

## Labeling Situations That Can Not Have A Temporary Approval

A. When the following ingredients are in the product, but not declared in the ingredients statement:

- Ingredients that are know allergens, e.g.,
  - Crustacea
  - Eggs and egg products
  - Fish and fish products
  - Milk and milk products (including lactose)
  - Peanuts
  - Soybeans
  - Tree nuts
  - Wheat
- Other proteinaceous ingredients, e.g., kind of poultry or species of meat
- Cereals containing gluten: e.g., wheat, rye, barley, oats, spelt or their hybridized strains
- Salt
- Monosodium glutamate
- Restricted ingredients as listed in [9 CFR 424.21 \(c\)](#), e.g., *sodium nitrite*

B. When sulfiting agents are not declared on the label but greater than 10 parts per million (ppm) in individual products.

C. When the ingredients statement does not adequately represent the product because of drastic formula changes.

D. When a standard is not met.

Examples:

“Breaded veal patty” contains more than 30% breading  
70/30 rule not met  
Byproducts in Kielbasa

E. When cooking instructions are not adequate to render the product safe. (For example: ground beef label states, “cooked to 150° F for medium rare”).

F. Label missing one or more mandatory features.

1. Product name
2. Ingredients statement (if applicable)
3. Handling instructions
4. Safe handling instructions (if applicable)
5. Signature line
6. Net weight statement (if applicable)
7. Nutrition facts (if applicable)
8. Inspection legend including establishment number

G. When certain errors exist on labeling affecting nutrition facts, nutrition claims or nutrient claims.

Examples:

Nutrition facts does not support claim  
Serving size is incorrect  
Nutrition values are over or under by more then 20% of actual product  
Unacceptable health/nutrition claim  
Nutrition claim or nutrient content claim on label but nutrition facts missing

H. Failure to sublist composite ingredient (enriched flour, soy sauce, etc.).

I. Misuse of the term “fresh” on poultry

J. When mechanically separated poultry is in a product, but not properly declared in the ingredients statement i.e., the phrase “mechanically separated” is missing from the poultry ingredient.