# Label Submission and Approval System

# LSAS

Webinar Presentation
February 20, 2013

Labeling and Program Delivery Division
USDA, FSIS, OPPD

# Agenda

- Introduction and Background
- Submitter Benefits
- Review of Navigating Your Dashboard
- Review of Managing Establishments
- Brief Review of Creation and Submission of a Label Application
- How to check for Status
- How to respond to a Return
- Helpful Tips (Formula Examples, Claims & Supporting Documents, Appeals, and Miscellaneous Tips)
- Resources
- Questions

# Introduction and Background

The Labeling and Program Delivery Division (LPDD) within the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) develops and provides labeling guidance, policies and inspection methods and administers programs to protect consumers from misbranded and economically adulterated meat, poultry, and egg products which ensure that all labels are truthful and not misleading. Labeling includes all forms of product identification, health-related claims, net weight, species identification and nutrition.

LSAS is a web-based software application that integrates and implements a **secure** electronic label application process for establishments to submit label applications and appeals.

LPDD launched the Label Submission Approval System (LSAS) on May 22, 2012.

# LSAS Submitter Benefits

- **Wizard** available **to assist submitters** with determining which labels can be submitted through the **Generic Label** submission process will **reduce submission errors and questions** to LPDD staff around generic approval
- **Application processing** will be **faster vs. paper submission**
- Realize **cost and time savings** vs. shipping via surface mail
- **Quick** and ready **online access** to application **status**
- Access via **Level 2 eAuthentication**

# LSAS: Submitter Benefits (Continued)

- Storage and record keeping in an electronic environment allowing establishments to save & re-submit standard documentation (e.g., documents that support claims; written protocols) vs. having to print and re-submit with each label application

- Edit checks in the system will check for formatting and submission errors, allowing for corrections in “real time” vs. correcting upon return from LPDD, reducing turnaround time for label review

- Enhanced communication mechanisms (e.g., messaging within LSAS), reducing initial time spent on first time application submission and re-submissions

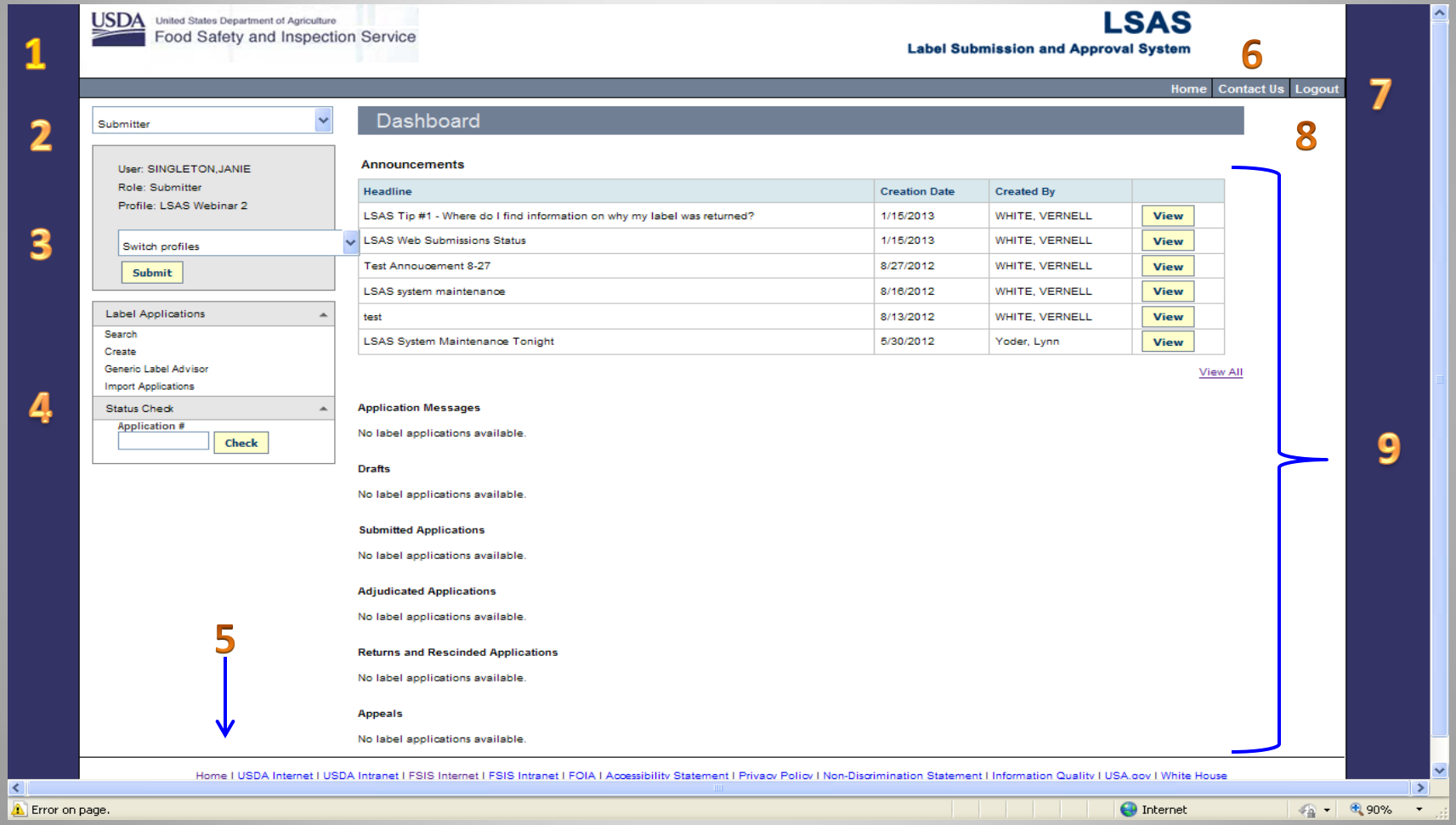
# Account Requirements

- Register for USDA Level 2 eAuthentication Account
- Respond to email confirmation within 7 days
- Make an appointment with a Local Registration Authority (LRA) at a USDA Service Center nearest you. Appear in person so they may validate your identification
- Complete FSIS Enrollment Wizard to request activation of your account for LSAS
- Create organizational or establishment profile name for LSAS

# Account Requirements (Continued)

- Register for an Level 2 USDA eAuthentication: **http://www.eauth.usda.gov/**
- **Local Registration Authority (LRA) locations:** **http://offices.sc.egov.usda.gov/locator/app?type=lra**
- **FSIS Website for LSAS:** **http://www.fsis.usda.gov/Regulations_&_Policies/Label_Submission_Approval_System/index.asp**
- **LSAS Login Access/Enrollment:** **https://lsas.fsis.usda.gov/**

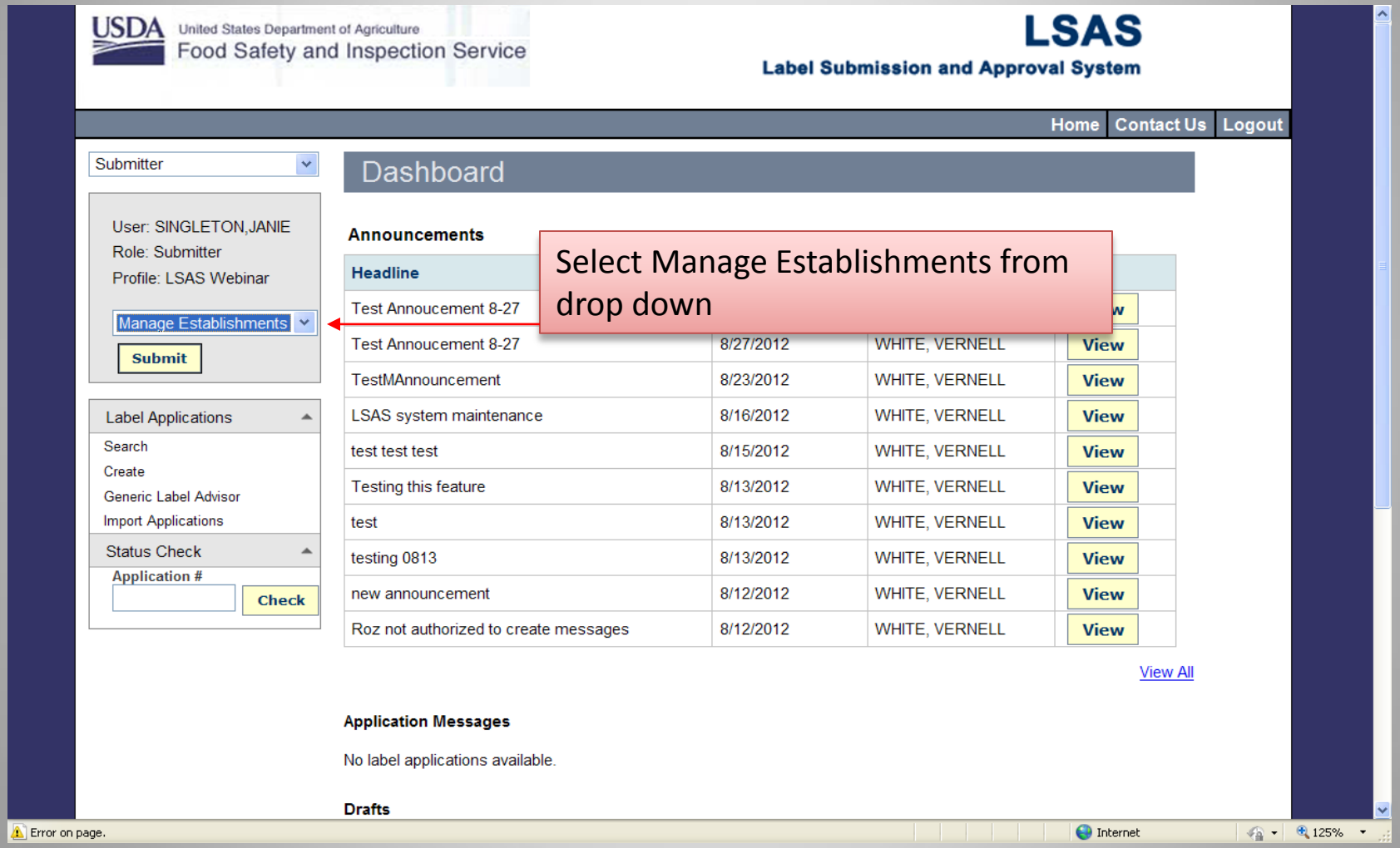
# Navigating Your Dashboard



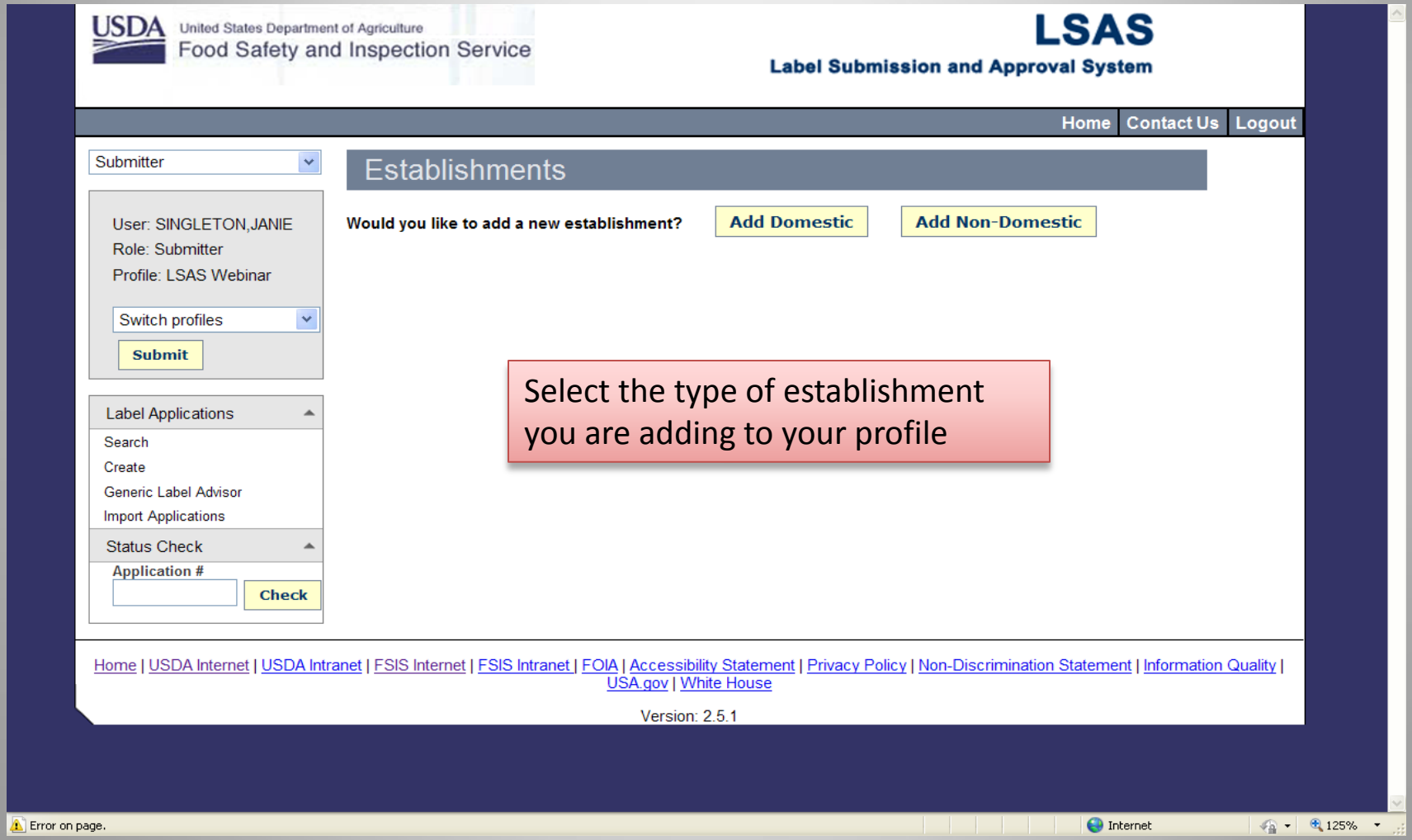
# Navigating Your Dashboard (Continued)

| Item | Name | Notes |
|---|---|---|
| 1 | Banner | With the exception of the LSAS logo, this banner appears on all USDA web pages. |
| 2 | Role | Displays the user's current role. Certain users may be assigned multiple roles and can select role by using the dropdown list. |
| 3 | Profile Menu | Allow user to change their role, share applications, manage establishments. |
| 4 | Navigation Menu | Appears on many LSAS pages; menu options depend upon user role. |
| 5 | Quick links | Appears at the bottom of every page; links to additional resources. It displays the current application version. |
| 6 | LSAS logo | Appears on all pages within the LSAS system. |
| 7 | Navigation Bar | Includes Home, Contact Us and Logout |
| 8 | Header | Appears on every LSAS page; indicates the functionality being displayed in the context area. |
| 9 | Content Area | Central to all LSAS screens, this area of the screen provides the functionality needed to enable the user to perform a task within LSAS. |

