



NICHE MEAT PROCESSOR ASSISTANCE NETWORK
WEBINAR PRESENTATION
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FSIS Labeling Update

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Office of Policy and Program Development (OPPD)
Food Safety and Inspection Service (FSIS)***

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FSIS Prior Label Approval System

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

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Prior Labeling Approval Authority Distinct Regulatory Approach for Labeling is Set by Law

- FMIA and PPIA require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed
- “No article subject to this [Act] shall be sold or offered for sale But established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.”
- USDA interprets statutory language as mandating “pre-approval” of all food labels before products may be offered for sale

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Submitting for Sketch Label Approval

- 9 CFR 317.4 (c) and 381.132(c) require all labeling to be submitted for sketch approval *except* for labeling that is generically approved. For example:
 - LPDD sketch approval required for non-standardized meat and poultry products (e.g., Pasta with Chicken and Vegetables)
 - LPDD sketch approval required for any meat or poultry product bearing special statements or claims (e.g., organic, healthy, breed claims)
- Requests for sketch approval are submitted to LPDD using FSIS Form 7234-1

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IF YOU NEED ADDITIONAL SPACE, THERE IS A CONTINUATION SHEET ON PAGE 3

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0205-0002. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This form has been approved by OMB for web distribution. PAGE _____ of _____

<p>U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE</p> <p>APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE</p> <p><small>FSIS has determined that information provided in items 8, 9, and 10 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).</small></p> <p><small>APPLICANT: See Page 2 for instructions.</small></p>	<p>1. AGENT NAME, ADDRESS, TELEPHONE NO. <i>(If using an agent, complete this block, otherwise leave blank.)</i></p>	<p>2. FOR USDA USE ONLY</p>	<p>3. FOR USDA USE ONLY</p>	<p>4. ESTABLISHMENT NO. / FOREIGN COUNTRY <i>(if applicable)</i></p>
<p>5a. NAME OF PRODUCT</p>				
<p>5b. TYPE OF APPROVAL REQUESTED</p> <p><input type="checkbox"/> SKETCH <input type="checkbox"/> TEMPORARY</p> <p><input type="checkbox"/> EXTENSION OF TEMPORARY</p> <p><small><i># Temporary or Extension is label use continuation sheet</i></small></p>	<p>5c. WAS THE LABEL PREVIOUSLY APPROVED?</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><small>Date of approval: _____</small></p> <p><small>Prior approval number: _____</small></p> <p><small>Number of labels on hand: _____</small></p> <p><small>Number of days requested: _____</small></p>	<p>7a. AREA OF PRINCIPAL DISPLAY PANEL <i>(Square inches)</i></p>		<p>5d. HACCP PROCESS CATEGORY</p>
<p>8. PRODUCT FORMULA</p> <p><input type="checkbox"/> PCT <input type="checkbox"/> WEIGHT <i>(No Fractions)</i></p>		<p>7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE <i>(Square inches)</i></p> <p>9. PROCESSING PROCEDURES <i>(Approval of the sketch does not constitute approval of the processing procedures)</i></p>		
<p>TOTAL <i>(Percent must total 100%)</i></p>				
<p>10. NAME AND ADDRESS OF FIRM <i>(Below and between dots)</i></p>		<p>11. SIGNATURE OF APPLICANT OR AGENT</p>		<p>DATE</p>
<p>12. CONDITIONS APPLYING TO USE OF LABELS OR DEVICE (FOR USDA USE ONLY)</p>				

FSIS FORM 7234-1 (10/03/2002) REPLACES FSIS FORM 7234-1 (11/87), WHICH IS OBSOLETE. *Designed in FarmFour software.*

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Sketch Labeling Definition

- Sketch labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in Sec. 317.2.
- FSIS will accept sketches that are hand drawn, computer generated, or other reasonable facsimiles that clearly reflect and project the final version of the label.

Label Application Process

- Labels may be submitted by mail, express mail, courier, label consultants, and fax
- Complete label application consists of:
 - Two copies of completed FSIS Form 7234-1 (triplicate for labels with animal production raising claims)
 - A sketch label attached to each completed copy of FSIS Form 7234-1
 - Supporting documentation (e.g., feed formulation, raising practices) required by claims or special statements need to be attached to each copy of FSIS Form 7234-1

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Requests for Temporary Approval

- 9 CFR 317.4(f)(1) and 381.133(f)(1) provide for the temporary use of labeling that may be deficient in some manner but does not create a health/safety issue or create an economic advantage, e.g.,
 - Ingredients out of order of predominance
 - Net weight not declared in dual declaration
- FSIS can grant temporary approval for up to 6 months. Extension of temporary approval can be granted for another 6 months depending upon the circumstances

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Submitting Requests for Temporary Approval

- Procedures and forms needed for submitting for temporary approval are identical to those for submitting for sketch approval
- Differences include:
 - Checking the box for “temporary” instead of “sketch” in Block 6a of FSIS Form 7234-1
 - Explaining on the label application (can be attachment) the reason for the need for temporary approval

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11 Most Common Mistakes on Label Submittals

- No sublisting of multi-ingredient components on the label (e.g., soy sauce, teriyaki marinade)
- Percent restricted ingredients not provided or supported in submission (e.g. the percent of fat in the product is required for some ingredients)
- Binders in the solution pumped in meat or poultry products are not included in product names/qualifiers
- Order of predominance of ingredients is wrong
- Geographic claims and styles not supported by data

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11 Most Common Mistakes (continued)

- Nutrition claims not supported by data or permitted by regulations
- Not enough copies of submission forms
- Submission is not legible (labels or application)
- Reason for a temporary label approval is not supported by required information (see below)
- Product name prominence/letter size conflict with requirements
- Meaningful terms/claims are not validated on the application, e.g., “#1 seller of franks in the West” is not supported by data

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Generic Labeling Definition

Generic labeling approval refers to the prior approval of labeling or modifications to labeling by the Agency without submitting such labeling to FSIS for sketch approval.

Generic labeling approval requires that all mandatory labeling features are in conformance with FSIS regulations (9 CFR 317.5(a)(1) and 381.133(a)(1)).

Although such labeling is not submitted to FSIS for approval, it is approved and, therefore, may be applied to product in accordance with the Agency's prior labeling approval system

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Generically Approved Labeling

- 9 CFR 317.5 and 381.133 paragraphs (b)(1) through (b)(8) outline the types of product labels that are considered generically approved without submission to FSIS
- Examples include:
 - Labeling for single ingredient products which do not bear any special statements or claims (e.g., animal production claims and nutrient content claims)
 - Labeling for consumer test products not intended for sale
 - Meat inspection legends
 - Labeling for products with a standard of identity in Federal Regulations or the Food Standards and Labeling Policy book which do not bear any special statements or claims

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Generically Approved Modifications to Labeling

- 9 CFR 317.5(b)(9) and 381.133(b)(9) describe the types of changes that can be made to previously approved labeling generically
- Examples include:
 - All labeling features are proportionately enlarged or reduced, provided all minimum size requirements are met and the labeling is legible
 - The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information
 - Any change in the net weight, provided the size of the net weight statement complies with 317.2 or 381.121

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Maintenance of Official Labeling Records

- 1995 Final rule transferred responsibility for maintaining labeling records to establishments. Consistent with other record keeping requirements under HACCP.
- Each labeling record needs to include: copy of final labeling, product formulation, processing procedures
- Labeling records must be made available to any authorized USDA official upon request within 24 hours (FSIS Directive 7221.1)

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