

CHAPTER 21 - FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS

SUBJECT: DOMESTIC AND IMPORT NLEA, NUTRIENT SAMPLE ANALYSIS, AND GENERAL FOOD LABELING REQUIREMENTS PROGRAM	IMPLEMENTATION DATE Upon Receipt
	COMPLETION DATE Continuing
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODES:02-41,	PAC 21005 Domestic & Import

FIELD REPORTING INSTRUCTIONS

PAC 21005 (Domestic & Import) - Use this PAC to report label reviews for the FD&C Act and FPLA labeling requirements. Domestic and Import samples collected and analyzed for nutrient content as instructed in this compliance program are also to be reported against this PAC. **DO NOT REPORT** economic deception or food standards work against this PAC. See additional reporting PACs below.

PACs 21003(Domestic & Import) and for seafood, 21842(Domestic)/21844 (Import)- use these PACs to report sample collections and analyses performed to support an economic deception or food standard violations only. Report only sample collections and physical sample analyses against these PACs. **DO NOT REPORT** label reviews against these PACs. The label is used to guide the analyses only and the review of the label for this purpose is not reportable as a label review (operation 51). Use Problem Area Flag FDF, and the appropriate Result Flag (FDE Economic Deception; FDQ Standard of Quality; or FDI Standard of Identity).

Refer to Parts III, IV, and V for specific FACTS data reporting instructions.

PART I - BACKGROUND

This program provides directions to the field concerning inspections and label reviews to determine compliance with food labeling laws and regulations for domestic and imported food products. This program focuses on: (1) requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), (2) Other labeling associated with the safe use of foods (e.g., declaration of FD & C Yellow 5 & 6 and sulfiting agents in the ingredient statement), (3) NLEA related requirements (e.g., trans fat, serving size, health claims, qualified health claims, nutrient content claims, [% juice label requirement]), (4) other mandatory food labeling (e.g., a statement of identity; a statement of the net quantity of contents; the name and place of business of the manufacturer, packer, or distributor; if fabricated from two or more ingredients, a list of ingredients), and (5) analysis of samples of foods for compliance with nutrient declarations.

This program also focuses on conventional foods (e.g., soups, snacks, etc.) that bear a "Supplement Facts" instead of a "Nutrition Facts" panel and products labeled as medical foods that do not meet the statutory definition (see 7321.002 Medical Foods; Domestic and Import).

A. Allergen Declarations

Section 403(i)(2) of the Federal Food, Drug and Cosmetic Act (the 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)). Although ingredient declarations complying with section 403(i)(2) provide some information to food allergic consumers, in some cases, the common or usual name of an ingredient may be unfamiliar to consumers and many consumers do not recognize that certain ingredients contain or are derived from a major food allergen. This situation led, at least in part, to the enactment of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282).

All packaged foods regulated under the Act that are labeled on or after January 1, 2006, must comply with food allergen labeling requirements instituted as a result the passage of FALCPA.

FALCPA amended the Food, Drug and Cosmetic Act to define "major allergen". Under 201(qq), a "major food allergen" is an ingredient that is one of the following eight major foods or food groups or is an ingredient that contains protein derived from one of the following:

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

For information on the allergen source labeling requirements see <http://www.fda.gov/Food/FoodSafety/FoodAllergens/default.htm>).

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

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 100.22(j) and (k) for ingredient declaration requirements for these and other colors and chemical preservatives. In addition, aspartame (21 CFR 172.804) and sorbitol (21 CFR 184.1835) have statements associated with their safe use in foods. Also refer to 21 CFR 101.17 for required warning statements for the safe use of food.

C. Nutritional Labeling Exemptions: Domestic & ForeignSmall Business

Firms that are entitled to an exemption from nutrition labeling under the regulations for small business based on low volume sales/number of employees must file a notice of eligibility. They must provide the information necessary to verify their exempt status to the Office of Nutritional Labeling and Dietary Supplements (ONLDS), HFS-800, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland, 20740-3835. We are encouraging firms to use the web-based submission process (see <https://www.accessdata.fda.gov/scripts/NLE/client/login.cfm>). However, firms may submit a notification by mail or fax. Firms, other than importers, that have fewer than 10 full-time equivalent employees do not have to file a notice for exemption from nutrition labeling for any food product with annual sales of fewer than 10,000 total units.

A list of firms, domestic and foreign, that submitted notices for exemption from nutrition labeling based on the small business provisions can be found at <https://www.accessdata.fda.gov/scripts/nle/client/report/>. Districts should refer to this Internet website before conducting label examination. If the District needs additional information they should contact ONLDS' Small Business Coordinator at 301-436-2373.

Other Exemptions

Refer to "The Food Labeling Guide"

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>; "A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-from-Home Foods"

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053455.htm>; and "Guide to Nutrition Labeling and Education Act (NLEA) Requirements"

<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.

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). Specific questions about the exempt status of a firm should be directed to FDA/CFSAN/ONLDS, HFS-820, (301) 436-2371.

Alternative Approaches to Nutrition Labeling

Firms seeking alternative approaches for compliance with nutrition labeling under 21 CFR 101.9(g)(9) should submit a request to ONLDS. The home district for the firm requesting a 21 CFR 101.9(g)(9) exemption receives a copy of ONLDS' response to the firm's request.

Refer to the current edition of "Guide to Nutrition Labeling and Education Act (NLEA) Requirements" for additional information on exemptions from NLEA. This publication will hereafter be referred to as "the NLEA guide"
<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.

D. Nutrition Labeling Criteria

FDA seeks to encourage good nutrition among consumers in a variety of ways, including promoting and enhancing better consumer food choices. Obesity, diabetes, and other chronic illnesses can often be prevented through better consumer choices. The Nutrition Facts label on food packages is used by consumers to help them decide what foods to choose. Therefore, the information should be accurate. This program places emphasis on assuring that the declared nutrient levels in the Nutrition Facts label are accurate and in assuring that the serving size declared on the food label is correct and does not misrepresent the amount of calories or other nutrients in the product.

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

- For any added vitamin, mineral, protein, dietary fiber, or potassium, 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, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium, 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, 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.

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

If further assistance is required contact, CFSAN/OC/DE, Labeling Compliance Team (LCT), HFS-608.

E) Conventional Foods Labeled as Dietary Supplements or Medical Foods

Conventional foods should be properly labeled and should not be marketed as a dietary supplement or a medical food. Dietary supplements have different requirements than conventional foods with respect to safety and to the types of claims that can be made on the nutrition label. Medical foods are exempt from nutrition labeling, nutrient content claims and the health claims provisions of the Act.

