



District Correlation Meeting January 16, 2014

FSIS Directive 7221.1 **PRIOR LABELING APPROVAL**



**Labeling and Program Delivery Staff
Food Safety and Inspection Service (FSIS)**



Purpose

- Directive issued to clarify General Labeling task in PHIS
- Final Rule “Prior Label Approval System: Generic Label Approval,” effective January 6th
 - Expands generic label approval
 - Consolidates labeling approval regulations into 9 CFR 412
 - Eliminates regulations 9 CFR 317.4, 317.5, 381.132 and 381.133



New regulation: 9 CFR 412

- 412.1: Only certain labels require prior approval by the LPDS. 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 (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>).
- 412.2: All other labels may be generically approved without evaluation by LPDS.
 - Must display required label features and comply with Federal regulations.



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 381.122 (corrected) | 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 |



Establishment Responsibilities

- IPP should be aware of the responsibilities of the establishment.
- Label design: labels should comply with federal regulations
 - CFR: required features, product standards, and defined claims
 - Food Standards and Labeling Policy Book
- Prior labeling approval
 - By LPDS if required by 9 CFR 412.1
 - Generically if permitted by 9 CFR 412.2
- Label record must include (9 CFR 320.1(b)(11), 381.175(b)(6), 412.1)
 - LPDS label application and approval if required
 - Product formulation and processing procedures
 - Documentation for any claims
 - Final label that is in use



IPP Responsibilities

- General Labeling task in PHIS
 - Select one or more labels for products in production
 - Verify that establishment is maintaining label record and that record is complete and accurate
 - Verify that final label is in compliance with regulations: check required features
 - Be attentive to public health concerns
 - FSIS ingredient and allergen compliance guidelines are available online (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>)



Documentation

- Complete routine General Labeling task as scheduled. Initiate and complete directed General Labeling task for “stumble-upon” noncompliances.
- Record findings from General Labeling task in PHIS.
- Noncompliance Records
 - Label requires LPDS approval, but has not been approved
 - Regulatory reference: 9 CFR 412.1
 - Label is not in compliance with regulatory requirements
 - Regulatory reference in Required Labeling Features table in directive 7221.1
 - Product contains undeclared allergen or other public health concern
 - Contact supervisor for direction; a recall may be warranted



Documentation, continued

- Acceptable corrective actions include:
 - Obtain temporary label approval from LPDS for non-compliant labels per 9 CFR 412.1(c)(4)
 - A temporary label approval may be granted for labels with a regulatory deviation that does not pose any potential health, safety, or dietary problems to the consumer. Determined by LPDS on a case-by-case basis.
 - Approval not to exceed 180 days
 - Plant transfers are granted for up to 60 days
 - Temporary labels cannot be generically approved
 - Replace the noncompliant labels with labels that have received prior approval (by LPDS or generically) and are in compliance
 - Apply pressure sensitive stickers to bring the labels into compliance



Points of Clarification

- PHIS will be updated to indicate the new regulations.
- Hard-copies of CFR will reflect update at next printing; regulatory text can be accessed at <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.
- Generic approval is granted for labels that comply with the regulations. It is not granted by IPP.
- If IPP are uncertain about the compliance status of a label, contact LPDS for clarification.



Resources

- FSIS Directive 7221.1

<http://www.fsis.usda.gov/wps/wcm/connect/9a2ebc76-2d43-4658-841a-f810b1f65f04/7221.1.pdf?MOD=AJPERES>

- Labeling and Program Delivery Division

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>

- Compliance Guide - Labeling that Needs to be Submitted for Evaluation and Approval . Will continue to be updated.

- Electronic Code of Federal Regulations

<http://www.ecfr.gov/cgi-bin/ECFR?page=browse>

- FSIS Food Standards and Labeling Policy Book

http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_PolicyBook_082005.pdf



Questions?

Contact us

Phone: 301-504-0870

askFSIS: <http://askfsis.custhelp.com/>

