## Labeling

## Objectives

After completing this module, the student will be able to:

- 1. Define the following terms:
  - Immediate container
  - Label
  - Principal display panel

- Generic labeling
- Sketch labeling
- Shipping container
- 2. Identify the eight mandatory features of an immediate container label.
- 3. Describe the regulatory requirements for each of the mandatory features.
- 4. Identify the mandatory features that must be shown on shipping containers.
- 5. Identify the two types of labeling approvals granted by the Labeling and Program Delivery Staff (LPDS).
- 6. Identify the product name labeling requirements for raw meat and poultry products that contain added solutions.
- 7. Identify the product name and cooking instruction labeling requirements for mechanically tenderized raw beef products.
- 8. Describe the recordkeeping requirements for labels.
- 9. Identify the requirements for transferring labels.
- 10. Describe how to perform the General Labeling inspection task.
- 11. Given an example label, verify that the labeling regulatory requirements are met.

## **Resource Materials**

- Federal Meat Inspection Act (FMIA)
- Poultry Product Inspection Act (PPIA)
- 9 CFR Parts 301, 316, 317, 319, 381 Subpart N, 412, and 442
- FSIS Directive 7000.1 "Verification of Non-Food Safety Consumer Protection Regulatory Requirements"
- FSIS Directive 7235.1, "Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products"

- FSIS Directive 7237.1, "Labeling of Ingredients"
- FSIS Directive 7221.1, "Prior Labeling Approval"
- FSIS Directive 7000.4, "Verifying Certain Transferred Labeling"
- FSIS Directive 7220.1, "Food Labeling Division Policy Memoranda" (Policy (www.fsis.usda.gov/OPPDE/larc/Policies/Policy\_Memos\_082005.pdf)
- Food Standards and Labeling Policy Book (www.fsis.usda.gov/OPPDE/larc/Policies/Labeling\_Policy\_Book\_082005.pdf)
- FSIS Labeling Website www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/labeling
- Prior Label Approval System: Generic Label Approval <u>www.fsis.usda.gov/wps/wcm/connect/3b0efaeb-9a81-4532-a1ccb4d1cdb30f4a/2005-0016F.pdf?MOD=AJPERES</u>
- FSIS Compliance Guidance For Label Approval <u>https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-</u> <u>940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES</u>
- Questions and Answers Concerning the Recently Published Generic Labeling Final Rule <u>https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-</u> <u>compliance/labeling/labeling-policies/faq-generic-labeling</u>
- Questions and Answers on Descriptive Designation for Needle-or Blade Tenderized (Mechanically Tenderized) Beef Products <u>https://www.fsis.usda.gov/wps/wcm/connect/e42698a1-1949-4828-9909-</u> <u>5ff919f275c6/FAQs-2008-0017.pdf?MOD=AJPERES</u>
- Questions and Answers on Descriptive Designation for Raw Meat and Poultry Products with Added Solutions <u>https://www.fsis.usda.gov/wps/wcm/connect/70c4707c-d4cf-4845-b97f-ad8dc23e4c46/Q-A-Added-Solutions-122415.pdf?MOD=AJPERES</u>

## Overview

#### **Product Amenability**

Just because a food product has meat or poultry as a component does not mean it is automatically subject (or amenable) to the regulatory requirements in the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) and must bear the official mark of inspection. Some food products have small amounts of meat or poultry

or meat or poultry fat added to their preparations to give them particular flavor. A food product is exempt from FSIS inspection if:

- It contains 3% or less raw meat or less than 2% cooked meat
- It contains 3% or less raw poultry or less than 2% cooked poultry
- It is not a product that historically has been considered by consumers as a product of either the meat or poultry industry

Closed-faced meat and poultry sandwiches, bouillon cubes, dehydrated meat soup mixes are examples of products that are not amenable to the FMIA or PPIA and therefore, their labeling is not verified by FSIS. For additional poultry examples see §381.15.

#### **Regulatory Authority**

Containers or packages of inspected and passed meat and poultry products must bear a label or other labeling when shipped from official establishments. The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) give FSIS authority to maintain a labeling approval program. Before a label or other labeling can be applied to Federal and State inspected meat and poultry products, it must comply with labeling requirements. In certain cases, labels must be sketch approved by the Labeling and Program Delivery Staff (LPDS) prior to use, however only some types of labels must be submitted to LPDS for approval.

The prior approval program benefits both consumers and the regulated industry. Consumers receive products that have informative labeling that's not false or misleading. Unfair competitive advantages are prevented because all establishments under State and Federal inspection must comply with the same label requirements and standards.

Labeling means all labels and other written, printed, or graphic matter (1) upon any product or any of its containers or wrappers, or (2) accompanying the product. Official marks and other markings are considered labeling. Certain labeling, such as labels bearing no special statement or claims, is given generic approval and may be used by the establishment without FSIS authorization. Other types of labeling, such as labels for temporary approval and labels bearing certain special statements or claims must be submitted to LPDS for review and approval. Some labeling after sketch approval can be modified and the establishment can treat them as generic labels. The establishment is

fully accountable for the content and production of all labeling, whether generically approved or submitted to FSIS for review and approval.

Mandatory information must be prominently shown on labels attached to immediate containers. This information must accurately describe the enclosed product.

When IPPs perform the General Labeling inspection task, they will verify that the label is approved, contains the mandatory information, and accurately reflects the product. This module will familiarize IPPs with labeling regulatory requirements that official establishments must meet.

### Labeling Regulatory Requirements

Labeling regulatory requirements for **meat** products appear in Part 317—Labeling, Marking Devices, and Containers. Labeling regulatory requirements for **poultry** products appear in Part 381—Poultry Products Inspection Regulations, Subpart N— Labeling and Containers. This segment of the module will specifically address the requirements in Subpart A of Part 317 of the regulations. The section of the poultry inspection regulations that references the same or similar requirements is identified in brackets at the end of pertinent paragraphs.

#### §317.1—Labels required; supervision by program employee.

§317.1(a)—When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an **immediate container**, there shall be affixed to such container a **label** as described in §317.2 [§381.115]

§301.2 identifies an *immediate container* as the receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Products, such as whole or half carcasses or carcass parts, bearing the required, legible marks of inspection may be removed from the official establishment without further restriction. Once an official establishment places any inspected and passed product into any receptacle (carton, box, etc.) or covering (wrapper, plastic bag, etc.) constituting an immediate container, a *label* that complies with the regulations, must be affixed to it prior to it leaving the establishment.

Some coverings or immediate containers don't have to have a label affixed to them. These exceptions are identified in §317.1(a)(1) through (6). For example, properly marked products enclosed in uncolored, transparent coverings, such as cellophane, do not have to be labeled if the markings are clearly legible through the covering. The coverings cannot have any printed or graphic material on them.

**Note:** §301.2 identifies a **shipping container** as the outside container (box, bag barrel, crate or other receptacle) containing or wholly or partly enclosing any product packed in one or more immediate containers. In some cases the shipping container becomes the immediate container (e.g., when product units are bulk packed and not individually wrapped and labeled) and must then bear a label with all the required features.

§317.1(b)—Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear **all features** required on a label for an immediate container.

Paper, or similar covering, that has any written, printed, or graphic material must bear all the mandatory features required on an immediate container label. This is true even if the covering only partly encases product.

§317.1(c)—No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee. [§381.136]

Only inspected and passed product that meets all regulatory requirements, is unadulterated, and has an accurate label may be packaged. Packaging and labeling operations can only be performed under the supervision of an IPP. Under the supervision of the IPP only means that he or she is on duty. The IPP **does not** need to **continually oversee** the filling and labeling of packages or containers.

#### §317.2—Labels: definition; required features.

#### Label Definition

§317.2(a)—A **label** within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the **immediate container** (not including package liners) of any product.

#### Placement of Mandatory Label Information

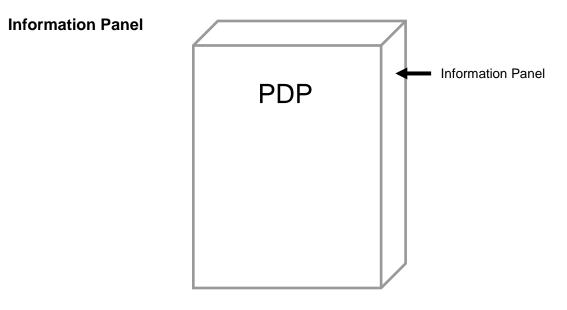
§317.2(b)—Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [§381.116(a)]

All mandatory information must appear on the label's **principal display panel**, except as otherwise permitted in 9 CFR 317.2 and 9 CFR 381.116. Except for products exported to foreign countries or distributed solely to Puerto Rico, the required information **must be** printed in the **English** language.

