

Procedures for Labeling Evaluation Submissions and Policy Advisory Consultations

(Effective September 27, 1999)
(Updated February 15, 2012)

These instructions serve to implement the changes in the label review procedures that were described in the July 27, 1998, Notice of Procedural Change (63 FR 40010).

1. For in-person submissions, labeling submittals may be dropped at Patriots Plaza III, 355 E Street, SW, Washington, DC:

Monday, Tuesday, Thursday, and Friday:

Morning: 10:00 - 11:30 a.m.

Afternoon: 1:30 – 3:00 p.m.

Wednesday:

Afternoon: 1:30 – 3:00 p.m.

Because access to the Labeling and Program Delivery Division will be limited, please call ahead to the Distribution Team at 301-504-0883 or 301-504-0878 to announce your arrival.

"Log In" Sheets and bar code strips may be obtained during these times, as well.

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, LPDD
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, LPDD
Distribution Unit
Patriots Plaza III, 8-168
355 E. Street, SW
Washington, DC 20024-3221

2. For in-person submissions, labeling submittals (i.e., transmittal form, sketch, supporting information, etc.) should be sorted by category as outlined on the Log In Sheet. 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.

3. Resubmissions will be directed to the original Labeling Evaluation Specialist who performed the label review. Indicate on the Log In Sheet the name of the original Labeling Evaluation Specialist (use a separate Log In Sheet for each Labeling Evaluation Specialist).
4. Bar codes must be attached to each label transmittal form in the upper left corner of the top copy. Please leave the original bar code attached and include the comments provided by the Labeling Compliance Team (LCT). For mail submissions, bar codes will be applied by the team.
5. Regardless of the mode of delivery, labeling submittals will be evaluated on a first-come, first-serve basis. 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.**
6. Careful thought should be given before submitting a label that can be generically approved. Agency review of such labels only slows down the review process.
7. The consulting or expediting firm will be notified by fax or telephone that bundles are completed and may be picked up.
8. There will be advisory and consultation time each working day between 8:00 a.m. and 4:00 p.m. with the Division staff (including the Labeling Evaluation Specialists) to ask questions concerning labeling, standards, additives, product composition policy, and returned labeling. Please contact the Labeling Program Delivery Division (LPDD), at (301) 504-0878 to arrange appointments with Labeling Evaluation Specialists and other technical policy staff. There will be no approvals granted by the staff during these appointments.
9. Appeals of labeling policy decisions should be submitted in a separate envelope marked "Appeal" with the Appeal Form, the labeling submittal (including sketch, transmittal form and supporting documentation), and LCPS staff 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 Labeling Evaluation Specialist, and if necessary, the Staff Director.