FSIS DIRECTIVE

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 to align with the expansion of generic labelling approval eligibility established by the final rule, "Prior Label Approval System: Expansion of Generic Label Approval" [88 FR 2798], which is effective as of March 20, 2023. This revision also clarifies that, as part of the General Labeling task, IPP are to routinely verify that establishments make required modifications to their labels prior to use in commerce.

KEY POINTS:

- *FSIS has expanded the generic label approval criteria in 9 CFR part 412.*
- *Any label that does not require evaluation by the Labeling and Program Delivery Staff (LPDS) as described in 9 CFR part 412 is generically approved without evaluation if the label displays all mandatory label features in compliance with applicable Federal regulations.*
- *After March 20, 2023, LPDS will no longer evaluate generically approved labels that firms voluntarily submit for review.*
- *IPP are to continue to verify establishments receive necessary label approval and compliance with labeling requirements through the General Labeling task in PHIS.*
- *When conducting the General Labeling task in PHIS, IPP are to routinely select both labels that require a prior label approval from LPDS and those that are eligible for generic approval*.

II. CANCELLATION

FSIS Directive 7221.1 Revision 2, *Prior Labeling Approval*, 06/07/21

III. BACKGROUND

A. On January 18, 2023, FSIS published the final rule "Prior Label Approval System: Expansion of Generic Label Approval" (88 FR 2798). This rule amended the Federal meat, poultry, and egg products inspection regulations found in 9 CFR to expand the circumstances under which labels for meat, poultry, and egg products are generically approved.

B. Specifically, the final rule:

1. Extends generic label approval to products only intended for export that deviate from domestic labeling requirements by removing 9 CFR 412.1 (c) (2).
2. Revises the types of "special statements and claims" requiring label submission (9 CFR 412.1(e) and 412.2(b)) by providing for generic approval of three additional types of claims:
    a. "Organic" claims that appear in a product label's ingredients statement which designate an ingredient as certified "organic" under the Agricultural Marketing Service's (AMS's) National Organic Program.
    b. "Geographic landmarks" displayed on a product label, such as a foreign country's flag, monument, or map.
    c. "Negative" claims made on product labels that identify the absence of certain ingredients or types of ingredients (e.g., "No MSG Added," "Gluten Free")

3. Permits the generic approval of the labels of products that receive voluntary FSIS inspection on the same basis as amenable meat, poultry, and egg products. Products that may receive voluntary FSIS inspection include rabbits (9 CFR 354), certain non-amenable species of livestock and poultry animals such as elk, bison, and migratory waterfowl (9 CFR 352, subpart A, and 9 CFR 362), and products that contain meat, poultry, or eggs (9 CFR 592) but are not under FSIS jurisdiction, such as closed faced sandwiches (9 CFR 350.3(c) and 362.2(a)), and non-amenable egg patties or omelets (9 CFR 592.20).

4. Specifies that, effective March 20, 2023, LPDS will no longer evaluate generically approved labels submitted voluntarily for FSIS review.

C. Effective March 20, 2023, 9 CFR 412.1(c), specifies the three 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; and

3. Labels with special statements and claims. Special statements and claims are explained in detail in the 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, provided the label displays all mandatory label features in compliance with applicable Federal regulations (9 CFR 412.2). Refer to Table 1 in Section IV Paragraph D 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 are not false or misleading, and for ensuring that labels comply with the Federal meat, poultry products inspection regulations and policies.

NOTE: FSIS Directive 5030.1, *Inspection Methodology Utilizing the Public Health Information System for the Verification of Regulatory Compliance in Egg Products Plants,* provides instructions pertaining to label verification tasks in egg product plants.

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 prior to use, except for labels that are generically approved. Labels that are to be submitted for evaluation are described in 9 CFR 412.1(c) (Section III, Part D of this directive). Label submissions may be mailed in duplicate, or entered into the FSIS Label Submission and Approval System (LSAS). If a label is generically approved or if the sketch label is approved by LPDS, establishments may print a final label, create a final label record in accordance with 9 CFR 320.1(b)(10) and 9 CFR 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 in duplicate to LPDS.

IV. 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. IPP are to routinely select generically approved labels when conducting this task. To complete this task, IPP are to select both labels that require a prior label approval from LPDS and those that are eligible for generic approval.

B. IPP are to verify that the establishment is maintaining records of the selected labels in accordance with 9 CFR 320.1(b)(10) for meat products and 9 CFR 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 prior approval by LPDS per 9 CFR 412.1(c), the completed 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 was granted by LPDS. Accordingly, the final label is to comply with any/all modifications and conditions of use put forth by LPDS in the label approval (9 CFR 412.1(a)). For example, IPP verification of a "grass fed beef" claim on a label approved by LPDS with supporting documentation that the beef used was sourced from grass fed beef from XYZ Farm is performed by verifying that the actual beef used in product bearing said label was derived from beef identified as grass

fed from XYZ Farm. Note that IPP are not to reverify the supporting documentation as it relates to the beef from XYZ Farm being "grass fed" because LPDS evaluated this information as part of the label approval process.

NOTE: Egg product plants must maintain records in accordance with 9 CFR 320.1(b)(10). FSIS Directive 5030.1 provides instructions pertaining to label verification tasks in egg product plants.

C. IPP are to verify that when a label is stamped "APPROVED AS MODIFIED" by LPDS that the establishment has modified the label as instructed prior to use. If the necessary modifications have not been made to the label being applied to product, the label approval is not valid, and IPP are to follow the instructions in Section V.

D. 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	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)	Any 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 misbranded and 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 or more of the "big 8" allergens [wheat, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), soybeans] or other ingredients of public health concern has entered commerce. FSIS ingredient and allergen compliance guidelines are available online.

V. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. IPP are to document the results of their verification, including any noncompliance, in PHIS as instructed in Chapter VI of FSIS 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 through askFSIS as outlined in Section VIII below. 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 III, Paragraph G, 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 the regulatory requirements, IPP are to document the noncompliance on an NR in PHIS, citing the relevant reference from Table 1. In addition, IPP are to retain any product bearing that label and require establishments to update labels that are not in compliance with FSIS' labeling regulations. Before the product may enter commerce, the establishment must take corrective action by using a pressure sensitive sticker to correct the non-compliance, replacing the

noncompliant label with a compliant label or, if applicable, obtaining temporary label approval through LPDS.

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 the affected product, and document the noncompliance in PHIS as described above.

NOTE: IPP are to contact their Frontline Supervisor (FLS) for guidance if at any time they have reason to believe that misbranded product has entered commerce.

VI. 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 may pose a public health concern. The District Office is to share the information with the Recall Management and Technical Analysis Division in Headquarters to handle per FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

VII. DATA ANALYSIS

PHIS tracks the inspection activities conducted by IPP. OPPD will review data, as needed, 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.

VIII. QUESTIONS

Refer questions regarding this directive to your supervisor or OPPD through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Labeling for the Inquiry Type.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

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