MSA DIRECTIVE	7221.1 Rev. 3	07/10/2023

LABEL APPROVAL AND PHIS GENERAL LABELING TASK

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) when submitting labels to the Label Review Staff (LRS) for approval and provides instructions for completing the MSA Z-1 Form. The directive also provides instructions for IPP when conducting the General Labeling task in the Public Health Information System (PHIS).

II. BACKGROUND

A. 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 State meat and poultry products inspection regulations and policies.

B. IPP are to be aware that sketch labels, along with a completed MSA Z-1 form and all supporting documentation are to be submitted to LRS for evaluation prior to use.

III. SKETCH LABEL SUBMISSION AND APPROVAL

A. A LRS and IPP approved MSA Z-1 form must be completed before meat and poultry products, labeled under MSA regulations, may enter commerce.

B. IPP are to work closely with establishment personnel to complete the Z-1 using the instructions include with the form.

C. IPP should review the completed Z-1 and any/all supporting documents. Once the IPP has completed their review, IPP must sign and date the prepared Z-1. The establishment may then email or mail the completed Z-1 to the LRS using the instructions included with the Z-1.

D. The LRS will work with IPP during the label review process should questions arise or if additional information is needed.

E. Once LRS has completed its review, IPP will be provided with the sketch approved Z-1. IPP are to review the sketch approved Z-1 with the establishment and communicate any needed revisions. IPP shall document this meeting and the topics discussed in a MOI.

F. The establishment will provide IPP with a copy of the final label. IPP will review the final label to make sure it matches the sketch approved Z-1. Once the label matches the sketch approved Z-1, IPP are to place a check mark in the "Final" box on the original sketch approved Z-1 and include their initials and the date next to the "Final" box. IPP shall notify the establishment of the label's final approval via MOI.

G. IPP are required to retain the LRS approved Z-1 and a copy of the final label in the establishment files as a reference when conducting future General Labeling task in PHIS.

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.

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 MSA personnel 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 State meat and poultry regulations and policies on labeling as described in 9 CFR 412.1. Establishments should also provide the completed MSA Z-1 Form and is to indicate that approval was granted by LRS. Accordingly, the final label is to comply with any/all modifications and conditions of use put forth by LRS 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 in the bottom 30%	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 9" allergens [wheat, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), soybeans, sesame] 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.

B. 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 MSA 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 or replacing the noncompliant label with a compliant label. IPP should contact their Circuit Manager if improperly labeled product has entered commerce.

NOTE: The replacement labels must be submitted to LRS for review if the establishment either does not have a label on file or the label does not match the label on file.

C. 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 State 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 Circuit Manager (CM) 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 9" allergens or other ingredients of public health concern are not properly declared, a recall may be warranted. The CM is to alert the Central Office to potential distribution of products that may pose a public health concern.

VII. QUESTIONS

Refer questions through supervisory channels.

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