

## **Comprehensive List of Reasons for Label Modifications and Returns**

This document is provided to further explain reasons why a label was modified or returned after evaluation by a staff member of the Labeling and Program Delivery Division (LPDD). Each reason corresponds to a number that will be placed on a label or label application that is either modified or rejected. While LPPD has endeavored to be comprehensive, this list is not all inclusive. There are certain reasons for modifications or rejection, reasons that are very specific and cannot be generalized. In these situations, the reason will be noted on the label application or in a return letter.

### **Key abbreviations and terms used throughout this document:**

X –number or amount

\*\*\*\*\* - product name

XXX – specific regulation citation

### **Label Application and Label Presentation: (9 CFR 317.4(c) and Instructions for Preparations for FSIS Form 7234.1**

1. Two copies of the label must be submitted. A copy of the label must be attached to each application. To assemble the submission: Staple a copy of the label to each application. Then staple the applications together. Refer to the Instructions for Preparation of FSIS Form 7234-1.
2. Labeling submitted for sketch approval must be a printer's proof or reasonable facsimile that clearly shows all mandatory features. If this text is to be printed on a master label, provide a copy of the master label.
3. To facilitate the processing of the submission, please put the application on top of each label. Refer to the Instructions for Preparation of FSIS Form 7234-1.
4. The label applications are not legible. Please resubmit legible copies.
5. Complete all applicable boxes on the FSIS Form 7234-1. Refer to the Instructions for Preparation of FSIS Form 7234-1.
6. The product formula is incomplete. Provide a complete product formula that agrees with the ingredients statement.
7. In the product formula, provide a percent pick-up of solution based on the meat component calculated as pounds solution divided by pounds of raw meat or poultry.

### **Product Name: (9 CFR 317.4(e) and 9 CFR 381.117, Food Standards and Labeling Policy Book, and FSIS Directive 7220.1)**

8. Delete the term "Marinated" or "Basted" from the product name. The amount of solution in products labeled as "marinated" or "basted" are limited to 10% for red meat products,

8% boneless poultry products and 3% bone-in poultry products. Refer to the entry for “marinated” in the FSIS Standards and Labeling Policy Book.

9. Correct the product name. See the entry “\*\*\*\*\*” in the FSIS Food Standards and Labeling Policy Book.
10. Correct the product name because the standard of identity for “\*\*\*\*\*” is not met. See 9 CFR 319, 381 subpart P or the FSIS Food Standards and Labeling Policy Book.
11. Correct the product name. See FSIS Directive 7220.1, Policy Memo 030A or 029.
12. Correct the size of the product name. The smallest letter in the product name must be at least one-third the size of the largest letter in the product name. See FSIS Directive 7220.1, Policy Memo 087A.
13. Correct the size of the fanciful name. The smallest letter in the fanciful name must be at least one-third the size of the largest letter in the product name. See FSIS Directive 7220.1, Policy Memo 087A.
14. Correct the product name. The product does not meet the regulatory standard for “\*\*\*\*\*,” therefore, the product name should be “Imitation “\*\*\*\*\*.” See the entry “\*\*\*\*\*” in the 9 CFR 319.
15. Correct the product name. The kind of poultry must be identified in the product name, that is, “White Bean Chili with Dark Chicken.” See 9 CFR 381.117(d).
16. Binders such as modified food starch or carrageenan, are not permitted in whole muscle red meat products.
17. Provide the percent of maltodextrin in the purchased seasoning and provide the dextrose equivalency (DE). The maltodextrin may not exceed 1% of the finished product. If the DE is 5 or greater the maltodextrin may not exceed the percentage of the finished product. Maltodextrin may not be a direct addition to formula.
18. Country Sausage must be made in the country. See 9 CFR 317.8(b) (2).
19. Indicate on the application how this product meets the standard for “\*\*\*\*\*.” Refer to the Food Standards and Labeling Policy Book for established standards and the listing of ingredients that enable the product to meet the standard for this product.
20. Correct the placement of the ingredient statement on the label. Nonspecific product like “loaves” needs a descriptive name or need to be followed immediately by the ingredient statement. A product labeled “Olive Loaf” is a non-specific product. Therefore, it must be descriptively labeled or the name must be followed by the ingredient statement. See 9 CFR 317.2(e) and the entry “Nonspecific Meat Food Products” in the FSIS Standards and

Labeling Policy Book.