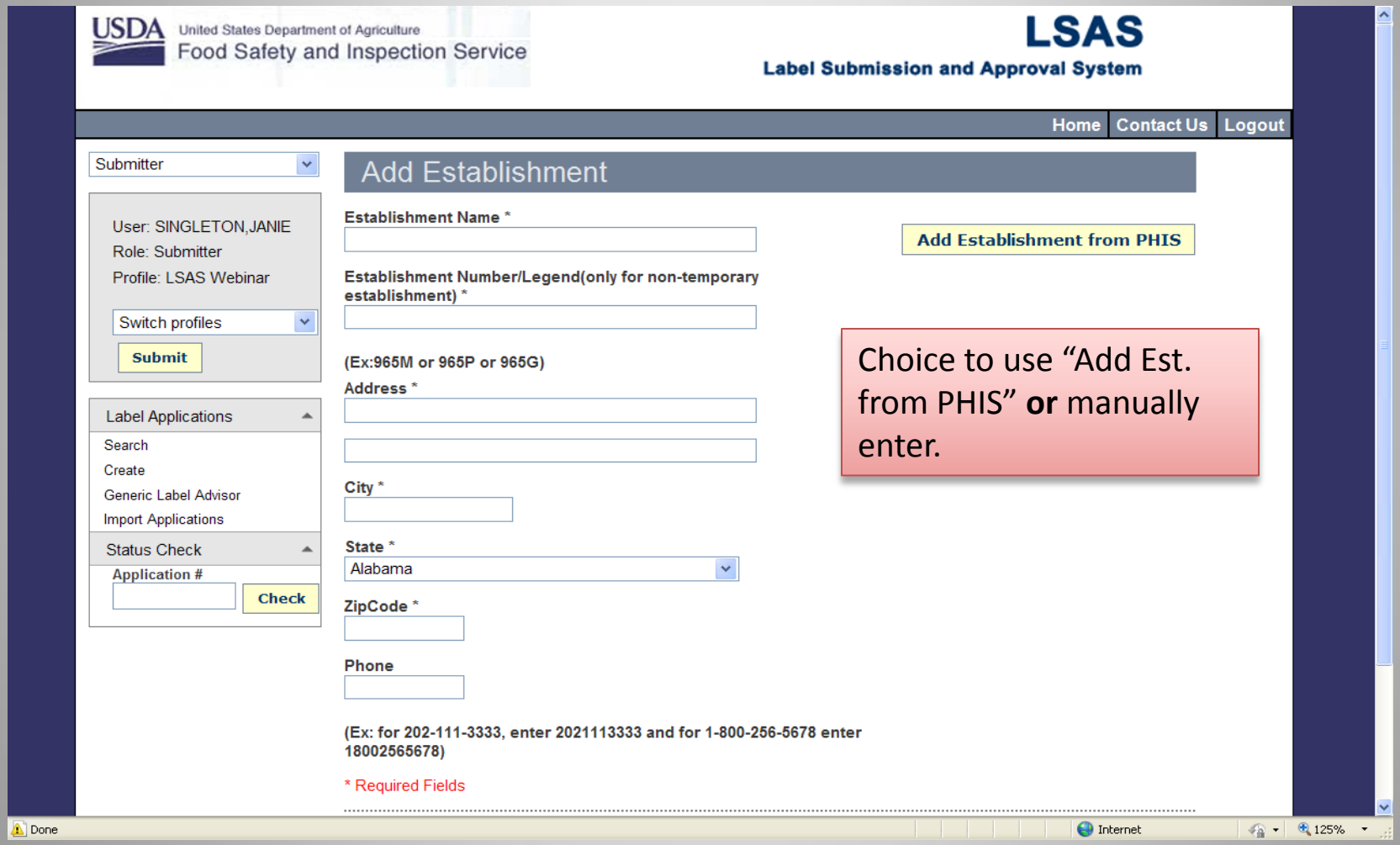
# Manage Establishment



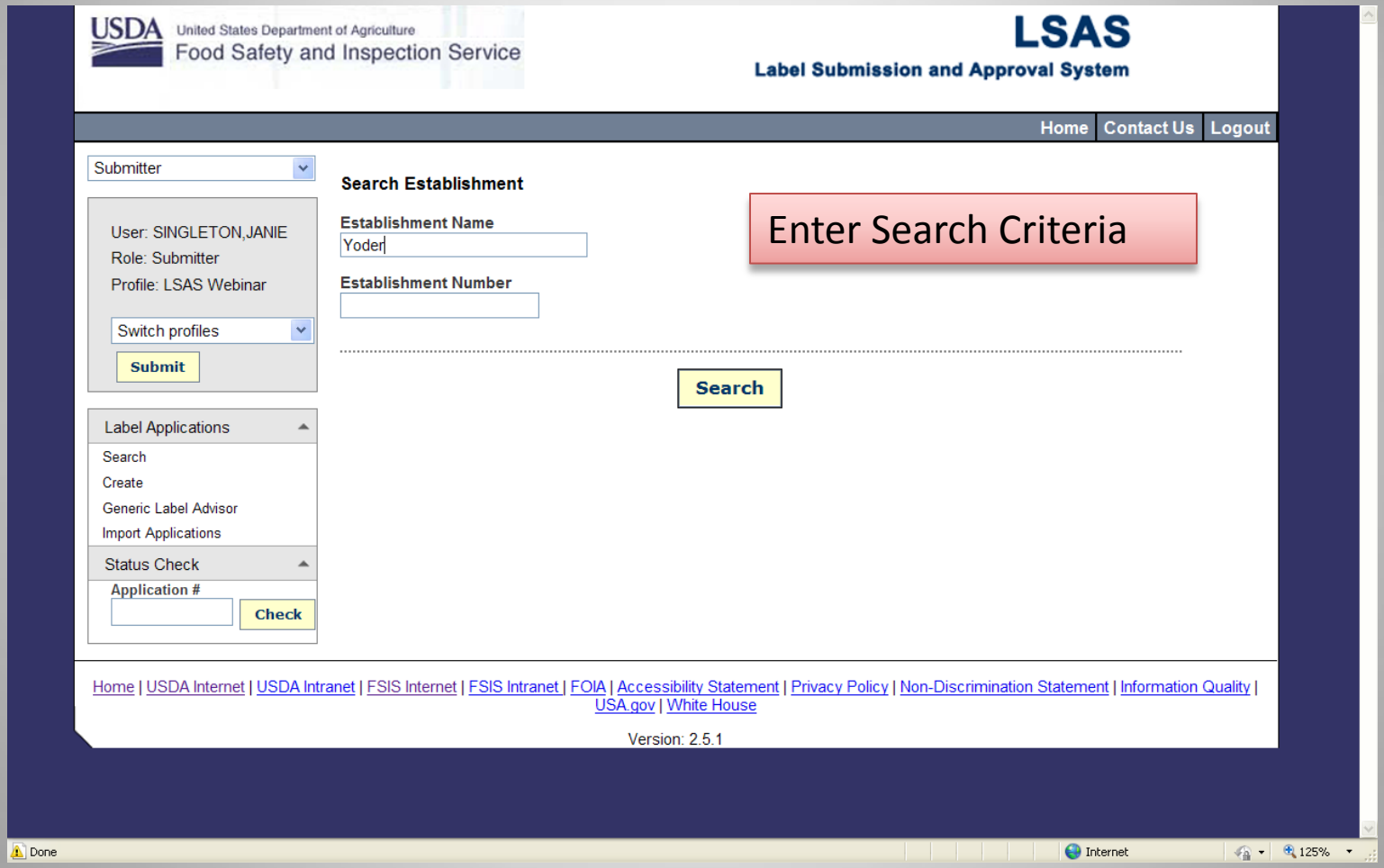
# Add New Establishment



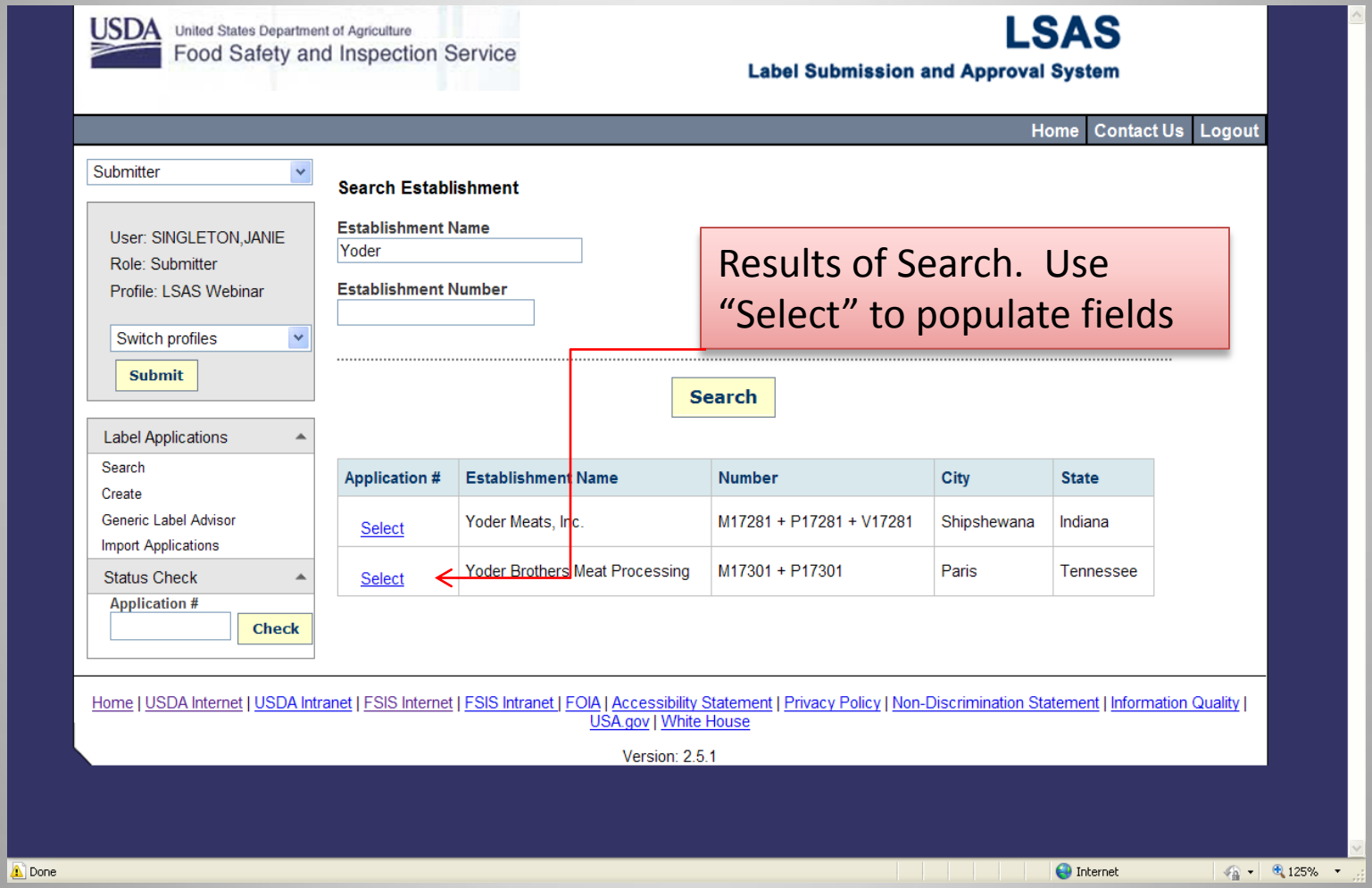
# Add New Establishment (Continued)



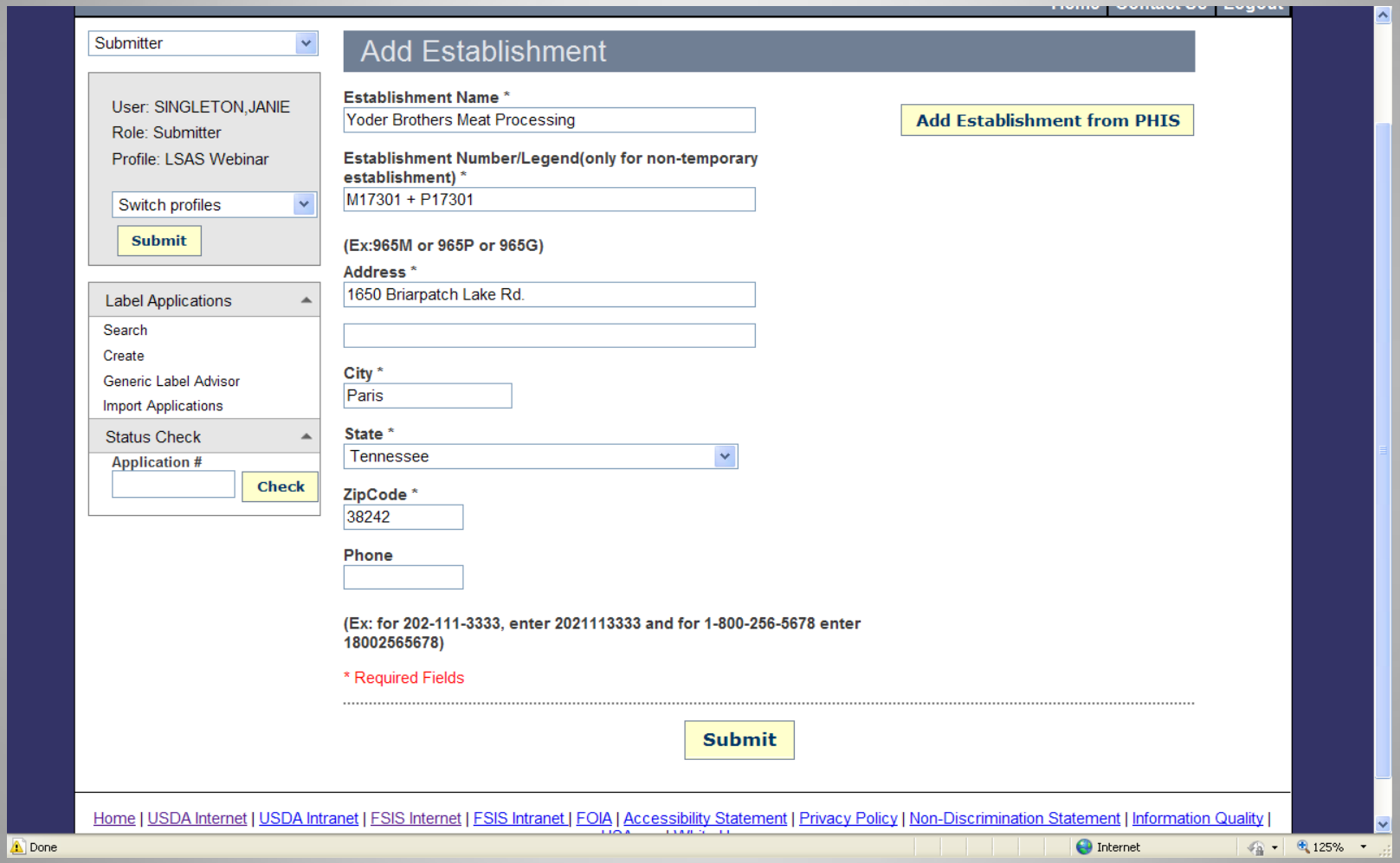
# Add New Establishment – (Continued) Selection of PHIS Link



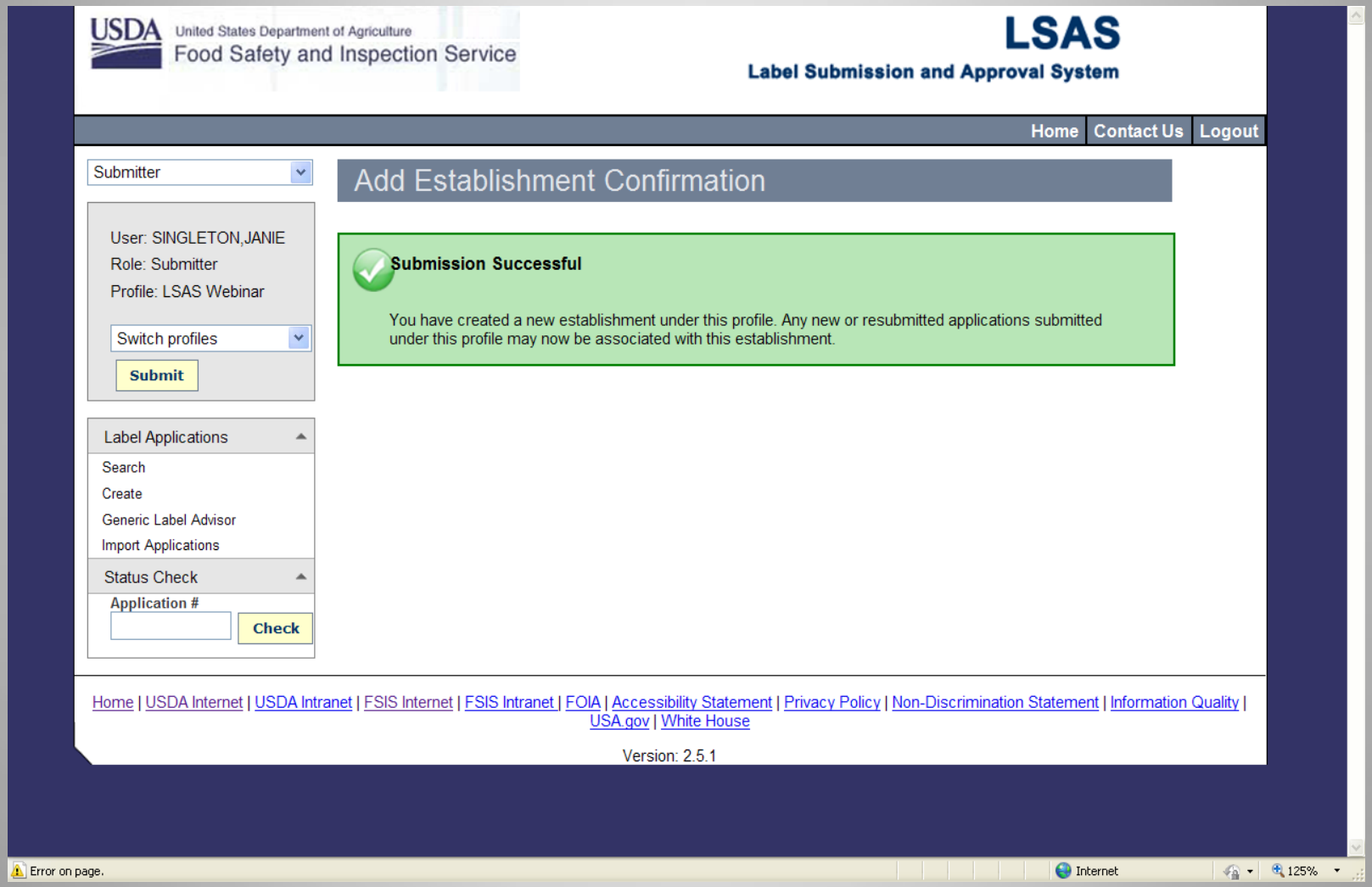
# Results from PHIS search



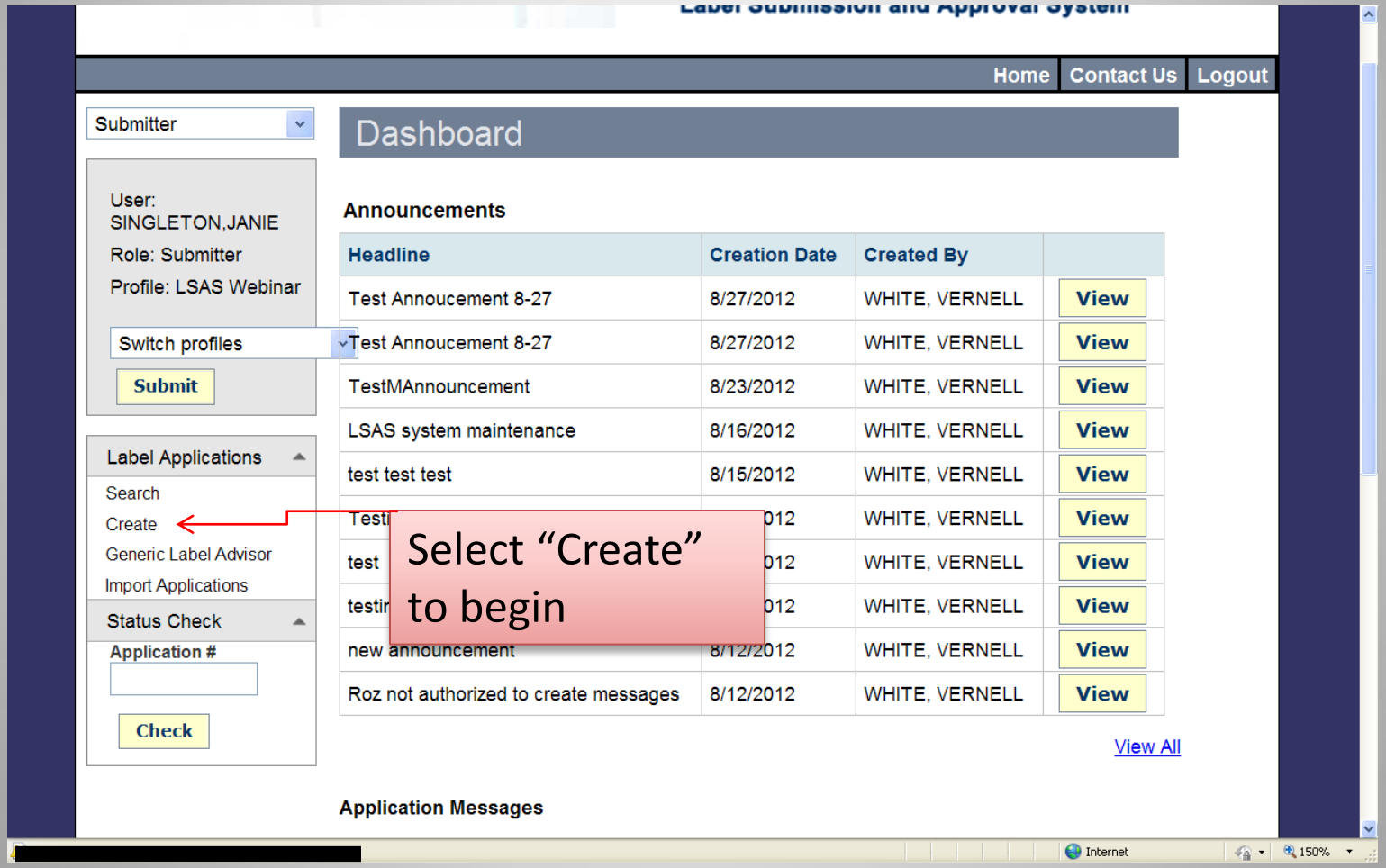
# Selection made and fields populated



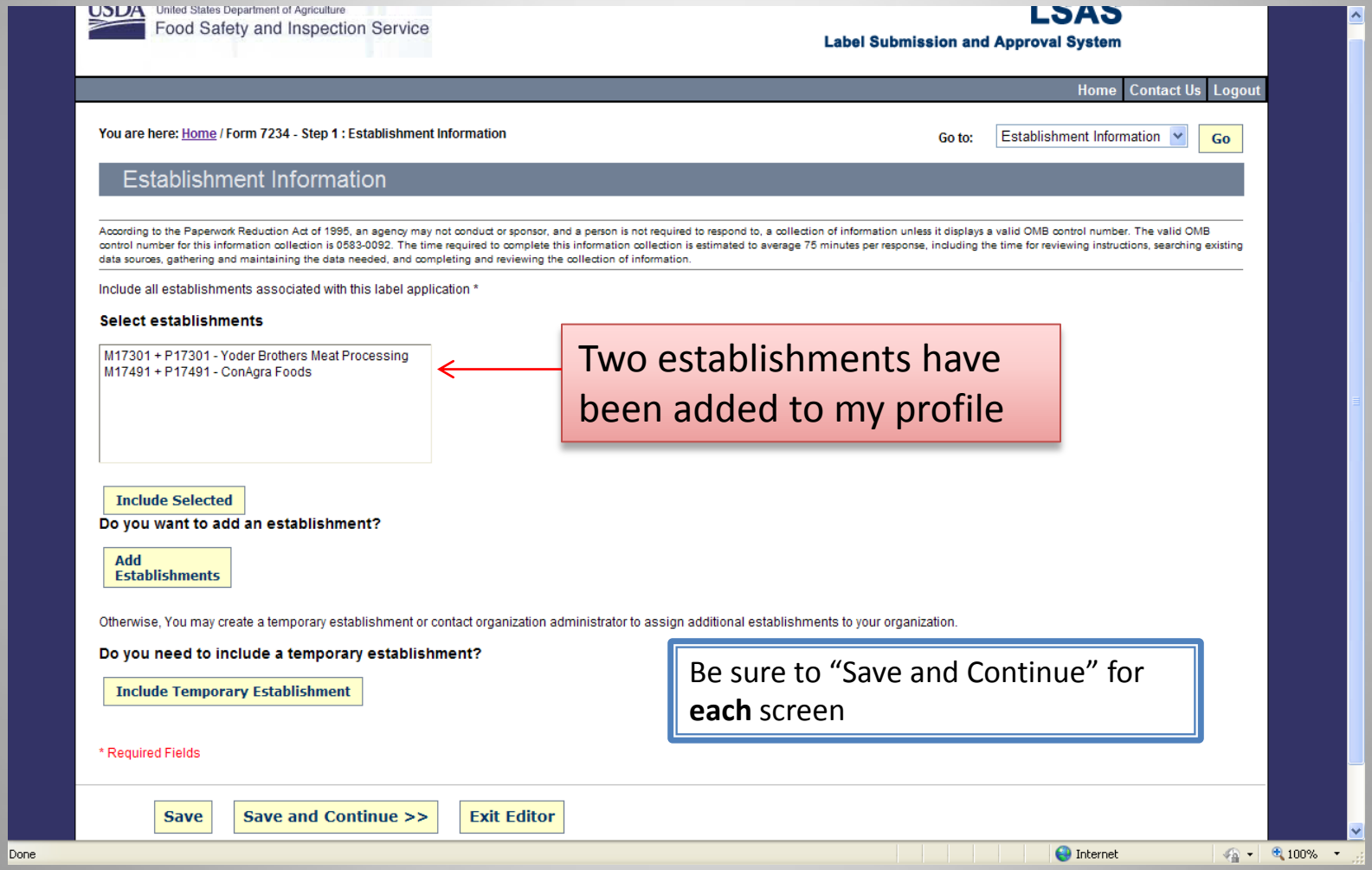
# Confirmation Message – (Submit/Confirm)



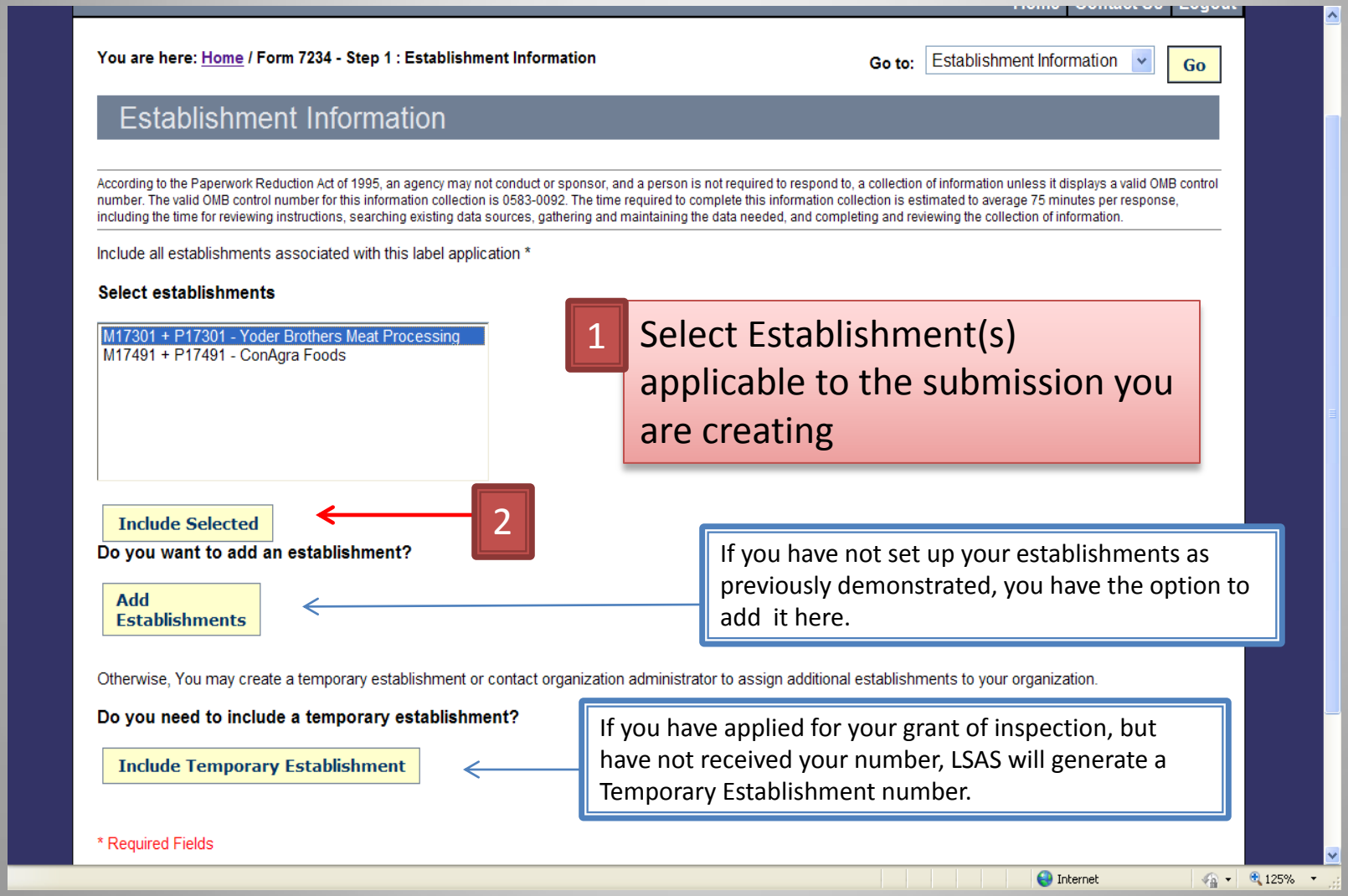
# Create Label Submission



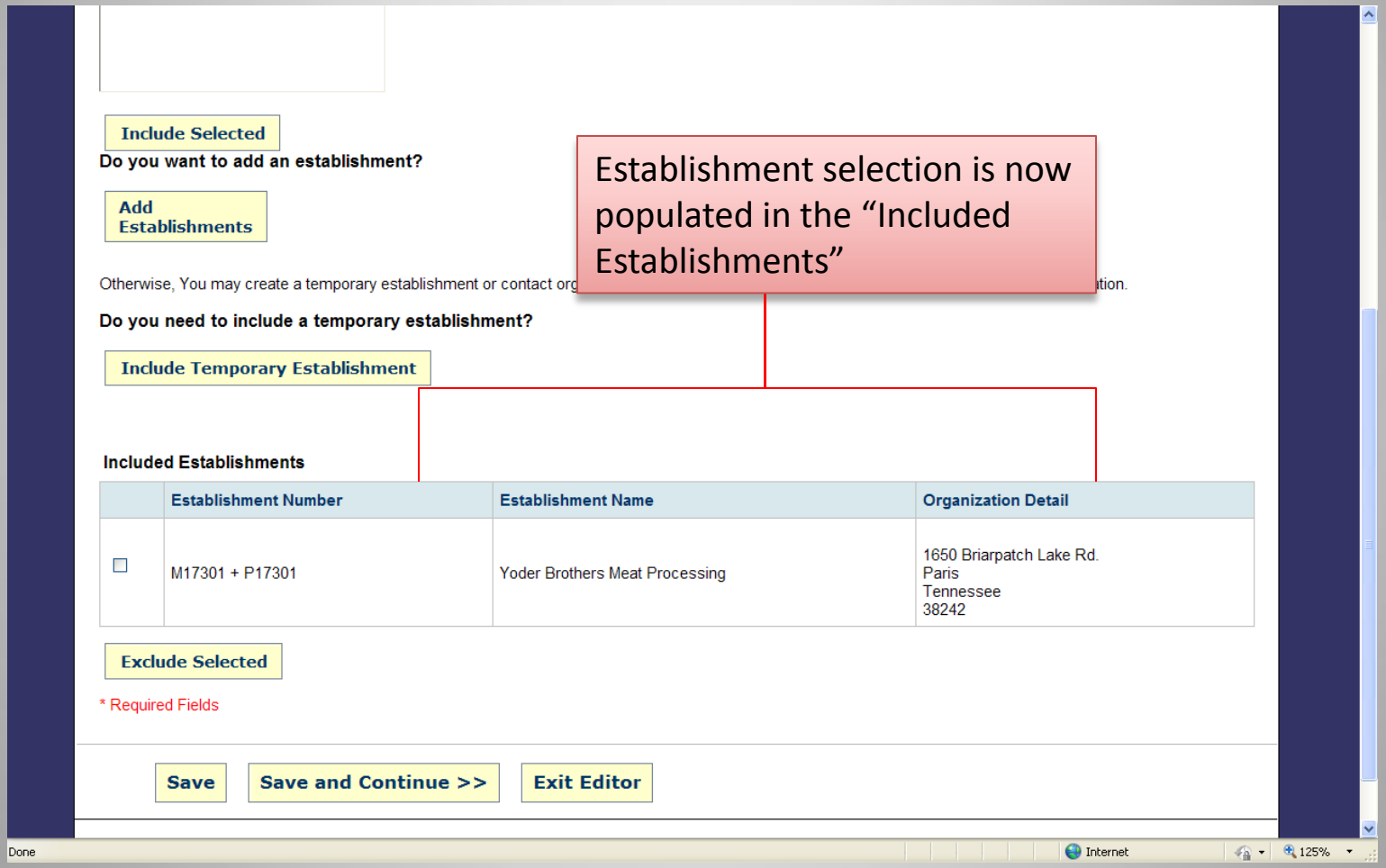
# Establishment Selection - Step 1



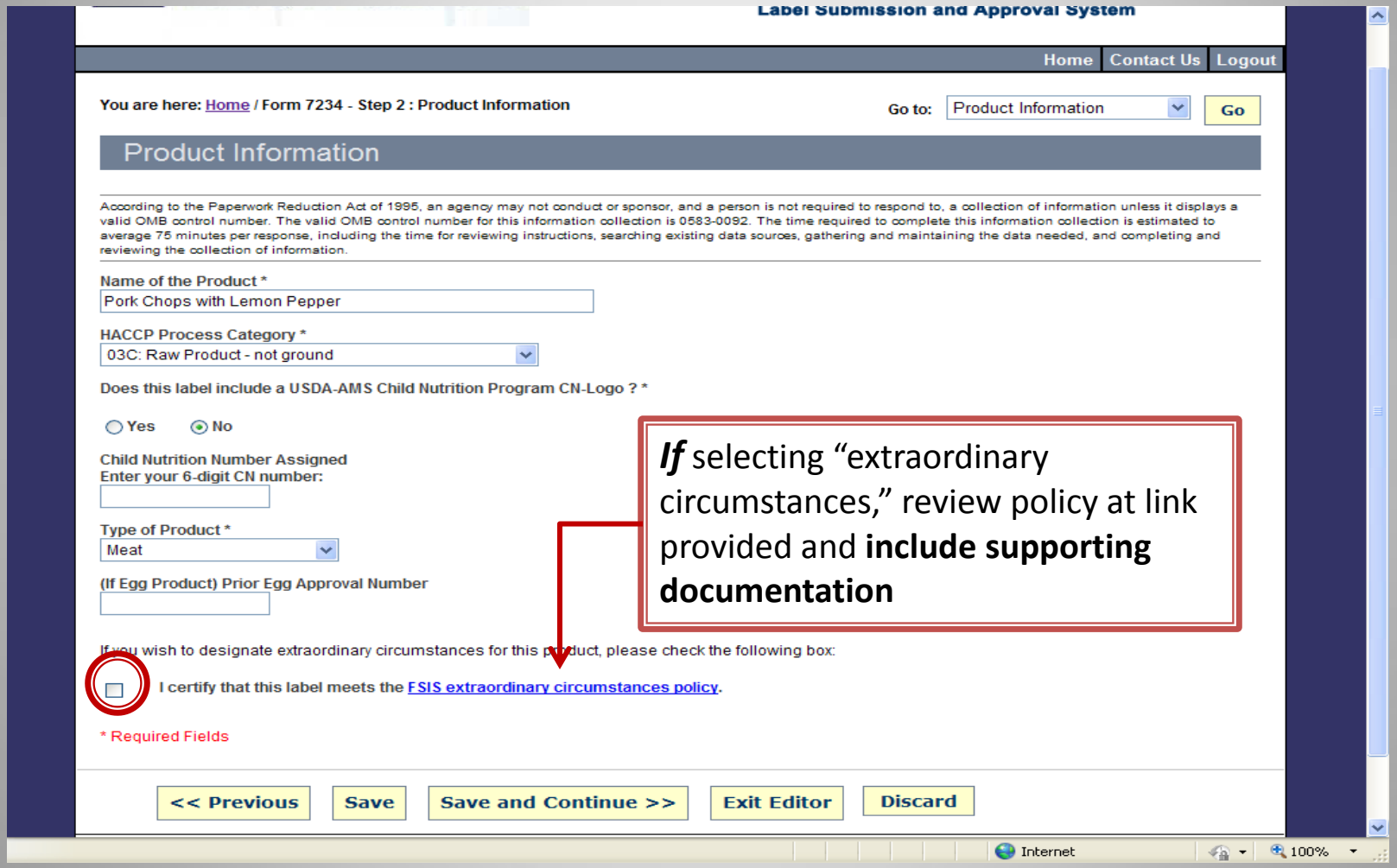
# Establishment Selection – Step 1 (Continued)



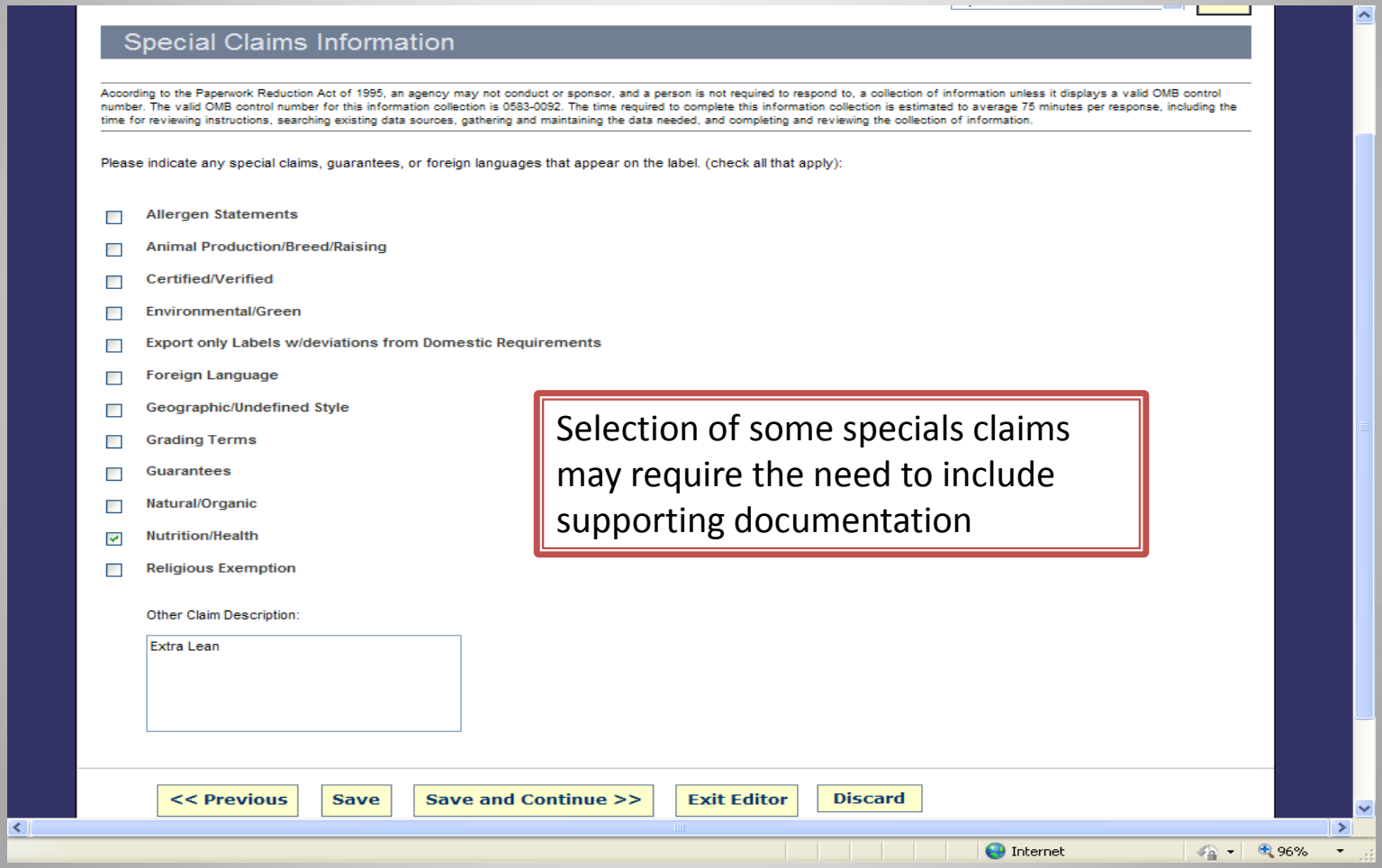
# Establishment Selection – Step 1 (Continued)



# Product Information – Step 2

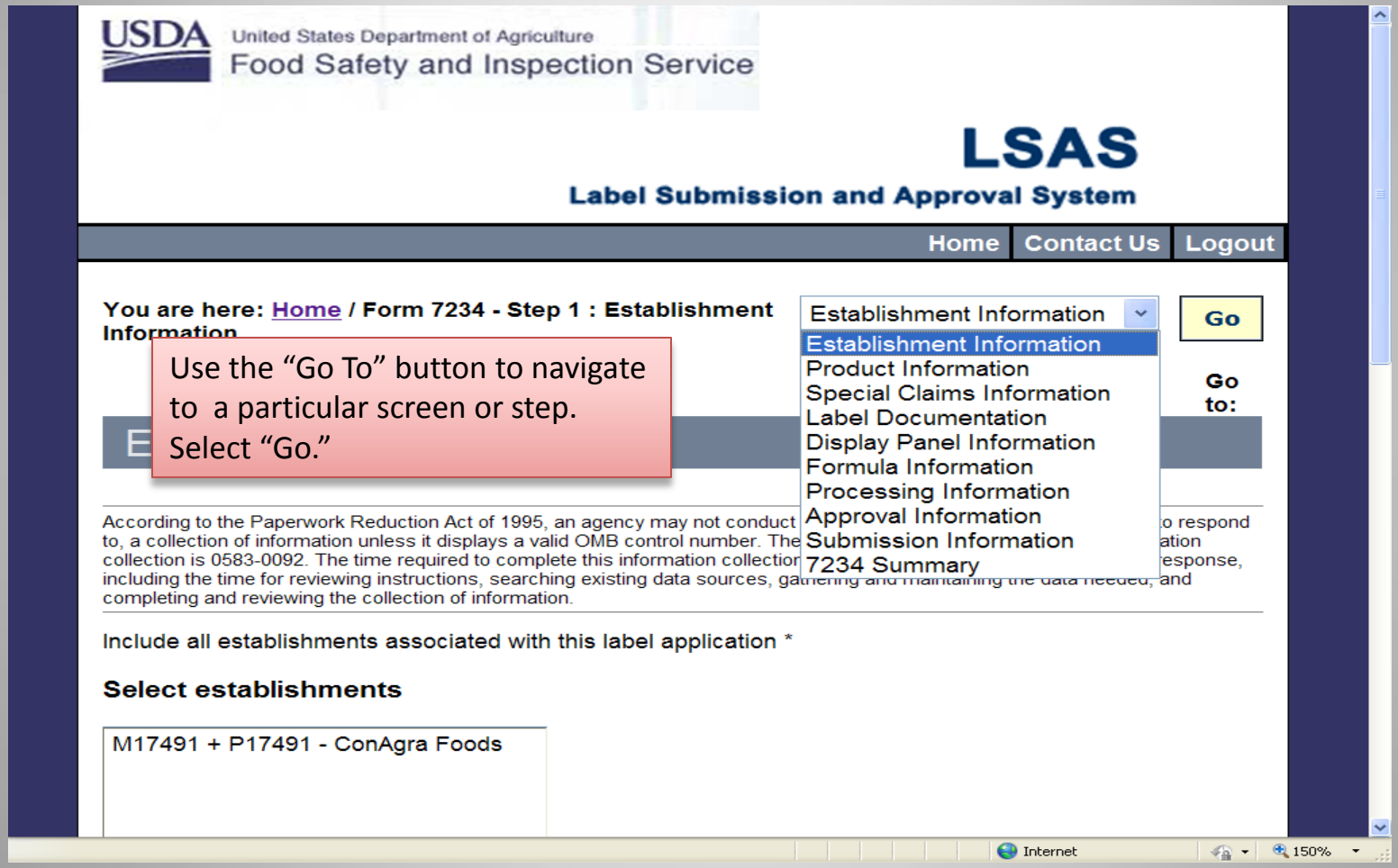


# Special Claims Information – Step 3

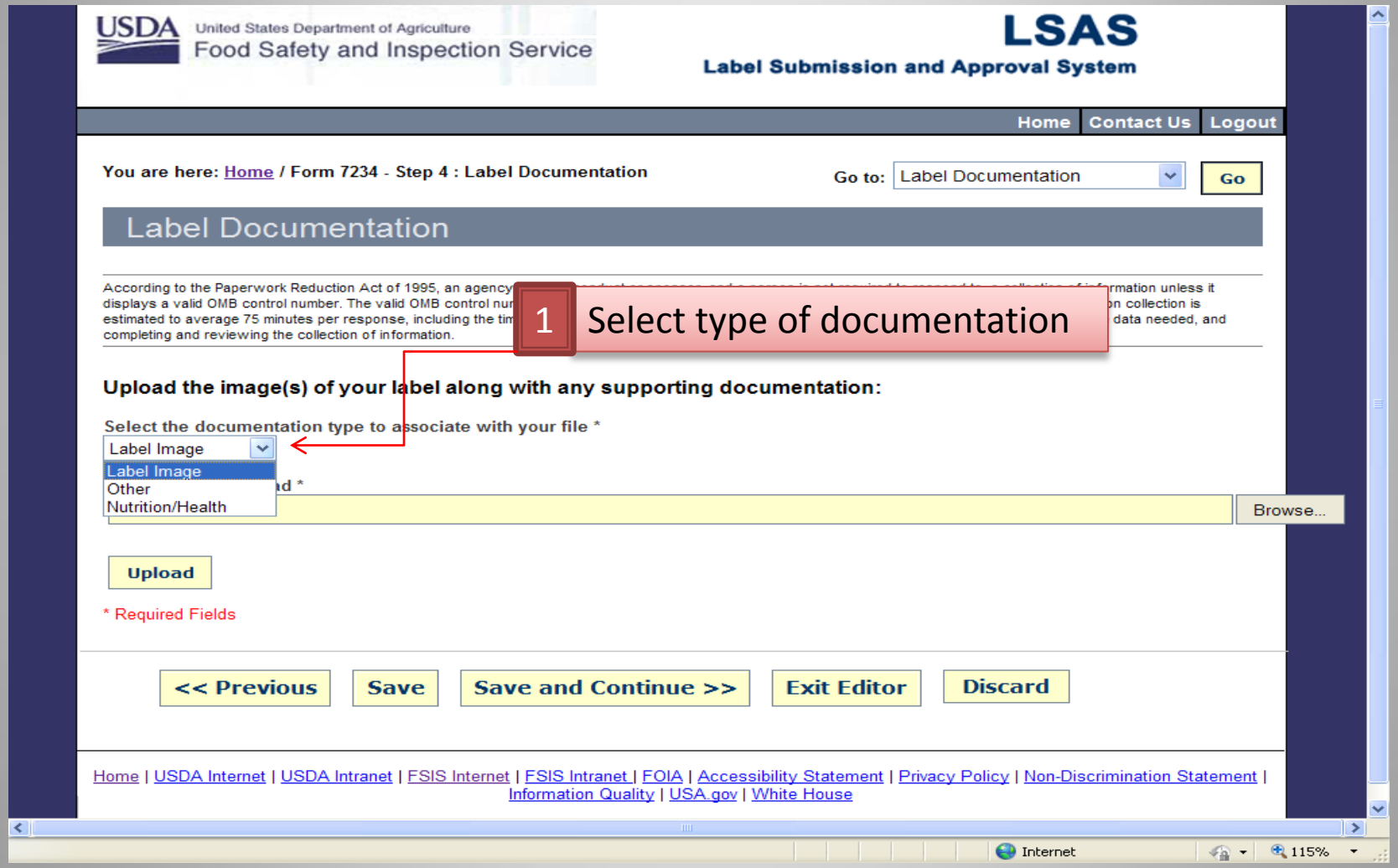



Selection of some specials claims may require the need to include supporting documentation

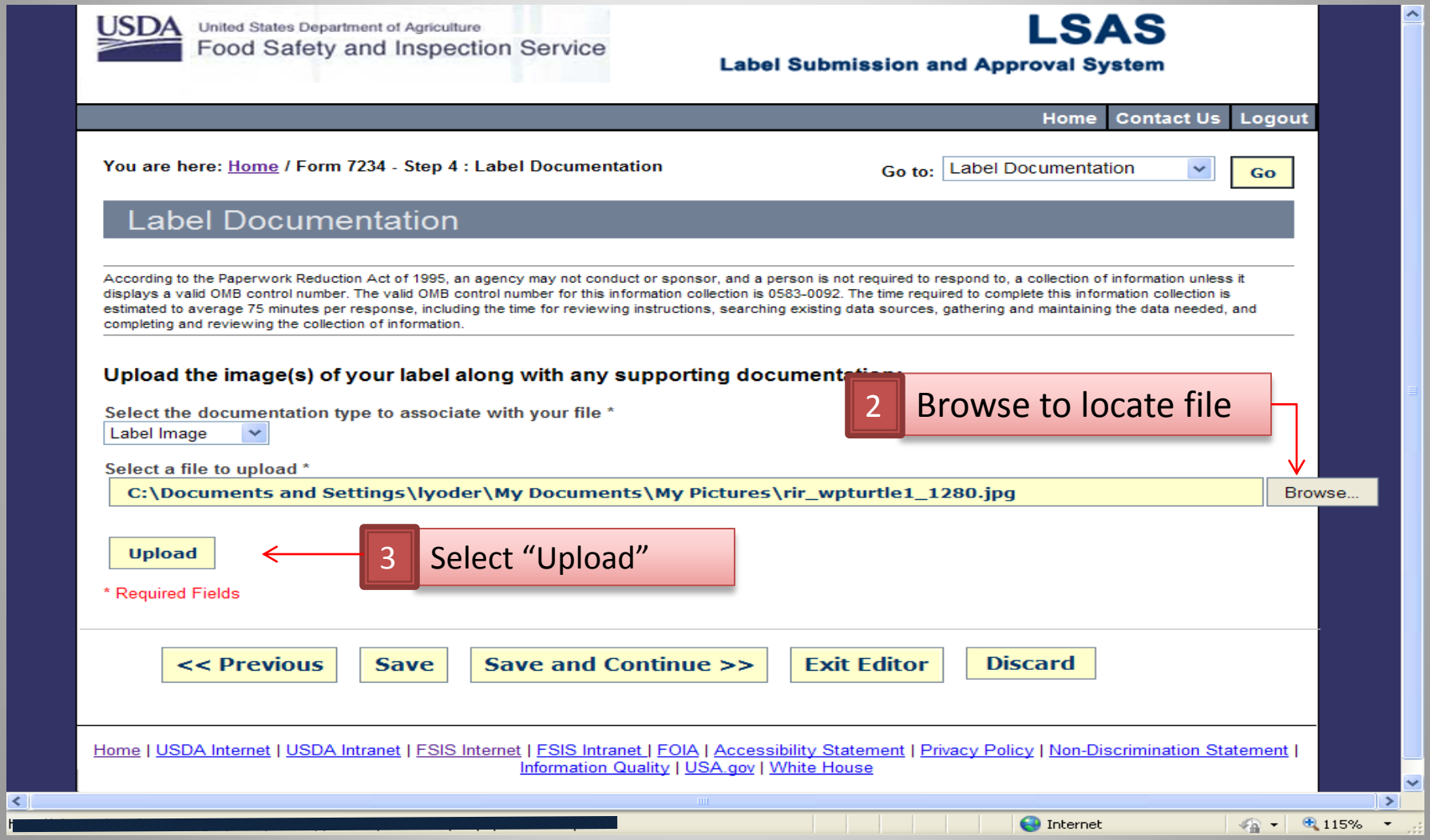
# Using the “Go To” Selection



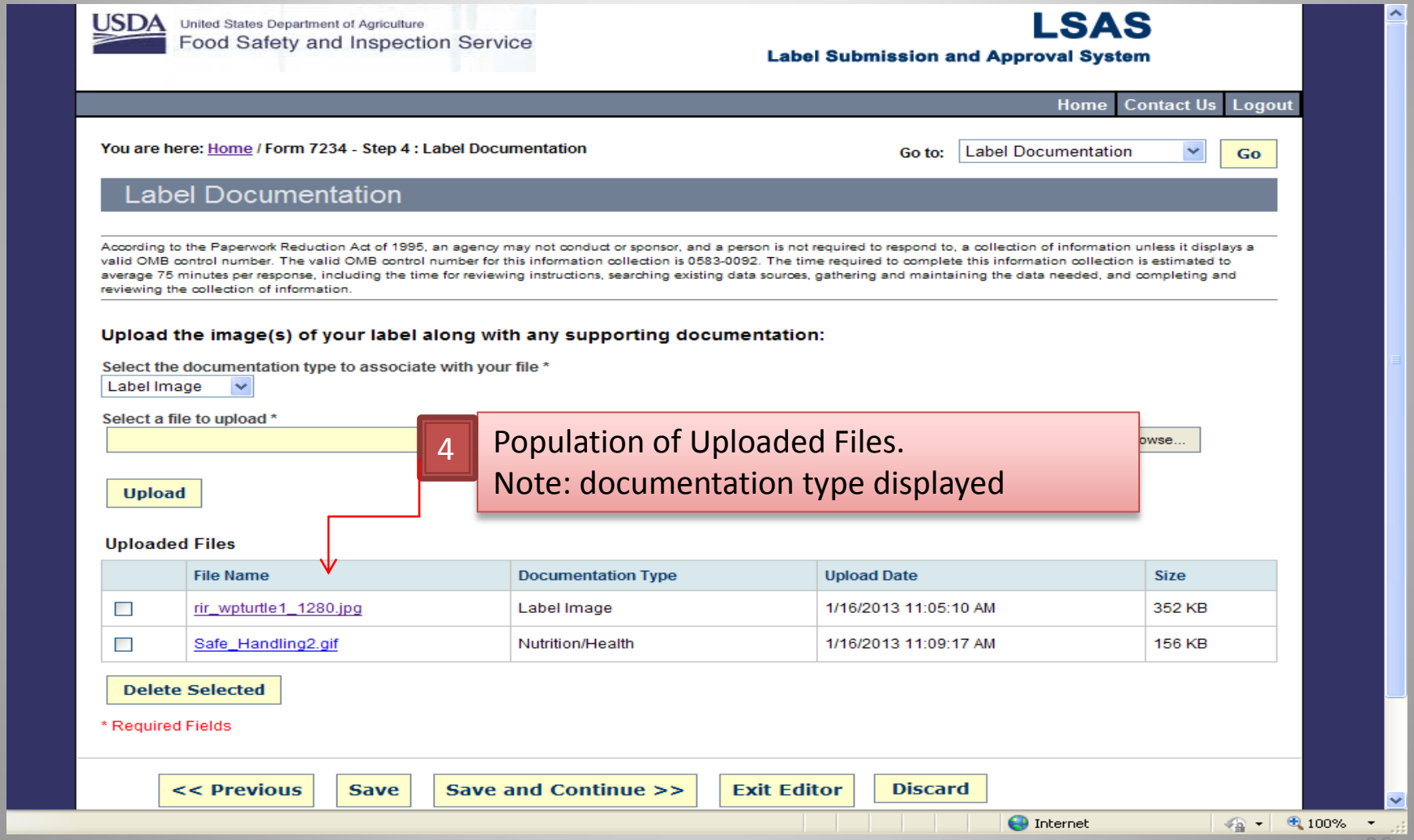
# Label Documentation – Step 4



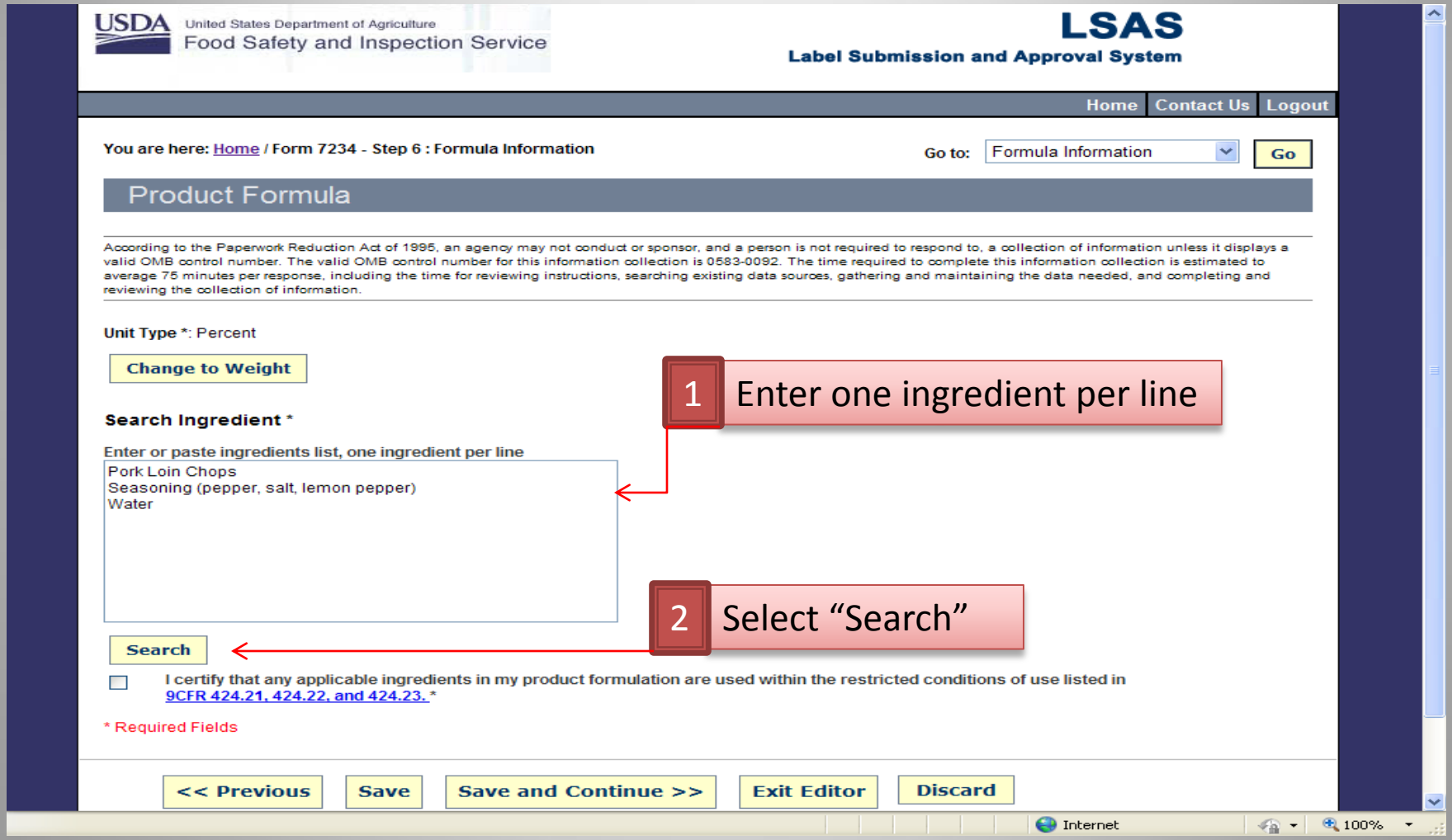
# Label Documentation – Step 4 (Continued)



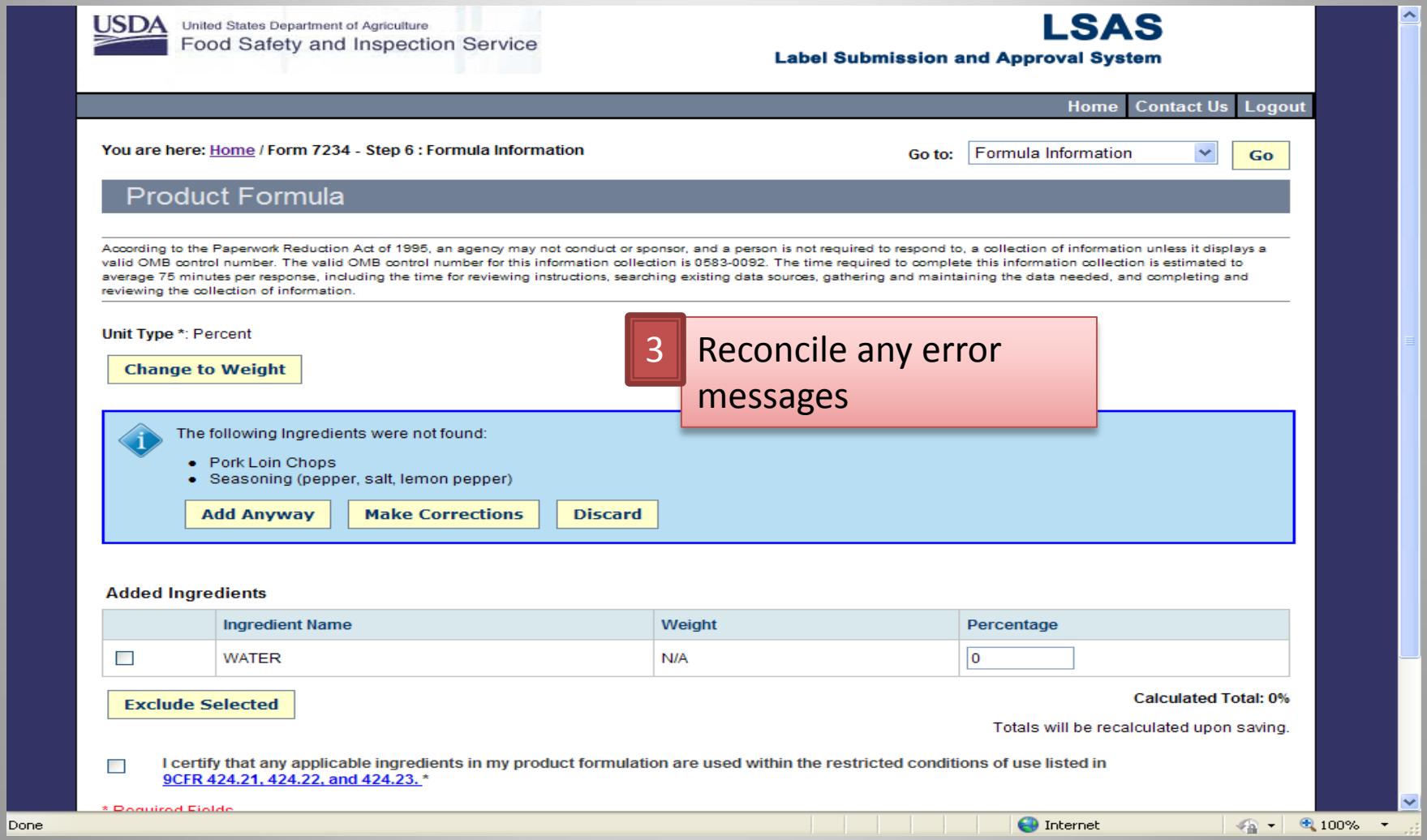
# Label Documentation – Step 4 (Continued)



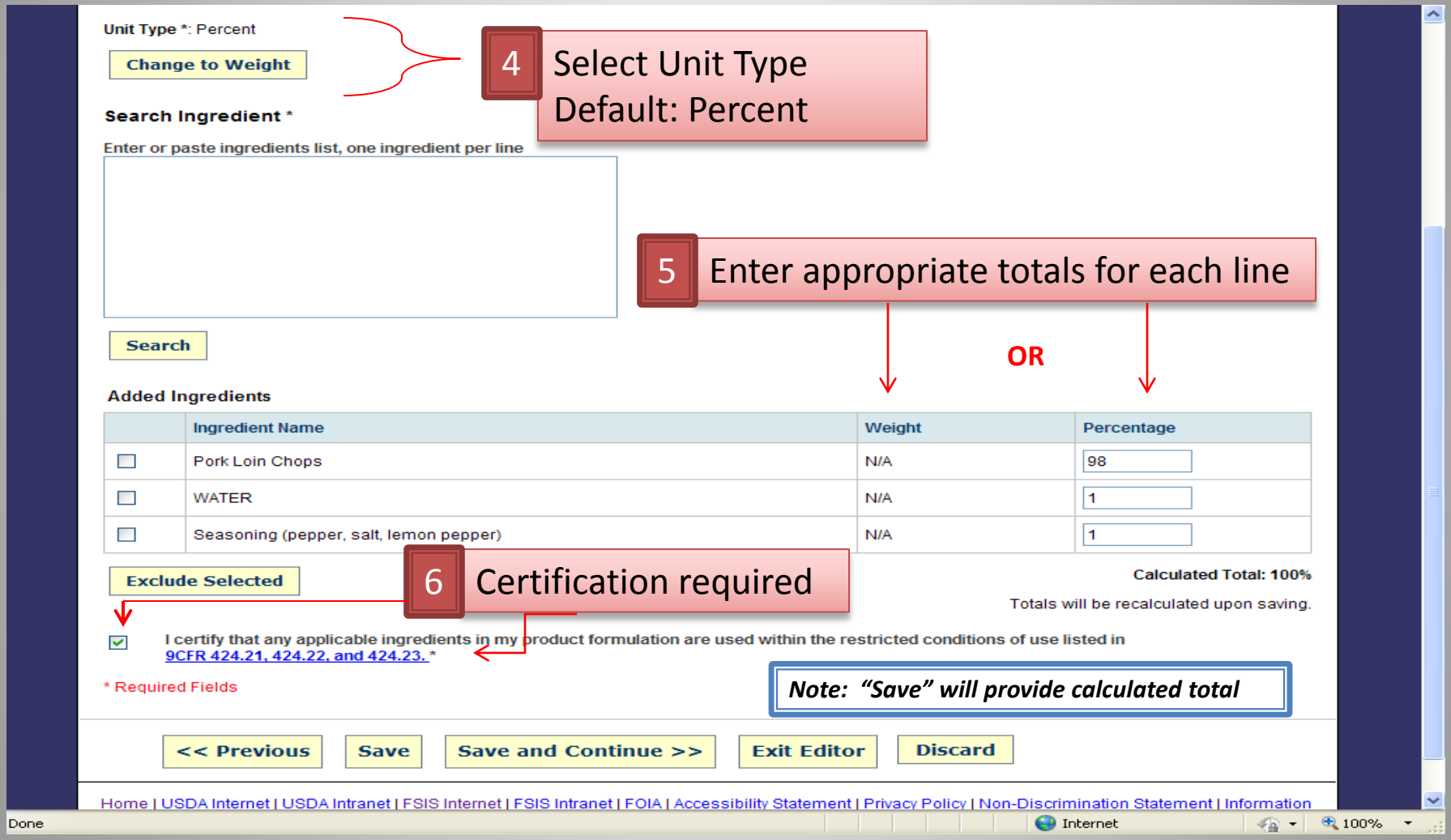
# Formula Information (Product Formula ) – Step 6



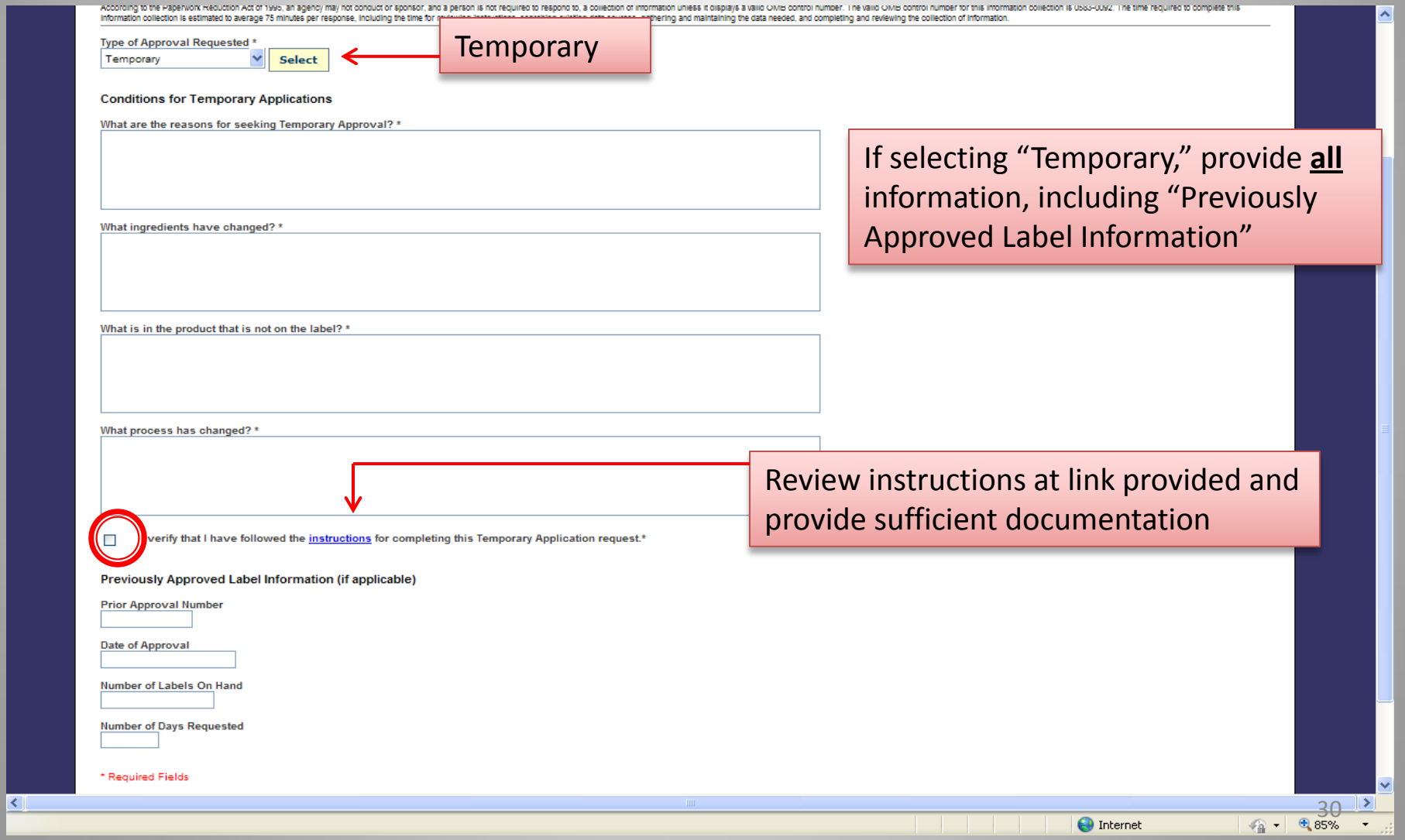
# Product Information – Step 6 (Continued)



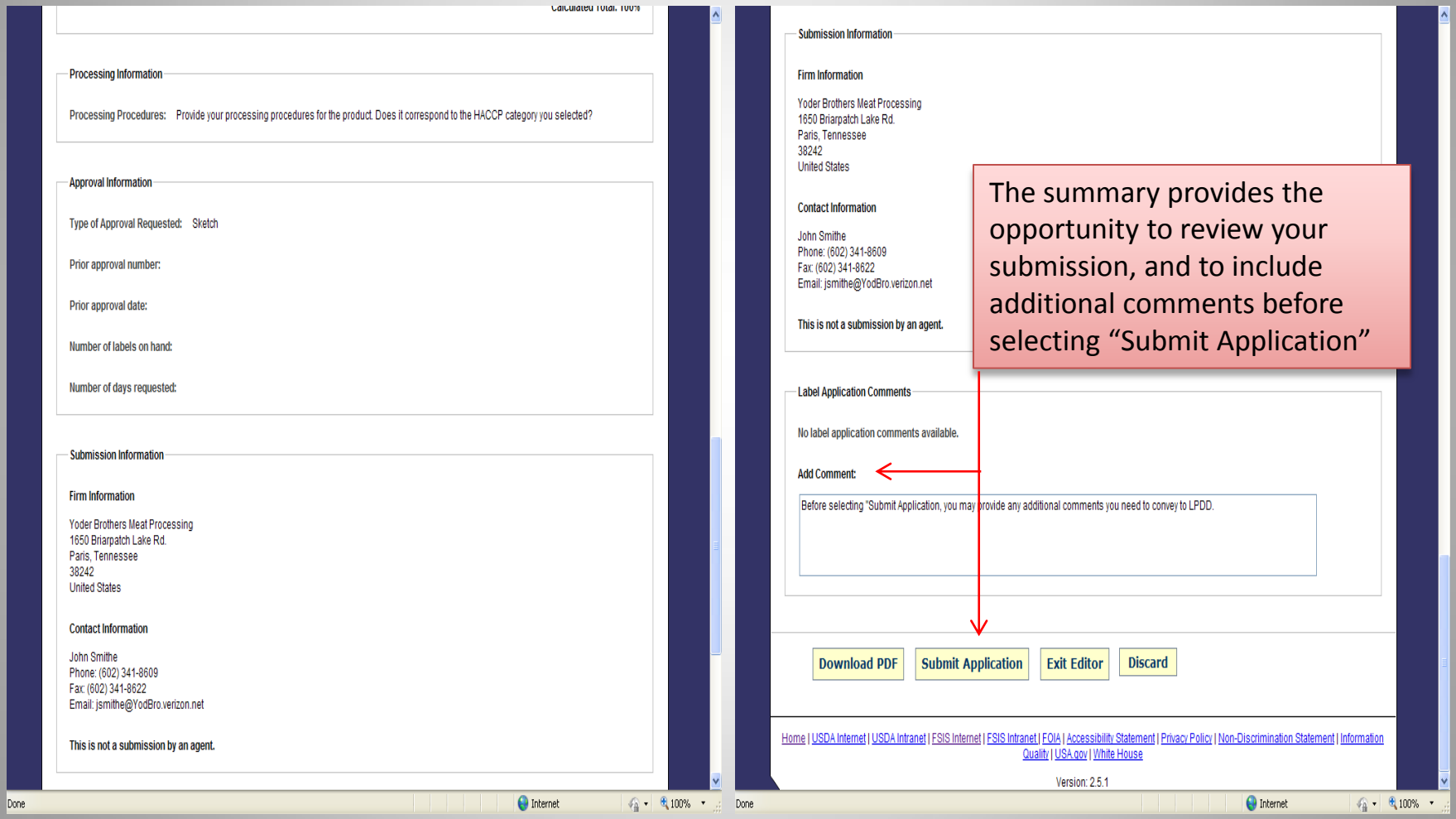
# Product Formula – Step 6 (Continued)



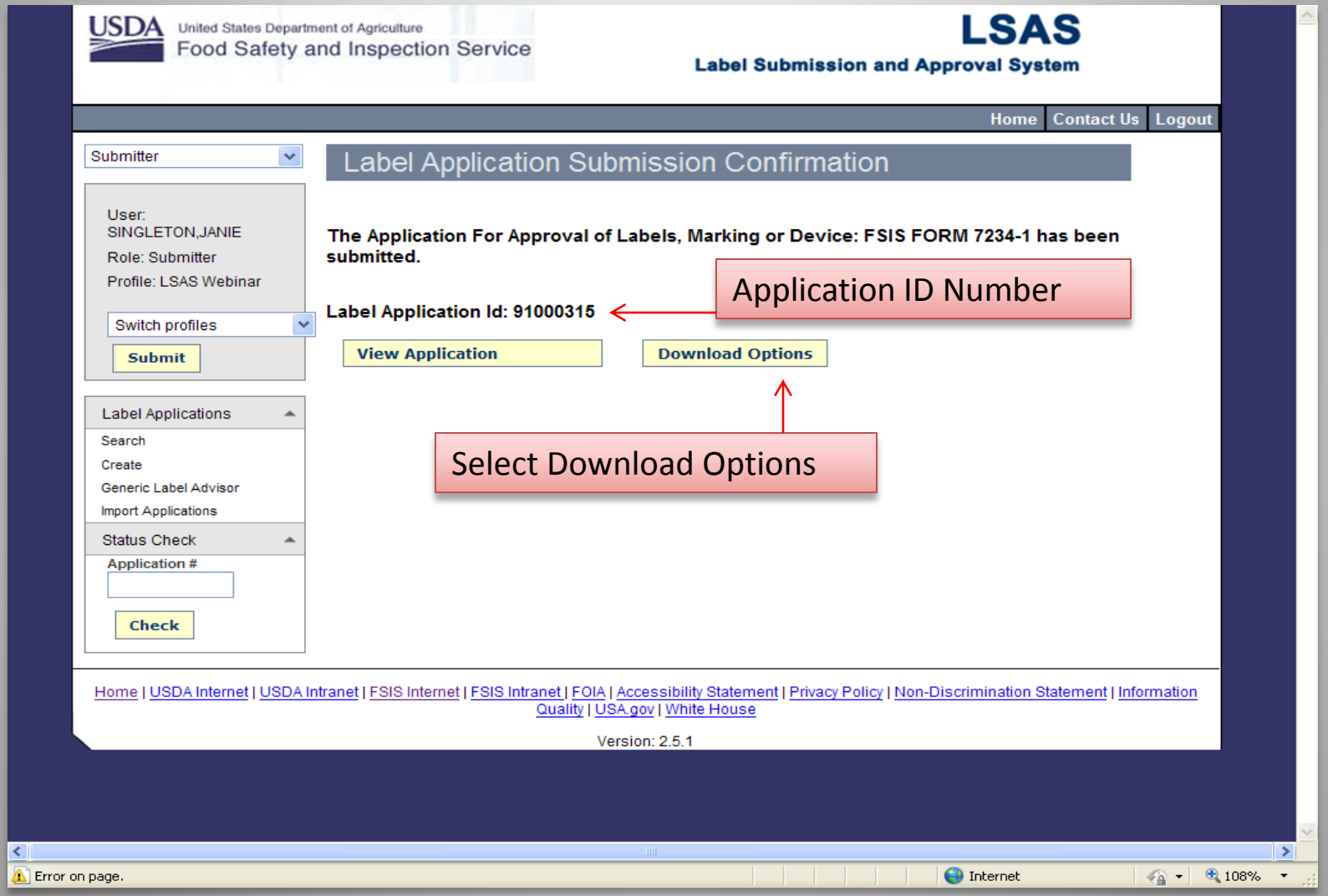
# Approval Information (Temporary) – Step 8



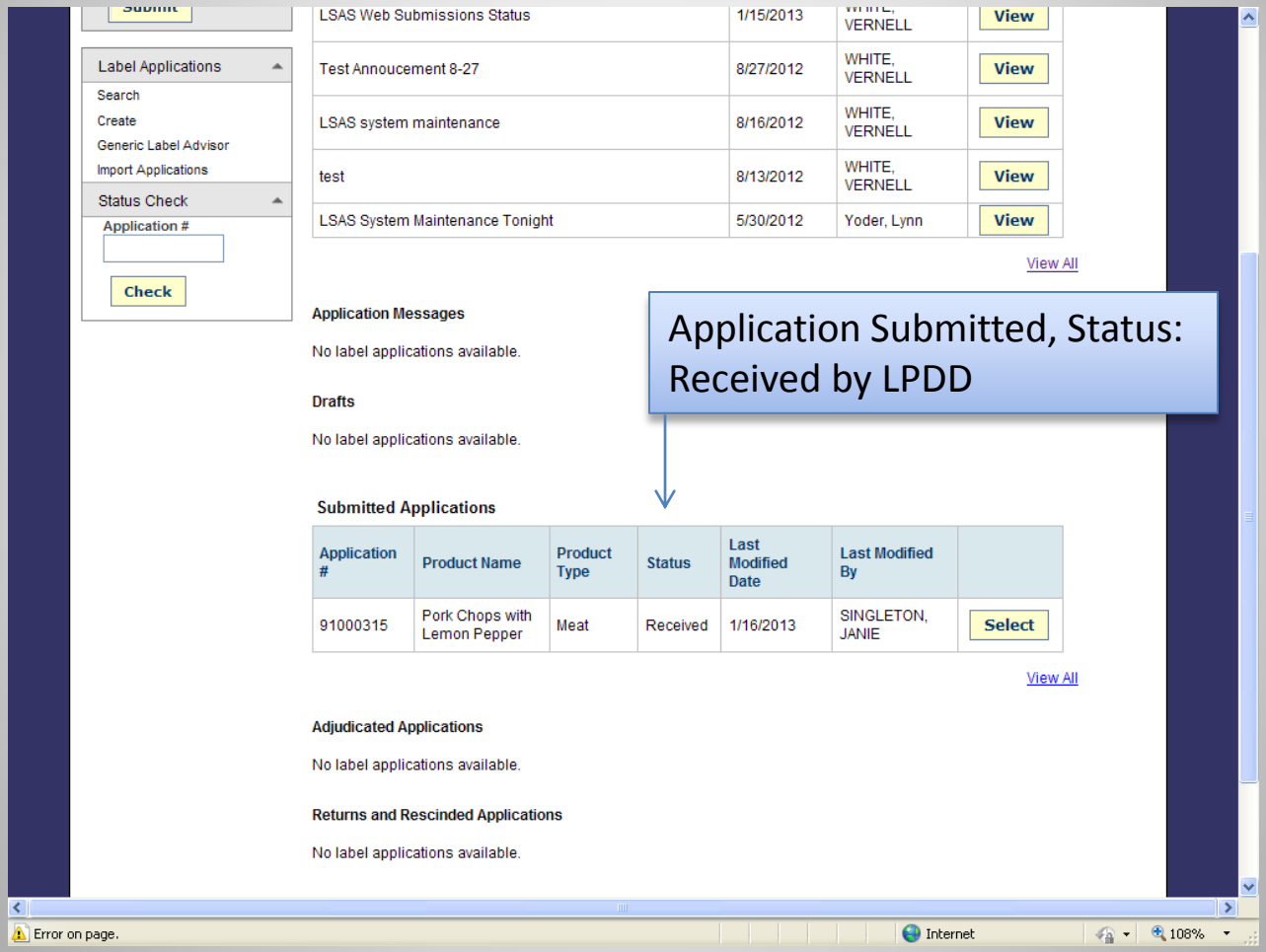
# Summary – Step 10



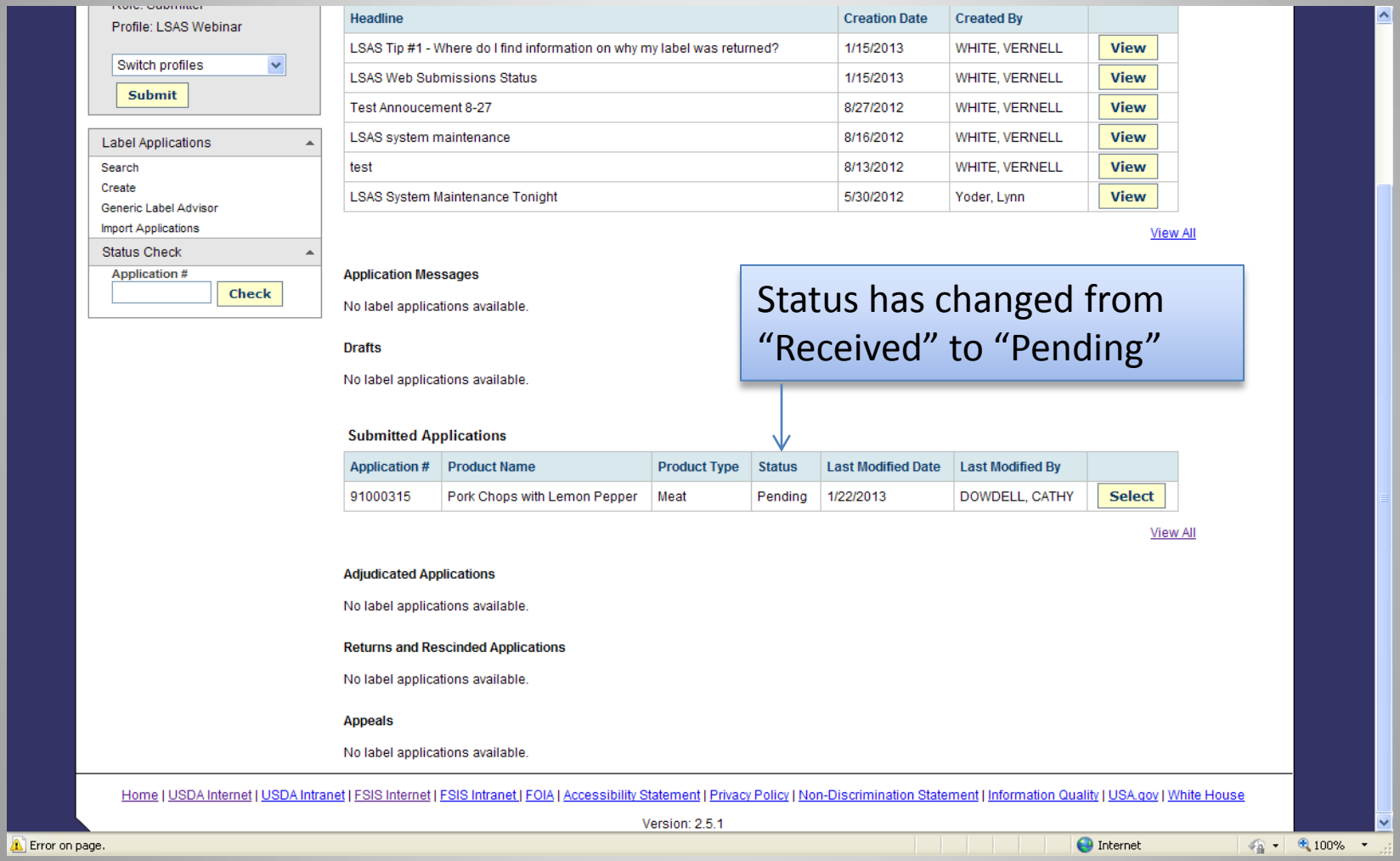
# Submit Application, Confirmation – Final Step