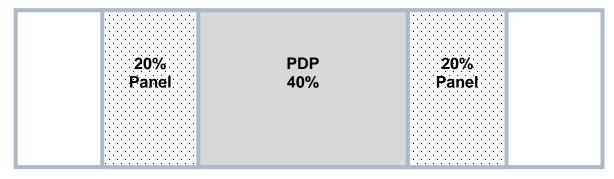
§317.2(d)—The **principal display panel** shall be the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale...The principal display shall be large enough to accommodate all of the **mandatory label information** required to be placed thereon...with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. [§381.116(b)]

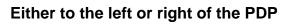
Principal display panels have specific size requirements to accommodate the mandatory information (features). The size requirements for the principal display panel for the various shapes of containers or packages are identified in §317.2(d)(1) though (3) and 381.116(b)(1) through (3).

Additional panels where certain mandatory label information may be shown in lieu of showing it on the principal display panel are identified in 9 CFR 317.2 and 9 CFR 381.116. For example, the ingredients statement, signature line, and/or nutritional facts may be placed together to form the information panel. Certain mandatory features may also be displayed on the front riser panel of a frozen food cartons and the 20% panel of a cylindrical container.

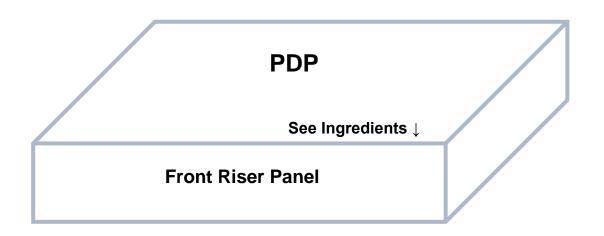


#### 20% Panel on a Cylindrical Container









#### Mandatory Features of a Label

Up to eight features may be required on an *immediate container* label. The eight mandatory features are identified in the table in Attachment 1.

#### • Name of the Product

§317.2(c)(1)—The name of the product, which in the case of a product which purports to be or is represented as a product which a definition and standard of identity or composition is prescribed in part 319...shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation as prescribe in paragraph (e) of this section... [§381.117(a)] Fresh pork sausage (§319.141), Italian sausage (§319.145) and frankfurters (319.180(a)) are examples of products that have standards of identity we have covered in this course. Ground beef is another meat product that has a standard of identity (§319.15(a)). Pork Shoulder and Beef Rib Eye Steak are common and usual names. "Sloppy Joe" is a fanciful name and must be qualified with the descriptive name "barbecue sauce with (species)".

#### Product names must be prominently shown on the principal display panel.

# Raw Meat and Poultry Products Containing Added Solutions Descriptive Designations (if applicable)

§317.2(e)(2)—The product name for a raw meat product that contains added solution and does not meet a standard of identity in 9 CFR part 319 must contain a descriptive designation that includes:

(i) The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ``containing" or ``contains" (such as, ``contains 15% added solution of water and salt," or ``containing 15% added solution of water and teriyaki sauce").

The word "contain" or "contains" is not required. Other words that may be used in the descriptive designation include "added," "with," or "up to", "injected," or "flavored."

The word "solution" is not required in the descriptive designation as long as the added ingredients are included. The words "marinated" and "basted" may be used in the descriptive designation without restriction to the level of solution. *All ingredients that make up the solution, including water if that is the liquid used in the formula, must be declared in the descriptive designation.* 

(ii) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

(iii) When the descriptive designation includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the descriptive designation includes multi-ingredient components and the ingredients of the component are not declared in the descriptive designation, all ingredients in the product must be declared in a separate ingredients statement on the label as required in Sec. 317.2(c)(2) and (f).

A multi-ingredient component is an ingredient added to the formula that itself is made up of two or more ingredients, for example, seasoning (salt and spices) or soy sauce (water, soybeans, wheat).

(iv) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (1/3) the size of the largest letter.

(v) The word ``enhanced" cannot be used in the product name. [381.117(h)]

This rule applies to:

- raw meat or poultry products where added solution increases the raw weight of the meat or poultry by any amount, for example, chicken with 2% solution of water and potassium lactate
- products where solution has been incorporated into raw meat or poultry through any method, for example, marinating, basting, injection, vacuum tumbling, and
- raw products with added solution going to Food Service, HRI, and retail.

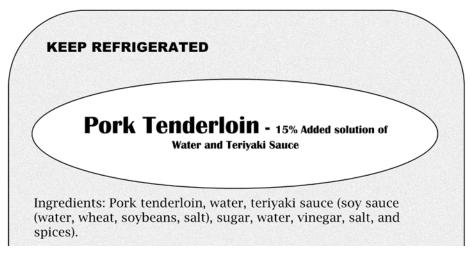
The regulation does not apply to cooked product or products with a standard of identity where added liquid ingredients comply with the standard.

The product name and descriptive designation may appear on more than one line provided there is no intervening text or graphics. The font sizes may be different provided they meet the 1/3rd size requirement.

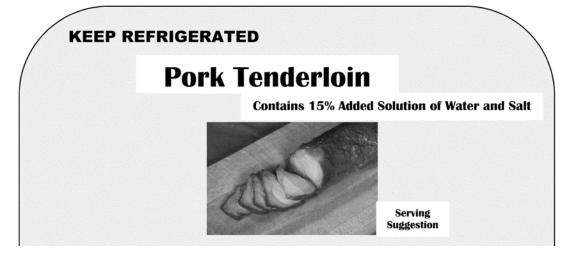
The manufacturer must monitor the percent solution pick up to verify that product labeling is not false or misleading. Determining the percent pick up involves weighing the raw meat or poultry before solution is added, weighing the raw meat or poultry after adding solution, and performing a calculation to determine the percent solution pick up. *The percentage of added solution is the total weight of the solution ingredients divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100.* We will cover the procedure for verifying percent solution pick up in a module covered later in this course.

Based on the compliance level for pumped product in FSIS Directive 7620.3, Processing Inspectors' Calculations Handbook, the compliance level is 20% of the amount of solution stated on the label. Therefore, if the product is labeled "containing up to 7% of a solution", the label would be out of compliance if the actual amount solution added was more than 8.4% (7% plus 1.4%). IPP should retain the product until the establishment addresses the labeling noncompliance. In cases where the added solution is within the 20% allowance but the process consistently adds more solution than declared on the product's label, the establishment should correct the label to reflect the actual amount of solution retained.

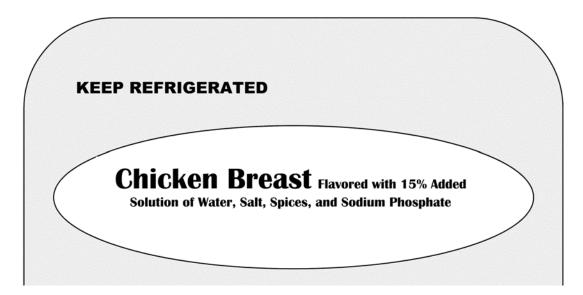
**Label Example 1:** The product name includes a descriptive designation at one-third  $(1/3^{rd}$  the size of the largest letter (9 CFR 317.2(e)(2)(iv)), a multi-ingredient component (Teriyaki Sauce), all ingredients in the product are declared in a separate ingredients statement (9 CFR 317.2( e)(2)(iii)).



**Label Example 2:** The product name includes a descriptive designation at one-third (1/3rd the size of the largest letter (9 CFR 317.2(e)(2)(iv)), includes the word "contains" (9 CFR 317 .2(e)(2)(i)), the individual ingredients in the solution listed in descending order of predominance by weight (9 CFR 317.2(e)(2)(ii), followed by a vignette of the product.



**Label Example 3:** The product name includes a descriptive designation at one-third  $(1/3^{rd}$  the size of the largest letter (9 CFR 381.117(h)(4)), includes the term "flavored with," the individual ingredients in the solution listed in descending order of predominance by weight (9 CFR 381.117 (h)(2)).



# Mechanically Tenderized Beef Product Name and Cooking Instructions (if applicable)

317.2(e)(3)—Product name and required validated cooking instructions for needleor blade-tenderized beef products.

(i) Unless the product is destined to be fully cooked or to receive another full lethality treatment at an official establishment, the product name for a raw or partially cooked beef product that has been mechanically tenderized, whether by needle or by blade, must contain the term "mechanically tenderized," "needle tenderized," or "blade tenderized," as a descriptive designation and an accurate description of the beef component.