21. Delete the honey claim. The product must contain at least 3 percent honey. See the entry “Honey Claims in Product” in the FSIS Standards and Labeling Policy Book.
22. The product name does not agree with the processing procedures.
23. Qualify the use of the coating contiguous to the product name. See the entry “Coated With” in the FSIS Standards and Labeling Policy Book.
24. Based on the formula provided, the raw meat picks up x% of its weight from the seasoning solution. Therefore, a containing statement must qualify the product name. See FSIS Directive 7220.1, Policy Memo 066C.
25. The country of origin, for example, “Product of Canada,” must appear immediately below the product name. See 9 CFR 327.14(b) (1).
26. The use of a geographic reference on labeling needs to comply with 9 CFR 317.8(b)(1). However, if the product is made in a locality other than that referenced in the product name, the name should be qualified by the word “brand,” in the same size and style lettering as the geographic term and accompanied with a prominent qualifying statement identifying the country, state, territory or locality in which the product was actually prepared, that is, Danish Brand Ham, Made in USA. See 9 CFR 317.8(b) (1) and the FSIS Food Standards and Labeling Policy Book entry for Geographic Style and related terms.
27. Correct the product name to add “Textured Vegetable Protein (TVP)” because the ratio of meat or poultry meat to TVP is less than 7:1. See the entry “Textured Vegetable Protein (TVP) Products - Fresh Meat or Poultry Meat Ratios” in the FSIS Food Standards and Labeling Policy Book.
28. The use of “Textured Vegetable Protein (TVP)” needs to be qualified to the product name (that is, Textured Vegetable Protein added” because the ratio of meat or poultry meat to TVP is less than 10:1. See the entry “Textured Vegetable Protein (TVP) Products - Fresh Meat or Poultry Meat Ratios” in the FSIS Food Standards and Labeling Policy Book.
29. For Sausage Pizza, the use of pizza topping containing sausage and textured vegetable protein (TVP) must provide the percent of meat and TVP. The meat=TVP ratio determines if TVP should be in the product name.

**Ingredients: (9 CFR 317.2(f), 381.118, 424.21 and FSIS Directive 7220.1)**

30. The term “Ingredients:” must precede the declaration of the ingredients. See 9 CFR 317.2(c) (2).

31. The ingredient statement is not legible. See 9 CFR 317.2(b).
32. Multi-ingredients in the ingredients statement (for example, soy sauce) should be sublisted in the ingredient statement.
33. Garlic powder and onion powder are not spices and should be declared in the ingredient statement as “garlic powder” or “onion powder” or as “flavorings.” See 9 CFR 317.2(f)(1)(i)(A) or 9 CFR 381.118(2)(c)(1).
34. “And/or” labeling of major components of the product is not acceptable. See FSIS Directive 7220.1, Policy Memo 072.
35. The source of milk (for example, cow’s milk) for the Romano cheese should be identified in the sublisting of the cheese in the ingredients statement. See 21 CFR 133.183 (f)(1)
36. The ingredient statement does not agree with the formula. Provide an ingredient statement that agrees with the formula. See 9 CFR 317.2(f)(1) or 9 CFR 381.118(a)(1).
37. Provide a simple product formula that proves the order of predominance of the ingredient statement. See 9 CFR 317.2 (f)(1) or 9 CFR 381.118 (a)(1).
38. Correct the order of predominance in the ingredient statement. See 9 CFR 317.2 (f)(1) meat and 9 CFR 381.118 (a)(1) poultry.
39. Correct the declaration of the meat component in the ingredient statement. The correct declaration for the ingredient statement is “Beef Tenderloin Containing up to X% of a Solution of ....” See FSIS Directive 7220.1 Policy Memo 066C.
40. Correct the placement of the containing statement. The containing statement, “Contains up to X% of a Solution,” must appear contiguous to the product name.
41. Paprika is not permitted in fresh sausage.
42. Paprika and extractives of paprika are not permitted in this product. See 9 CFR 424.23 and the FSIS Food Standards and Labeling Policy Book entry for “Paprika.”
43. Correct the size of the “containing statement.” The smallest letter in the “containing statement” must be at least ¼ the size of the largest letter in the product name. See FSIS Directive 7220.1 Policy Memos, 042, 044,066C and 084A.
44. Products containing seasoning packets must declare their presence in the product name, that is, “Cooked Pork Meatball with Seasoning Packet Included.” See Directive 7220.1 Policy Memo 099.
45. In the ingredient statement, identify the ham component by its common and usual name, that is, “Ham Water Added” or “Ham and Water Product, X % of weight are added

ingredients.” See 9 CFR 319.104 (d).

