

Labeling and Establishment Responsibilities

The Labeling and Program Delivery Staff (LPDS) grants temporary and sketch approvals of labels. Before submitting label applications for approval, establishments should ensure that the print is legible and that all required features (i.e., inspection legend, ingredients statement, handling statement, product name, signature line, and safe handling instructions, net weight, and nutrition facts, when required) are present and in compliance with requirements.

The generic approval labeling regulations (9 CFR 412.2) provide for use of final labeling without further authorization from FSIS. It is the establishment's responsibility to prepare final labeling in accordance with applicable regulations/policies, and to create and maintain records of all final labeling.

Establishment Responsibility

- Create a record of final labeling for labeling previously approved as a sketch by LPDS. Final labeling includes modifications made by LPDS during evaluation.
- Create a record of final labeling that has been generically approved.
- Create a record of final labeling when changes are made to a label that do not require LPDS re-approval (changes that do not affect any special statements or claims and are in compliance with all regulations; adding additional products to a blanket label approval)
- Update labeling records with temporary approvals where regulatory deviations occur that have received temporary approval from LPDS.
- Maintain labeling records and provide them for FSIS inspectors upon request.

Label Record

Each label record consists of:

- The actual product's label
- The product formulation
- Processing procedure
- All documentation required to demonstrate the label's compliance with regulatory requirements, including sketch or temporary approvals if appropriate.

For additional information, please contact LPDS at (301) 504-0878.