PART II - IMPLEMENTATION**OBJECTIVES**

- To determine compliance with the requirements put into effect as a result of passage of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), including the presence of undeclared ingredients to which some consumer may be sensitive, and absence of required label statements associated with the safe use in food.
- To collect and evaluate labels for the requirements of other major food labeling elements (e.g., nutrition labeling, ingredients, claims, net weight, percent juice).
- To collect and analyze samples of domestic and imported food products to assure that nutrients are present at levels declared on labels.
- To collect and evaluate labels of conventional foods labeled as dietary supplements or as medical foods.

PROGRAM MANAGEMENT INSTRUCTIONS**A. Domestic**

The objectives of this part of the program should be accomplished as an add-on to ALL routine inspections of firms that are manufacturing and/or labeling or re-labeling food products at the site to be inspected under the following five existing compliance programs:

- Domestic Food Safety Program (C.P. 7303.803);
- Domestic Acidified and Low Acid Canned Foods Program (C.P. 7303.803A);
- Domestic and Import Cheese and Cheese Products Program (C.P. 7303.037);
- Domestic Fish and Fishery Products Inspection Program (C.P. 7303.842);
- and
- Juice HACCP Inspection Program (C.P. 7303.847).

The program includes collection of samples for general nutrient analyses. These samples can be collected at the wholesale/retail level if the district is unable to meet its sampling obligations during inspections conducted under the above four compliance programs.

B. Import

The objectives of this part of the program are directed to allergenic ingredients, nutrient and nutrition labeling areas. 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 coverage is for formal entries of conventional foods. dietary supplements are not covered under this program (see C.P.7321.008).

Alerts

Products subject to detention without physical examination (DWPE) due to nutrition deficiencies should be listed in Import Alert #99-20. Products subject to detention for sulfites can be found in Import Alert #99-21.

All import alerts are available through the MARCS-CMS at:
<http://cms.fda.gov/vts/imports/default.cfm>

Program Interaction

Time expended on the collection/analysis of imported infant formula, medical foods or dietary supplements (for nutritional analysis and/or label review) should be reported under the following programs:

- Infant Formula - Import and Domestic (CP 7321.006) (PAC21006);
- Medical Foods - Import and Domestic (CP 7321.002)(PAC21002);
and
- Nutrient Content of Dietary Supplements - Import and Domestic
(CP 7321.008) (PAC21005)

Time expended for activities related to economic deception (e.g., flagrant deficiencies related to misbranding or economic deception) should be reported under PAC 21003. Before embarking on economic deception initiatives, the district should consult with CFSAN/OC/Division of Enforcement contact to ensure Center support.

PART III - Inspectional

A. Inspections

Inspectional coverage of the following requirements must be included during each inspection that includes coverage under this program and deficiencies must be fully documented in the EIR.

Requirements for Allergen Source Labeling

During the course of the inspection, the investigator must utilize the information below to determine if the firm's finished product labels comply with requirements of Section 403(w). Review material labels, especially flavors, spices, and colors for ingredients that are or contain one or more of the eight major food allergens. Review finished products made with these raw materials to determine if the major food allergens are appropriately identified on the label.

If the investigator observes that the firm's labels are not identifying all of the major food allergens in a manner required by Section 403(w), document the deficiencies found in the EIR. Supporting records such as raw material and finished product labels and affidavits should also be collected. Document the firm's corrective action plan for meeting the labeling requirements of Section 403(w).

Section 403(w) of the Act requires specific label declaration of major food allergens for foods except for raw agricultural commodities and ingredients specifically exempt from the definition of a major food allergen. (See <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>)

Section 403(w) provides two ways to declare a major food allergen:

- By placing the word "Contains" followed by the name of the food source from which the major food allergen is derived immediately after or adjacent to the list of ingredients, in a type size no smaller than that used for the list of ingredients (e.g., "Contains milk and wheat"); or
- By placing the common or usual name of the major food allergen in the list of ingredients followed in parenthesis by the name of the food source from which the allergen is derived (e.g., "natural flavoring [eggs, soy]").

In the case of tree nuts and seafood, Section 403(w) requires that the specific type of tree nut (e.g., walnut, almond, and cashew) or species of fish (e.g., cod, tuna) or crustacean shellfish (e.g., shrimp, lobster) be specified.

The name of the food source is not required if:

- The common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived (e.g., "Ingredients: whole **wheat** flour, **buttermilk**, **eggs**, **peanut** butter")
- The name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list (e.g., nonfat dry **milk**, **whhey**, natural flavoring (**egg**), **albumin**).

The Act provides the following exemptions from labeling a major food allergen:

- Exemption for all highly refined oils derived from a major food allergen or an ingredient derived from such highly refined oils;
- Exemption for a food ingredient derived from a major food allergen based on a petition that demonstrates that the ingredient does not cause an allergic response that poses a risk to consumers; and
- Exemption for a food ingredient derived from a major food allergen based on a premarket notification containing evidence that demonstrates the food ingredient does not contain allergenic protein or FDA has made a determination through the food additive approval process that the ingredient does not cause an allergic response that poses a risk to consumers.

For additional food allergen information refer to:

- The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucml06187.htm>
- Questions and Answers on the Food Allergen Labeling and the Consumer Protection Act of 2004
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucml06890.htm>
- Inventory of Petitions received under 21 U.S.C. 343(w)(6) for exemptions from Food Allergen Labeling
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm076631.htm>
- Inventory of Notifications Received under 21 U.S.C. 343(w)(7) for exemptions from Food Allergen Labeling
- <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/ExemptionsfromFoodAllergenLabelingPetitionNotificationProcess/ucm076656.htm>

Ingredient Declarations and Labeling Associated with Safe use in Food

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

- For information on declaration of colors see 21 CFR 101.22(k).
- For information on the declaration of preservatives see 21 CFR 101.22(j) and 21 CFR 101.100(a)(4)(sulfiting agents).
- For information on warning statements and safe use statements see 21 CFR 101.17 (multiple foods or ingredients), 21 CFR 172.804(aspartame), and 21 CFR 184.1835 (sorbitol).

Nutrition Information

During the course of the inspection, if the investigator observes a questionable practice that is clearly related to the nutrient content or nutrition labeling of a product, the practice should be documented in the EIR and labels associated with the practice should be included in the documentary sample collection.