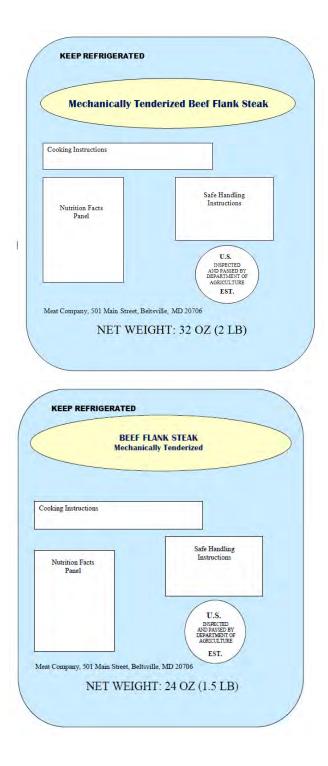
(ii) The product name must appear in a single easy-to-read type style and color and on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than 1/3 the size of the largest letter.

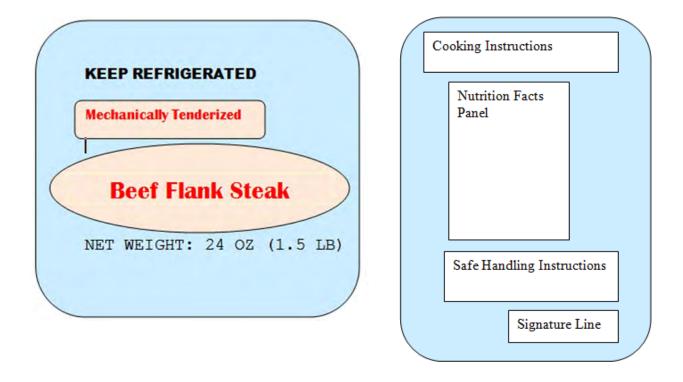
(iii) The labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions must contain validated cooking instructions, including the cooking method, that inform consumers that these products need to be cooked to a specified minimum internal temperature, whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product, and a statement that the internal temperature should be measured by a thermometer. These validated cooking instructions may appear anywhere on the label.

- Products covered: Needle- or blade-tenderized raw beef products destined for household consumers, hotels, restaurants, or similar institutions (HRI)
- Products not covered:
  - Non-intact beef products that are clearly non-intact (e.g., ground beef patties, hamburger patties, beef patties)
  - Beef products tenderized by other than needle/blade, such as pounding or cubing, which visibly changes the appearance of the product, e.g., cubed beef steak
  - Fully cooked beef products and those destined to another Federal establishment for a full lethality treatment

- Raw or partially cooked products labeled as "Corned Beef" that have been mechanically tenderized (including through injection of a solution)
- Raw mechanically tenderized beef products that are less than 1/8" thick, such as, beef bacon or carne asada, or raw mechanically tenderized beef products that are diced, such as stew meat
- Labels must bear:
  - The descriptive designation "mechanically tenderized," "blade tenderized," or "needle tenderized" and an accurate description of the beef component in the product name; and
  - In close proximity; w/o intervening text or graphic
  - All words in the descriptive designation be in the same style, color, and on a single-color contrasting background
  - Upper and lower case allowed; however, the smallest letter must be at least 1/3 the size of the largest letter
  - Validated cooking instructions for subject products destined for household consumers, hotels, restaurants, or similar institutions

#### Label Examples:







Validated Cooking Instructions would address:

- A cooking method, (e.g., grill or bake)
- That these products need to be cooked to a specified minimum internal temperature,
- Whether these products need to be held for a specified time at that temperature or higher before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed throughout the product, and
- A statement that the internal temperature should be measured by a thermometer.

#### **Cooking Instruction Example:**

#### For Food Safety and Quality Follow These Cooking Instructions:

Gas Grill:

1) Heat gas grill on Medium-High.

2) Cook for 6 minutes to an internal temperature of 145°F as measured with a food thermometer. Flip steak over at least twice during cooking.

3) After removing from the gas grill, for safety, allow meat to rest at or above 145° F internal temperature for at least three minutes before serving.

**Note**: Cooking instructions may not be the same as these; however, the instructions should provide the preparer with clear instructions to get to the necessary end point temperature.

To assist industry develop validated cooking instructions the FSIS published the **FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products.** The guideline is available on the internet.

#### Mechanically Tenderized Beef Labeling Workshop

You have scheduled a General Labeling task and selected the label for a raw mechanically tenderized beef flank steak destined for household consumers, hotels, restaurants, or similar institutions.

1. Describe how to verify the labeling requirements for mechanically tenderized raw beef products.

2. Does the label below comply with §317.2(e)(3) of the regulations? Identify all

- noncompliance. Use the space on the next page to answer the question. **KEEP REFRIGERATED Beef Flank Steak** Nutrition Facts Serving Size 1 Piece (142g)/5oz. **Smoke Flavor Added** Servings Per Container 4 **Amount Per Serving** Calories 290 Calories from Fat 190 Containing Up to 15 percent of a Solution % Daily Value\* Total Fat 16g Mechanically 25% Saturated Fat 8g Tenderized 40% Trans Fat Og Cholesterol 75mg 25% Sodium 440ma 18% Total Carbohydrate 10 SAFE HANDLING INSTRUCTIONS 0% THIS PRODUCT WAS PREPARED FROM INSPECTED AND PASSED MEAT AND/OR POULTY, SOME FOOD Products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions, Dietary Fiber Og 0% **Cooking Instructions:** Sugars 1g KEEP RAW MEAT AND POULTRY SEPARATE FROM OTHER Foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw KEEP REFRIGERATED To ensure adequate cooking, grill 5 minutes Protein 240 OR FROZEN. THAW IN Refrigerator or over medium heat. Then flip over and grill MICROWAVE. MEAT OR POULTRY. KEEP HOT FOODS HOT. REFRIGERATE LEFTOVERS Vitamin A 0% Vitamin C 8% an additional 5 minutes. COOK THOROUGHLY. MMEDIATELY OR DISCARD Calcium 2% Iron 15% \*Percent Daily Values are based on a 2,000 calorie diet Ingredients: Beef flank steak, water, salt, spices, sodium phosphate, smoke flavor
  - Meat Company 501 Main St, Beltsville, MD 00000

NET WEIGHT: 20 OZ (1.25 LB)



- 3. By reviewing the label and associated formulation records, you are aware the product contains up to 15% added solution.
  - a. Does the label comply with the §317.2(e)(2) of the regulations? Identify all noncompliance.

- b. Is the product misbranded?
- c. What actions should you take?

#### • Ingredients Statement (if needed)

§317.2(c)(2)—If a product is fabricated from two or more ingredients, the word "ingredients" followed by a list of ingredients as prescribed in paragraph (f) of this section... [§381.118(a)]

The word "ingredients" must be spelled out, never abbreviated. The ingredients must be listed by their common and usual name in descending order of predominance according to the amounts used in the product's preparation. There are a few exceptions.

Spices (e.g. mustard, pepper, etc.) and flavorings (e.g., oleoresin of black pepper, garlic oil, etc.) as defined in §317.2(f)(i) may be listed as "spice" or "flavoring" as appropriate in the ingredients statement. For instance, spices, spice extractives, essential oils, oleoresins, onion powder, garlic powder, celery powder, onion juice, and garlic juice may be listed as flavorings but flavorings (e.g., oleoresins, essential oils, etc.) cannot be listed as spices in the ingredients statement.

Ingredients present in individual amounts of 2% or less may be listed in other than descending order of predominance if:

- Such ingredients are listed by their common or usual name at the end of the ingredients statement; *and*
- Such ingredients are preceded by a quantifying statement such as "contains \_\_\_\_\_\_ percent of \_\_\_\_," or "less than \_\_\_\_\_ percent of \_\_\_\_." The blank before the word "percent" shall be filled with a threshold level of 2% (or less, as appropriate, e.g., 1.5%, 1%, or 0.5%). No ingredient subject to the quantifying statement may be present in an amount greater than the stated threshold. Such ingredients may be adjusted in the formulation without changing the label if the adjusted amount complies with §318.7(c)(4) or §381.147(f)(4) and does not exceed the stated threshold level.

# The ingredient statement must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food carton.

**Note:** For some products an ingredients statement can be substituted with a "Cured with statement." The label states "Cured with water, salt, sodium phosphate......"

The meat is left out and just includes all of the other ingredients. We see this with bacon, corned beef, ham, and other cured products.

#### • Signature Line

§317.2(c)(3)—The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section... [§381.122]

The name and place of business of the product's manufacturer, packer, or distributor is known as the signature line. The place of business shall be shown on the label by city, state, and zip code when the business is listed in a telephone or city directory; and if not listed in such a directory, the place of business shall also show the street address. The signature line must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food carton. When the product is prepared by one company and distributed by a different company, phrases like "prepared for..." or "distributed by" must precede the name and business address.

