

# *Labeling and Establishment Responsibilities*

The Labeling Review Branch only grants temporary approvals and sketch approvals since July 1, 1996. The generically approved labeling regulations (9 CFR 317.5 and 381.133) provide for use of final labeling without further authorization from FSIS. An establishment responsibility is to create and maintain records of final labeling, otherwise known as, generic approvals.

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## *Establishment Responsibility*

- Create a record of final labeling for labeling previously approved as a sketch by the Labeling Review Branch
  - Modifications (per sketch approval) are made to label before final printing
- Create a record of final labeling for amenable single ingredient products or amenable standardized multi-ingredient products that bears no special claims, guarantees, foreign language
- Create a record of final labeling when minor changes occur to labeling as permitted by generically approved labeling regulations 9 CFR 317.5(b)(9) and 381.133(b)(9), e.g., changes to net weight, vignette, serving instructions, etc.
- Create a record for any other final labeling as indicated by 9 CFR 317.5(b) and 381.133(b), e.g., shipping containers, animal food, legends, etc.
- Maintain labeling records
  - Temporary approvals
  - Final labeling (generic approvals)

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## *Generic Label Record (Final Labeling)*

Each generic label record consists of

- The actual product's label
- The product formulation
- Processing procedure
- Sketch approvals, if appropriate

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Also, refer to labeling regulations 9 CFR 317.4 and 381.132