Firms that are exempt from nutrition labeling should not be covered under this portion of the program. The district should provide sufficient documentation in the EIR to enable the Center to verify that products are exempt from nutrition labeling. This information may include, for retailers, the reporting of the annual gross sales made or business done in food to consumers [21 CFR 101.9(j)(1)]. It may also include, for small firms other than importers, the reporting of the number of employee and number of units per product [21 CFR 101.9(j)(18)(iv)].

Conventional Foods Labeled as Dietary Supplements or Medical Foods

During the course of the inspection, if the investigator observes products that are subject to regulation as conventional foods but that are labeled as dietary supplements or medical foods, the practice should be documented in the EIR and product labels should be included in the documentary sample collection.

Dietary supplements have different requirements than conventional foods with respect to safety, to the types of claims that can be made on the label, and to the kinds of information that must be provided in the nutrition label. The definition for a dietary supplement excludes products represented as a conventional food. **Products labeled as a dietary supplement but represented as a conventional food are covered under this program (See [Dietary Supplements: Overview.](#))**

Medical foods are defined in section 5(b) of the Orphan Drugs Act [21 USC 360ee (b)(3)]. Medical foods are exempt from the nutrition labeling, nutrient content claim, and the health claim provisions of the Act. Products labeled as medical foods that do not meet the statutory definition are subject to the nutrition labeling, nutrient content claim, and the health claim provisions of the Act. **Products labeled as medical foods that do not meet the statutory definition are covered under this program. (See <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm054048.htm>)**

B. Field Exams

Investigators are to perform field exams to cover all of the labeling for at least 3 food products per firm, focusing on products that are not exempt from nutrition labeling. The Areas of Emphasis below should be the focus of the field exams.

The district should provide sufficient documentation in the EIR to enable the Center to verify that products are not exempt from nutrition labeling. For retailers this may include the annual gross sales made or business done to consumers (21 CFR 101.9(j)(1)). For small firms other than importers, it may also include the reporting of the number of employees and the number of units (21 CFR 101.9(j)(18)(iv)).

This program contains instructions for collecting information and labels for further evaluation based on the following Areas of Emphasis:

1. Product labels that fail to bear required allergen source labeling and/or other ingredient labeling requirements. Product labels that fail to declare other ingredients (e.g., color additives, such as FD&C Yellow 5; chemical preservatives such as sulfiting agents [sulfur dioxide, sodium sulfite, sodium bisulfate, potassium bisulfate, sodium metabisulfite, and potassium metabisulfite]; label statements associated with safe use in foods; and required warning statements;
2. Product labels that fail to bear nutrition labeling and are not covered by an exemption;
3. Product labels that bear nutrient content claims that are not authorized by law or regulation. Product labels that bear health claims that are not authorized by law or regulation, and are not the subject of FDA enforcement discretion (qualified health claims), or that bear disease claims;
4. Products subject to regulation as conventional foods but are labeled as dietary supplements or medical foods;
5. Product labels that bear authorized nutrient content claims/health claims but the products do not qualify for making the claims. Product labels that bear qualified health claims subject to enforcement discretion but do not qualify for making the claims;
6. Product labels that bear significant nutrition labeling deficiencies (e.g., absence of trans fats or other mandatory nutrient in nutrition labeling, incorrect serving size, labeling that misrepresents the amount of calories or other nutrient declarations); and
7. Product labels that bear significant deficiencies from other labeling requirements (e.g., percent of juice).

Note: See Part VI for additional references to information on the Areas of Emphasis.

NOTE: Be aware that the nutrition labeling format requirements provide for the declaration of trans fat and other mandatory nutrients as part of a "Not a significant source of..." statement under certain conditions (see 21 CFR 101.9(c) and 21 CFR 101.9(f))

Be aware that the simplified format limits the number of mandatory nutrients that must be present in nutrition labeling under some situations (see 21 CFR 101.9(f)).

C. Discussions with Firm Management on Food Labeling Requirements

During an inspection of a firm at which physical samples or documentary samples of labels are collected for additional review or follow-up, investigators should use the following language with the firm's management and document this in the EIR:

"The collection of products 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."

D. Import Coverage

Emphasis given during field exams to ensure that labeling provisions are being met should be conducted **under the same instructions listed above under Domestic Coverage (field exams)**.

Review product labels to ensure that labeling meets allergen source declaration requirements. The investigator should look at labels of various products to ensure that they bear appropriate ingredient declaration. For example, if the product bears a picture of tree nuts on the label but the common or usual name of the tree nut is not declared in the list of ingredients, the entry should be detained and the product placed on I.A.

Dual 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 allergens, BSE and herbal/botanical ingredients, FD&C Yellow 5 and Sulfites. If there is a BSE countrywide ban on beef products, and product labeling does not declare beef in the English translation, but the product labeling has a picture with beef, a translation of the foreign language ingredient statement should be made to determine its accuracy. If the district does not have a staff member who can translate, please contact the General Program contact person for assistance.

Import Alerts

See instructions listed in Program Management Instructions under Imports.

E. Sample Collection

COMPLIANCE SAMPLES

The following may assist you in collecting appropriate Documentary Samples (labels) under this program:

- Area of Emphasis 1 - Products that fail to identify the presence of a major food allergen as defined in Section 403(w); products that fail to lack other ingredient declaration (e.g., color additives, such as FD&C Yellow 5; chemical preservatives such as sulfiting agents [sulfur dioxide, sodium sulfite, sodium bisulfate, potassium bisulfate, sodium metabisulfite, and potassium metabisulfite]; products that lack label statements associated with safe use in foods; and products that lack required warning statements;
- Area of Emphasis 2 - Products that fail to bear nutrition labeling

and are not exempt;

- Area of Emphasis 3 - Product labels that bear nutrient content claims that are not authorized by law or regulation or health claims that are not authorized by law or regulation and are not the subject of FDA enforcement discretion (qualified health claims);
- Area of Emphasis 4 - Products subject to regulation as conventional foods but are labeled as dietary supplements or medical foods;
- Areas of Emphasis 6 - Products that bear significant deficiencies in the nutrition or other mandatory labeling requirements, e.g., absence of trans fat; serving size.
- Area of Emphasis 7 - Products labeled as juice that do not bear percent juice labeling.

The following may assist you in collecting appropriate Physical Samples under this program:

- Area of Emphasis 5 - Products that bear authorized nutrient content claim or health claims but do not appear to meet nutrient level requirements or products that bear qualified health claims for which FDA is using enforcement discretion but do not appear to meet nutrient requirements.

