued Notice of Detention shall consist of a description of the significant deviation(s).

(4) Detention Without Physical Examination (DWPE) – Add to Red List – Import Alert (IA)

- Divisions should review Table 1: Import Alerts Relevant to the Food Labeling Compliance Program for a list of possible IAs for consideration. This list is not exhaustive and subject to change.
  - Divisions should review the criteria for each IA before recommending application of DWPE.
- To subject a firm to DWPE or add the firm/product onto Import Alert, divisions should follow the criteria stated in Regulatory Procedures Manual (RPM) subchapter 9-8.

- DWPE recommendations where DRA has NOT been granted should be submitted to HFP via CMS for center concurrence with all supporting information, including analytical package (if applicable), as noted in RPM subchapter 9-8-3. A **legible** digital copy of the label and all supporting information **MUST** be included in the package submitted to HFP for review.
- DWPE recommendations where DRA has been granted should be submitted to the Division of Import Operations (DIO), Import Compliance Branch inbox in CMS with all supporting information, including analytical package (if applicable), as noted in RPM subchapter 9-8-3. A **legible** digital copy of the label and all supporting information **MUST** be included in the package submitted to DIO for review.
- For information regarding the removal of firms and/or products from DWPE, review RPM subchapter 9-8-15 thru 9-8-19 and the applicable IA.

(5) Seizure

Seizure of product may be appropriate when the label of the product is a potential health hazard to the consumer. For example, a product does not declare a major food allergen as required and the product poses a significant public health hazard to the consumer (e.g., due to an incorrect ingredient list and/or "Contains" statement but the firm doesn't voluntarily recall the product). Other examples may apply as the above is not an exhaustive list. Cross-contact within the manufacturing facility of the finished product or ingredient supplier may also be a hazard but it is not a labeling violation. Cross contact should be evaluated under Preventive Control requirements. Follow the instructions in the RPM, Chapter 6 for additional guidance.

(6) Other actions – Recalls and Administrative Detention

Recalls may be either voluntary or mandatory, but all recalls must have, at its foundation, a violation of the Act. Follow the instructions in the RPM, Chapter 7, for additional guidance.

Administrative detention is a tool that can be used to place a hold on the distribution of product, generally pending additional enforcement action. Follow the instructions in the RPM, Chapter 5, for additional guidance.

If an allergen misbranding or adulteration situation presents a reasonable likelihood of serious adverse health consequences or death to humans (SAHCODH), immediate action to remove the food from commerce should be considered. If the firm does not initiate a voluntary recall, the FDA will consider other appropriate actions to remove product from commerce, such as mandatory recall or administrative detention. When appropriate, the FDA may also consider suspension of facility registration. See Section 403(w) and 201(qq) for a list of major food allergens.

(7) Injunction

Injunction, permanent or preliminary, may be appropriate if the firm has a history of violations and such history implies that the violations will be continuing. For example, a firm that deliberately uses incorrect nutritional data in their Nutrition Facts label, and is told of the violations, yet continues to use the incorrect information, may be a candidate for consideration for a permanent injunction. A firm that consistently fails to declare major food allergens as

required may be a candidate for preliminary injunction. Follow the instructions in the RPM, Chapter 6 for additional guidance.

B. Recommendations for Further Regulatory Follow-Up (Domestic)

A timely follow-up inspection is encouraged to ensure compliance and corrections to violations at a firm where the most recent inspection was classified OAI for labeling deficiencies or sampled product was classified as Lab Class 3 (with concurrence from HFP/OCE/OE/DCFDSE/Critical Foods and Labeling Enforcement Branch). See FMD-86 on the Field Management Directives website. The covering divisions should conduct a follow-up inspection which may include the collection of a compliance sample(s) (see instructions in *PART III Inspectional*) of the product(s) in question, at the division's discretion.

Prior to initiating the re-inspection, the division should contact HFP/OCE for guidance and to discuss potential follow-up actions if the firm continues to have significant violations. If the follow-up inspection reveals the firm continues to have serious conditions that are likely to lead to the misbranding of foods, the HFP/OCE should consider enforcement action based on the repeat offense.

Additional enforcement actions HFP/OCE may consider include:

- Administrative Detention of Foods, in accordance with RPM Chapter 5
- Regulatory Meeting, in accordance with RPM Chapter 10
- Recalls in accordance with RPM Chapter 7
    - Firm Initiated
    - FDA Requested Recall
    - FDA Mandated and Ordered Recalls

C. Recommendations for Further Regulatory Follow-Up (Imports)

Specimen Charge - The available Import Detention Violation Codes, with associated charge statements and statutory citations, may be found on the Import Detention Violation Code Table and/or a relevant IA.

4. **Data Reporting**

All warning letters, seizures, and injunction considerations resulting from this program **must** be entered through CMS. All cases must include all relevant evidence needed to support the action. A copy of the draft Warning Letter should be included in the case.