#### • Net weight statement (if needed).

317.2(c)(4)—An accurate statement of the net quantity of contents as prescribed in paragraph (h) of this section...[381.121(a)]

As stated in §317.2(h)(1) through (5), the net weight statement must:

- **Appear on the principal display panel** in a conspicuous and easily legible boldface print or type in distinct contrast to other material on the container.
- Not be false or misleading and shall express an accurate statement of the quantity of contents exclusive of wrappers and packing materials. The term "Net Weight" or "Net Wt." refers to contents in terms of weight. "Net Content" refers to fluid measure.
- Appear in the lower 30 percent portion of the principal display panel, unless otherwise exempt in the regulations. §317.2(h)(3)
- Be expressed in terms of Avoirdupois weight (US system) or liquid measure. Per §317.2(h)(4), a <sup>3</sup>/<sub>4</sub> pound retail package would be labeled "Net Wt. 12 oz.". Retail

packages containing one pound and less than four pounds are required to declare the net weight statement in *both* pounds and ounces (dual declaration), for example, "Net Wt. 24 oz (1 lb 8 oz)." per §317.2(h)(5).

The net weight statement has a size and a spacing requirement as specified in \$317.2(h)(6) through (8). \$317.2(h)(9) identifies several exemptions from the requirements for the net weight statement. A net weight statement is not required for bulk containers or wholesale (non-retail/consumer size) product, such as combo bins of product for further processing. However, if a net weight statement *is* on the bulk container it must be on the principal display panel and accurately represent net quantity of contents. Individual catch weight or random weight items are not required to have a net weight statement. However, the shipping container for these products must bear a net weight statement [317.2(h)(9)(i)]. Sliced shingle packaged bacon in rectangular containers is exempt from the placement and dual declaration requirements.

**Note:** Net weight may also appear in grams (g) on the label. Declaring net weight in grams does not remove other net weight requirements, and an optional net weight expressed in grams may not interfere with other net weight requirements.

#### Inspection Legend and Establishment Number

§317.2(c)(5)—An official inspection legend and...the number of the official establishment...[§381.123(a)(b)]

Labels on all products shall show an official inspection legend as illustrated in §312.2, §352.7, or §381.96 of the regulations. The inspection legend shall be in the exact form and arrangement as shown in the examples. It may be of any size, provided it is sufficient, and any color as long as it is conspicuous and readily legible. The proportions of letter size and boldness must be as illustrated in the regulations. **The legend must be located on the principal display panel or on the 20% panel of a cylindrical container.** 

As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling; for example, it may be located on the end of a can if it is prominent, legible, and accompanied by the prefix "Est". The establishment number may be located off the exterior of the container when there is

a statement identifying the location of the number; for example, "Est. No. on clip" is printed on a bag containing product.

#### • Handling Statement (if needed)

§317.2(*k*)—Packaged products which require any special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: [§381.125(a)]

- Keep Refrigerated.
- Keep Frozen.
- Perishable, Keep Refrigerated.
- Previously handled frozen for your protection. Refreeze or Keep Refrigerated.

**Note**: Except for canned perishable products (e.g., canned hams), there are no type or print size specifications for the handling statement.

#### • Safe handling instructions (if needed)

§317.2(I)—Safe handling instructions shall be provided for: all meat and meat products...that do not meet the requirements contained in §318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations for Fully Cooked Patties in §318.23 [§381.125(b)].

As described in §317.2(I)(1), the instructions are required to be prominently and conspicuously displayed on products (described above) destined for household consumers, hotels, restaurants and institutions (HRI). Lettering must be no smaller than 1/16 inch, set off by a border, all in one color on a single color contrasting background. The heading, "Safe Handling Instructions," must be in larger print than the rationale statement and the safe handling statements. The rationale statement identified in §317.2(I)(2) must be immediately after the heading and before the safe handling statements. The specific safe handling statements that must appear as part of the product's labeling are identified in §317.2(I)(3). Each statement must have the graphical illustration beside it.

Product that will be further processed at another official establishment is exempt from the safe handling requirements.

The safe handling instructions may be located anywhere on the outside of an immediate container.

#### • Nutrition Facts Panel (unless an exemption applies)

§317.300—(a) Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301 and are not major cuts of single-ingredient, raw meat products identified in §317.344, unless the product is exempted under §317.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in §317.344, either in accordance with the provisions of §317.309 for nutrition labels, or in accordance with the provisions of §317.345 for point-of-purchase materials, except as exempted under §317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in §317.301, nutrition labeling must be provided in accordance with the provisions of §317.301, nutrition labeling must be provided in accordance with the provisions of §317.309; except as exempted under §317.400.

FSIS requires nutrition labeling of the top 40 major cuts of single-ingredient, raw meat and poultry products (as defined in §317.344 and §381.444). This nutrition labeling must be on labels or at point-of-purchase, unless an exemption applies, however, the small business exemption specifically is not applicable to these cuts. FSIS also requires nutrition labels on all ground or chopped meat and poultry products as defined in §317.301 and §381.401 respectively, with or without added seasonings, unless an exemption applies. In addition, when a ground or chopped product does not meet the regulatory criteria to be labeled "low fat" (317.362(b)), a lean percentage statement may be included on the label or in labeling as long as a statement of the fat percentage that meets the specified criteria also is displayed on the label or in labeling when in compliance with §317.362(f) or §381.462(f). Note: Ground and chopped product does not include products such as sausage, meatballs, beef patties. The "ground/chopped" products only includes products named "ground beef," "hamburger," "ground pork," "ground chicken," "ground turkey," "chopped beef," etc.

The format of the nutrition panel shall be in accordance with §317 Subpart B. These regulations also prescribe the standard serving size, which nutrients are mandatory to list, and which are voluntary to list. Additionally, the other nutritional information

regulations specify requirements to be met before any nutritional claims, such as "light," may be made on the label. [§381 Subpart Y]

Nutrition labeling information may be shown on the principal display panel, on the information panel, or anywhere on the immediate container. There are exceptions for gift packs or when packaging doesn't allow for sufficient space (§317.302 or §381.402).

Establishments may voluntarily provide nutrition labeling for single ingredient, raw meat and poultry products that are not one of the top 40 major cuts, and are encouraged to do so.

The regulations in §317.302 exempt products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information. There are two criteria for exemption, 1) less than 500 employees AND 2) less than 100,000 pounds of a specific product formula/nutrition profile per year. When calculating the total pounds of a formula, both retail and custom exempt with all pack sizes are included. For example, an establishment has a ground beef 70/30 formula. This formula is sold in bulk, as patties, in various retail sized packages, under various brand names, for HRI, some retail exempt, and some as custom exempt. All of this ground beef 70/30 is counted together for the total pounds per year. Each specific product formula/nutrition profile will need to be evaluated for the small business exemption and both criteria need to be met for that product labeling to be exempt from bearing the nutrition facts panel. It is possible for popular products manufactured in quantities larger than 100,000 pounds per year to be exempt but other products with production lower than 100,000 pounds per year to be exempt even though they are manufactured in the same establishment.

The establishment has the responsibility to determine whether a product is exempted from the nutrition labeling requirements. The IPP should ensure that all products, except those identified by the establishment as exempted, carry the "Nutrition Facts" panel on the label. Guidelines for enforcing nutrition labeling of meat and poultry products can be found in FSIS Directives 7130.1 and 7221.1.

#### **Date of Packing/Processing**

Two types of product dating may be shown on a product label. "Closed Dating" and "Open Dating."

Packing codes are a type of closed dating which enable the tracking of product in interstate commerce. These codes consist of a series of letters and/or numbers applied by manufacturers to identify the date and time of production. They enable manufacturers to rotate their stock and locate their products in the event of a recall. The codes are not meant for the consumer to interpret as a best or peak quality date.

A calendar date applied to a food product by the manufacturer or retailer is a type of open dating. The calendar date provides consumers with information on the estimated period of time for which the product will be of best quality and to help the store determine how long to display the product for sale. For meat, poultry, and egg products under the jurisdiction of the Food Safety and Inspection Service (FSIS), dates may be voluntarily applied provided they are labeled in a manner that is truthful and not misleading and in compliance with FSIS regulations. If calendar dating is used, the requirements of §317.8(b)(32) and 381.129(c)(1)(2) must be met. The calendar date must express both the month and day of the month. In the case of shelf-stable and frozen products, the year must also be displayed. Additionally, immediately adjacent to the date must be a phrase explaining the meaning of that date such as "Packing", "Sell By", "Use Before" or "Best if Used By."