46. The product name must be qualified to indicate the presence of the caramel coloring, that is, Caramel Coloring Added.” See entry for "Caramel Color" in the FSIS Food Standards and Labeling Policy Book.
47. Identify the source of protein in the hydrolyzed vegetable protein, that is, “hydrolyzed corn protein.” See FSIS Directive 7237.1.
48. Correct the declaration of ingredients in the ingredient statement. Specifically, the ingredient statement does not comply with FSIS Directive 7237.1 Revision 1. This directive requires the full disclosure of the ingredients in all Food and Drug Administration (FDA) regulated foods identified on the labels of meat and poultry products, for example, soy sauce or seasoning.
49. On the application, identify the spices used in the product.
50. Sublist “\*\*\*\*\* powder” in the ingredients statement on the label for example= chili powder (chili pepper, cumin and turmeric).

**Restricted Ingredients: ( 9 CFR 424.21 and FSIS Directive 7220.1)**

51. The sodium erythorbate amount is excessive. Sodium erythorbate is limited to 547 parts per million of the meat block in comminuted product.
52. Sodium erythorbate is approved for use only in cured meat products. Since this product is not cured that is, contain sodium nitrite or nitrate, the sodium erythorbate must be removed from the product. See 9 CFR 424.21
53. The sodium nitrite level is excessive. Sodium nitrite is limited to 156 parts per million of the meat block in comminuted product. See 9 CFR 424.21.
54. The sodium nitrite level is insufficient. Cured comminuted meat product should have at least 120 parts per million of sodium nitrite. See 9 CFR 424.21.
55. Non-amenable species, such as ostrich, cannot be cured unless an amenable species, such as beef, pork, or poultry, is added to the product. The product must contain 2% cooked poultry in the total product.
56. Minimum fat content of the raw product must be disclosed on the application to determine antioxidant compliance. See 9 CFR 424.21
57. Minimum fat content and the percent antioxidants in the seasoning must be disclosed on the application to determine antioxidant compliance. See 9 CFR 424.21.

58. Based on the information provided, the percent of antioxidants in the product are excessive. The antioxidants are limited to X % of the fat content of the product. See 9 CFR 424.21.
59. Antioxidants and synergist are not permitted in cooked sausage. See 9 CFR 424.21.
60. The binder, that is, soy protein concentrate, level is excessive. Binders are limited to 3.5 percent of the finished product weight. See 9 CFR 424.21.
61. The sodium phosphate level is excessive. Sodium phosphate is limited to 5000 parts per million in the total product. See 9 CFR 424.21.

**Signature Line: (9 CFR 317.2 (g) or 381.116)**

62. Correct the placement of the Signature Line on the information panel. When on an information panel, this feature must be contiguous to the ingredient statement. See 9 CFR 317.2(m) or 381.116(c) (2) (ii).
63. A qualifying statement needs to precede the signature line because the product is not produced at the address shown on the label. See 9 CFR 317.2(g) (1) or 381.116(c) (2) (ii)
64. Include the zip code in the address line. See 9 CFR 317.2 (g) (1).

**Net Weight: (9 CFR 317.2(h) and 381.121)**

65. Correct the net weight size and spacing. See 9 CFR 317.2(h) or 381.121(c). Correct the placement of the net weight statement. See 9 CFR 317.2(h) (3) or 381.121(c) (1). See 9 CFR 317.2(h) or 381.121(c).
66. Correct the net weight declaration. The quantitative declaration should be preceded by the phrase "NET WT."
67. Correct the placement of the net weight declaration. The net weight should appear in the lower 30% of the principal display panel. See 9 CFR 317.2(h).
68. Correct the net weight declaration. Net weight between 1 and 4 pounds or 1 pint and 1 gallon must be expressed as a dual declaration, that is, Net Wt. 32 OZ (2 lb). See 9 CFR 317.2(h) (4) or 381.12(c) (5).
69. The size of the net weight statement must comply with 9 CFR 317.2(h) or 318.121(c). The size of the net weight statement is based on the size of the principal display panel, not the label.

**Legend and Est and Plant Number: 9 CFR 312.2, 317.2(i), 381.96, 381.123**

70. The inspection legend is incorrect. The Federal inspection legend must comply with the illustration in 9 CFR 312.2 or 381.96.
71. The inspection legend is incorrect. Poultry products should bear the mark of inspection illustrated in 9 CFR 381.96.
72. The wrong inspection legend is on the label. The Federal inspection legend for red meat products must comply with the illustration in 9 CFR 312.2.
73. The wording in the inspection legend is incorrect. The Federal inspection legend must comply with the illustration in 9 CFR 312.2 or 381.96.
74. Correct the placement of the Federal inspection legend. The legend must appear on the principal display panel. See 9 CFR 317.2(c) (5).
75. Only one Federal inspection legend may appear on product sold at retail (that is directly to consumers).
76. The Federal inspection legend is missing from the label. See 9 CFR 312.2 or 381.96.