All Detentions and DWPEs must be entered into the import system as Activity 60 for Detention Request and Activity 61 for DWPE Requests.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. **References**

A. PART I – BACKGROUND

- Changes to the Nutrition Facts Label
- Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021
- Title 21 of the Code of Federal Regulations
- 21 CFR Part 101
- 201(qq) (21 U.S.C. 321(qq)) Major food allergens listed
- Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5) | FDA
- Food Allergens/Gluten-Free Guidance Documents & Regulatory Information
- Food Labeling Compliance Program Resource Page
- The 2020 final rule regarding Gluten-free labeling of fermented and hydrolyzed foods
- Gluten-Free Labeling of Foods
- 21 CFR Part 172
- 21 CFR Part 184
- 21 CFR Part 73
- Federal Register: Food Labeling: Revision of the Nutrition and Supplement Facts Labels Final Rule
- Small Entity Compliance Guide: Revision of the Nutrition and Supplement Facts Labels
- Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels
- Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals
- Guidance for Industry: Policy Related to Cranberry Products with Added Flavorings
- Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products
- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments
- Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics
- Food Labeling; Revision of the Nutrition and Supplement Facts Labels; Technical Amendments

B. PART II – IMPLEMENTATION

- Food Compliance Programs (public access)
- Office of Compliance and Enforcement's Compliance Programs (FDA access)
- Import Alerts (public access)
- Distilled Spirits Memorandum of Understanding 225-18-003
- FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration
- FDA Memoranda of Understanding

C. PART III – INSPECTIONAL

- Food Labeling Compliance Program Resource Page
- 21 CFR Part 101
- Small Entity Compliance Guide: Gluten-Free Labeling of Foods
- Gluten-Free Labeling of Foods
- Questions and Answers on the Gluten-Free Food Labeling Final Rule
- Federal Register: Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods
- 21 CFR Part 74
- 21 CFR Part 73
- 21 CFR Part 172
- 21 CFR Part 179
- 21 CFR Part 180
- 21 CFR Part 184
- 21 CFR Part 170
- Firms That Have Filed for a Small Business Nutrition Labeling Exemption
- Details of Key Changes with a side-by-side comparison of the old vs. Current label
- At a Glance: Highlights of the Final Nutrition Facts Label Fact Sheet
- Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints
- FDA Issues Guidance, Science Review, and Citizen Petition Responses on Dietary Fiber
- Questions and Answers on Dietary Fiber
- Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Guidance for Industry Small Entity Compliance Guide
- Guidance for Industry: Food Labeling Guide
- Nutrient Content Claims
- Label Claims for Food & Dietary Supplements
- Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard
- FDA Modernization Act (FDAMA) Claims
- Qualified Health Claims
- Qualified Health Claims: Letters of Enforcement Discretion

- Structure/Function Claims for Conventional Foods
- Questions and Answers: Authorized and Qualified Health Claims in Food Labeling
- Label Claims for Conventional Foods and Dietary Supplements
- Guidance for Industry: Frequently Asked Questions About Medical Foods – Third Edition
- Title 21 of the Code of Federal Regulations
- Labeling & Nutrition Guidance Documents & Regulatory Information
- Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)
- Food Allergens/Gluten-Free Guidance Documents & Regulatory Information
- Translation web tools
- CPG Sec 562.400 Foreign Language Declarations on Food Labels
- FDA Laboratory Servicing Table (LST) Dashboard

D. PART IV – ANALYTICAL

- FDA Laboratory Servicing Table (LST) Dashboard
- 21 CFR Part 101
- Food Labeling Compliance Program Resource Page
- FDA Foods Program Compendium of Analytical Methods
- Elemental Analysis Manual (EAM) for Food and Related Products
- Guidelines for the Validation of Chemical Methods

E. PART V – REGULATORY/ADMINISTRATIVE STRATEGY

- 21 CFR Part 101
- 21 CFR Part 172
- Food Labeling Compliance Program Resource Page
- Regulatory Procedures Manual
- FMD-86 on the Field Management Directives
- Import Detention Violation Codes

2. **Attachments**

Intentionally left blank.

3. **Program Contacts**

A. Human Foods Program (HFP)

Purpose	Name	Organization	Contact
General Program Guidance	Jolene Hedgecock	HFP/OCE/OCOI/DCI/Compliance Programs and Assignment Branch	240-402-1804
Enforcement Guidance	Tyra Wisecup	HFP/OCE/OE/DCFDSE/Critical Foods and Labeling Enforcement Branch	240-402-5854

Enforcement Guidance - Imports	Rob Genzel	HFP/OCE/OE/DPIE/Imports Enforcement Branch	240-402-2708
Label Policy Guidance	Eric Myskowski	HFP/NCE/ONFL/DFLS/LRIB	612-791-9530
Low Volume/ Small Business Exemption Questions	James Hall	HFP/NCE/ONFL/DFLS	240-402-2371
Scientific Contact	Christine Parker Patrick Gray	HFP/OLOAS/OCT/DBC HFP/OLOAS/OCT/DBC/CHCB	240-402-2019 240-402-5026

B. Office of Inspections and Investigations (OII)

Purpose	Name	Organization	Contact
Domestic Investigation Guidance	Rina Vora	OII/OHFI/OGSHFI/DCSF/HFPEB	561-416-1065 x1117
Import Investigation Guidance	OII OIO HFP Liaisons	OII/OIO/HFP Liaisons	---
Scientific Contact	Yanxuan (Tina) Cai	HFP/OLOAS/ORTS/DSPC	240-402-1369

PART VII - HUMAN FOODS PROGRAM RESPONSIBILITIES

The Office of Nutrition and Food Labeling (ONFL) will provide subject matter expertise in the maintenance and evaluation of the Compliance Program and provide guidance to the Office of Compliance and Enforcement (OCE) about program priorities, relevant evaluation questions, and recommended program changes. OCE will lead the effort and work in conjunction with the ONFL to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation.