

Procedures for Labeling Evaluation Submissions and Policy Advisory Consultations

(Updated January 20, 2015)

In order to ensure that the labeling process is efficient, and to maintain timely label reviews, the Labeling and Program Delivery Staff (LPDS) will implement the following procedures:

- There will be advisory and consultation time each working day between 1:00 and 2:00 p.m. with LPDS staff to ask questions concerning labeling, standards, product composition policy, and returned labeling. Please contact the Labeling and Program Delivery Staff at (301) 504-0878 to arrange appointments. **THERE WILL BE NO APPROVALS GRANTED BY THE STAFF DURING THESE APPOINTMENTS.**
- Because access to the Labeling and Program Delivery Staff will be limited for security reasons, Label Consultants/Company Representatives should call ahead to the Distribution Team at 301-504-0883 or 301-504-0878 to announce their arrival inside the building.
- A complete label submission includes:
 - Typewritten form [FSIS 7234-1 Application for Approval of Labels, Marking or Device](#)
 - All required features should be clearly represented on the label. If hand drawn, regulation should be cited i.e., Legends -P-381.96, M-312.2, Safe Handling -P-381.125(b), M-317.2(l), Nutrition Facts (M-317.309, P-381.409). Attachments are acceptable if referenced on the label, i.e., Safe Handling Instruction.
- Supporting documentation for all special statements and claims, deviations from labeling requirements, and requests for expedited review or temporary approval
- Expediting Firms/Company Representatives are requested to pre-screen the label submissions for legibility, features and information that conflict with current regulations or policies, and the completeness of the entire form before submitting for review.
- Expediting Firms/Company Representatives are requested to separate labels submitted for mandatory review from those submitted for voluntary review (generic-eligible labels) and to enter “generic” in block 10 of labels submitted for voluntary review to indicate this request. Within each category described on the Log In Sheet*, please further sort submittals by establishment and, within establishment, by similar product type. Submit labels and related information in a bundle of no more than 10 labels per bundle, with a completed Log In Sheet attached as the cover of the bundle. Please fill in **all** information blocks on the Log In Sheet.
- Resubmissions will be directed to the original staff member who performed the label review. Indicate on the Log In Sheet the name of the original Staff Officer (use a separate Log In Sheet for each Staff Officer).

- For in-person submissions, labeling submittals may be dropped at Patriots Plaza III, 355 E Street, SW, Washington, DC. Label Consultants will receive a daily email when labels are available for pick-up.
- Drop off/Pick up hours are (unless otherwise specified by LPDS):
 - Monday, Tuesday, Thursday, and Friday:
9:00 a.m. - 3:00 p.m.
 - Wednesday:
Morning: 9:00 - 11:00 a.m.
Afternoon: 1:00 - 3:00 p.m.

These times may vary due to staff availability.

- Labeling may also be submitted by mail which includes U.S. Postal Service, regular and priority, and U.S. overnight at the address below:

USDA, FSIS, OPPD, LPDS
Distribution Unit
Stop Code 3786, Patriots Plaza III, 8-168
1400 Independence Avenue, SW
Washington, DC 20250-3700

Labeling submitted by UPS, FedEx, or Courier should be shipped to the address below:

USDA, FSIS, OPPD, LPDS
Distribution Unit
Patriots Plaza III, 8-168
355 E. Street, SW
Washington, DC 20024-3221

- Regardless of the mode of delivery, labeling submittals will be evaluated on a first-come, first-serve basis. Mandatory reviews will be prioritized over voluntary reviews. Please note that "turn-around" time depends on the volume of labeling submitted for evaluation, the extent to which corrections are needed, the complexity of the information provided, and other extenuating circumstances. It is advantageous to completely review labeling submissions ahead of time, filling in all transmittal information blocks, correcting any errors or information gaps, and most importantly, having the necessary documentation included. **Incomplete or illegible labeling submittals will be returned without evaluation.**
- Careful thought should be given before voluntarily submitting a label that can be generically approved. Such labels will receive lower priority than those requiring Agency approval and may take longer to be reviewed. Agency review of such labels may also slow down the review process for labels that are not generically approved and must be submitted to the Agency for approval.

- Appeals of labeling policy decisions should be submitted in a separate envelope marked "Appeal" with the form [FSIS 8822-4 Request for Label Reconsideration](#), the labeling submittal (including application form, copy of the label, and supporting documentation), and LPDS comments. Written arguments supporting the basis for the appeal must be enclosed with the appeal. In addition, **all uncontested modifications to labeling must be made prior to the submission of an appeal**. As always, the appeal process involves the Staff Officer, and if necessary, the Staff Director.

* A copy of the Log In Sheet may be obtained from LPDS