CHAPTER 21 – FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS

SUBJECT:	**IMPLEMENTATION DATE**
DOMESTIC AND IMPORT NLEA, NUTRIENT SAMPLE ANALYSIS, AND GENERAL FOOD LABELING REQUIREMENTS PROGRAM (FY 07/08) This program has completed a Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in August 2006.	October 1, 2006
	COMPLETION DATE 9/30/08

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODES:02-41,	PAC 21005 Domestic & Import [**Note**: PAC 21007 is no longer used, report all Import Activities under 21005]

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

FIELD REPORTING INSTRUCTIONS

PAC 21005 (Domestic & Import)- Use this PAC to report label reviews for the FD&C Act as well as the 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 operations 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 on enforcing the Nutrition Labeling and Education Act of 1990 (NLEA) and other food labeling laws and regulations as they relate to domestic and imported food products. This program focuses on: (1) the Food Allergen Labeling and Consumer Protection Act (FALCPA) requirements, (2) Nutrition labeling requirements including serving size and trans fat, (3) other labeling associated with safe use of food and (4) other mandatory food labeling that include: 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 for most foods nutrition information. This program also focuses on conventional foods (e.g., soups, snacks, etc.) that bear a "Supplement Facts" instead of a "Nutrition Facts" panel.

A) Nutritional Labeling Exemptions: Domestic & Foreign

Small 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 Products, Labeling and Dietary Supplements (ONPLDS), HFS-810, Center for Food Safety and Applied Nutrition, Food and Drug Administration 5100 Paint Branch Parkway, College Park, Maryland, 20740-3835. However, firms, other than importers, that have fewer than 10 full-time equivalent employees do not have to file a notice for exemptions 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 could be found on at **www.cfsan.fda.gov/~ear/sbellist.html**. Districts should refer to this Internet website before conducting label examinations.

Other Exemptions

Refer to “Food Labeling Questions and Answer Volume I” **(www.cfsan.gov/~lrd/qa2.html)** and “Food Labeling Questions and Answers Volume II” **(www.cfsan.fda.gov/~frf/qaintro.html),** and for additional guidance on foods that are exempt from nutrition labeling **(www.fda.gov/ora/inspect_ref/igs/nleatxt.html).** 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 and/or its products under the small business exemption should be directed to FDA/CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810, (301) 436-2375.

Alternative Approaches to Nutrition Labeling

Additionally, firms seeking alternative approaches for compliance under 21 CFR 101.9(g)(9) must submit a request to ONPLDS. The home district for the firm requesting a 21 CFR 101.9(g)(9) exemption receives a copy of ONPLDS' 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" **www.fda.gov/ora/inspect_ref/igs/nleatxt.html.**

B) Nutrition Labeling Criteria

FDA is seeking 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 be prevented through better consumer choices. The Nutrition Facts panel on food packages is used by consumers to help them decide what foods to choose. Therefore, the information must be accurate. Emphasis will be placed on assuring that the declared nutrient levels in the nutrition labeling are accurate and in assuring that the serving size declared on the food label is correct and does not misrepresent the amount of calories 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 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 must be 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 must be at least equal to # 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 must not be more than # in excess of the value declared on the label for that nutrient. If unique situations occur and further guidance is required contact label policy contact, HFS-812.

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.

***C) FALCPA Criteria**

As originally enacted in 1938, section 403(i) of the Federal Food, Drug and Cosmetic Act (the Act) required 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). Although ingredient declarations complying with section 403(i) 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 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 FALCPA’s food allergen labeling requirements. Under FALCPA, 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
- Crustacean shellfish
- Tree nuts
- Wheat
- Peanuts
- Soybeans

For information on the requirements of FALCPA see www.cfsan.fda.gov/~dms/wh-alrgy.html).

D) Labeling Associated with the Safe Use of Food

For additional information concerning FD&C Yellow No.5 see 21 CFR 74.705 and Sulfiting agents see 21 CFR 101.100(a)(4)*.

E) Conventional Foods Labeled as Dietary Supplements

The food industry has continued to market conventional foods that contain added “novel” ingredients, e.g., herbs and botanicals. In many cases, the labels for these foods bear claims about the value of these added ingredients. These claims can range from unauthorized health claims to claims regarding the effect of an ingredient on the structure or function of the body. Some of these products seek to escape certain areas of regulation by being labeled as dietary supplements. 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 kind of information that must be provided in the nutrition label.

PART II - IMPLEMENTATION

OBJECTIVES

- *To collect information to determine the extent to which domestic and imported food products are in compliance with the labeling requirements of FALCPA and the nutrition labeling regulations as required under the Nutrition Labeling and Education Act of 1990 (NLEA), and with other labeling requirements under the Act.

- To collect information to determine the extent to which domestic and import foods are in compliance with labeling elements associated with safe use of food (e.g., yellow 5 and sulfites)*.

- To collect information to evaluate whether products represented as conventional foods that contain “novel” ingredients, e.g., herbs and botanicals, etc., are properly labeled as conventional foods.

- To collect and analyze samples of domestic and imported food products for nutrients.

PROGRAM MANAGEMENT INSTRUCTIONS

A. Domestic

The objectives of this part of the program will 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 does not direct inspections solely for labeling issues covered by this program. The program also includes collection of samples for general nutrient analyses. These samples may be collected at the wholesale/retail level if the district is unable to meet sampling obligations during inspections conducted under the above four compliance programs.

B. Import

The objectives of this part of the program will direct field office attention to the nutrient and nutrition labeling area. 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 labeling deficiencies will be listed in **Import Alert #99-20**.

Program Interaction

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

- CP 7321.006, Infant Formula - Import and Domestic;
- CP 7321.002, Medical Foods - Import and Domestic; and
- CP 7321.008, Nutrient Content of Dietary Supplements - Import and Domestic

*****Time expended for activities economics deception (e.g., flagrant violations of misbranding or economic deception) should be continue to be reported under PAC, 21003. Before embarking on economic deception initiatives, the field should consult with CFSAN regulatory contact to ensure Center support*.

PART III – Inspectional

General Information

1. Prior to reviewing the labeling of food products, become familiar with all food labeling requirements in 21 CFR 101 with emphasis on:

- *FALCPA Requirements see (www.cfsan.fda.gov/~dms/alrgact.html)*
- 21 CFR 101.3 – Identity labeling of foods in packaged form;
- 21 CFR 101.4 – Food; designation of ingredients;
- 21 CFR 101.5 – Food; name and place of business of manufacturer, packer, or distributor;
- 21 CFR 101.9 - Nutrition labeling of food;
- 21 CFR 101.13 - Nutrient content claims-general principles;
- 21 CFR 101.14 - Health Claims: general requirements;
- 21 CFR 101.17 - Food labeling warning, Notice and safe handling statements;
- 21 CFR 101.22 – Foods: labeling of Spices, flavoring, colorings and chemical preservative;
- *21 CFR 101.30 – Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice;*
- 21 CFR 1.24 and 101.100 – Exemptions from food labeling requirements; and
- 21 CFR 101.105 – Declaration of net quantity of contents when exempt.

2. *Exempt firms and/or products should not be covered under this 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 importer, the reporting of the number of employee and number of units [21 CFR 101.9(j)(18)(iv)]*.

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 needed compliance samples, meets their full workplan obligation. See area of emphasis No.5.

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

Note: See Part VI- Reference for additional information on the Areas of Emphasis.

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

2. Product labels that bear health claims or nutrient content claims that have not been authorized by FDA;

3. *Product labels that fail to declare major allergens in accordance with FALCPA and ingredient labeling requirements and product labels that fail to declare other labeling information associated with safe use of foods (e.g., FD&C Yellow 5 and sulfites)*;
4. Products represented as conventional foods but are labeled as dietary supplements;

5. Product labels that bear approved nutrient content claims/health claims but the product fails to qualify for making the claims;

6. Product labels that bear significant nutrition labeling deficiencies *(e.g., absence of trans fats)*; and

7. Product labels that bear significant deficiencies from other labeling requirements (e.g., percent of juice).

B. Domestic Inspections - Program Coverage

The field exams and sample collections required under this program are to be conducted during 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).

During the course of an inspection under one of the above programs, if the investigator observes a practice that is related to the nutrient content/nutrition labeling of a product, the practice should be documented and reported in the EIR along with supporting records, labels, and affidavits. One example would be the observation of fat being added to a product that is labeled as "fat free." Collection and analysis of a physical sample to support a regulatory action may be required. If in doubt as to whether to collect a physical sample, contact the domestic regulatory contact listed in Part VI of this program.

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 identified Areas of Emphasis (see Part V) should be the focus of the field exam.

The district should provide sufficient documentation in the EIR to enable the Center to verify that products are not exempt from nutrition labeling. This information may include, for retailers, the reporting of the annual gross sales made or business done in sales to consumers and 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 employees and number of units [21 CFR 101.9(j)(18)(iv)].

Discussions with Firm Management on Food Labeling Requirements

During an inspection of a firm in 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:

> "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."

*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 & 6 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, or, if during a field exam beef is observed as a component of the product, 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 notify the General Program contact person for assistance*.

D. Sample Collection

Areas of Emphasis Nos. 1, 2, 4, 6, and 7

Domestic & Import:

- Collect a labeling sample of any product that appears, on the basis of the field exam, to be deficient in one or more of the above areas of emphasis.

- The sample will consist of three (3) original labels for the product being sampled. No physical sample is required. For domestic samples prepare a Collection Report (C/R) 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's Compliance Branch for label review, sample classification, and regulatory consideration.

- Investigators should refer to the specific regulations to determine if the amount of the nutrient listed on the nutrition label qualifies the product to make the claim (area of emphasis No.2). Analysis of a physical sample may be necessary to verify the level of the nutrient in the product at the discretion of the District's Compliance Branch.

- *Sample Classification: Instruction for Label Review

    1. **Class I**: no labeling deviation or non – significant.
    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 a significant label deviation exists.
    3. **Class III**: significant labeling deviations and labeling deficiencies that have the potential of requiring appropriate regulatory follow-up*.

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

Area of Emphasis No. 3

Domestic & Import:

- Collect finish product and raw material***** labeling that document allergens without the appropriate declarations required in FALCPA. The investigator should review the product label to determine whether it bears appropriate declaration in accordance with FALCPA requirements.

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

&

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

- Collect a sample for analysis of any product labels that fail to declare other label information associated with safe food use (e.g., FD&C Yellow 5 and sulfites). The investigator should document in the EIR any observation regarding these ingredients not declared on a product's label. For FD&C Yellow No.5 document what is on the label of the bulk color ingredient and if FDA has certified the color.

- Samples collected for food and color additive analysis must be collected in accordance with the guidance in the 2006 IOM, Sample Schedule Chart 9 in Chapter 4:

  A) Specify the undeclared ingredient (e.g., FD&C Yellow No. 5 or sulfiting agents) in the remark section of the C/R and;

  B) Ship samples to be analyzed for FD&C Yellow No.5 or sulfiting agents to your district's servicing laboratory. Contact the servicing laboratory prior to shipping samples.

Note: Routine sampling of imported foods for food color and color additives are covered under Imported Foods and Color Additives, C.P. 7309.006.

Area of Emphasis No. 5

Under this program, resources are provided to each district in the ORA Field Workplan for import and domestic sample collections. The collections include both samples for district review, and, for this area of emphasis, physical sample for nutrient analysis by ACNA. Each district should attempt to provide both import and domestic samples to ACNA for nutritional analysis, in-line with district sample collection and ACNA's sample analysis obligations. Surveillance samples should be collected if sufficient compliance samples do not materialize. Coordinate with ACNA as needed.

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 # grams of fat per reference amount and per labeled serving. For further information refer to FDA/CFSAN Food Labeling, Health Claims and Nutrient Content Claims at **www.cfsan.fda/gov/~dms/lab-hlth.html.**

Physical samples for nutrient analysis are 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.

All physical samples (Domestic, Import, and DI) collected for analysis under area of emphasis No.5 are to be shipped to:

Atlanta Center for Nutrient Analysis (ACNA),
HFR-SE 680
60 Eighth Street, N.E.
Atlanta, GA 30309
(404) 253-1181

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 must 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 must be collected from a lot of twelve or more cases with the same manufacturing lot code.

- Most import samples under this area of emphasis should be collected in

domestic import status immediately after a "May Proceed" notice has been issued. The sample type in FACTS will be "I", and the country of origin must be entered into the FACTS record as well.

- If there is a strong suspicion or indication of a deficiency of an imported food under this area of emphasis, the district may wish to collect the sample in import status and hold the entry pending analytical results. **However, it is necessary to obtain concurrence from the ACNA Lab Director beforehand to ensure appropriate import timeframes can be met.**

Domestic-Import samples can be collected in two ways:

1. Domestic-import (D-I) samples can be collected in domestic channels from wholesalers or commercial markets after clearing U.S. Customs as long as the country of origin can be determined.

OR

2. Samples can be collected immediately after a release is issued. Import samples should be collected in D-I status

Surveillance Samples

- Surveillance sample 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 # 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.

- Samples are to consist of (12) consumer-size retail packages, one package from each of twelve (12) randomly selected shipping cases. The sample must 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 2006 IOM section 5.4.9 (Other Government Inspection)*.