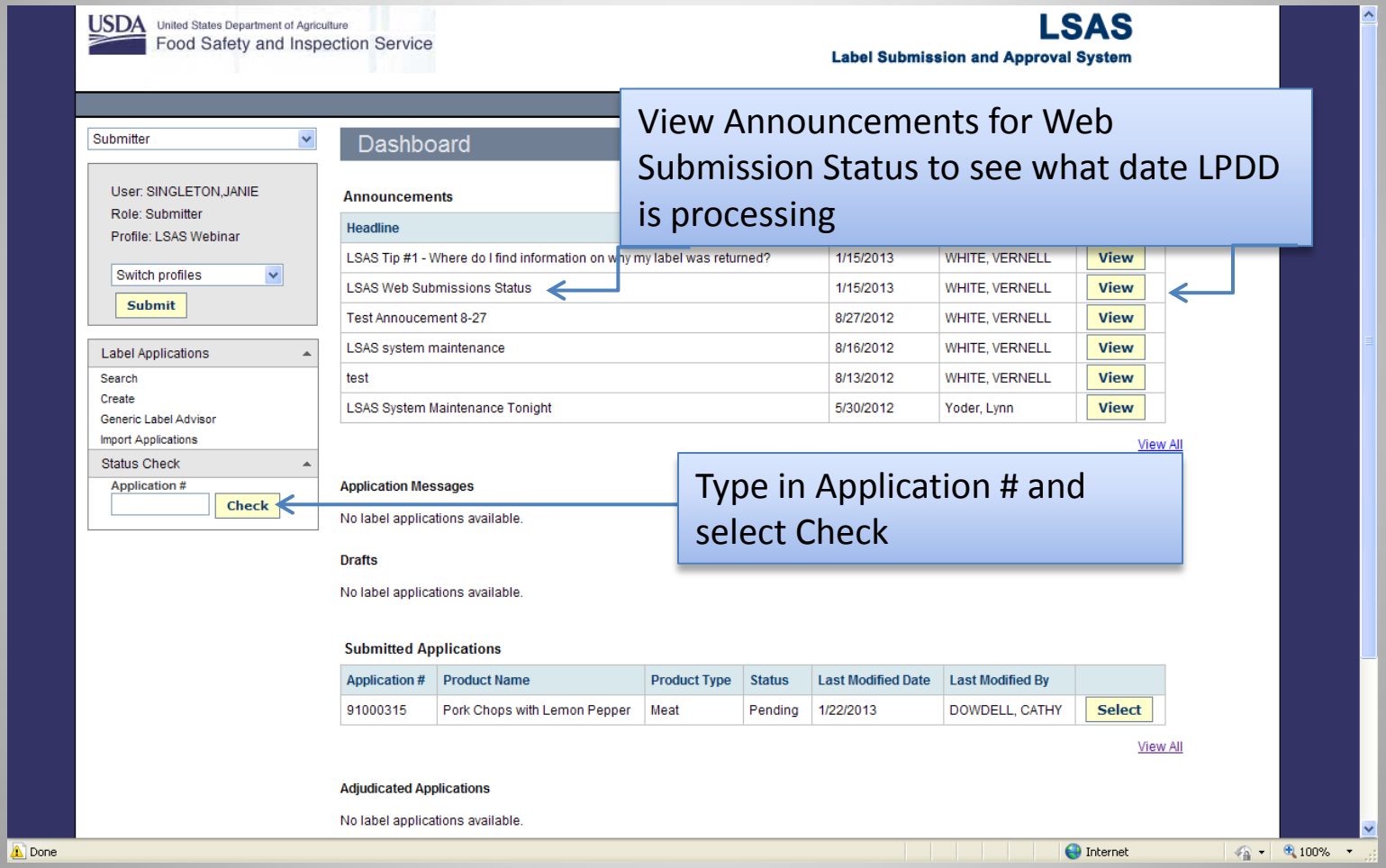
# Dashboard: Submitted Application Pool



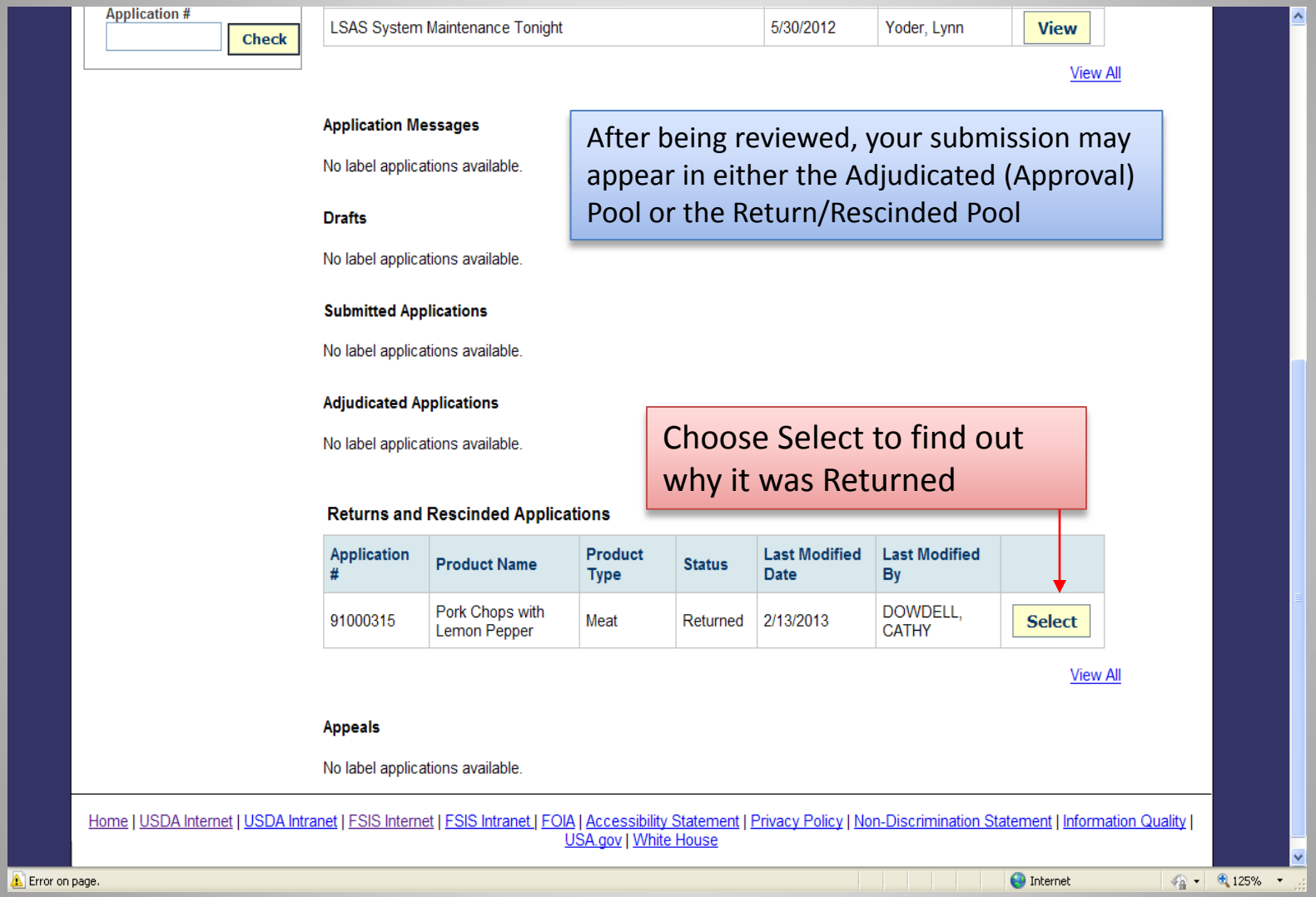
# Status Check



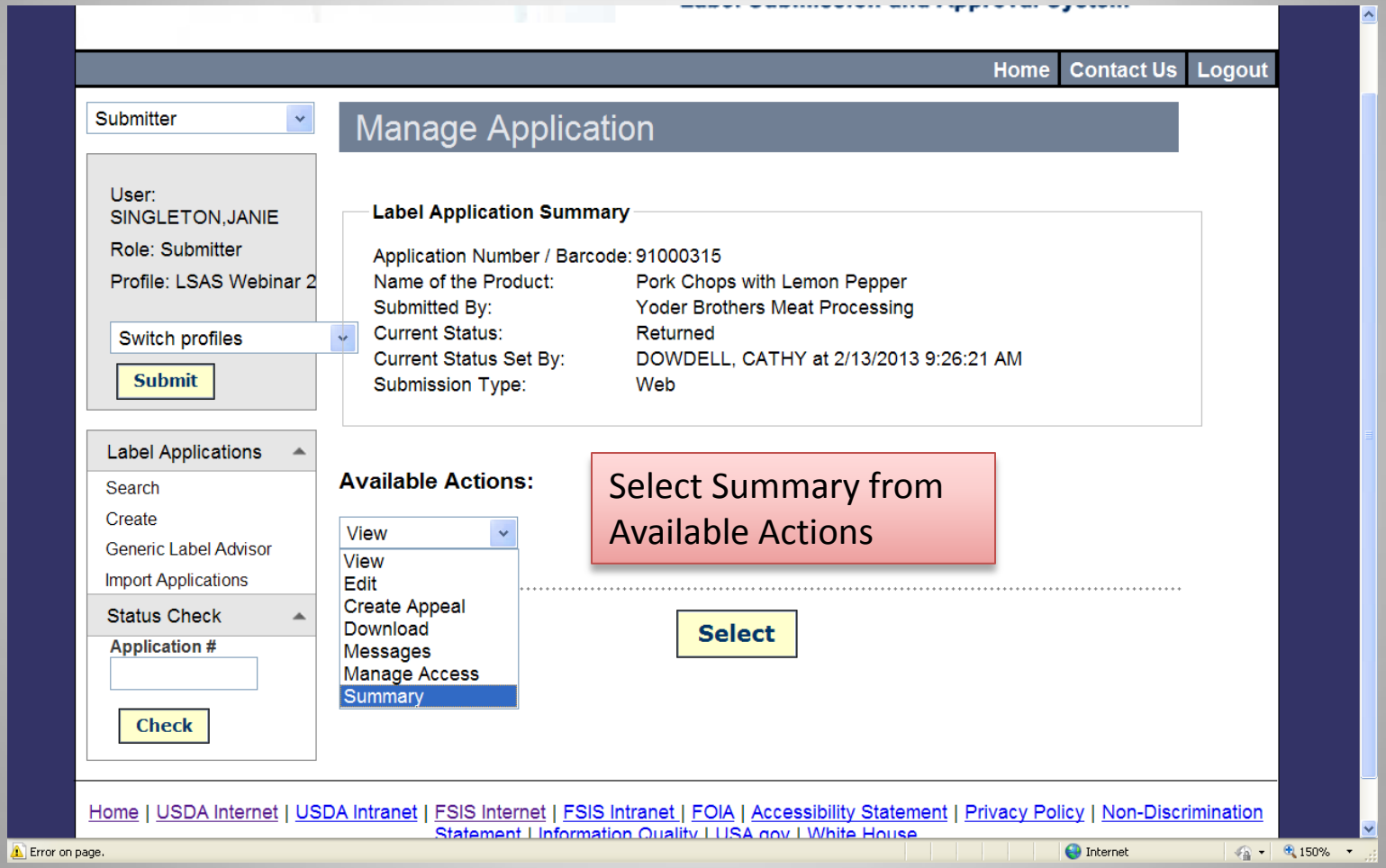
# Status Check (Continued)



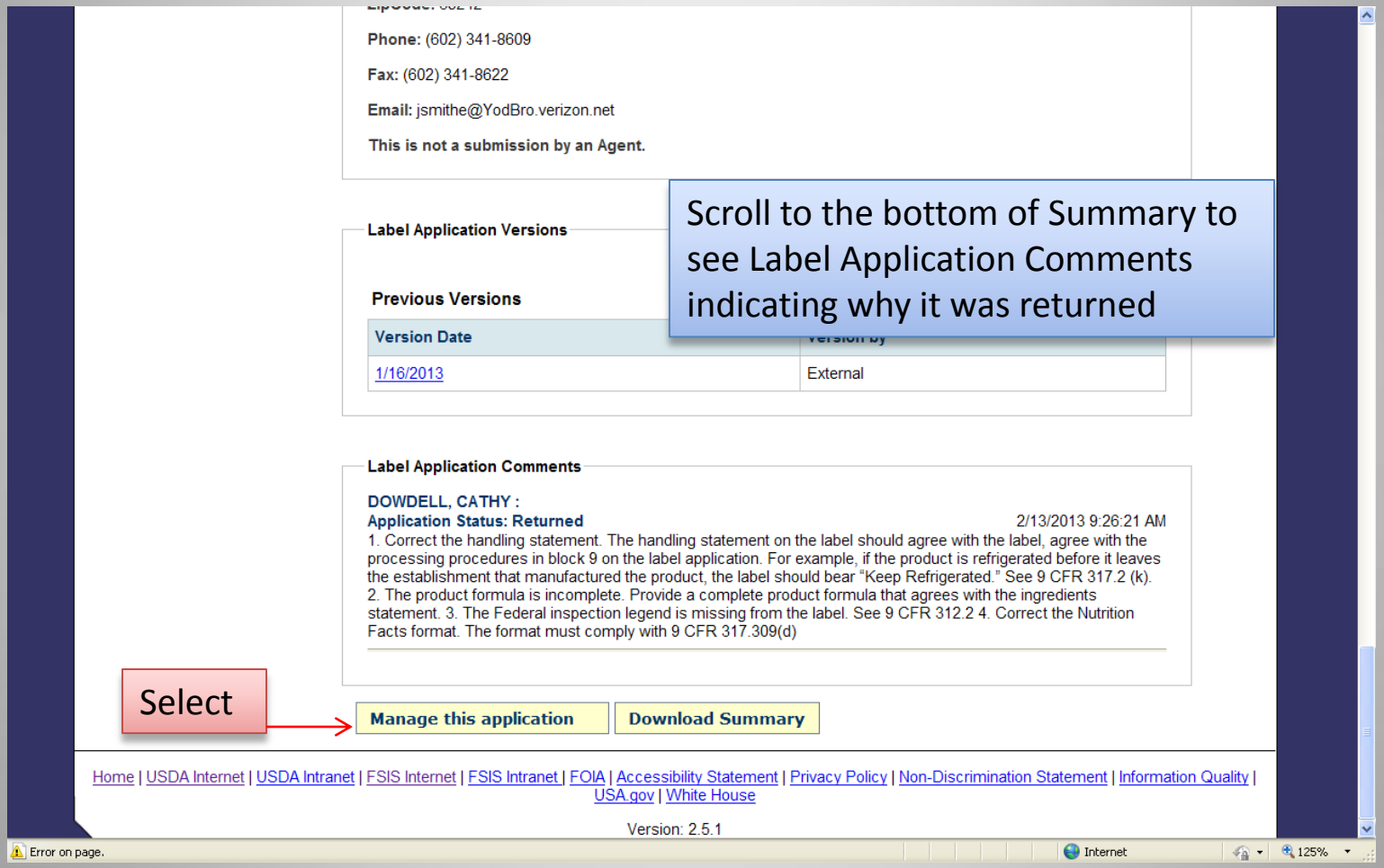
# Returned Application



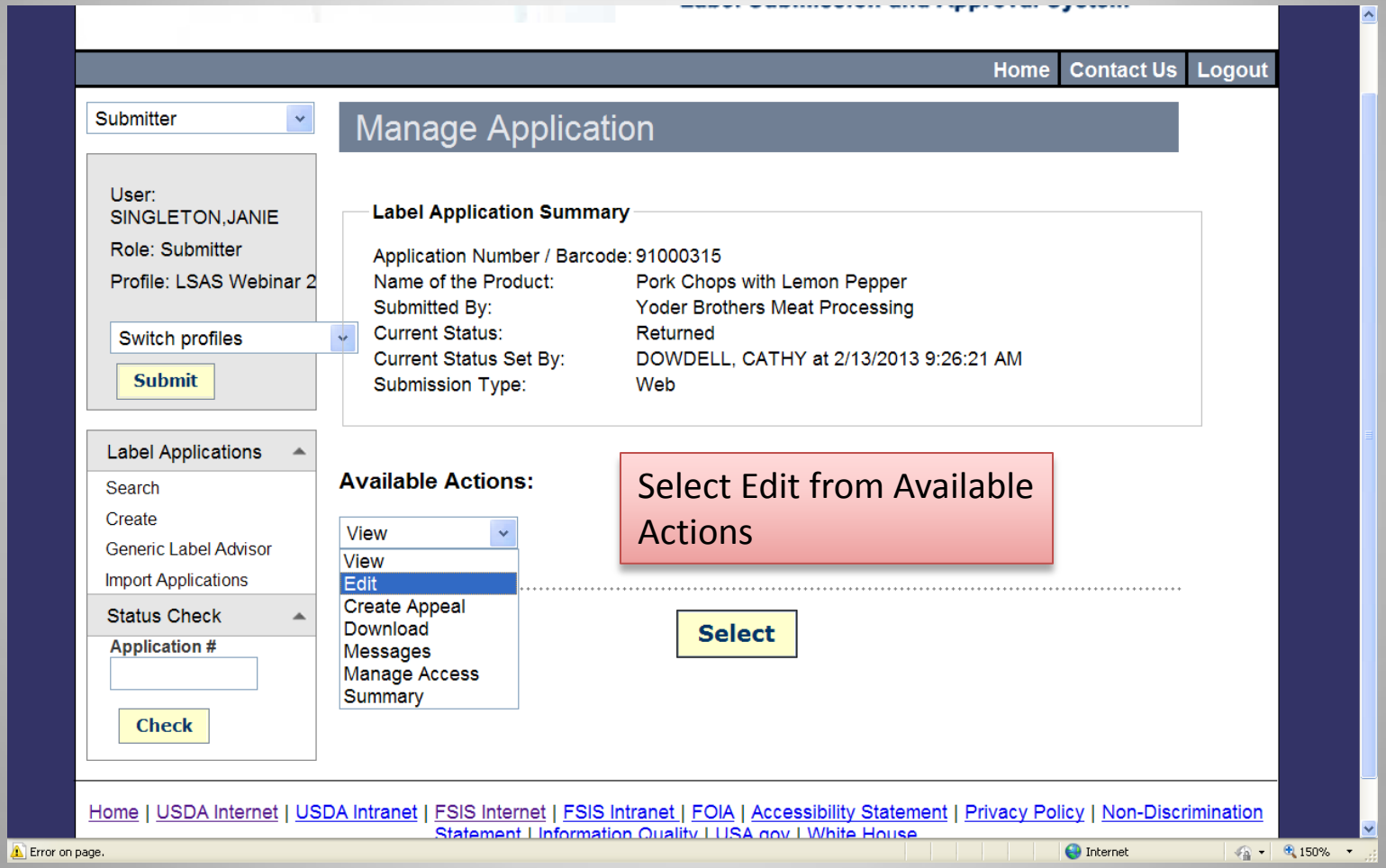
# Returned Application (Continued)



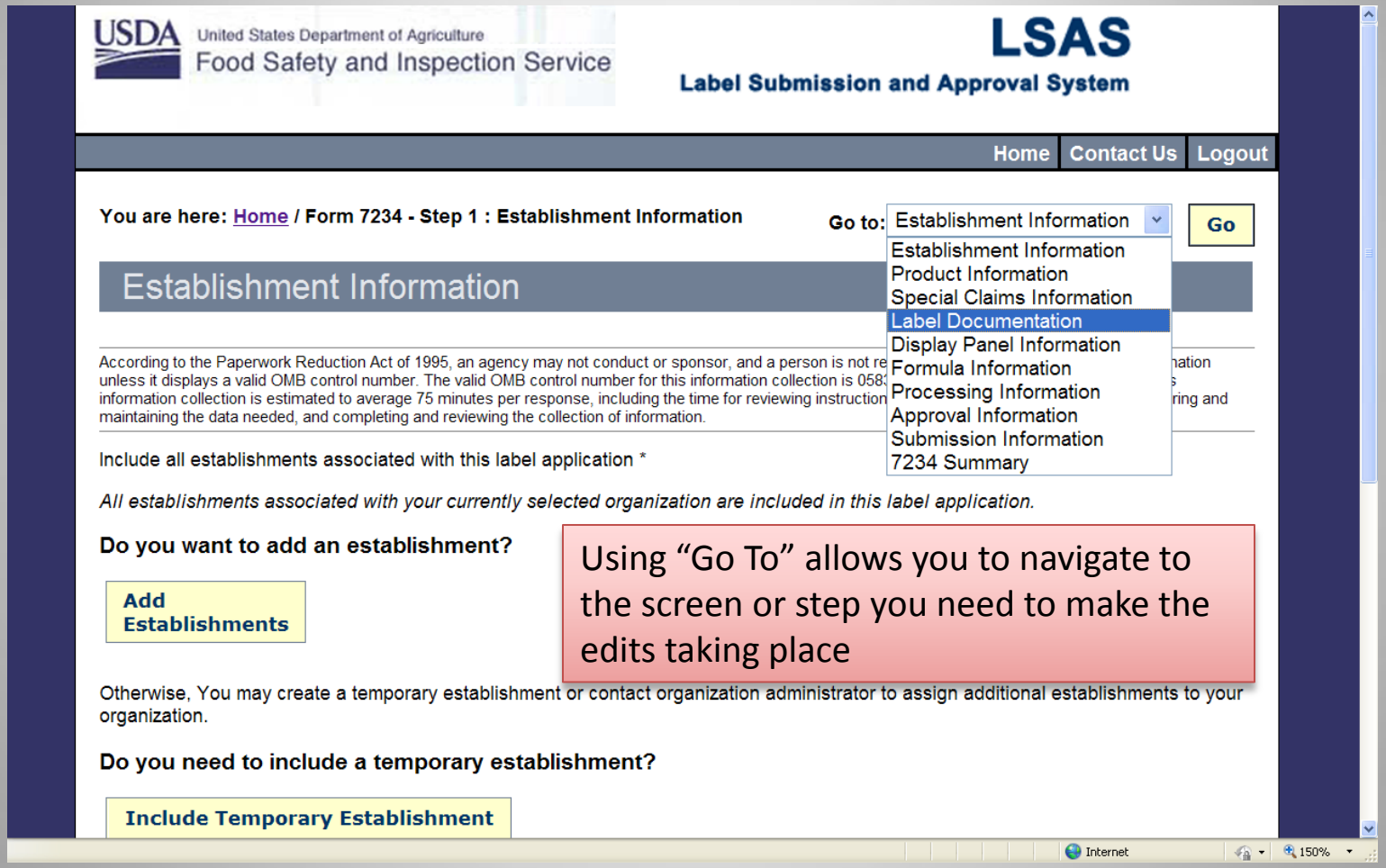
# Returned Application (Continued)