Either the immediate container or the shipping container of all poultry food products shall be plainly and permanently marked by code or otherwise with the date of packing (381.126(a)). The immediate container for dressed poultry must be marked with a lot number which must be the number of the day of the year on which the poultry was slaughtered (slaughter date) or a coded number (381.126(b)). Dressed poultry, for the application 381.126(b) of the regulations, means *slaughtered*, defeathered, eviscerated whole birds with the head and feet removed, i.e., a ready-to-cook whole bird. Canned products must exhibit a code or the date of canning (381.126(c)). Canned products may also display "open" or calendar dates. The IIC must be informed of the meaning of the code when the container is marked with a code (381.126(d)).

#### **Mandatory Features for Shipping Containers**

Shipping containers must bear the following mandatory features:

- Inspection legend [316.13(a)] and establishment number [317.2(i)]
- Handling statement (if needed) [317.2(k)]
- Net weight statement (if needed) [317.2(h)(9)(i)]

The establishment number may be located outside the inspection legend or elsewhere on the exterior of the container or its labeling if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix "EST."

**Note:** The shipping container must bear a *net weight* statement per 381.121(a) and the following statements: "*Tare weight* of consumer package \_\_\_\_\_ oz." (weighed to nearest 1/8 ounce or less), and the "Net wt." to be marked on consumer packages prior to display and sale" when *retail random weight poultry products* without the *net weight* statement are in the shipping container.

# §317.3—Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.

§317.3(a)—The Administrator may approve and authorize the use of abbreviations of marks of inspection under the regulations in this subchapter. Such abbreviations shall have the same force and effect as the respective marks for which they are authorized abbreviations.

Only LPDS may approve and authorize the use of abbreviated marks of inspection.

§317.3(b)—Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph apply only to labels, or other marking devices, bearing or containing an official inspection legend shown in §312.2(b), §312.3(a)...or §312.3(b) ... or any abbreviations, copy or representation thereof.

Except for samples to be submitted to FSIS for approval, no marking device containing an official mark can be made and no label bearing an official mark can be reproduced without authorization from FSIS. Once FSIS approves or authorizes its use, additional supplies of the label or marking device may be made without further approval. §317.3(c)—No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a brand or other marking device containing an official inspection legend, or simulation thereof, shown in §312.2(a), §312.3(a)..., § 312.3(b) ...or §312.7(a).

No brand or other marking device containing the official inspection legend can be made without an official certificate signed by an IPP authorizing its manufacture. §317.3(c)(1) through (4) describes the completion and distribution of the certificate, and the requirement that each brand or other marking device be identified with its own unique permanent serial number.

#### §412.1—Labeling approval.

§412.1(a)---No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in §412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS except for generically approved labels authorized for use in 9 CFR 412.2. A sketch label is a printers proof or the equivalent which clearly shows all labeling features, including the size, and location.

FSIS requires the submission of labeling applications for the following four categories:

- 1. Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
- Labels for products for export with labeling deviations other than foreign language on the label or net weight in accordance with the usage of the country to which the product is exported (9 CFR 412.1(c)(2))
- 3. Labels with special statements and claims (9 CFR 412.1(c)(3))
- Labels for temporary approval (9 CFR 412.1(c)(4)). Under certain conditions, LPDS may grant a temporary approval for the use of a final label that may be deficient in some particular for up to 180 calendar days

Any label that was previously approved as a sketch by FSIS qualifies to be used without any further approval.

"Special statements and claims" are claims, logos, trademarks, and other symbols on labels that are not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book, (except for "natural" and negative claims (e.g., "gluten free")), health claims, ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., "for cooking only" or "not tested for E. coli O157:H7"). Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims do not include allergen statements (e.g., "contains soy") applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

A parent company for a corporation may submit only one labeling application for a product produced in other establishments that are owned by the corporation. Establishments must maintain records to support the use of labeling on meat and poultry products. These records must be available to IPPs upon request. A company that has multiple establishments may keep the labeling file at corporate headquarters.

When LPDS approves a label or other labeling as a sketch, the label application is electronically stamped in the Label Submission and Approval System (LSAS) to indicate approval. The sketch may be modified by LPDS prior to approval to meet a labeling requirement. This sketch label will be stamped with "approved as modified". Once a label has been approved, approved as modified, or returned in LSAS; the submitter is notified via email. If the establishment submitted a paper copy of the label to LPDS, this paper copy is scanned into LSAS for review, and a hard copy is printed out and mailed back to the submitted once the label has been evaluated in LSAS.

The requirements for generically approved labels is covered in §412.2. IPP do not generically approve labels. Establishments do not generically approve labels. Generically approved labels are considered to be approved by FSIS provided that the label meets the criteria listed in §412.2(b). "Approved by FSIS" refers to compliance with the FSIS 9 CFR regulations, it does not mean that the labels have been submitted to Labeling and Program Delivery Staff (LPDS).

All labels that do not fit into one of the four categories (above) described in §412.1, with the exception of egg product labels and exotic species labels, are eligible for generic

approval. Some labels eligible for generic approval based on the regulations include labeling for:

- Geographic claims such as "German Brand Made in the US" in compliance with §317.8(b)(1).
- Allergen statements (e.g. "contains soy") applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FDA).
- Labels that bear claims and statements that are defined in FSIS regulations or the Food Standards and Labeling Policy Book (*except for natural and negative claims*).

The responsibility of ensuring that generic labeling complies with regulatory requirements rests with the establishment. The establishment is responsible for creating the generic labeling record and is required to keep a copy of all generic labeling and related information in its files. A corporate headquarters may create and maintain the labeling files for their associated establishments. When labeling records are needed, the IPP may request the labeling records from the assigned establishment. The labeling records are required to be made available to the requesting IPP within 24 hours (FSIS Directive 7221.1).

There is no specific format for a generic labeling record, however, it is required to include all information in FSIS Form 7234-1 that would be provided to LPDS as if they were submitting for sketch approval. Some establishments choose to use the FSIS 7234-1 form since they are familiar with the form and it is a reminder of what information is needed in the labeling record but they could provide all required information in another format. The labeling record should also include the final printed labeling that will be used on the finished packaged product and any supporting information that may be needed to verify that labeling is truthful and not misleading. Some companies choose to number their generic approvals as a way to track them internally, but there is no FSIS requirement to do so.

**Note:** The establishment's product formulations and other proprietary information should not be in IPP files or in the IPP possession except when he or she is performing an inspection task related to the product's formulation.

§317.8—False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

§317.8(a)—No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading. [§381.129(a)(b)]

The product or its packaging material may not bear any false or misleading label, marking or labeling. No written or graphic material on the product label or in its marking or labeling may convey a false impression or give a false indication of contents. A product's packaging material color, design or kind may not be misleading. Product that bears false or misleading marking or labeling is misbranded.

§317.8(b)(1)-(40) list requirements that product labels and containers must comply with to prevent them from having a false or misleading feature. A few examples are given below.

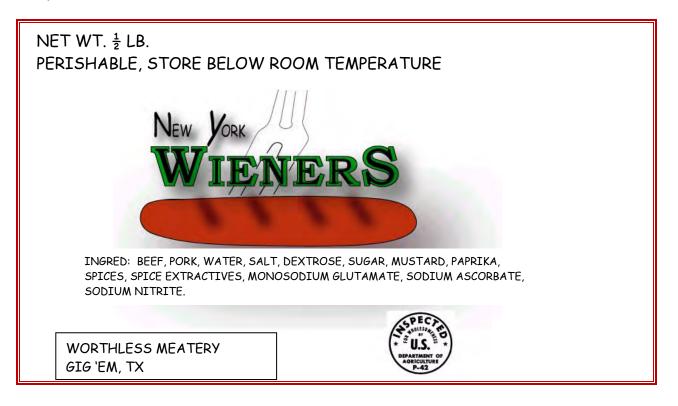
§317.8(b)(1)—Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word "style," "type," or "brand," as the case may be, in the same size and style of lettering as in the geographical term, and accompanied with a prominent gualifying statement identifying the country, State, Territory, or locality in which the product is prepared, using terms appropriate to effect the gualification. When the word "style" or "type" is used, there must be a recognized style or type of product identified with and peculiar to the area represented by the geographical term and the product must possess the characteristics of such style or type, and the word "brand" shall not be used in such a way as to be false or misleading: Provided, that a geographical term which has come into general usage as a trade name and which has been approved by the Administrator as being a generic term may be used without the qualifications provided for in this paragraph. The terms "frankfurter," "vienna," "bologna," "lebanon bologna," "braunschweiger," "thuringer," "genoa," "leona," "berliner," "holstein," "goteborg," "milan," "polish," "italian," and their modifications, as applied to sausages, the terms "brunswick" and "irish" as applied to stews and the term "boston" as applied to pork shoulder butts need not be accompanied with the word "style," "type," or "brand," or a statement identifying the locality in which the product is prepared.