Products to be collected by Quarter

Quarter	Product	Group I.D.
First	Canned/frozen/dried Vegetables and fruits Fruit & vegetable juices	A
	Beverages (soft drinks, Waters)	E
	Gelatins/puddings Candy Syrups/jam/honey	J
Second	Milk/milk products Cheese/cheese foods Frozen dairy products	D

	Dairy Substitutes Dressing Butter/Margarine Other oil/fat products Peanut butter/other nut products	K L
Third	Baked goods/baking mixes Noodles/noodle products/pastas Grains/grain products Corn flour products	B
	Soups	H
	Snack chips/crackers	I
Fourth	Cold/hot breakfast cereals Vegetable protein products Meal replacements & low/ reduced calorie foods	C
	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 6.

E. State-Collected Labels

1. States trained in NLEA regulatory enforcement will continue to provide coverage of nutrition labels during contract food safety inspections. The collected product labels will 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.

2. All label reviews conducted by district personnel on state-collected labels, whether the label is found to be in compliance or in violation, must 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 must 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 knowledge in working with the state concerning NLEA regulatory enforcement.

F. General: Industry Educational Materials:

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 **www.cfsan.fda.gov/** under the heading of CFR;

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 **www.cfsan.fda.gov/** under the heading of Food Labeling & Nutrition;

3. A series of booklets entitled, "Food Labeling Questions and Answers," which were developed by CFSAN, Office of Nutritional Products, Labeling, and Dietary Supplements. The booklets provide guidance to facilitate the process of developing or revising labels for foods other than dietary supplements. Contact the Office of Nutritional Products, Labeling and Dietary Supplements at (301) 436-1434; and

4. Information on food labeling policies and regulations can be found on FDA's Internet website at **www.cfsan.fda.gov/** under the heading Food Labeling and Nutrition.

5. *Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and additional information can be found at www.cfsan.fda.gov/~dms/wh-alrgy.html*.

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 must be entered into FACTS for each different product examined. The "Product Code" and the "Lot Detail" must be entered for each field exam. The **Data** that must 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, typically a "1" should be entered here for a label exam); and the "Adverse Results" if any. If a documentary sample must be collected as a result of the field exam, complete the remaining information as per FACTS. These requirements must be followed if the district is to receive accurate credit for each **field exam and documentary sample accomplished**.

The following coding instructions must 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 must be reported into FACTS using Problem Area Flag FDF, Result Flag FDL, see instructions above for reporting results. **Investigation branches or compliance branches must classify all samples.**

3. Physical samples for nutrient analysis (Area of Emphasis 6) 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 will 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 will transfer to FACTS as OP 52. **Do not** perform a Field Exam for labeling or NIS (FEX/LBL or FEX/NIS) as these will 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.6 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 must classify all Exams**.

4. Physical samples for nutrient analysis (Area of Emphasis 6) 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.

District Servicing Laboratories will analyze products containing undeclared FD&C Yellow No. 5 or sulfiting agents.

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

B. Analysis

1. 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 the 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 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, Office of Nutritional Products, Labeling and Dietary Supplements, Division of Research and Applied Technology (HFS-840), (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 the Office of Nutritional Products, Labeling and Dietary Supplements, Division of Research and Applied Technology (HFS-840).

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

Note: Physical Samples for Nutrient Analysis - Use Problem Area Flag NIS to report the analytical results.
ACNA Label reviews – Use Problem Area Flag FDF and Result under miscellaneous operation 51 to report the label review.

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

*All Warning Letters must go through the Office of Chief Counsel (OCC) for review and concurrence whether they are direct reference or have Center concurrence. For further instructions concerning Warning Letters refer to Regulatory Procedure Manual most current edition or the Agency established "Supplemental Procedures for Clearing FDA Warning Letters and Untitled Letters", dated March 5, 2002, on FDA's Office of Regulatory Affairs Intranet Website at #.

***Note:** The district should submit the recommendation via electronic copy (e.g., doc, pdf files, etc) via the "Compliance Management System" link located on Inside FDA's IT Applications Page under CFSAN Applications: #. The Center is requesting legible digital copies of labels and 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 violation of the food labeling regulations and in recommending an appropriate regulatory action:

A. Label violations

General

Domestic: Warning Letter recommendations must be submitted to CFSAN, Division of Enforcement, Domestic Branch (HFS-607) for review and concurrence prior to issuance, unless otherwise directed.

