

**FREQUENTLY ASKED QUESTIONS ABOUT THE FSIS LABEL
APPROVAL PROCESS AND LABEL EVALUATION PROCEDURES
CONDUCTED BY THE
LABELING AND PROGRAM DELIVERY DIVISION (LPDD)**

Q. 1 How can a company submit labels to the Agency for evaluation?

A. 1 Applications for label approval can be submitted to the FSIS Labeling and Program Delivery Division (LPDD) a number of ways. Label submissions can be sent via regular mail and express-mail services, hand-carried by a company representative, and delivered to FSIS through a courier (label expediting firm, consultant, law firm, etc.). In addition, small and very small companies may fax labels to LPDD for evaluation.

Q. 2 What information needs to be included by a small company faxing labels to FSIS for evaluation and approval?

A. 2 Label submissions require the completion of [FSIS Form 7234-1](http://www.fsis.usda.gov/Regulations_&Policies/Labeling_Procedures/index.asp) Application for Approval of Labels, Marking, or Device (which includes product formula, processing procedures, etc.). This form is available for downloading on the FSIS website at: http://www.fsis.usda.gov/Regulations_&Policies/Labeling_Procedures/index.asp. As with all label approval submissions, two copies of the transmittal form, [FSIS Form 7234-1](http://www.fsis.usda.gov/Regulations_&Policies/Labeling_Procedures/index.asp) and two copies of the sketch (3 of each for animal production, imports and exports, religious exemptions and certified pet food labels) must be faxed to the Labeling Tracking and Distribution Unit at (301) 504-0873. They must be legible. If all label features are not readable, the submission will be sent back with a request that they be mailed to LPDD because they are illegible. If you have more than 5 labels, they should not be faxed, but submitted in another manner. When faxing, please make it clear which transmittal form goes with which label.

Q. 3 What is the best way to mail labels to FSIS for evaluation?

A. 3 Express mail, with a return, pre-paid, express mail envelope, is going to get the labels to LPDD and returned to the company quickest of the mail options.

Q. 4 How long does it take to get a label evaluated?

A. 4 The time for the label evaluation process is dependent on a variety of factors: the complexity of the label (e.g., claims and special features) and the data accompanying it to support claims, the accuracy and completeness of label submissions, the number of labels in the queue and staff availability, and prevailing project priorities. Once the label is received by LPDD, the evaluation process could take up to 10 work days for labels with claims. Once the label is received by LPDD, it is assigned a unique number and logged

into a computer tracking system by the Distribution Unit. The labels are evaluated by the technical policy staff of LPDD and returned to the Distribution Unit for tracking. The Distribution Unit then processes the labels and returns them to the company that submitted them, often that day or the following work day.

Q. 5 Are some labels taken before others for label approval?

Labels are evaluated on a first-in/first-out basis. Some labels require more intensive evaluation due to the complexity of the label and the policy issues it presents, and may take additional time for evaluation. To ensure that products reach the marketplace when desired, companies should factor in the time necessary for consulting with the labeling policy staff and securing label approvals. Consider that some labels are returned for additional information/clarification. The return labels are handled as any other label submission, i.e., first-in/first-out. Thus, if a label is returned several times requesting additional information from the company, the submission and evaluation process will take more time. Companies need to keep this in mind when submitting labels for approval.

Q. 6 If there are minor errors on my label, will it be modified or returned?

A. 6 Whether your label is modified or returned is dependent on the nature of the errors on the application or on the label. LPDD staff will often make modifications and return the label “approved as modified.” In some cases, staff may modify formulations or processing procedures, based on information requested, if they are simple and required. For example, if a product is labeled “Hickory Smoked,” and the processing procedures state “smoked,” LPDD staff could stipulate “Hickory Smoked” in the processing procedures, as opposed to returning the label to question if 100% hickory smoke is used. If a chili product has a formula with 39% beef, and the standard requires 40%, LPDD might increase the beef and drop another ingredient, e.g., water, as a matter of efficiency. Sometimes, LPDD staff may contact companies directly before making such changes, or they may return labels for clarification or changes.

Q. 7 What if the company doesn’t want the modifications that were made to a label?

A. 7 The company can resubmit the label with other modifications that will fix the non-compliance issue that LPDD staff identified. If the company is not certain why the modifications were made, they should call LPDD and speak to the technical policy staff member that made the modifications and determine whether other modifications would be acceptable. Lastly, the company can appeal the decision through the label appeal process. More detailed information is explained on the LPDD website at: http://www.fsis.usda.gov/About_Fsis/labeling_&_consumer_protection/index.asp. While there are often many ways of modifying labeling to bring it into conformance with the Federal regulations and policies, LPDD is likely to choose the most common and obvious changes to make the label correct. If you do not wish to have modifications made to labels, we suggest you specify that prominently in the label submission along with a name of a contact person and telephone number. LPDD staff will try to contact

that person directly to discuss the labeling issues. Keep in mind that, because of time constraints, LPDD staff may make some modifications to labels or return the label unapproved if it can not contact the company quickly regarding the matter.

Q. 8 If a company wants to know where its label is in the label evaluation and approval process who should it contact?

A. 8 If the label is mailed, faxed, or express-mailed directly to LPDD, the company should contact the Distribution Unit at (301) 504-0883. However, please wait a reasonable amount of time before calling to account for transit. If a label is sent via a label courier firm, you should contact the courier firm to obtain the status of the label.

