QUESTIONS AND ANSWERS RELATED TO THE ELECTRONIC LABEL SUBMISSION AND APPROVAL SYSTEM (LSAS)

Q1. What is the Label Submission and Approval System (LSAS)?

A. LSAS is a secure web-based electronic label submission application. LSAS allows users who have obtained a Level 2 e-Authentication account an alternative way to submit label requests for evaluation to the Labeling and Program Delivery Division (LPDD) and the Agricultural Marketing Service (AMS) for Child Nutrition (CN) Label approval.

Q2. If I use LSAS, do I still need to complete the FSIS Form 7234-1?

A. No. The FSIS Form 7234-1 found on the FSIS website is strictly for paper submission. The information fields from the FSIS Form 7234-1 have all been incorporated into LSAS, which you will complete on-line. You will have the ability to attach additional documents to your application, such as your label image, supporting information, and other related documents necessary to support your label request.

Q3. What if I don't want to use the Label Submission and Approval System (LSAS)? How can I send in my label application?

A. If you choose not to submit your label request to LPDD using LSAS, you may continue to use the current paper submission process using the official <u>FSIS Form 7234-1</u> located on the FSIS website. For paper submissions you will want to review the Questions and Answers Related to the Application for Approval of Labels, Marking or Device, FSIS Form 7234-1.

Q4. After I complete all the fields required in LSAS, will I be able to make a copy of my application for my records?

A. Yes. You will have the opportunity to generate a PDF of the completed 7234-1 and any supporting documentation you have attached. You can also save the file to any location for your records.

Q5. How will I know if LPDD received my submission?

A. Once you select "submit application," LSAS displays a confirmation message that the application has been submitted and includes a Label Identification Number for tracking purposes.

Q6. How can I check on the status of my application?

A. Each submitter will have a dashboard that includes "pools." Typical pools found on a submitter's dashboard are Announcements (from the LSAS Administrator), Application Messages, Drafts, and status information, including, Submitted Applications, Adjudicated Applications, Returns and Rescinded Applications, and Appeals. If your application is still in the Submitted Applications pool with a received date, it is not in the review stage yet. Once your application is in review, the status date will change to pending. Depending on the outcome of the review, your applications will move to other pools, i.e. Adjudicated Applications, Returns and Rescinded Applications, etc.

Q7. Where can I find instructions or training for LSAS?

A. LPDD has provided a user guide for industry, PowerPoint presentations, and other information on our FSIS website. Additionally, the Agency's Outreach and Training Office (OEET) will be assisting LPDD in preparing webinars and other public presentations for training relevant to LSAS.

Q8. Who do I contact if I need assistance or have a technical issue concerning LSAS?

The LSAS administrator will be your first contact. You may email the administrator at LSAS@fsis.usda.gov or call 301-504-0837(M-F, 8:00am to 4:00pm EST). We ask that you use these resources first, rather than calling the main LPDD lines, so that we can track all issues and provide appropriate resolutions.

Q9. Who do I contact if I need help with my e-Authentication account?

A. For assistance with your Level 2 e-Authentication account or password issues, you may contact:

Service Desk 1-800-457-3642, Option 1 or <u>eAuthhelpdesk@ftc.usda.gov</u>

Q10. How will child nutrition label applications be processed in LSAS?

A. AMS technical staff has access to LSAS. LSAS will direct all child nutrition label applications first to the AMS technical staff. Once AMS adjudicates the label application as approved, LSAS will re-direct to LPDD for further evaluation and adjudication.

Q11. I have a child nutrition label application that I want to submit by using the paper submission process. Does the process for submitting child nutrition label paper applications change at this time?

A. No. AMS will continue to evaluate paper submissions as they have done in the past. For paper submissions you will want to review the Questions and Answers Related to the Application for Approval of Labels, Marking or Device, FSIS Form 7234-1. Once AMS adjudicates the paper submission as approved, it will be routed to LPDD in the usual manner. Once received by LPDD, it will be integrated into LSAS for further evaluation by LPDD technical staff. The adjudicated label will be printed and mailed back to the submitter.

Q12. I heard LSAS has a tool to help determine whether the label can be approved using the generic labeling regulations. Why would a submitter want to use this?

A. That is correct. LSAS includes a feature called the Generic Label Advisor (GLA) to determine whether a label can be generically approved. LSAS has incorporated the generic labeling regulations (9 CFR 317.5 and 381.133) into the GLA, which allows the submitter to respond to a series of questions. Based on the responses given by the submitter, the GLA will determine whether the label can be generically approved. Based on the responses, if the label can be generically approved. LSAS will generate a certificate that can be included in the submitter's labeling records.

Q13. Can an appeal be submitted using LSAS? If so, what is the process?

A. Yes. LSAS allows the submitter to appeal a LPDD decision, modifications, or denials. For instance, the submitter can select from their pool an adjudicated label with the status of sketch modified, and create the appeal by following the prompts provided. To use this option, the submitter should include the reason for requesting the label appeal and should include documentation to support the appeal. Note: All uncontested modifications to labeling must be made prior to the submission of an appeal.

Q14. Does LSAS require me to install or download any special software or tools?

A. No. The LSAS web application does not require you to install or download any tools in order to use it. All you need is a working Internet connection, Level 2 e-Authentication, and Adobe Reader.

Q15. I started working on my label application but did not finish it. Will I have to abandon it and start over?

A. No. LSAS will keep a draft of your label application in the Draft Pool. You may select the draft at a later date and continue to edit where you left off. Drafts will only be maintained for a period of 30 days from the date you last saved it.

Q16. When I need to request a duplicate copy of a prior approval, I need to send in a letter requesting this information. Will I be able to retrieve prior approvals in LSAS now?

A. Prior approvals (before LSAS implementation) are considered legacy data in LSAS and will not be available for viewing by the submitter. Therefore, for approvals prior to LSAS, you will need to continue to send in a letter requesting this information.

Only new label submissions submitted electronically through LSAS will be available for viewing by the submitter. For duplicate copies of prior approvals (before LSAS implementation) see <u>How</u> to Request Duplicate Copies of Approved Labels.

Q17. We have an in-house software system that incorporates the FSIS Form 7234-1. If we complete the label application using our in-house system, is there a mechanism to incorporate that information into LSAS?

A. Yes, LSAS provides a standard, computer format (XML) to interface with our LSAS system. By laying out your in-house data to comply with the official <u>FSIS Form 7234-1</u> into this XML schema format, your data will be easily imported and processed in our system. The in-house system may require modifications to export the XML file as it **must** fit the provided LSAS label import schema. For more information on how to use this feature, see the LSAS user guide.