***Note:** 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., Product labeled as "lowfat" that declares 5 g of fat per serving.)

oOther Physical Samples - Products to confirm by nutrient analysis levels declared in nutrition label.

Note: See Part VI for additional references to information on the Areas of Emphasis.

SAMPLE SIZES

Area of Emphasis No. 1

Domestic and Import

- Collect a documentary sample of any product that, on the basis of the field exam, fails to identify the presence of a major food allergen as defined in Section 403(w), or lacks appropriate ingredient declarations, or lacks other required label statements associated with safe use of foods;
- The sample should consist of three (3) **original labels*** for the product being sampled. No physical sample is required. Prepare a Collection Report (C/R) in FACTS or OASIS for each product label with the sample marked as **Sample Type D**. See IOM 4.1.4.2 for additional information.
- Flag as a compliance sample for label review only on the C/R. Indicate in the remarks section the deficiency noted.
- Send samples to the collecting District Compliance Branch for label review, sample classification, and any follow-up recommendation.

*Note for allergen source labeling samples. Collect finished product

and **raw material*** labeling that document the failure to declare a major food allergen as defined in Sections 403(w) and 403(i)(2). The investigator should review the raw material and finished product label to determine whether the finished food bears appropriate declarations in accordance with FD&C Act requirements.

*Note: raw material labeling is not applicable for imports.

- At this time, **Do not collect** a physical sample if the product is suspected to contain undeclared major food allergens, i.e., tree nuts, eggs, milk, Crustacean shellfish, wheat, fish, soybeans and peanuts unless directed by CFSAN/OC/Division of Enforcement contact. However, labels should be collected as instructed above.

As methods become available, CFSAN may direct collection of samples for major food allergen analyses.

- **Do not collect** physical samples for analysis for undeclared colors or food additives, including FD&C Yellow No. 5 and sulfiting agents under this program. If the field exam and inspectional observations determines that a product may contain an undeclared color or food additive, sampling and analysis must be conducted under the Domestic Food Safety Program (7303.803) for domestic products and the Import Food and Color Additives Program (7309.006) for imports. See instructions in those programs for sampling instructions.

Areas of Emphasis Nos. 2, 3, 4, and 7

Domestic and Import:

- Collect a documentary sample of any product that appears, on the basis of the field exam, to be deficient in one or more of these areas as described above.
- The sample should consist of three (3) original labels for the product being sampled. No physical sample is required. Prepare a Collection Report (C/R) in FACTS or OASIS for each product label with the sample marked as **Sample Type D**. See IOM 4.1.4.2 for additional information.
- Flag as a compliance sample for label review only on the C/R. Indicate in the remarks section the deficiency noted.
- Send samples to the collecting District Compliance Branch for label review, sample classification, and any follow-up recommendation.
- For Area of Emphasis No. 3: Investigators should refer to the specific regulations to determine if the amount of the nutrients listed on the nutrition label qualifies the product to make the claim. Analysis of a physical sample may be necessary to verify the level of the nutrient in the product at the discretion of the District Compliance Branch.

- Sample Classification: Instruction for Label Review
- 1. **Class I:** no significant labeling deficiencies.
- 2. **Class II:** labels that in the opinion of the district's compliance branch do not clearly meet Class I or Class III. These labels require evaluation by CFSAN to determine if significant labeling deficiencies exist.
- 3. **Class III:** significant labeling deficiencies that have the potential of requiring appropriate follow-up recommendation.

Note: Label classification should be reported under miscellaneous operation 51.

Area of Emphasis No. 5

Domestic and Import

- To make authorized health claims or nutrient content claims, products must meet certain nutritional requirements. For example, to make a "fat free" 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 [FDA/CFSAN Food Labeling, Label claims](#).
- Physical samples for nutrient analysis may be required to support regulatory action under this Area of Emphasis. Specify the nutrient forming the basis for the health claim or nutrient content claim in the remarks section of the C/R.
 - *Note:** 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., Product labeled as "lowfat" that declares 5 g of fat per serving.)
- **Domestic samples** collected for analysis in support of a health claim or nutrient content claim 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 (flag as a compliance sample for analysis).
- **Import samples** 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.
- If there is a strong suspicion or indication of a deficiency of an imported food under this area of emphasis, the district should contact the ACNA Lab Director beforehand to ensure appropriate import timeframes can be met.

- All physical samples (Domestic and Import) collected for analysis are to be shipped to ACNA for analysis only for the specific nutrients subject to the claim:

Atlanta Center for Nutrient Analysis (ACNA),
HFR-SE 680
60 Eighth Street, N.E.
Atlanta, GA 30309
(404) 253-2262

SURVEILLANCE SAMPLES

Workplan Sampling Obligations

See the current ORA Field Workplan for domestic and import sampling obligations for each district. 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 Area of Emphasis No. 5 above). Coordinate with ACNA as needed.

Each district should attempt to provide both import and domestic routine surveillance samples to ACNA for nutritional analysis, in line with district sample collection obligations and ACNA's sample analysis obligations.

Surveillance samples (to meet district's sampling obligations) of domestic or imported foods may be collected of any product from the list below which has at least one nutrient with a label declaration of 10% or more of the daily value (DV) (or is an enriched food) and which has been manufactured within the collecting district. Give higher priority to the product category listed first in each quarter. The collection schedule helps the laboratory by grouping analyses.

Sample Size

Samples are to consist of (12) consumer-size retail packages, one package from each of twelve (12) randomly selected shipping cases. The sample should be collected from a lot of twelve (12) or more cases with the same manufacturing lot code.

For sampling instructions for milk/milk products see the most current IOM section 5.4.9 (Other Government Inspection).

Products to be collected by Quarter

<u>Quarter</u>	<u>Product</u>	<u>Group I.D.</u>
First	Canned/frozen/dried Vegetables and fruits Fruit & vegetable juices	A
	Beverages (soft drinks, Waters)	E
	Gelatins/puddings Candy Syrups/jam/honey	J

Products to be collected by Quarter

<u>Quarter</u>	<u>Product</u>	<u>Group I.D.</u>
Second	Milk/milk products	D
	Cheese/cheese foods	
	Frozen dairy products	
	Dairy Substitutes	
	Dressing	K
	Butter/Margarine	
	Other oil/fat products	
	Peanut butter/other nut products	L

Third	Baked goods/baking mixes	B
	Noodles/noodle products/pastas	
	Grains/grain products	
	Corn flour products	
	Soups	H
	Snack chips/crackers	I

Fourth	Cold/hot breakfast cereals	C
	Vegetable protein products	
	Meal replacements & low/ reduced calorie foods	
	Infant foods (other than infant formulas, see 7321.006)	F
	Gravies/sauces/ketchup	M

NOTE: The product group identifications 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. Submit these samples to ACNA at the address listed in Part III, page 11.