A Warning Letter recommendation should include three (3) original labels for each product and containers if necessary, and for violations documented by analytical findings, the complete analytical work sheets.

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.

Import: All detention recommendations (except where direct reference authority has been granted) must be submitted with a copy of the **ORIGINAL** label to CFSAN, Division of Enforcement, Import Branch, HFS-606 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. An **ORIGINAL** 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 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 Domestic Enforcement and regulatory contacts listed in Part VI of this program.

Import - Districts should follow the advice in Import Alert (IA), IA 99-20: Automatic Detention of Imported Food Product due to NLEA Violations **(see www.fda.gov/ora/fiars/ora_import_alerts.html).**

2. Area of Emphasis No.2 - 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 labeling bears unapproved health claims or nutrient content claims. Submit recommendation to CFSAN, Division of Enforcement, Domestic Branch for review and concurrence.

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

3. *Area of Emphasis No. 3 – Product labels that fail to declare major allergens in accordance with FALCPA and products labels that fail to declare other label information associated with safe use of food. Some of the ingredients that are most commonly known to cause adverse reactions include:

- 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, Division of Enforcement, Domestic Branch.

Import - Districts may consider detaining products that fail to include FALCPA labeling requirements for the ingredients listed above in the first bullet or that fail to declare ingredients listed above in the second and third bullet.

4. Area of Emphasis No 4 -Products represented as conventional foods but are labeled as dietary supplements.

Domestic - Do not prepare Warning Letter recommendations for these products. Submit three (3) original product labels to CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-812 for review. The Center will prepare a Warning Letter with appropriate charges if appropriate.

Import - Districts may recommend detaining the products that are represented as conventional foods and labeled as dietary supplements. Districts should submit original labels to CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements HFS-812 and CFSAN, Division of Enforcement, Import Branch,

HFS-607 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, e.g., a product labeled as "fat free" that contains more than # grams of fat per reference amount and per labeled serving. The Warning Letter recommendation should be submitted to CFSAN, Division of Enforcement, Domestic Branch, HFS-607.

Import - Districts may consider detaining products bearing an approved health claim or nutrient content claim that is not supported by nutrient analysis, e.g., a product labeled as "fat free" that contains more than # gram of fat per reference amount 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, Division of Enforcement, Domestic Branch, HFS-607.

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, Division of Enforcement, Domestic Branch, HFS-607.

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. pork parts).

B. Nutrient Violations

Domestic - Warning Letter recommendations should be prepared and submitted to CFSAN, Division of Enforcement, Domestic Branch, HFS-607 under the conditions listed below.

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

- The sample (domestic and import) does not meet 21 CFR 101.9(g)(4) [i.e., contains less than # of declared vitamin, mineral, protein, dietary

fiber or potassium]

- The sample (domestic and import) does not meet 21 CFR 101.9(g)(4) [i.e., contains less than # of declared of any naturally occurring vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, poly unsaturated or monounsaturated fat or potassium];

- The sample (domestic and import) does not meet 21 CFR 101.9(g)(5) [i.e., contains more than # of declared 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, then 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 Field Accomplishments and Compliance Tracking System (FACTS). Include the sample numbers for Warning Letters, seizures, and injunctions. A copy of the Warning Letter should be submitted to CFSAN, the Division of Enforcement, Domestic Branch, Chief, HFS-607.

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 for Areas of Emphasis Nos. 1,2,3,6, and 8

REFERENCES

*For Areas of Emphasis:

- No.1- see 21 CFR 101.9(j)-exemptions to Nutritional Labeling of Food; for small business exemptions see www.cfan.fda.gov/~dms/sbel; for NLEA Q & A see www.cfsan.fda.gov/~lrd/qa2 and www.cfan.fda.gov/~dms/flg-toc (food labeling guide); 21 CFR 101.100 (exemptions from food labeling requirements).
- No.2- see 21 CFR 101.4 (Foods; designation of ingredients), and Subpart E for health claims and 21 CFR 101.13- Subpart D for nutrient content claims. For NLEA Q & A (www.cfsan.fda.gov/~lrd/qa2 and health claims (www.cfsan.fda.gov/~dms/lab-hlth).
- No.3- see FALCPA Act (www.cfsan.fda.gov/~dms/alrgact.html) and Q & A's (www.cfsan.fda.gov/~dms/alrguid3.html).
- No.4- see 21 CFR 101- Subpart B, Specific food labeling requirements.
- No.5- see 21 CFR 101.13 (Nutrient content claims), and Subpart D & 21 CFR 101.14 and Subpart E, and for claims (www.cfsan.fda.gov/~dms/lab-hlth) & for food labeling guide (www.cfsan.fda.gov/~dms/flg-toc).
- No.6- see 21 CFR 101.9(b) for nutrient declaration rules, 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- see 21 CFR 101.3 (Identity labeling for food in packaged form), 21 CFR 101.4 (Food; designation of ingredient), 21 CFR 101.5 (Food; name and place of business of manufacturer, packer or distributor), 21 CFR 101.17 (Food labeling warning, notice and safe handling statements), 21 CFR 101.22 (Foods; labeling of spices, flavorings, colorings and chemical preservatives), 21 CFR 101.30 (Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice), 21 CFR 101.105 (Declaration of net quantity of contents when exempt) and food labeling guide (www.cfsan.fda.gov/~dms/flg-toc).*