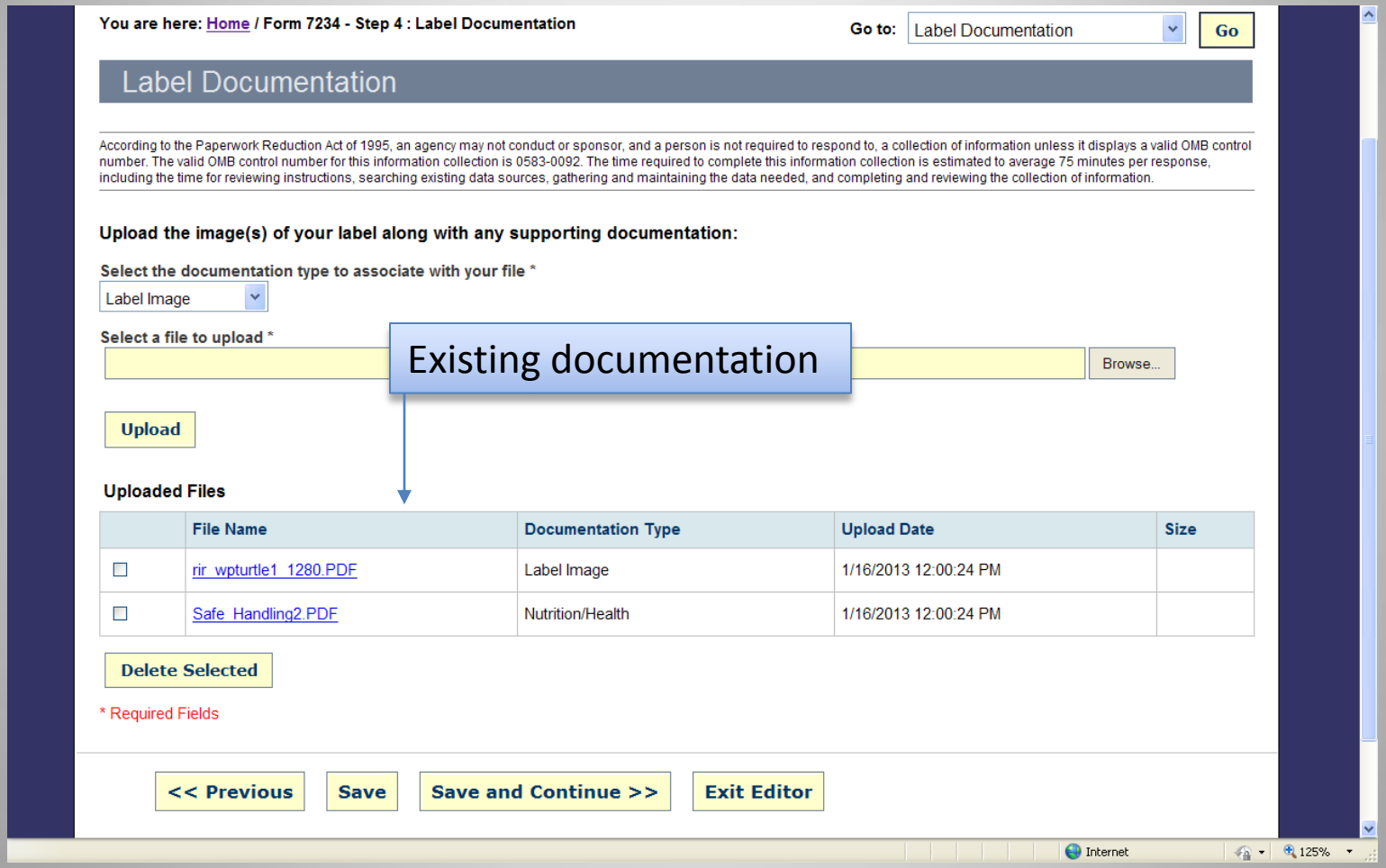
# Returned Application (Continued)



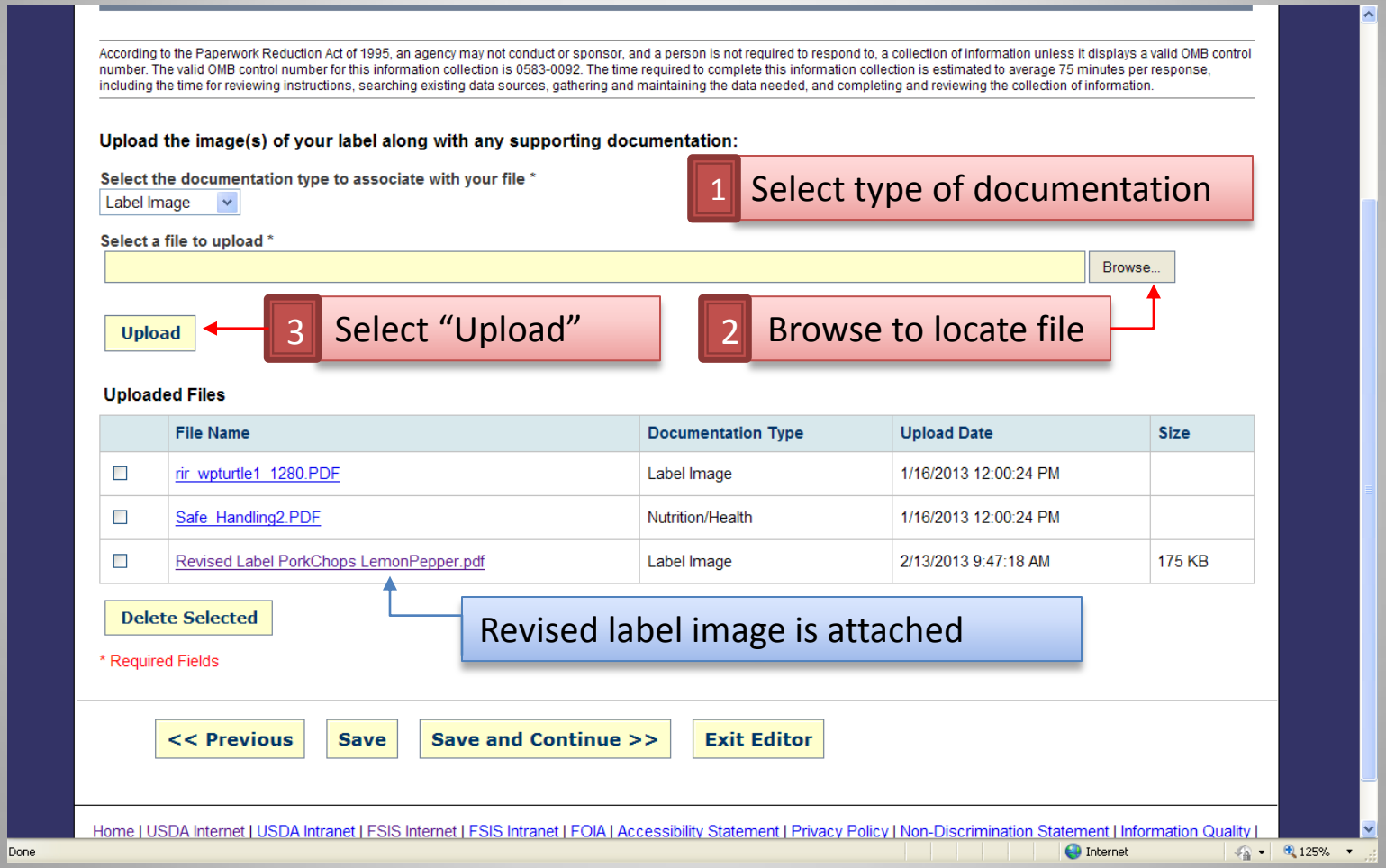
# Returned Application (Continued)



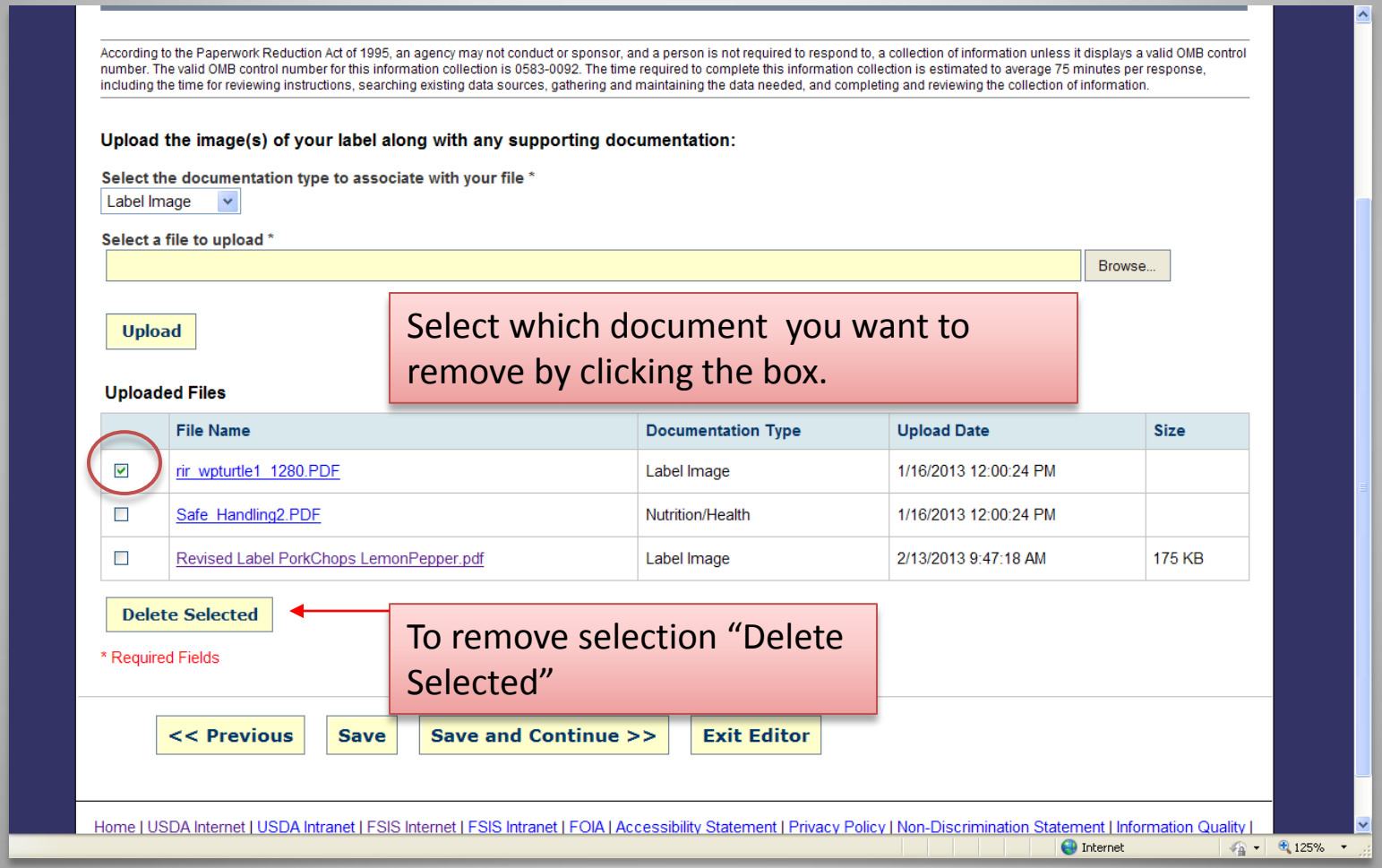
# Returned Application – (Continued)



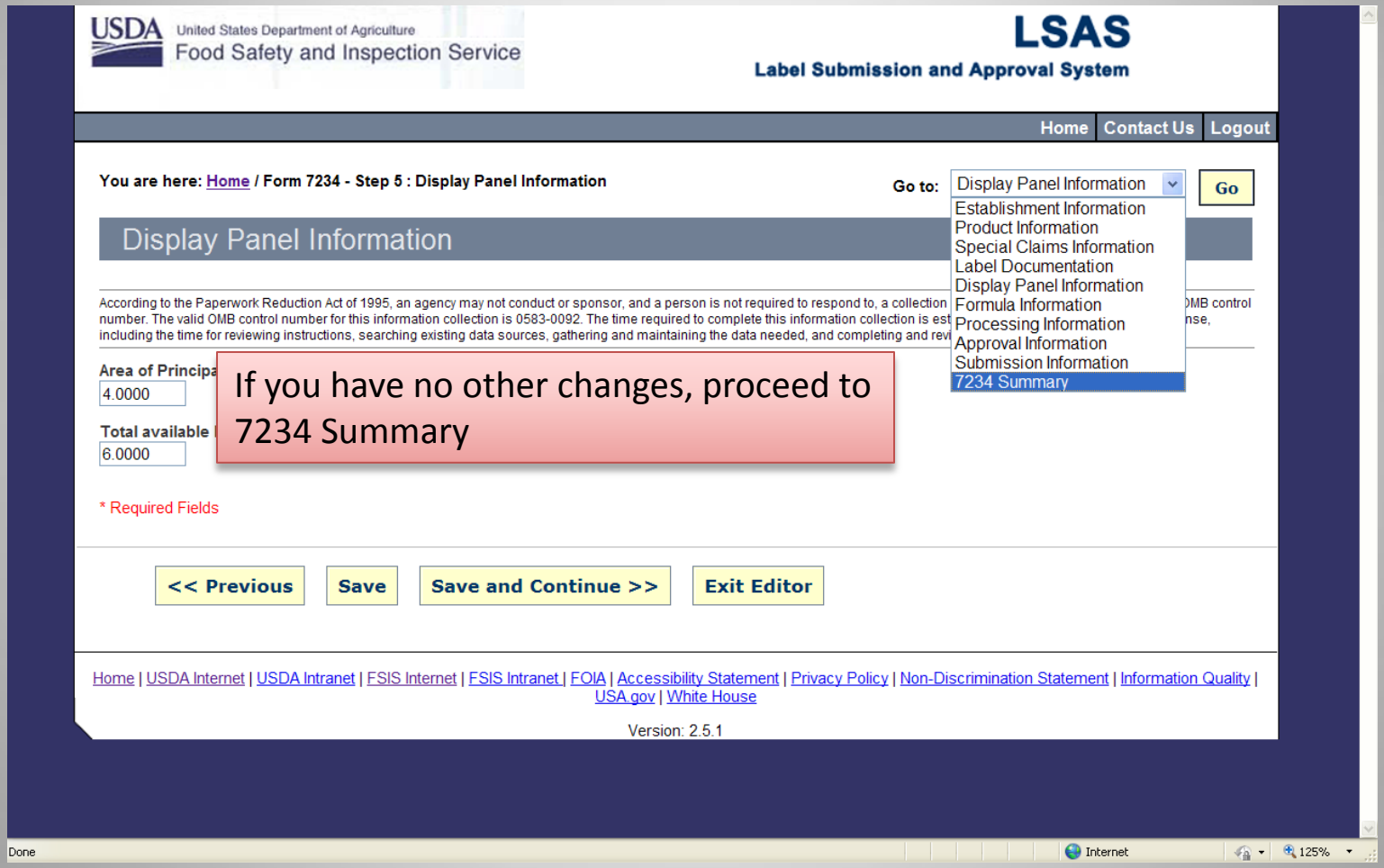
# Returned Application – Adding New Documentation



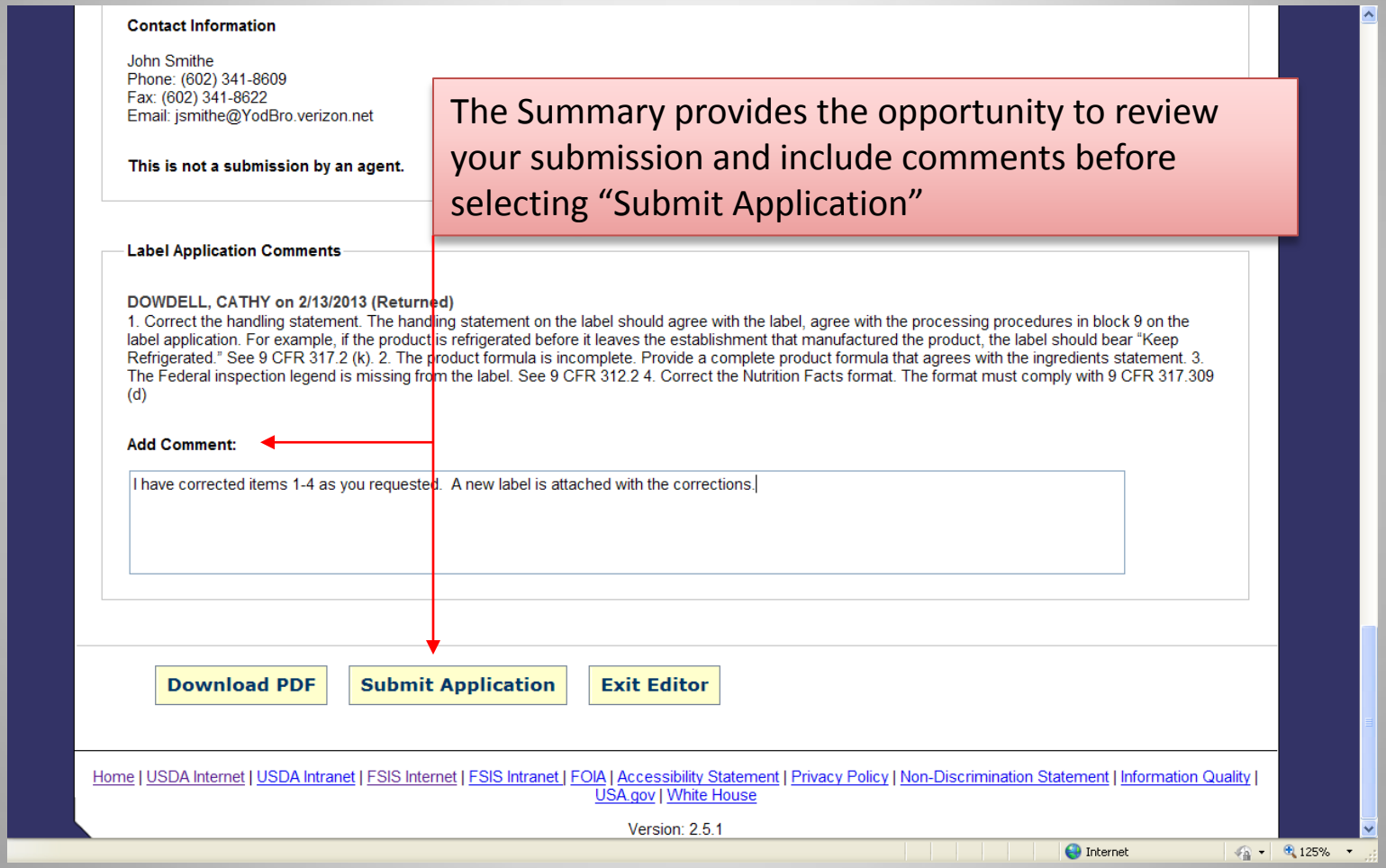
# Returned Application – Removing Incorrect Documentation



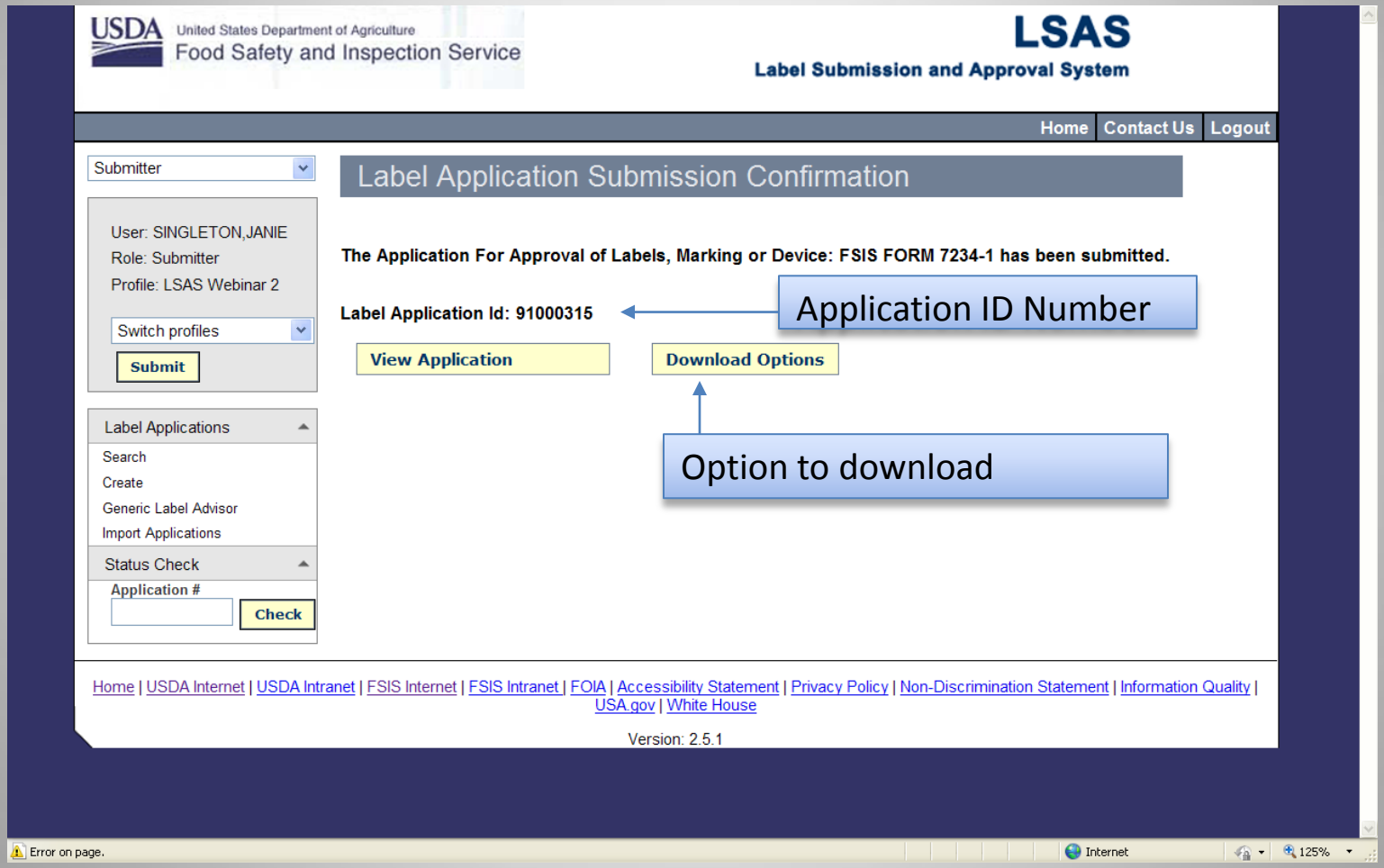
# 7234 Summary in preparation of Submitting