F. State-Collected Labels

States trained in labeling requirements should continue to provide coverage of food labels during contract food safety inspections. The collected product labels should be submitted by the states to their district with the inspection reports. Only district personnel trained in conducting food label reviews should determine whether the labels comply with all food labeling regulations.

All label reviews conducted by district personnel on state-collected labels, whether the label is found to be in compliance or in violation, should be entered into FACTS. Prepare an abbreviated collection report for each label so that time can be reported for the label review. Each label review should be classified as in compliance or deficient. See Section H: Data Reporting for further instructions. Some states are taking follow-up action to label deficiencies independently and some are enforcing embargos. Latitude given to each state would depend on the district's experience in working with the state concerning labeling issues.

G. General: Food Labeling Educational Materials:

The following food labeling educational materials are readily available and should be discussed with firm management.

- 1) Code of Federal Regulations - Available from local Government Printing Office (GPO) Bookstores or by telephoning GPO at (202) 512-1800 and on FDA's Internet website at <http://www.fda.gov/> under the heading of Regulatory Information/Code of Federal Regulations;
- 2) A booklet entitled "A Food Labeling Guide", which provides additional guidance in understanding the food labeling regulations may be obtained on FDA's Internet website at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm2006828.htm>
- 3) Information on food labeling policies and regulations can be found on FDA's Internet website at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>
- 4) Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and additional information can be found at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm>
- 5) Guide To Nutrition Labeling and Education Requirements (<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>)

H. Data Reporting

In addition to the Reporting Instructions on page 1, the following also apply:

- 1) Resources for conducting import field exams and collecting physical samples and labeling samples have been allocated in ORA's Field Work Plan for this program. District personnel should use the appropriate OASIS Activity when reporting these operations into OASIS; and
- 2) A separate field examination record should be entered into FACTS for each different product examined. The "Product Code" and the "Lot Detail" should be entered for each field exam. The **Data** to be completed are: the "Examination Type", select either **Label-Food General** or **Label-NLEA**; the "Number of Units Examined" (Not the total number of field exams conducted); and the "Adverse Results" if any. If a documentary sample was collected as a result of the field exam, complete the remaining information as per FACTS. These requirements should be followed if districts are to receive accurate credit for each **field exam and documentary sample accomplished**.

The following coding instructions should be followed when reporting sample collections and exams into OASIS and FACTS. This coding is essential for headquarters to determine whether a sample was collected for label review only or analysis, and whether a state employee collected the labels.

Domestic

- 1) Documentary samples (label review) use Problem Area Flag FDF, Results Flag FDL. Indicate whether the sample was collected by FDA or by a State investigator.
- 2) Label reviews conducted on domestic documentary samples by investigative branches or compliance branches should be reported into FACTS using Problem Area Flag FDF, Result Flag FDL, see instructions above for reporting results. **Investigation branches or compliance branches should classify all samples.**

- 3) Physical samples for nutrient analysis (Area of Emphasis 5) use Problem Area Flag NIS to report the analytical results in FACTS and Problem Area Flag FDF, Result Flag FDL to report the label review which should be conducted on each physical sample analyzed under this program. Indicate whether the physical sample was collected as a surveillance sample or a compliance sample.

Import

- 1) Label Exams (LEX) or Label Record Exams (label review) use OASIS PAF LBL for general labeling and NIS for nutrition labeling. These should transfer to FACTS as OP 52. **Do not** perform a Field Exam for labeling or NIS (FEX/LBL or FEX/NIS) as these should transfer to FACTS as Operation 21.
- 2) Samples for deficient label review only use OASIS PAF LBL for general labeling and NIS for nutrition labeling. Physical samples for analyses by ACNA are collected under area of emphasis No.5 use PAF NIS to report the analytical results in FACTS and PAF FDF, Result Flag FDL to report the label review to be performed on each physical sample analyzed under this program. Physical samples collected for food and color additive analyses, e.g., FD&C Yellow 5 and sulfites (see 09006 for reporting instructions).
- 3) When only label reviews are conducted on paper collections or physical samples (e.g., non-nutrient analysis), the operation must be reported into OASIS as Label Exams for import inspectional branches and for Label Record Exam (LEX) for compliance branches. **Investigation branches or compliance branches should classify all Exams.**
- 4) Physical samples for nutrient analysis (Area of Emphasis 5) use Problem Area Flag NUT to report the analytical results in FACTS.

PART IV - ANALYTICAL**A. Analyzing Units**

Atlanta Center for Nutrient Analyses (ACNA) will perform nutrient analyses and label reviews of compliance samples collected under Area of Emphasis No. 5 as well as of surveillance samples collected according to procedures in Part III. ACNA should report time in accordance with Part IV C.

District Compliance Branches will review all label samples collected by FDA investigators and on all labels submitted by states to FDA for deficiencies.

B. Analysis1) Label Review

The label of each sample will be reviewed for compliance with 21 CFR 101.3, 101.4, 101.5, 101.9, 101.13, 101.14, 101.17, 101.22, 101.30, 101.100, and 101.105, where applicable. Refer to the information contained in the NLEA guide for specific instructions.

ACNA will conduct a label review of each physical sample collected for nutrient analysis under this program. To accurately account for work time, the label review conducted by ACNA should be reported as per Part IV, C: "Reporting Results."

For instructions use Attachment B for recording observations only. **Do not** submit Attachment B to CFSAN.

2) Nutrient Analysis

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.

a) **Compliance Samples**

Analyze only for the nutrient(s) forming the basis for a health claim or nutrient content claim (See Area of Emphasis No. 5. in Part III) that is not supported by the label declaration.

b) **Surveillance Samples**

Analyze up to a maximum of 4 nutrients per sample. Order of priority for selecting surveillance nutrient samples for analysis is the following:

- (1) Nutrient(s) forming the basis for a nutrient content claim or health claim, regardless of the label declaration for that nutrient;
- (2) Select for analysis up to four (4) of the following nutrients only if they are declared as being present at or above 10% of the DV; calories; total fat; saturated fat; cholesterol; or sodium.
- (3) For any remaining analysis, select either: Vitamin A, Vitamin C, Calcium, or Iron.

c) Perform analyses for the selected nutrients as follows:

Composite 12 sub-samples according to directions from CFSAN. If a compliance sample, use all of the "a" or "b" sub-samples. Retain the remaining sub-samples as the 702(b) portion; and

Analyze the composite by the most current AOAC official methods, where available. If AOAC official methods are not available, or the particular matrix has not been previously analyzed using the AOAC official method, contact Dr. Jeanne Rader/ORS/DBC, HFS-715, (301) 436-1786.

d) Immediately reanalyze the original composite of an apparently violative sample. Reanalysis should be done by an experienced second analyst using the AOAC official method or one approved by CFSAN/ORS, HFS-715.