Q. 9 How can companies help to speed up or improve the label approval process?

A. 9 There are a number of ways to help make the label approval process more efficient:

- Labels that can be applied to products under the generic labeling approval regulations, i.e., labels for products that are not for household consumers and that do not include claims, guarantees, or foreign language, **should not** be submitted to LPDD for evaluation and approval. Most minor modifications to labels can also be made under the provisions of the generic labeling regulations (refer to [Title 9, Code of Federal Regulations](#) (9 CFR) Sections [317.5](#) and [381.133](#)).
- Ensure that the label submissions are complete and that the labeling is in accordance with labeling, food standards, and ingredient regulations and policies before submitting it. For example, ensure that there are two legible copies of the label submission, all required features are on the label, the ingredients statement agrees with the formula, and the data needed to support claims accompanies the submission. Check the FSIS website for helpful guidance, e.g., the “Ten Most Commonly Asked Questions” (http://www.fsis.usda.gov/Regulations_&Policies/Labelings_Ten_Questions/index.asp) and the “Suggested Label Submission Checklist” (http://www.fsis.usda.gov/Regulations_&Policies/Label_Submission_Checklist/index.asp).
- Ensure that requests for temporary label approvals conform to the provisions of [9 CFR 317.4](#) and [381.132](#). For multiple label applications, e.g., a temporary approval to add sodium lactate and sodium diacetate to deli products, send in a “blanket” temporary request for approval. In the request, include one completed [FSIS Form 7234-1](#), including formula and processing procedures, one label, and a list of all of the other products/labels to be covered by the temporary approval.
- Do not send multiple copies of the same label for approval through a variety of delivery modes, i.e., do not fax the label to LPDD for evaluation and follow it with a mailed copy.

- If your company has policy issues, e.g., a new claim about soy protein, the use of a new ingredient, a trademarked logo that represents a kind of third party certification, these issues should be submitted as a letter requesting a written opinion on the issue. Do not submit labels for evaluation to address the policy issues. Because of the volume of labels reviewed, it is likely that such issues could be overlooked in the approval process. Therefore, it is to the company's benefit to present the policy issues to LPDD in a manner (e.g., in correspondence) in which they will be thoroughly reviewed and result in a written response on the matter. By handling policy issues separately from label submissions, it avoids a situation where LPDD discovers that the labels were approved in error and is forced to rescind the approval.
- When multiple labels for the same product are submitted with minor variations, specify the differences between the labels. Otherwise, the labels will likely be returned with a note asking why multiple labels were submitted that appear to be identical.
- Do not send the same inquiry to multiple staff members. This will likely slow down the label approval process.
- When calling the LPDD office, provide the administrative assistants with the subject of concern so that they can best direct the calls to the staff members with the appropriate expertise. The technical staff strives to return phone calls and emails within 48 hours. When leaving a phone message, speak slowly and clearly. In case there is a poor connection, state your name and phone number at least twice and spell the last name. Leave an establishment number for your plant (if you are located at a federally inspected facility). Leave a message that briefly explains the issue of concern so that the staff member can be best prepared for the return phone call.

Q. 10 How are labels returned to companies after they are evaluated?

- A. 10 Generally, labels are returned in the same manner as they are submitted. However, labels express mailed in will only be express mailed back if a prepaid express mail envelope is enclosed.

Q. 11 How does a company request a temporary label approval and when is a temporary approval not likely to be granted?

- A. 11 Temporary label approvals are typically for situations when labels that are previously approved are no longer accurate because of changes to product formulation, processing, or marketing, or when errors are found on labels in commerce. Requests for temporary approvals must be submitted to LPDD through regular submission procedures. Requests need to address the four conditions required for granting temporary approvals that are stated in [9 CFR 317.4](#) or [381.132](#). In addition, the submission should state the specific reason for requesting a temporary approval, e.g., the company is removing MSG from the formulation. Temporary label approvals will not be granted when the errors on labels constitute health and safety issues, economic fraud, or if the temporary approval would

create an unfair competitive advantage. Minor errors can generally be granted temporary use for up to 6 months. For ingredient changes, highlight all individual ingredients that are in the product but NOT on the label. For example, if a new breeding is used, do not just provide old and new breeding ingredients. Highlight the ingredients in the new breeding that will be in the product and not on the label. This avoids the staff time needed for comparing two alternative components that contain 10 or more ingredients. For more significant errors, temporary label approvals are likely to only be granted for several days to allow the company to ship product that is produced and labeled, but tagged by FSIS inspection personnel. There is additional information regarding temporary approvals on our website at:

<http://www.fsis.usda.gov/OPPDE/larc/Procedures/TempApproval.pdf>.

Q. 12 If a company gets a label sketch approved by FSIS that contains an error, is it eligible for a temporary label approval?

A. 12 Granting a temporary label is not dependent on having obtained a LPDD sketch approval; it relates to the nature of the error. Consider, too, that all final labels are eligible to be applied to products in accordance with the generic label approval regulations. Federal establishments are responsible for ensuring that final labels are in accordance with all laws, regulations, and policies before they ship the products in commerce. The LPDD sketch approved stamp states this information. LPDD sketch approval does not absolve a company of responsibility for applying final labels and producing products that conform with the regulations.

Q. 13 Is it necessary to resubmit labels for approval to show the corrections when receiving a modified sketch on evaluation?

A. 13 No. The corrections should be made as shown on the sketch and the final label is eligible to be applied under the generic approval regulations without submitting it to FSIS again (unless further changes are made by the company). FSIS no longer provides final label approvals.

Q. 14 What does LPDD charge for label approval?

A. 14 LPDD does not charge for label approval. It is one of the services provided by FSIS with funds appropriated by Congress.