§317.8(b)(6) states the word "fresh" cannot be used on the label of a product that contains sodium or potassium nitrate or nitrite or salt at a level that preserves it.

§317.8(b)(31) states that the term "blood" must be in the product name when a product has been prepared with livestock blood and the specific kind of blood must be identified in the ingredients statement, e.g., Swine Blood.

#### **General Label Review Workshop**

You are a CSI covering a very small "mom and pop" wiener processing establishment that employees two people located in Cut and Shoot Texas. It produces one product (New York Wieners in ½ lb packages) that conforms to the standard of identity in §319.180. The production volume has averaged 1,800 pounds per week over the past 2 years. Today, you have scheduled a General Labeling task and decide to verify whether the label (below) being applied to a lot of wieners complies with regulatory requirements.



After reviewing the label, identify all noncompliance with the regulatory requirements and provide the corresponding regulation(s).

# §317.10—Reuse of official inspection marks; reuse of containers bearing official marks, labels, etc.

§317.10(a)—No official inspection legend or other official mark which has been previously used shall be used again for the identification of any product, except as provided for in the following paragraph.

§317.10(b)—All stencils, marks, labels, or other labeling on previously used containers, whether relating to any product or otherwise, shall be removed or obliterated before such containers are used for any product, unless such labeling correctly indicates the product to be packed therein and such containers are refilled under the supervision of a Program employee.

Official inspection legends or other official marks cannot be reused on product. Product containers can be reused if the establishment removes or obliterates all marks, labels or labeling that is on the containers before refilling them. The labeling does not need to be removed if it will accurately reflect the product being placed into the container. When these containers are used, they must be refilled under the supervision of the IPP.

# §317.11—Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.

§317.11(a)—No person shall in any official establishment apply or affix, or cause to be applied or affixed, any label to any product prepared or received in such establishment, or to any container thereof, or fill any container at such an establishment, except in compliance with the regulations in this subchapter.

The official establishment may not attach or affix a label to product or to a container or fill a container unless all regulatory requirements have been met.

§317.11(b)—No covering or other container shall be filled, in whole or in part, at any official establishment with any product unless it has been inspected and passed in compliance with the regulations in this subchapter, is not adulterated, and is strictly in accordance with the statements on the label, and such filling is done under the supervision of a Program employee.

Again, only inspected and passed product that has met all regulatory requirements (unadulterated, accurately label, etc.) may be packaged. Packaging and labeling

operations must be performed under the supervision of an IPP. Remember, "under the supervision of the IPP" has been interpreted to mean while the IPP is on duty. §317.11(c)—No person shall remove, or cause to be removed from an official establishment any product bearing a label unless such label is in compliance with the regulations in this subchapter, or any product not bearing a label required by such regulations.

A product's label or labeling must comply with the regulatory requirements before it is shipped from the establishment. Products that must carry a label cannot be shipped from the establishment without being labeled.

#### §317.12—Relabeling products; requirements.

When it is claimed by an official establishment that any of its products which bore labels bearing official marks has been transported to a location other than an official establishment, and it is desired to relabel the product because the labels have become mutilated or otherwise damaged, a request for relabeling the product shall be sent to the Administrator, accompanied with a statement of the reasons therefor. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with labels bearing any official marks shall be done under the supervision of a Program inspector. The official establishment shall reimburse the Program...for any cost involved in supervising the relabeling of such product. [§381.140]

If the establishment needs to relabel inspected and passed product that is stored at an off-premises location because the labels are mutilated or damaged or for any other reason, it must obtain permission from the DO. The official establishment cannot ship the labels to the off-premises location until it has received DO permission to relabel the product. The DO will make arrangements for IPP to supervise the relabeling. The establishment must pay FSIS for this reimbursable service.

#### §317.13—Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material

involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter. [§381.138(b)]

The movement of labels, wrappers, or containers bearing the official mark of inspection from one official establishment to another official establishment is allowed if the originating establishment obtains prior authorization from the IIC. LPDS approval is not required for the movement of such labeling however depending on the intended use of such labeling LPDS sketch or temporary approval may be required, or in other situations the receiving company may use the generic regulations for sketch approval to use the labeling. To identify product origin in the event of a product control problem (e.g., product recall), establishments must document the transfer of labels and their subsequent use. These records must be available to the IPP upon request. **FSIS Directive 7000.4** provides guidance in how to verify that certain transferred labeling was done in accordance with the regulations. Before transferring Child Nutrition (CN) labels, establishments must also obtain prior approval from the USDA, Food and Nutrition Service.

#### §317.16—Labeling and containers of custom prepared products.

Products that are custom prepared...must be **packaged immediately** after preparation and **must be labeled**...with the words "**Not For Sale**" in lettering not less than threeeighth inch in height.

Custom prepared product must be properly labeled and have a prominent "Not for Sale" statement. The establishment may include additional labeling on custom prepared products or their containers provided it is not false or misleading.

#### §317.24—Packaging materials.

§317.24(a)—Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA). [§381.144(a)]

# Part 442—Quantity of Contents Labeling and Procedures and Requirements for Accurate Weights.

§442.1—This part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with 9 CFR 317.2(c)(4), 317.2(h), and 381.121.

### **NFSCP PHIS Task**

#### Performing the General Labeling Task

Inspection program personnel perform this task to verify general labeling regulatory requirements and determine if the label accurately reflects the finished product.

#### • General Labeling Requirements

Verifying that the general labeling requirements involves:

- o observing the application of the label or labeling,
- o selecting labels and labeling for review, and
- o reviewing the establishment's labeling records

When IPP observe the packaging and labeling operations, they ensure that immediate containers of meat and poultry products have a label attached to them and that shipping containers bear the required information.

When IPP select and review the label/labeling applied to the container or package, they determine if:

- the label contains the mandatory features and other required information such as a qualifying statement or descriptive designation, and
- any printing or colors on the label and packaging material gives a false impression or does not meet specific formatting criteria

Product is misbranded if its label is missing a required feature, qualifying statement, or descriptive designation or is anyway false or misleading.

When IPP review the establishment's labeling file, they determine if the:

- label is on file and either met the generic approval requirements or was sketch approved by LPDS,
- label required sketch approval by LPDS and if so, the sketch is attached to the final label,
- label is being used beyond the expiration date if it has been granted a temporary approval by LPDS, and
- product's formulation (if applicable) and processing procedures are attached to or accompany the label/labeling.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure misbranded product does not enter commerce.

#### • Label Accurately Reflects the Product

Determining that the label accurately reflects the finished product involves reviewing the product's formulation record and observing its actual preparation and in some cases performing formula calculations.

When IPP perform this task, they should select one or more batches of product at formulation and verify ingredient amounts comply with the formula on file and that no undeclared ingredients are added or declared ingredients are omitted.

The verification may involve:

- o observing pre-weighed ingredients for proper identification and weights, or
- o observing establishment employees weighing ingredients or
- actually weighing pre-weighed ingredients to determine if the weight on the container is accurate.

An ingredient added at a different level than indicated in the product formula could affect the ingredient order of predominance on the label. The product is misbranded if a declared ingredient is omitted, an ingredient is added but not declared on the label, or the ingredient order of predominance is not accurate. Depending on the type of undeclared ingredient (e.g., an allergen) that is added to the product, it may be either adulterated or misbranded or both.

The regulations and many product standards of identity allow the establishment to add various ingredients to the formulae of certain meat and poultry products. Some meat and poultry components used in the formulation may have regulatory limits. Some nonmeat ingredients have a specified maximum amount or percentage allowed in the product. These nonmeat ingredients are called **restricted** ingredients. The establishment **MAY** add the component or ingredient in any amount up to its permitted limit.

If the product is formulated with a meat or poultry component with a regulatory limit or with a restricted ingredient, the IPP should select one or more batches of product during formulation. They should determine the amount or percentage of the meat or poultry component and/or the amount one or more restricted ingredients used in the formula. The IPP verifies that the:

- o percentage of meat or poultry component meets the regulatory limit,
- o restricted ingredient is allowed in the product, and
- the amount of the restricted ingredient added to the product does not exceed the regulatory limit.

Verifying meat and poultry components or restricted ingredients are in compliance with regulatory limits usually requires the IPP to perform a formula calculation.