CAUTION: Vitamins A and C break down when improperly handled. Begin original analysis and check analysis (if necessary) as soon after mixing as possible.

C. Reporting Results

ACNA will report all lab class 3 samples based on nutrient analysis to the compliance branch of the collecting district for appropriate regulatory follow-up.

Use the following Problem Area Flags for reporting sample analyses into FACTS and or OASIS:

Domestic

Label Reviews: (OP 51)
PAF: FDF
Result Flag: FDL
Nutrient Analysis: (OP 41)
PAF: NIS

Import

Nutrient Analysis: (OP 43)
PAF: NUT
Screen PAF: NIS
Label Review OASIS: Activity #27 for Import Operations Branches and Activity #43 for Compliance Branches
OASIS PAF: NIS - Nutrition Labeling

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

For further instructions concerning Warning Letters refer to Office of Enforcement's website at <http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/Enforcement/ucm023598.htm>.

Note: The district should submit the recommendation via the MARCS Compliance Management Services (CMS) link located on Inside FDA's IT Application Page under ORA Applications: <http://cms.fda.gov/vts/imports/default.cfm>.

The Center is requesting that legible digital copies of labels along with all supporting documentation be submitted via the internet site as well.

If warranted, the following instructions should be used in assessing the significance of the deficiencies found in the food labeling regulations and in recommending an appropriate regulatory action:

A. Label violationsGeneral

Domestic: Warning Letter recommendations must be submitted to CFSAN/DE/LCT, HFS-608, for review and concurrence prior to issuance, unless otherwise directed.

A Warning Letter recommendation should include one (1) original label for each product, container if necessary, and raw material labels when appropriate for violations documented by analytical findings, the complete analytical work sheets. Where appropriate, the recommendation should also include formulation information and raw material labels.

A Warning Letter recommendation should be based on no more than three (3) products. If labels from more than three (3) products are collected, the district should select three (3) products that best represent the violations in all products to form the basis of the Warning Letter. The recommendation should also include formulation information and raw material labels.

Import: All detention recommendations (except where direct reference authority has been granted) must be submitted with a copy of the label to CFSAN/DE/LCT, HFS-608 for review and concurrence.

Detention Without Physical Examination (DWPE)- Districts should follow the criteria stated in RPM Chapter 9 - Import Operations/Actions Subchapter - Automatic Detention to place a firm/product on DWPE.

DWPE recommendations should be submitted to the Division of Import Operations and Policy (DIOP), HFC-170 for review and subsequent CFSAN concurrence. A **legible** copy of the label **MUST** be included in the package submitted to DIOP for review.

Note: See Part VI - References for information on areas of emphasis.

1. Area of Emphasis No. 1 - Product labels that fail to declare major allergens in accordance with FD&C Act and products labels that lack ingredient declarations, and product labels that lack other label information associated with safe use of food. For example:

- Peanuts, soybeans, milk, eggs, fish, Crustacean shellfish, tree nuts, wheat;
- FD&C Yellow No.5; and
- Sulfiting agents (sulfur dioxide, sodium sulfite, sodium bisulfate, potassium bisulfate, sodium metabisulfite, and potassium metabisulfite).

Domestic - For domestic enforcement actions, districts may submit Warning Letter recommendations (see Attachment B) for review and concurrence by CFSAN/DE/LCT

Import - Districts may consider detaining products that fail to meet allergen labeling requirements for the major food allergens listed above in the first bullet or that fail to declare ingredients listed above in the second and third bullet.

2. Area of Emphasis No. 2 - Product labels that fail to bear nutrition labeling and are not covered by an exemption.

Domestic - Districts may consider issuing a Warning Letter directly to a firm whose product(s) fails to bear nutrition labeling without prior CFSAN review and concurrence.

This direct reference authority applies only to products whose labels fail to bear nutrition labeling but are not deficient in any other area of emphasis or in other mandatory labeling information. Regulatory recommendations against product labels that are also found deficient in one of the other areas of emphasis noted must be handled as directed under the area(s) of emphasis. Questions on the appropriate handling of regulatory recommendations must be directed to the Regulatory Contact listed in Part VI of this program.

Note: Districts should contact the ONLDS small business contact to verify that a small business notification has not been submitted. Districts should be assured 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)).

Import - Districts should follow the advice in Import Alert (IA), IA 99-20: Automatic Detention of Imported Food Product due to NLEA Violations (**see** <http://cms.fda.gov/vts/imports/default.cfm> and other applicable import alerts).

3. Area of Emphasis No.3 - Product labels that bear health claims or nutrient content claims that have not been authorized by FDA.

Domestic - Districts may submit Warning Letter recommendations against firms whose product labels or labeling bear unauthorized health claims or nutrient content claims. Submit recommendation to CFSAN/DE/LCT, HFS-608 for review and concurrence.

Import - Districts may consider detaining products that bear labels or labeling with deficiencies in this area. The Notice of Detention should consist of a description of the significant deviation(s) that resulted in the detention.

4. Area of Emphasis No 4 -Products represented as conventional foods but are labeled as dietary supplements. Products labeled as medical foods but do not meet the statutory definition of a medical food.

Domestic - Districts may submit Warning Letter recommendations against firms whose products are represented as conventional foods but are labeled as dietary supplements or medical foods. Submit recommendation to CFSAN/DE/LCT, HFS-608 for review and concurrence.

Import - Districts may recommend detaining the products that are represented as conventional foods and labeled as dietary supplements or medical foods. Districts should collect labels of products labeled as dietary supplements or medical foods that do not meet the statutory definitions for CFSAN evaluation. Districts should submit original labels to CFSAN/DE/LCT, HFS-608 along with their detention recommendations.

5. Area of Emphasis No. 5 -Product labels that bear approved nutrient content/health claims but fail to qualify for making the claims.