**Handling Statement: 9 CFR 317.2 (k) or 381.125 (a)**

77. Correct the placement of the handling statement (for example, Keep Refrigerated or Keep Frozen). The handling statement must appear on the principal display panel. See 9 CFR 317.2(k) or 381.125(a).
78. Correct the handling statement. The handling statement on the label should agree with the label, agree with the processing procedures in block 9 on the label application. For example, if the product is refrigerated before it leaves the establishment that manufactured the product, the label should bear “Keep Refrigerated.” See 9 CFR 317.2 (k).

**Safe Handling Statement: 9 CFR 317.2(l) or 381.125**

79. Safe Handling Instructions (SHI) are missing from the label. SHI are mandatory for all the raw or not ready to eat meat and poultry uncooked products. See 9 CFR 317.2(l) or 9 CFR 381.125.
80. Remove Safe Handling Instructions (SHI) from the label. SHI are not needed on ready to eat meat and poultry products. See 9 CFR 317.2(l) or 9 CFR 381.125.
81. The heading “Safe Handling Instructions” must be larger than 1/16 inch. All other lettering in the safe handling instruction block has to be a minimum of 1/16 inch. See 9 CFR 317.2(l) or 9 CFR 381.125.

82. The size of the text in the SHI is too small. All text in the Safe Handling Instructions block must be at least 1/16 inch. See 9 CFR 317.2(l) or 9 CFR 381.125.
83. Safe Handling Instructions must appear in one color on a solid background.
84. Safe Handling Instructions must have a border.
85. Provide a copy of the Safe Handling Instructions with each label as part of the label application.

**Nutrition Facts: 9 CFR 317.300-400, 381.400-500**

86. Correct the Nutrition Facts format. The format must comply with 9 CFR 317.309(d) or 381.409(d).
87. The core nutrients and percent daily values in the Nutrition Facts must be in bold print. See 9 CFR 317.309(d) (1) (iii) or 381.409(d) (1) (iii).
88. The serving size must be in a discrete unit that most closely approximates the reference amount customarily consumed for example, 85 grams for an entrée without sauce. See 9 CFR 317.309(b)(4)&(5) or 9 CFR 317.409(b)(4)&(5).
89. The quantitative data must be present in the Nutrition Facts panel when the labels are presented for approval. See 9 CFR 317.309(d)(7) or 9 CFR 317.409(d)(7).
90. Remove the nutrition claim from the labeling. The claim does not comply with the regulation. See 9 CFR 317.XXX or 381.XXX.
91. When making a nutrition claim, that is, 97% Fat Free, the product must be nutritionally labeled. See 9 CFR 317.313(b) or 9 CFR 381.413(b).
92. Based on the amount of labeling space available, that is, greater than 40 square inches, the tabular format and abbreviations are not permitted. See 9 CFR 317.309(d) and 381.409(d)
93. On the application, provide a rationale for the serving size used. The serving size of some of the products can be declared by multiple reference amounts, that is, mixed dish not measurable by a cup or entrée with sauce. In addition, provide the expected cook yield. See 9 CFR 317.309(b)(7) or ( CFR 381.409(b)(7).
94. Remove the nutrition claim from the labeling. The claim does not comply with the regulation. See 9 CFR 317.XXX or 381.XXX.

**Amenability:**

95. Upon reviewing the formulation of this product, we have determined that it is not amenable to the Poultry Products Inspection Act. Generally, product should contain at least 2% cooked poultry meat and 3% raw poultry meat.
96. Upon reviewing the formulation of this product, we have determined that it is not amenable to the Federal Meat Inspection Act. Generally, product should contain at least 2% or more cooked red meat and more than 3% raw red meat.

**Temporary Approval: 9 CFR 317.4, 381.132**

97. Provide the specific reason for temporary approval on the application form; for example removing dextrose from the product formulation or replacing sodium erythorbate with sodium ascorbate. Reasons such as “changing the product formula or “removing ingredients from the label” are not specific enough and will be returned for more information.
98. When requesting an extension of a current temporary approval, explain on application what new circumstance has happened since last temporary was granted. Also specify details of the 4 conditions in 9 CFR 317.4(f) (1) or 381.132(f) (1).
99. The 4 conditions of 9 CFR 317.4(f) (1) or 381.132(f) (1) have to be met prior to receiving a temporary approval. Specify details of all conditions on application. Refer to temporary approval handout. Or see information below:
- (f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Labeling and Program Delivery Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:
    - The proposed labeling would not misrepresent the product;
    - (ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
    - (iii) Denial of the request would create undue economic hardship; and
    - (iv) An unfair competitive advantage would not result from the granting of the temporary approval.

**Generic**

100. Many of these labels can be generically approved based on previously approved labels. Refer to 9 CFR 317.5(b) (9) or 381.133(b) (9)