When meat or poultry components or restricted ingredients are added at levels in excess of their maximum regulatory limit, they become **economic adulterants**.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure adulterated or misbranded product does not enter commerce.

## Labeling Summary Workshop

### Scenario

You are a CSI with a small raw ground beef product establishment on your assignment. The establishment produces ground beef patties, hamburger patties, and beef patties. *The standards of identity for these products are provided at the end of the workshop.* 

The establishment has one HACCP plan under the Raw Product Non-Intact HACCP category. The company has 50 employees and produces about 50,000 lbs of raw beef products a week. It operates two continuous production lines 8 hours per day, 5 days per week. Half of the total production is 70/30 ground beef plus 70/30 hamburger the other half is beef patties; the establishment has determined one day's production of a raw beef product is a lot.

The ground beef patties are 100% beef and produced using a two-step grinding method. The hamburger patties and beef patties have non-meat ingredients added at the blending step. The process of producing these patties involves a coarse grind, mixing and blending the meat and ingredients, and a final grind. Ingredients added to the hamburger patties include: salt, and spices. Ingredients added to the beef patties include: water, salt, dried onions, natural flavorings and soy flour. The company does not rework broken or misshaped patties and it does not accept returned products. The patties are distributed in shelf ready 36 ounce trays or bulk packed in 20 lb boxes.

The General Labeling task appears on your task schedule today.

1. Describe how you should perform this task?

You make your way to the production floor and ask the production supervisor what raw beef products are being produced. She states that tray packed beef patties are being

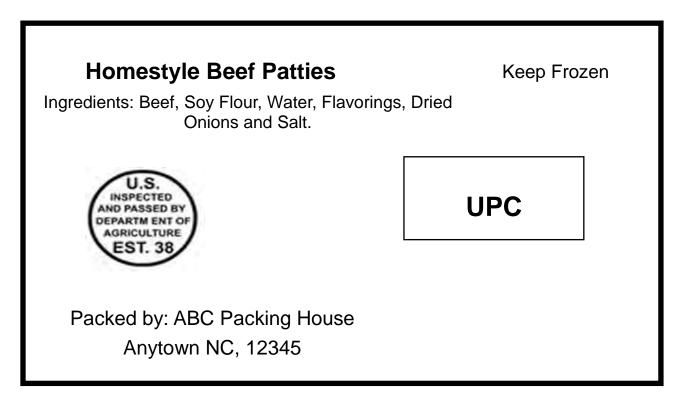
produced on both lines. You review the labels, product formulation, and production procedures for the beef patties on file in the production supervisor's office.

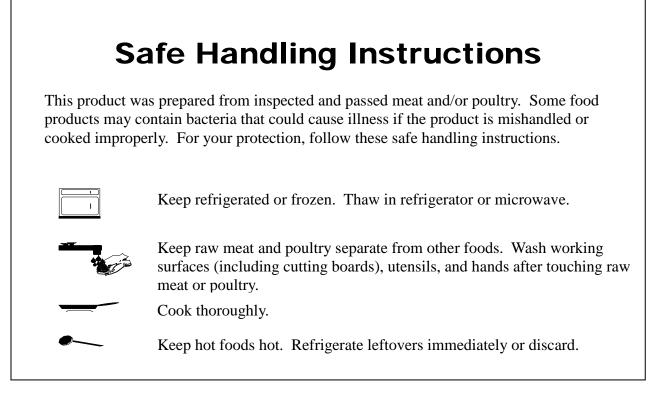
You decide to verify product formulation. So, you observe the following ingredients added to the large blender on line 1 and line 2.

300.0 lb 60/40 Beef Trimmings 85.0 lb Water 60.0 lb Soy Flour 25.0 lb Flavorings 17.5 lb Dried Onions <u>12.5 lb Salt</u> Total batch 500 lbs

You follow the product through the process. At the packaging step for *line one*, you observe the label/labeling being placed on the trays (immediate container) and the labeling on the pre-printed shipping container.

The label below is being placed on the top of the tray and the safe handing instructions are placed on the bottom of the tray. This is the only labeling applied to the trays.





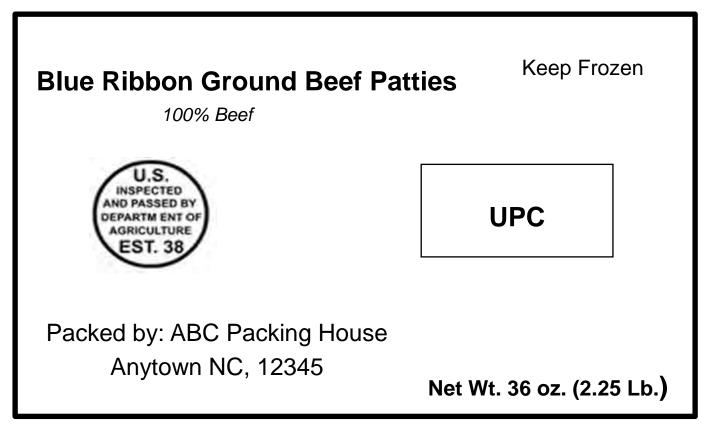
The shipping container has the inspection legend on it in the upper right corner. This is the only printed information on the outside of the box, no other labeling is being applied.



At the packaging step for *line two*, you observe the label/labeling being placed on the trays (immediate container) and the shipping container markings.

The label below is being placed on the top of the tray and the safe handing instructions illustrated above are placed on the bottom of the tray. This is the only labeling applied to the trays. The shipping container for these trays has the inspection legend on it in the

upper right corner - this is the only printed information on the outside of the shipping container.



2. Based on the review of the product formulation and the labeling applied to the immediate containers and shipping containers, has the establishment produced misbranded product? Yes or No for each LINE and explain Why for each LINE.

LINE 1	LINE 2
Label:	Label:
Shipper label:	Shipper label:

3. Based on the review of the product formulation and the labeling applied to the immediate containers and shipping containers, has the establishment produced adulterated product? Yes or No for each LINE and explain Why for each LINE.

LINE 1	LINE 2

4. Is there a food safety hazard associated with the production of the product? Yes or No for each LINE and explain Why for each LINE.

LINE 1	LINE 2

5. What action(s) should you take next?

You review the establishment's HACCP plan and hazard analysis. The establishment found that food allergens were potential food safety hazards, but determined that they were not likely to occur in this process because the establishment has a food allergen control program which prevents the hazard. You review the establishment's food allergen control program. You find that the establishment lists several daily in-plant checks and verification activities and the associated documentation that will be kept. You request recent records and your review reveals that the food allergen control program verification activities are not being done at the frequency listed in the program. Records are also not available for some of the days.

6. Which corrective action regulation would apply in this situation?

7. How should you document the finding of this task? What regulations would you cite?

- 8. What action should you take next?
- 9. Could what you observed indicate an inadequate food safety system?

## **Workshop Reference Materials**

#### **Product Standards**

FSIS regulations prescribe standards of identity, or composition, for many meat and poultry products. Standards of identity set specific requirements for a products make - up. For instance, a product standard may identify:

- the kind and percentage of meat or poultry required in the product,
- the maximum percentage of a non-meat/non-poultry ingredient allowed in the product,
- the maximum percentage of a specific meat or poultry ingredient such as beef cheek meat or Mechanically Separated (Species)
- ingredients that are allowed or expected in the product, and
- in some situations, any ingredient that **is not** allowed in the product.

Non-meat ingredients that have a maximum percentage allowed in the finished product are called **restricted ingredients**. The establishment MAY add the ingredient in any amount up to its **permitted limit**. When restricted ingredients are added at levels in excess of the regulatory limit, **they become adulterants**.

### §319.15 Miscellaneous beef products.

(a) *Chopped beef, ground beef.*" Chopped Beef" or "Ground Beef" shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product.

(b) *Hamburger.* "Hamburger" shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.

(c) *Beef patties.* "Beef Patties" shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, mechanically Separated (Species) used in accordance with §319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat pattie.