Domestic - Warning Letter recommendations may be prepared for any product whose label bears a health claim or nutrient content claim that is not supported by nutrient analysis or that clearly does not meet the criteria, e.g., a product labeled as "fat free" that contains 0.5 grams of fat or more per reference amount and per labeled serving. The Warning Letter recommendation should be submitted to CFSAN/DE/LCT, HFS-608.

Import - Districts may consider detaining products bearing an approved health claim or nutrient content claim that is not supported by nutrient analysis or that clearly does not meet the criteria, e.g., a product labeled as "fat free" that contains 0.5 gram of fat or more per reference amount customarily consumed and per labeled serving.

6. Area of Emphasis No. 6 - Product labels that bear significant nutrition labeling deficiencies.

Domestic - Warning Letter recommendations may be prepared for any product whose nutrition label contains significant nutrition labeling deficiencies, e.g., products with an incorrect serving size declaration that results in a significantly incorrect nutrient profile. The Warning Letter recommendation should be submitted to CFSAN/DE/LCT, HFS-608

Import - Districts may consider detaining products that bear labels with significant nutrition labeling deficiencies. The Notice of Detention should consist of a description of the significant deviation (s).

7. Area of Emphasis No. 7- Product labels that bear significant deficiencies from other labeling requirements.

Domestic - Warning Letter recommendations may be prepared for any product whose label contains one or more other significant label deviations. The Warning Letter recommendation should be submitted to CFSAN/DE/LCT, HFS-608.

Import - Districts may consider detaining products that bear labels with one or more significant label deficiencies. The Notice of Detention should consist of a description of the significant deficiencies that resulted in the detention.

- One example includes the failure to list the specific common or usual name of a major ingredient (other than the identified allergens) where the ingredient has an impact on consumer cost or acceptance (e.g. shrimp).

B. Nutrient Violations

Domestic - Warning Letter recommendations should be prepared and submitted to CFSAN/DE/LCT, HFS-608 under the conditions listed below.

Imports - Districts may consider detaining products under the conditions listed below.

District must submit recommendations to CFSAN for clearance:

- The sample (domestic or import) contains less than 80% 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.

C. Recommendations for Further Regulatory Follow-Up After Issuance of a Warning Letter to a domestic firm.

Non-Compliant Firms

If a firm's response to a Warning Letter is not adequate, the collecting district should conduct a follow-up inspection including collection of a compliance sample of the product in question from a seizable size lot.

D. Data Reporting

All Warning Letters, seizures, and injunction recommendations resulting from this program **must** be entered into the MARCS-CMS. Include the sample numbers for Warning Letters, seizures, and injunctions. A copy of the Warning Letter should be submitted to CFSAN/DE/LCT, HFS-608.

All Detentions and DWPEs must be entered into the Operational and Administrative System for Import Support (OASIS) as Activity 60 for Detention Request and Activity 61 DWPE Requests.

PART VI - ATTACHMENTS, REFERENCES AND PROGRAM CONTACTS**ATTACHMENTS**

Attachment A-Model Nutrition Labeling Review Format
Attachment B-Standard Language for Warning Letters

REFERENCES

Food Labeling Guide

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>

Trans Fatty Acids

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053479.htm>

Food and Drug Administration Modernization Act of 1997 (FDAMA) Health Claims

<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006874.htm>

Health Claims that Meet Significant Scientific Agreement (SSA)

<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006876.htm>

Qualified Health Claims

<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006877.htm>

Structure/Function Claims

<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm>

Draft Guidance - Whole Grain Label Statements

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm059088.htm>

A list of firms that have submitted an NLEA Small Business Exemption Notification is available on the internet at

<https://www.accessdata.fda.gov/scripts/nle/client/report/>

FDA Import Alerts Retrieval System (FIARS)- Import Alert 99-20, "Products Subject to Automatic Detention Due to NLEA Violations" at

<http://cms.fda.gov/vts/imports/default.cfm>

Guide to Nutrition Labeling and Education Act (NLEA) at

<http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>.

Claims That Can Be Made for Conventional Foods and Dietary Supplements at

<http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm>

Title 21, Code of Federal Regulations (CFR) at

<http://www.gpoaccess.gov/nara/index.html>:

- 21 CFR 101-Food Labeling;
- 21 CFR 104-Nutritional Quality Guidelines for Foods;
- 21 CFR 105-Foods for Special Dietary Use, and

Reference Material for Specific Areas of Emphasis:

- No.1- see FALCPA Act The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm> and
Questions and Answers on the Food Allergen Labeling and the Consumer Protection Act of 2004
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106890.htm>
- No.2- Exemptions to food labeling requirements see 21 CFR 101.9(j) and 101.100. For small business exemptions see
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053857.htm>; and General Food Labeling Guide
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm> and
- No.3-Health claims see 21 CFR 101.14 Subpart E . For nutrient content claims see 21 CFR 101.13- Subpart D and the general food labeling guide referenced above.
- No.4-Definition of dietary supplement see
<http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/FieldPrograms/UCM205916.pdf#backgr>
Definition of medical food
<http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/FieldPrograms/ucm019221.pdf#backgr>
- No.5-Health claims see 21 CFR 101.14 Subpart E . For nutrient content claims see 21 CFR 101.13- Subpart D and the general food labeling guide referenced above.
- No.6-Nutrient declaration rules see 21 CFR 101.9(b) 21 CFR 101.9(d) and (e) for normal formats, 21 CFR 101.9(f) for simplified formats and 21 CFR 101.9(j) for special labeling.
- No.7- Identity labeling for food in packaged form see 21 CFR 101.3; designation of ingredient see 21 CFR 101.4; name and place of business see 21 CFR 101.5; food labeling warning, notice of safe handling statements see 21 CFR 101.17; labeling of spices, flavorings, colorings, and chemical preservatives see 21 CFR 101.22; Percentage of juice labeling see 21 CFR 101.30; Declaration of net quantity of contents when exempt 21 CFR 101.105; general food labeling guide see guide listed above and 21CFR1.24; 21CFR101.100

PROGRAM CONTACTS

CFSAN General Program Questions: Kaniz Shireen, CFSAN/OC/DFP&G/Program Assignment Monitoring Branch, HFS-615, (240)402-2775; kaniz.shireen@fda.hhs.gov

CFSAN Regulatory Questions: Latasha Robinson, CFSAN/OC/DE/Labeling and Dietary Supplement Compliance Team, HFS-608, (240)402- 1890, latasha.robinson@fda.hhs.gov