FDA Import Alerts Retrieval System (FIARS)- Import Alert 99-20,"Products Subject to Automatic Detention Due to NLEA Violations" at.www.fda.gov/ora/fiars/ora_import_alerts.html.

Guide to Nutrition Labeling and Education Act (NLEA) at **www.fda.gov/ora/inspect_ref/igs/nleatxt.html**.

Claims That Can Be Made for Conventional Foods and Dietary Supplements at **www.cfsan.fda.gov/~dms/hclaims.html.**

Title 21, Code of Federal Regulations (CFR) at **www.access.gpo.gov/nara**:

- 21 CFR 101-Food Labeling;
- 21 CFR 104-Nutritional Quality Guidelines for Foods;
- 21 CFR 105-Foods for Special Dietary Use, and
- 21 CFR 120-Hazard Analysis and Critical Control Point (HACCP) Systems.

PROGRAM CONTACTS

General Program Questions: Glenn Bass, CFSAN, Office of Compliance, Division of Field Programs, Compliance Programs Branch, HFS-636, (301) 436-2774; **Glenn.Bass@fda.hhs.gov**.

Low Volume/Small Business Exemption Questions: Judith Kraus, CFSAN, ONPLDS, Compliance and Enforcement Branch, HFS-812, (301) 436-1434; **Judith.Kraus@fda.hhs.gov**

Label Policy Questions: Judith Kraus, CFSAN, ONPLDS, Compliance and Enforcement Branch, HFS-812, (301) 436-1434; **Judith.Krause.fda.hhs.gov**

Domestic Regulatory Questions: Lynn Szybist, CFSAN, Office of Compliance, Division of Enforcement, Domestic Branch, HFS-607, (301) 436- 2040; **Lynn.Szybist@fda.hhs.gov**.

Import Regulatory Questions: CFSAN, Office of Compliance, Division of Enforcement, Imports Branch, HFS-606, (301) 436-1742

Domestic Investigational Questions: Barbara Marcelletti, ORA, Division of Field Investigations, HFC-132, (301) 827-5635; **Barbara.Marcelletti@fda.hhs.gov**.

Import Investigational Questions: Ted Poplawaski, ORO, Division of Imports Operations and Policy, HFC-172, (301) 594-3849, **Ted.Poplawski@fds.hhs.gov**

Methodology Questions: Dr. Jeanne Rader, CFSAN, ONPLDS, Division of Research and Applied Technology, HFS-840, (301) 436-1786 or George Salem, ORA, Division of Field Science, HFC-141, (301) 827-1031; **George.Salem@fda.hhs.gov**.

PART VII - CENTER RESPONSIBILITIES

The Director, Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) 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 #. 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
FOR AREA OF EMPHASIS NOS. 1, 2, 3, 5, and 7

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

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(g)(5) of the Act.

AREA OF EMPHASIS NO. 2

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 FDA at this time.

*AREA OF EMPHASIS NO. 3

a) FALCPA:

The product is misbranded within the meaning of section 403(w) of the Act [21 U.S.C. 343(w)1 in that the labels fail to declare all major food allergens present in those products, 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 form 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).

NOTE: Include only the following ingredients, which are known to cause adverse reactions: milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, soybeans, and peanuts.

c) Ingredient Declaration – Color

The product is adulterated under section 403(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 bissulfite, sodium metabisulfite, and potassium metabisulfite*.

*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 unauthorized 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(r)(1)(A)/(B) of the Act in that the label bears the nutrient content claim/health claims "(quote wording of unauthorized claim from the product label)", but the product fails to qualify for making the claim.

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.**