

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

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# FSIS DIRECTIVE

7221.1  
Rev. 1

1/6/14

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## PRIOR LABELING APPROVAL

### I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for conducting the General Labeling task in the Public Health Information System (PHIS). FSIS is reissuing this directive because the final rule "Prior Label Approval System: Generic Label Approval," effective January 6<sup>th</sup>, 2014, expands generic label approval.

#### KEY POINTS:

- *Generic label approval criteria have been expanded and are in 9 CFR 412.*
- *Any label that does not require evaluation by the Labeling and Program Delivery Staff (LPDS) as described in 9 CFR 412 is generically approved by FSIS without evaluation if the label displays all mandatory label features in compliance with applicable Federal regulations.*
- *IPP are to verify establishments receive necessary label approval and compliance with labeling requirements through the General Labeling task in PHIS.*

### II. CANCELLATION

FSIS Directive 7221.1 amend. 1., Prior Labeling Approval, dated 08/19/1996

### III. LABEL APPROVAL

A. Labeling and Program Delivery Staff (LPDS): The staff in the Office of Program and Policy Development (OPPD) responsible for implementing the Agency's prior label approval system. LPDS also develops labeling policy, guidance to industry, and necessary instructions to IPP.

B. Prior Label Approval: All labels are to be approved before use (9 CFR 412.1(a)). Prior approval in the form of sketch approval or temporary approval from LPDS is to be obtained for labels described in 9 CFR 412.1(c). Prior approval is granted generically without submission to LPDS for labels that meet the requirements of 9 CFR 412.2.

C. Generic Label Approval: Prior approval of labels granted by the Agency without the company submitting the labels to LPDS for approval. Any label that does not meet one of the criteria in 9 CFR 412.1(c) is generically approved without submission to LPDS, provided the label displays all mandatory label features in compliance with applicable Federal regulations (9 CFR 412.2(b)).

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**DISTRIBUTION:** Electronic

**OPI:** OPPD

D. Sketch Label Approval: A sketch label is a printer's proof or other version that clearly shows all required label features, size, location, and indication of final color. FSIS approves sketch labels after companies submit them to LPDS, and LPDS finds the label features meet regulatory requirements. Sketch approval is required for all labels described in 9 CFR 412.1(c).

E. Final Label Approval: A final label is a label that is applied to product before leaving the establishment. Final labels are approved generically without review from LPDS.

#### **IV. BACKGROUND**

A. On November 7<sup>th</sup>, 2013, FSIS published the final rule "Prior Label Approval System: Generic Label Approval" (78 FR 2013-26639). This rule amended the Federal meat and poultry products inspection regulations found in 9 CFR to expand the circumstances under which labels for meat and poultry products can be generically approved. FSIS also combined the regulations that provide for the approval of labels for meat and poultry products (9 CFR 317.4, 317.5, 381.132, and 381.133) into a new CFR part, 9 CFR 412.

B. The final rule expands the circumstances under which labels are eligible for generic approval. IPP are to continue to verify that labels comply with regulatory requirements through the General Labeling task assigned in PHIS, whether labels are generically approved or sketch approved by LPDS.

C. Effective January 6<sup>th</sup>, 2014, 9 CFR 412.1(c) specifies the four categories of labels that are to be evaluated and specifically approved by LPDS before use. These are:

1. Labels for temporary approval;
2. Labels for products prepared under religious exemption;
3. Labels for products for export with deviations from FSIS labeling requirements; and
4. Labels with special statements and claims. Special statements and claims are explained in detail in an FSIS [compliance guide](#) that is maintained online.

D. Any label that is not included in one or more of the above categories is generically approved if the label displays all mandatory label features in compliance with applicable Federal regulations (9 CFR 412.2). Refer to Table 1 in section V paragraph C for a list of the mandatory label features.

E. IPP are to be aware that establishments are responsible for ensuring that labels used for meat and poultry products is not false or misleading, and for ensuring that labels comply with the Federal meat and poultry products inspection regulations and policies.

F. IPP are to be aware that sketch labels (as defined in 9 CFR 412.1(d)), along with a completed form 7234-1 and all supporting documentation are to be submitted to LPDS for evaluation, except for labels that are generically approved. Labels that are to be submitted for evaluation are described in 9 CFR 412.1(c) (Section IV, part C of this Directive). Label

submissions may be mailed or faxed in duplicate, or entered into the FSIS [Label Submission and Approval System](#) (LSAS). If a label is generically approved or sketch approved by LPDS, establishments may print a final label, create a final label record in accordance with 9 CFR 320.1(b)(11) and 9 CFR Part 381.175(b)(6), and use the label in commerce without further authorization from FSIS.