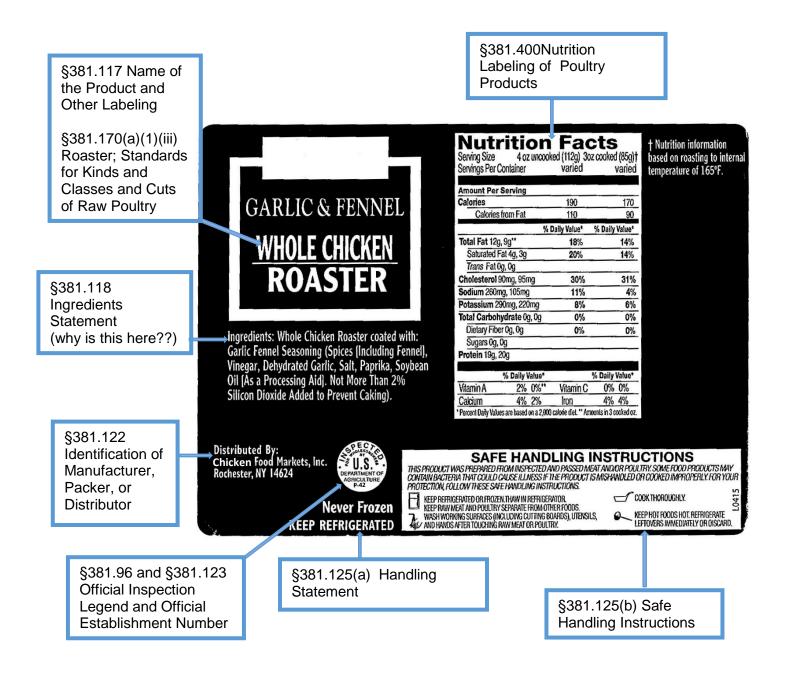
## Attachment 1: FSIS Directive 7221.1 Table 1 Required Label Features

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend and Establishment Number*	9 CFR 317.2(c)(5) or 381.123	Principal display panel, or 20% panel of a cylindrical container	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement**	9 CFR 317.2(f) or 381.118	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	Products with multiple ingredients
Name and Place of Business of the Manufacturer, Packer, or Distributor	9 CFR 317.2(g) or 381.122	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Principal display panel or Information panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Anywhere on the immediate container	Products with a not- ready-to-eat meat or poultry component

\*NOTE: As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling; for example, it may be located on the end of a can if it is prominent, legible, and accompanied by the prefix "Est". The establishment number may be located off the exterior of the container when there is a statement identifying the location of the number; for example, "Est. No. on clip" is printed on a bag containing product.

**\*\*NOTE**: All ingredients used in the product must be listed in the ingredients statement. Product is considered adulterated if an allergen is not listed in the ingredients statement. IPP are to contact their supervisor for guidance if at any time they have reason to believe that product failing to declare one of the "big 8" allergens [wheat, crustacean shellfish (e.g. crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g. almonds, pecans, walnuts), and soybeans] or other ingredients of public health concern has entered commerce. FSIS ingredient and allergen compliance guidelines are available online.

## Attachment 2: Poultry Label with Mandatory Features Identified



Note: This is a random weight product (e.g., the weight of each whole chicken will naturally vary), the retailer is responsible for applying the net weight to the retail package prior to display for retail sale, §381.121(a).

# **Attachment 3: Current Nutrition Labeling Format Examples**

Full Format-As Packaged – 9 CFR

Nutr	itio	n Fa	cts
Serving Si	ze 1 cup	(228g)	
Servings P	er Conta	iner 2	
Amount Pe	r Serving		
Calories	260 Calo	ries from	Fat 120
		% Da	ily Value*
Totai Fat	13g		20%
Saturated	d Fat 5g		<b>25</b> %
Choleste	rol 30mg		10%
Sodium 6	60mg		28%
Total Car	bohydra	<b>te</b> 31g	10%
Dietary F	iber 0g		0%
Sugars 5	g		
Protein 5	g		
Vitamin A 4	• %	Vitarr	nin C 2%
Calcium 15	• •	Iron 4	1%
<ul> <li>Percent Dail calorie diet. or lower dep</li> </ul>	Your daily v	alues may l	be higher
	Calones:	a she is a state of the state o	2,500
Total Fat	Less than		80g
Sat Fat	Less than		25g
Cholesterol	Less than Less than	300mg 2.400mg	300mg 2,400mg
Sodium Total Carboh		2.400mg 300g	375g
Dietary Fib		25g	30g
Calories per Fat 9 • Car	gram:		4

Full Format-As Prepared – 9 CFR

Our income	(44g, about 1/4 cup dry mix) Servings Per Container 12			
Servings P	er Contai	ner 12		
Amount Per	Serving	Mix	Bake	
Calories		190	280	
Calories f	rom Fat	45	140	
		% Del	ly Value	
Total Fat	5g*	8%	. 24%	
Saturated	the second se	10%	13%	
Cholester		0%	23%	
Sodium 3		13%	13%	
Total			a for all table ( 10	
Carbohyd	rate 34g	11%	11%	
Dietary Fi	ber 0g	0%	0%	
Sugars 18	3g			
Protein 2	)			
Vitamin A		0%	0%	
Vitamin C		0%	0%	
Calcium		6%	8%	
Iron		2%	4%	
*Amount in Mit	x			
** Percent Dai				
calorie diet. or lower dep				
or lower oep	Calories:		2,500	
Total Fat	Less than		80g	
Sat Fat	Less than	200	25g	
Cholesterol	Less than	300mg	300mg	
Sodium	Less than	2,400mg	2,400mg	
Total Carboh	ydrate	300g	375g	
10108 008 0001			30g	

The FDA formats (from 21 CFR) may be used voluntarily provided the company has LPDS sketch approval for each different format that will be used.

## Tabular Format<sup>†</sup> FDA 21 CFR 101.9(d)11(iii)

Nutrition	Amount/serving	% Daily Value*	Amount/serving	% Daily Value*	
	Total Fat 1.5g	2%	Total Carbohydrate 36g	13%	* The % Daily Value (DV) tells you how
Facts	Saturated Fat 0.5g	3%	Dietary Fiber 2g	7%	much a nutrient in a serving of food
10 servings per container	Trans Fat 0.5g		Total Sugars 1g		contributes to a daily diet. 2,000
Serving size 2	Cholesterol 0mg	0%	Includes 1g Added Sugars	2%	calories a day is
slices (56g)	Sodium 280mg	12%	<b>Protein</b> 4g		used for general nutrition advice.
Calories 170	Vitamin D 0mcg 0% • Calc Thiamin 15% • Riboflavin	U	ng 6% • Potassium 470mg 10%		

#### Dual Column Display, Per Serving and Per Container<sup>†</sup> FDA 21 CFR 101.9(e)(6)(i)

	1	2 servings per containerServing size1 cup (255g)			
			<sup>ontaine</sup>		
	% DV*		% DV		
5g	6%	10g	13%		
2g	10%	4g	20%		
0g		0g			
15mg	5%	30mg	10%		
240mg	10%	480mg	21%		
35g	13%	70g	25%		
6g	21%	12g	43%		
7g		14g			
4g	8%	8g	16%		
9g		18g			
			50%		
			30%		
1mg	6%	2mg	10%		
	22 5g 2g 0g 15mg 240mg 35g 6g 7g 4g 9g 5mcg 200mg	5g         6%           2g         10%           0g         15mg         5%           240mg         10%         35g         13%           6g         21%         7g         4g         8%           9g         5mcg         25%         200mg         15%           1mg         6%         10%         10%         10%	2220         44           % DV*         5g         6%           2g         10%         4g           0g         0g         0g           15mg         5%         30mg           240mg         10%         480mg           35g         13%         70g           6g         21%         12g           7g         14g         8g           9g         18g         18g           5mcg         25%         10mcg           200mg         15%         400mg           1mg         6%         2mg		

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

## Tabular Display for Small or Intermediate-Sized Packages<sup>†</sup>

FDA 21 CFR 101.9(j)(13)(ii)(A)(1)

Nutrition	Amount/serving	% DV Amount/serving	% DV	
Facts	Total Fat 2g	3% Total Carb. 15g	5%	
5 servings	Sat. Fat 1g	5% Fiber 0g	0%	
per container	Trans Fat 0.5g	Total Sugars 14g		
Serving size	Cholesterol 10mg 3%	Incl. 13g Added Sugars 26%	Sodium	
1/6 cup (28g)	200mg	9% Protein 3g		
Calories per serving <b>90</b>	Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%			

## Linear Display for Small or Intermediate-Sized Packages (with nutrients in 8 point font)<sup>†</sup>

FDA 21 CFR 101.9(j)(13)(ii)(A)(2)

#### Nutrition Facts Servings: 12, Serv. size: 1 mint (2g),

Amount per serving: **Calories 5,Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest**. 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb**. 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (6% DV).

## Linear Display for Small Packages (with < 12 sq. in. of labelling space)<sup>†</sup> FDA <sub>21 CFR 101.9(j)(13)(i)(B)</sub>

Nutrition Facts Servings: 12, Serv. size: 1 mint (2g), Amount per serving: Calories 5, Total Fat 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, Cholest. 0mg (0% DV), Sodium 0mg (0% DV), Total Carb. 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), Protein 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (6% DV).