CFSAN Low Volume/Small Business Exemption Questions: Pedro Cruz, CFSAN, ONLDS, Labeling Regulations Implementation Team, HFS-820, (240)402-1933; pedro.cruz@fda.hhs.gov

CFSAN Label Policy Questions: Lynn Szybist, CFSAN/ONLD, Labeling Regulations Implementation Team, HFS-820, (240)402-1690; lynn.szybist@fda.hhs.gov

ORA Domestic Investigational Questions: Rina Bhikha, ORA/OO/OFFO/DFFP, HFR-SE2560, 301-796-5483, rina.bhikha@fda.hhs.gov

ORA Import Investigational Questions: Max Brewster, ORA/OO/OEIO/DIO, HFC-172, 301-796-8994, max.brewster@fda.hhs.gov

CFSAN Scientific Contact: Gregory Noonan, CFSAN/ORS/DAC/MDA, HFS-715,240-402-2250, gregory.noonan@fda.hhs.gov

ORA Scientific Contact: Anthony Adeuya, ORA/ORS/FFSS, HFC-140, 301-796-9510, anthony.adeuya@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

The Director, Office of Nutrition Labeling and Dietary Supplements (ONLDS) has the responsibility to prepare periodic formal evaluations of this compliance program. When completed and cleared, the evaluation will be available for Agency personnel on CFSAN's OC Intranet site <http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm015758.htm>). Additionally, the evaluation should appear on CFSAN's Internet website.

Model Nutrition Labeling Review Format

Food _____ Sample # _____

Mark with: + = Information present and correct on label
- = Information present and incorrect on label
O = Information missing from label

Label Format

- 1. Type size _____
- 2. Upper & lower case letters _____
- 3. Bars and hairlines present _____
- 4. Good color contrast _____
- 5. Bolding on primary nutrients and % DVs _____
- 6. Headings: Nutrition Facts, Amt/Serving, % DV _____
- 7. Footnotes _____
- 8. Simplified or shortened format (qualifies? correct?) _____
- 9. Serving size _____
- 10. Servings/container _____

Label Content

- 1. Calories _____
- 2. Calories from fat _____
- 3. Total fat (g & % DV) _____
- 4. Saturated fat (g & % DV) _____
- 5. Cholesterol (mg & % DV) _____
- 6. Sodium (mg & % DV) _____
- 7. Total carbohydrate (g & % DV) _____
- 8. Dietary fiber (g & % DV) _____
- 9. Sugars (g) _____
- 10. Protein (g) _____
- 11. Vitamin A (% DV) _____
- 12. Vitamin C (% DV) _____
- 13. Calcium (% DV) _____
- 14. Iron (% DV) _____
- 15. Voluntary additional nutrients _____
- 16. Order of listed nutrients _____

Use this form for recording observations only, do not submit to CFSAN

STANDARD LANGUAGE FOR WARNING LETTERS

Follow the format in Chapter 4 of the current RPM and incorporating one or more of the following paragraphs as appropriate. This is agreed upon language for use in proposed Warning Letters.

AREA OF EMPHASIS NO. 1

a) Allergen Source Labeling:

The product is misbranded within the meaning of section 403(w) of the Act [21 U.S.C. 343(w)] in that the label fails to declare all major food allergens present in the product, as required by section 403(w)(1). Section 201(qq) of the Act [21 U.S.C. 321(qq)] defines as major food allergens milk, egg, fish, Crustean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- The word "Contains", followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients (section 403(w)(1)(A) of the Act [21 U.S.C. 343(w)(1)(A)]), or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source which the major food allergen is derived, except the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list, appears as part of the name of an ingredient that is not a major food allergen) (section 403(w)(1)(B) of the Act [21 U.S.C. 343(w)(1)(B)]).

b) Ingredient Declaration - General

The product is misbranded within the meaning of section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient in the product as required by 21 CFR 101.4(a)(1).

c) Ingredient Declaration - Color

The product is adulterated under section 402(c) of the Act [21 U.S.C. 342(c)] because it bears or contains a color additive that is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. 379(e)]. Section 721(a) deems a color additive to be unsafe unless its use is in conformity with the color additive's listing regulation. The listing regulation for FD&C Yellow No.5, a color additive in the product, requires that the color be specifically declared in the ingredient list on the label of foods for human use [21 CFR 74.705(d)(2)].

d) Ingredient Declaration - Sulfites

The product is misbranded within the meaning of section 403(i)(2) of the Act, in that the label fails to declare a sulfiting agent as an ingredient in the

product, and it is not exempt from labeling under 21 CFR 101.100(a)(4).

NOTE: Include the following sulfiting agents, provided they are not exempt from labeling under 21 CFR 101.100(a)(4): sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite*.

AREA OF EMPHASIS NO. 2

The product is misbranded within the meaning of section 403(q)(1) of the Act in that the label fails to bear nutrition labeling as required by 21 CFR 101.9 and the product is not exempt from this requirement under section 403(q)(5) of the Act.

AREA OF EMPHASIS NO. 3

The product is misbranded within the meaning of section 403(r)(1)(A)/(B) of the Act in that the label bears the nutrient content/health claim "(quote wording of unauthorized claim from product label)," which has not been authorized by regulation or the Act.

AREA OF EMPHASIS NO. 4

The product is misbranded within the meaning of section 403(r)(1)(A)/(B) of the Act in that the product is represented as a (insert dietary supplement or medical food) but the product does not meet the statutory definition of a (insert dietary supplement or medical) and therefore is not meet the labeling requirements of the Act.

AREA OF EMPHASIS NO. 5

The product is misbranded within the meaning of section 403(r)(1)(A)/(B) of the Act in that the label bears the nutrient content claim/health claim "(quote wording of authorized claim from the product label)", but the product fails to qualify for making the claim.

AREA OF EMPHASIS NO.6

The product is misbranded within the meaning of section 403(q) of the Act in that the label fails to bear the required nutrient [i.e., the absence of trans fat] "quote nutrient" as required by 21 CFR 101.9.

AREA OF EMPHASIS NO.7

The product is misbranded within the meaning of section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit or vegetable juice but the label fails to bear a statement on the information panel of the total percentage of such fruit or vegetable juice contained in the food (21 CFR 101.30 (a)).

Incorporate the following paragraph in each Warning Letter:

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

NOTE: Districts may wish to reference the educational materials available to industry for guidance in appropriately labeling their products, which can be found in Part III of this program.