G. Final labels that are not in compliance with Federal meat and poultry products inspection regulations may still be granted temporary approval under the conditions listed in 9 CFR 412.1(f). The final label along with a completed form 7234-1 and all supporting documentation, including support for conformity to the conditions in 9 CFR 412.1(f), are to be submitted to LPDS for temporary approval. Label submissions may be entered into LSAS, or mailed or faxed in duplicate to LPDS.

## V. IPP VERIFICATION ACTIVITIES IN OFFICIAL ESTABLISHMENTS

A. IPP in meat and poultry establishments are to continue to perform the General Labeling task when scheduled in PHIS. When scheduled, IPP are to randomly select one or more labels for verification from products in production at the assigned establishment.

B. IPP are to verify that the establishment is maintaining records of the selected labels in accordance with 9 CFR 320.1(b)(11) for meat products and 9 CFR Part 381.175(b)(6) for poultry products. Labeling records are to be made available to FSIS field personnel and any authorized USDA official within 24 hours of request. Each labeling record should include: a copy of the final label that is in use, the product formulation, the processing procedure for the product, and any supporting documentation needed to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling as described in 9 CFR 412.1. If the label requires LPDS evaluation per 9 CFR 412.1(c), FSIS form 7234-1, Application for Approval of Labels, Marking, or Device, is to be included in the labeling record and is to indicate that approval has been granted by LPDS. The final label is to comply with modifications and conditions of use put forth by LPDS in the label approval [9 CFR 412.1(a)].

C. IPP are to verify regulatory compliance of the final label by reviewing it for the presence of all applicable required features listed in Table 1: Required Labeling Features.

**Table 1: Required Labeling Features**

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend	9 CFR 317.2(c)(5) or 381.123	Principal display panel	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	Information panel or Principal display panel	Products with multiple ingredients

Address Line	9 CFR 317.2(g) or 381.112	Information panel or Principal display panel	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Information panel or Principal display panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Information panel or Principal display panel	Products with a not-ready-to-eat meat or poultry component

**\*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.

## VI. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. IPP are to document the results of their verification, including any noncompliance, in PHIS in a manner that accords with Chapter VI of FSIS PHIS Directive 7000.1, Verification of Non-food Safety Consumer Protection Regulatory Requirements.

B. When a label requires LPDS review and approval prior to use, and the labeling record does not include LPDS approval for that label, IPP are to document the noncompliance on a Noncompliance Record (NR) in PHIS, citing 9 CFR 412.1 as the relevant reference. If IPP are unsure as to whether a label requires LPDS approval, they are to contact LPDS for direction as identified in section IX of this directive. IPP are to retain any product bearing a label that requires, but has not received, LPDS approval. The establishment may take corrective action by obtaining label approval through LPDS as described in section IV, paragraph F, of this directive or by replacing the noncompliant labels with labels that have received prior approval and are in compliance with Federal meat and poultry inspection regulations and policies.

C. When a label is not in compliance with regulatory requirements, IPP are to document the noncompliance on an NR in PHIS, citing the relevant reference from Table 1. IPP are to retain any product bearing that label. The establishment may take corrective action by obtaining temporary label approval through LPDS, bringing the labels into compliance with a pressure-sensitive sticker, or replacing the noncompliant labels with compliant labels.

D. There may be times when an inspector is not performing the General Labeling task but observes a product label that is not in compliance with Federal meat and poultry regulations. For example, if during the course of duty, IPP find that an ingredient is not declared on the final label, the net weight is incorrect, or the order of predominance of the ingredients on the label is inaccurate, IPP are to initiate a directed General Labeling task, retain affected product, and document the noncompliance in PHIS as described above.

## VII. SUPERVISORY RESPONSIBILITIES

A. Supervisors are to ensure that IPP are familiar with reviewing, and know how to review, labels and labeling records.

B. When “big 8” allergens or other ingredients of public health concern are not properly declared, a recall may be warranted. The FLS is to alert the District Office to potential distribution of products that pose a public health concern. Refer to [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products* for additional information on the recall of meat and poultry products.

## VIII. DATA ANALYSIS

PHIS tracks the inspection activities conducted by IPP. OPPD will review data from both the routine and directed PHIS General Labeling task, along with associated compliance and noncompliance data with respect to applicable regulations, to determine whether potential trends exist. Findings will be shared with the Office of Field Operations.

## IX. QUESTIONS

Refer questions regarding this directive to the Labeling and Program Delivery Staff through [askFSIS](#) or by telephone at 1-301-504-0878. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: **Directive 7221.1.**

Question Field: Enter question with as much detail as possible.

Product Field: Select **Labeling** from the drop-down menu.

Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue**.



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