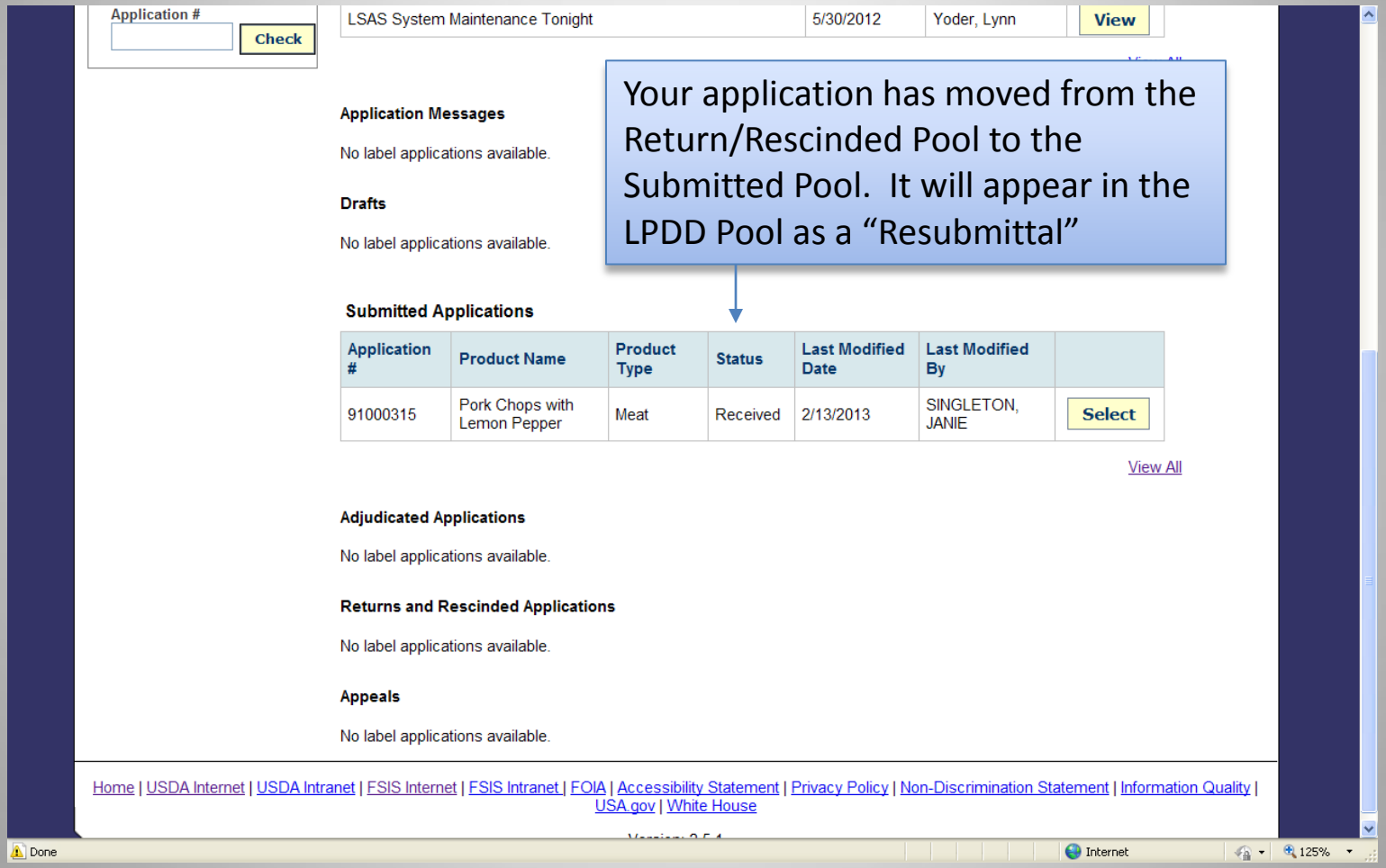
# 7234 Summary



# Submit Application - Confirmation



# Dashboard Shows Submitted Application Pool



FORMULA EXAMPLES

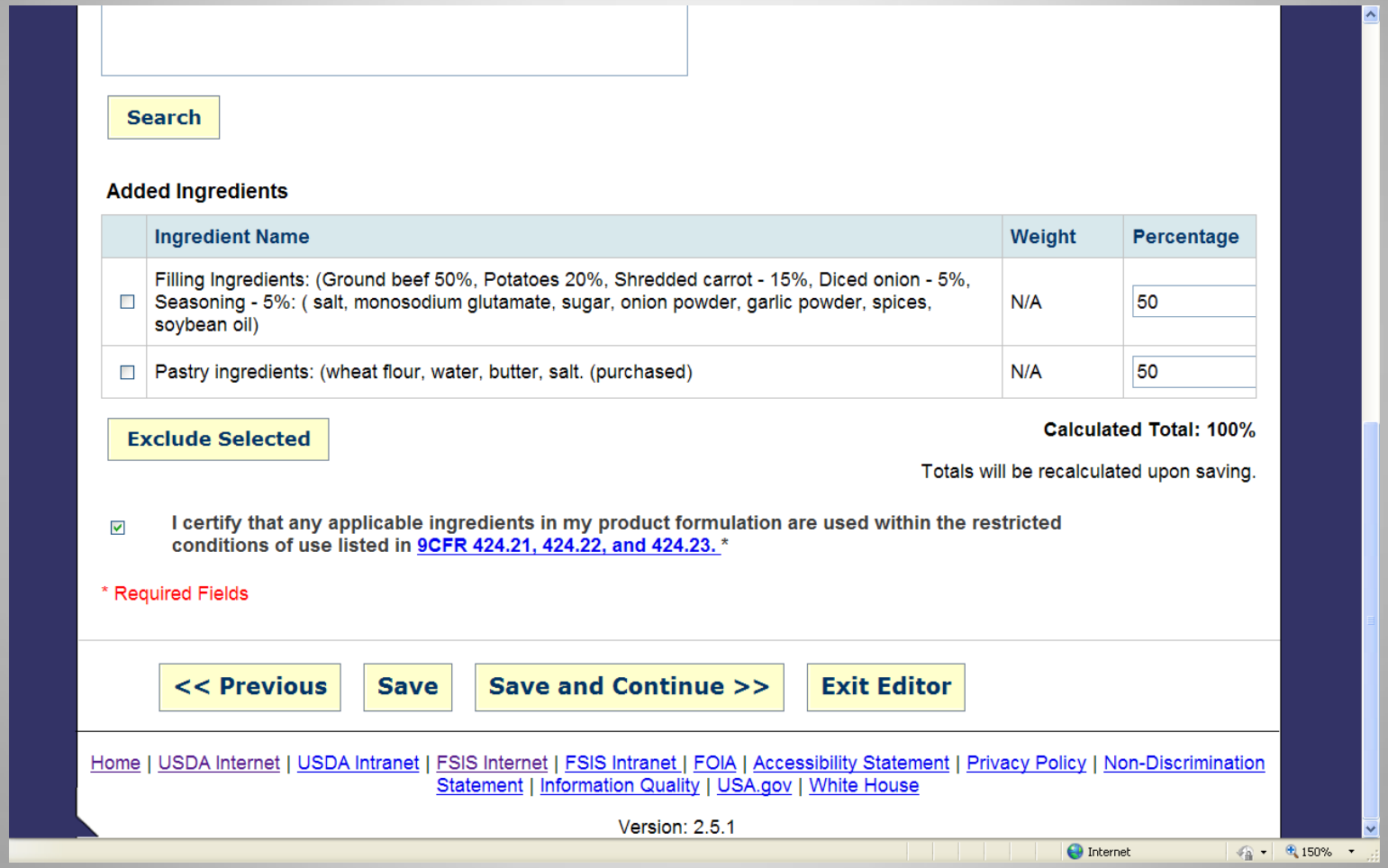
APPEALS

# HELPFUL TIPS

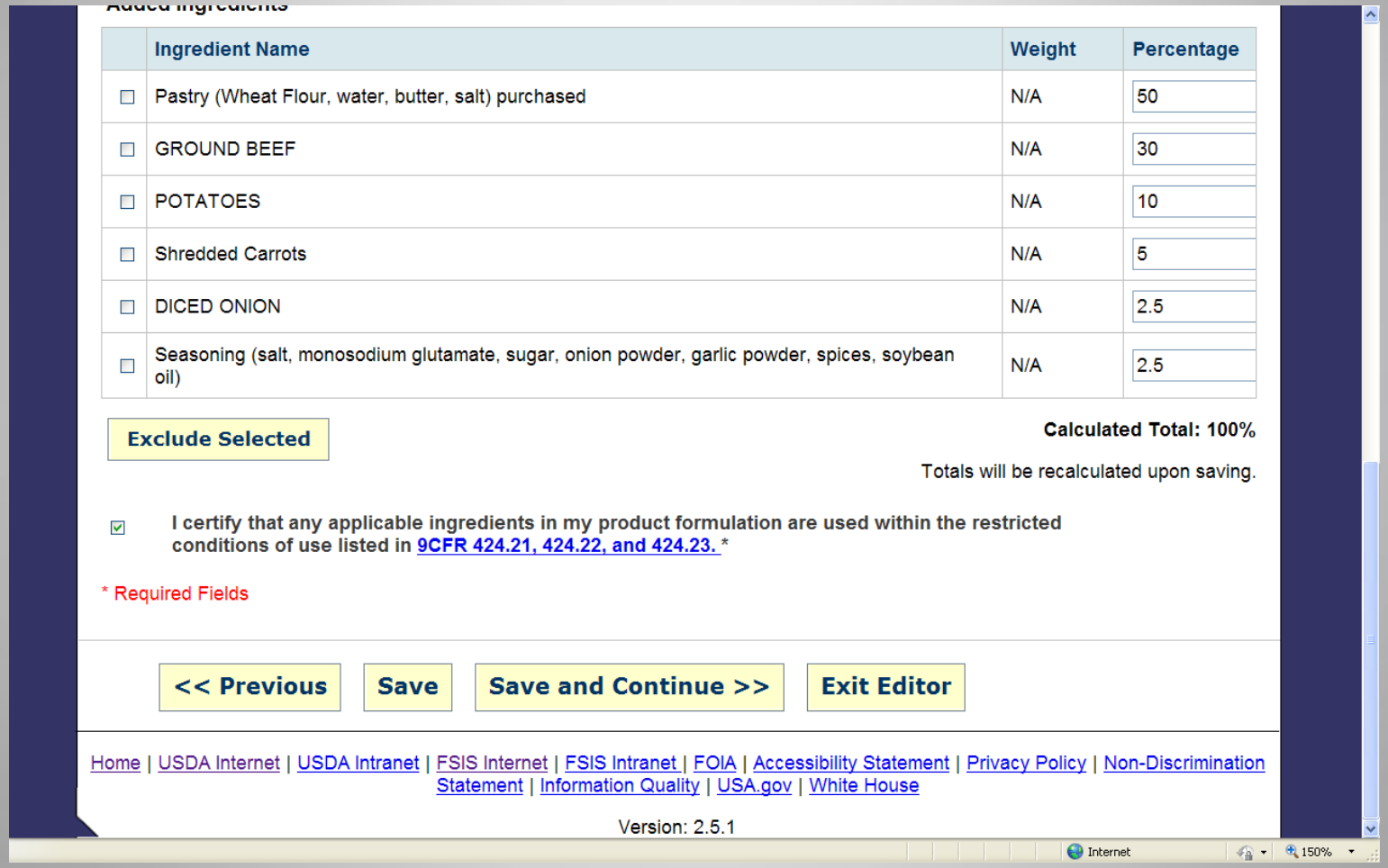
Miscellaneous Tips

Claims & Supporting Documents

# Formula Examples
# Component Formula



# Formula Examples (Continued)
# Composite Formula



Added Ingredients

| | Ingredient Name | Weight | Percentage |
|---|---|---|---|
| ☐ | Pastry (Wheat Flour, water, butter, salt) purchased | N/A | 50 |
| ☐ | GROUND BEEF | N/A | 30 |
| ☐ | POTATOES | N/A | 10 |
| ☐ | Shredded Carrots | N/A | 5 |
| ☐ | DICED ONION | N/A | 2.5 |
| ☐ | Seasoning (salt, monosodium glutamate, sugar, onion powder, garlic powder, spices, soybean oil) | N/A | 2.5 |

Exclude Selected

Calculated Total: 100%

Totals will be recalculated upon saving.

☑ I certify that any applicable ingredients in my product formulation are used within the restricted conditions of use listed in 9CFR 424.21, 424.22, and 424.23. *

* Required Fields

<< Previous | Save | Save and Continue >> | Exit Editor

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Version: 2.5.1

Internet 150%

# Formula Tips

- When listing your ingredients, DO NOT include bullets, special characters, or numbered listing, (e.g., # cheddar cheese, 109. Ham, **Parsley,
  - -Tomato paste, etc.).

- List all ingredients first. Perform search and reconcile error message. Then indicate the percentage or weight amounts.

# Claims & Supporting Documentation

- **Which claims need supporting documents?**
- **What specific documentation is required?**

**The following chart provides some general guidance.**

***Note: This chart is not all inclusive and should not be relied upon solely.***

# Claims & Supporting Documentation

| Claims, Guarantees, Foreign Language | Documentation Required | What to Provide |
|---|---|---|
| **Allergen Statements** | Depends on the claim | See the Compliance Policy Guide on Voluntary Allergen at: www.fsis.usda.gov/Regulations_&_Policies/Labeling_Allergens/index.asp |
| **Animal Production/Breed/Raising** | Yes | Detailed written protocol explaining controls for assuring the production claim from birth to harvest. If purchased, include protocol information from the supplier;<br>A signed affidavit declaring the specifics of the animal production claim(s) and that the claims are not false or misleading;<br>Product tracing and segregation mechanism from time of slaughter through further processing for wholesale or retail distribution;<br>A protocol for the identification, control, and segregation of non-conforming animals/product;<br>A complete, current feed formulation using common and usual language or copies of the feed tags; |
| **Certified/Verified** | Yes | Third party certifies/verifies a claim, a current copy of certification/verification needs to be provided |

# Claims & Supporting Documentation (Continued)

| Claims, Guarantees, Foreign Language | Documentation Required | What to Provide |
|---|---|---|
| **Environmental/Green** | Yes | **Green Claims:** have been approved on product regarding the packaging material used to hold the product.<br><br>**Environmental Claims**: All environmental claims need to be substantiated. They should be specific as to what part of the packaging they apply to, if not the entire package, and they should be sufficiently clear and understandable to prevent deception. Below is what we mean by "substantiation."<br><br>Substantiation: Any party making an express or implied claim that presents an objective assertion about the environmental attribute of a product, package or service must, at the time the claim is made, possess and rely upon a reasonable basis substantiating the claim. A reasonable basis consists of competent and reliable evidence, e.g. scientific evidence, such as tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area. Evidence to substantiate claims will be evaluated on a case by case basis and should be submitted with each application for sketch approval. |
| **Export Only Labels w/deviations from Domestic Requirements** | Yes | Documentation from the importing country that verifies the labeling deviation is in compliance with the laws of the importing country. A government document or letter from the importer (on company letterhead) usually is sufficient. Refer to 9 CFR 317.7 and 381.128. |
| **Foreign Language** | No | Translation information needs to be included on the label application; e.g., foreign language equals English |

# Claims & Supporting Documentation (Continued)

| Claims, Guarantees, Foreign Language | Documentation Required | What to Provide |
|---|---|---|
| **Geographical/Undefined Style** | Yes | When terms for new geographic styles (not in the Policy Book) are used on labeling, for example, "Laos Style," the geographic style would need documentation by a third-party authority. The third-party authority documentation should:<br>• Indicate the type of product as identified with and peculiar to the area represented by the geographical term;<br>• Indicate the particular characteristics of the X style in a manner that is quick and easy to understand. It may be a method of preparation and/or certain ingredients that are used;<br>• Have characteristics that are unique to the geographical style for which the documentation is being provided; and<br>• Should provide the credentials of the person who is claiming to be the third party authority.<br>Further, unless, the new style is documented in the Policy Book, the company needs to submit the documentation for each new label submittal. |
| **Grading Terms** | No | No documentation needed - the label application needs to validate the grade term in the product formula; e.g., USDA choice beef |
| **Guarantees** | No | No documentation needed. |
| **Natural/Organic** | Yes | **Natural:** No documentation needed. However, the definition, "minimally processed, no artificial ingredients" has to be connected to the claim by a symbol, such as an asterisk, or it has to be adjacent to the claim. See the specific criteria in the Policy Book.<br>**Organic:** A "current" or "up-to-date" organic certificate. These are required to be current as of a year. For additional information, see Agricultural Marketing Service, National Organic Program at: www.ams.usda.gov/AMSv1.0/nop |

# Claims & Supporting Documentation (Continued)

| Claims, Guarantees, Foreign Language | Documentation Required | What to Provide |
|---|---|---|
| **Nutrition/Health** | Depends on the claim. | If the claim is defined in the regulations, no documentation is need.<br>If the claim is not defined in the regulation, submit the following:<br>**Nutrition – comparative nutrition claims (**less, fewer, reduced, light): For a comparative claim when compared to your own regular product, we need to see a label of your regular product. When compared to USDA data, we need a copy of the page from the USDA website to ensure it is appropriate. For the market leader, top 3 or market basket, we need a current market basket survey (less than 1 year old) based on the volume of product and the labels of the products for comparison. |
| **Religious Exemptions** | No | Refer to Religious Exemption For The Slaughter And Processing Of Poultry, FSIS Directive 6030.1 |
| **Other Claims** | Depends on the claim. May need to contact the office for more information. | **Whole Grain:** Whole grain documentation is needed when whole grain references appear in the product name, the labeling includes a factual statement of the grams of whole grains, or when the labeling makes any type of statement about whole grain in the product outside of the ingredients statement. (Note, if the only reference to whole grain on the labeling is in the ingredients statement, no special documentation is required.) Always provide a calculation showing how the grams of whole grain per serving of product is obtained. The calculation should correspond to the formula provided and with any supplier documentation. It is not sufficient to just provide the grams of whole grain per serving. One serving is defined as the serving size in the nutrition facts panel. If there is no nutrition facts panel on the label, then the appropriate RACC as defined in 9 CFR 317.312 or 381.412 should be used as the serving size basis. In cases where a specific component is identified in the product name as whole grain, for example, whole grain tortilla, then a second calculation is required to show that the whole grain is at least 51 percent of the total grain component (excluding non-grain components).<br>**Omega 3 Fatty Acids:** For a factual statement , we need to see at least one piece of analytical data to support the information. |

# Difference in Appeal vs. Return

- Selection of an appeal **is not** a means to “resubmit” a returned application, Example: reviewer request a legible copy of label. Use “Edit” under available actions to address reviewer’s comments.

- The “appeal” function should only be used if an establishment disagrees with a specific modification or reason for rejection.

- 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.

- When prior approvals are mentioned in your argument, provide complete legible copies of the prior approval. If multiple prior approvals are involved, provide a listing.

# Miscellaneous Tips

- **Never share** your e-Authentication credentials with anyone. This account is specific to you as an individual.

- If you are using a temporary establishment number, (example: LSAS_Temp123) be sure that you update your establishment profile with the correct establishment number and address. This is particularly important, once you receive your final grant of approval, as it ensure that LPDD can provide effective reporting.

- If you have requested an Extraordinary Circumstance (EC), and your submission remains in Draft, be sure you have uploaded your supporting documentation .

- If you permanently leave your company or establishment, contact the LSAS Administrator immediately to ensure that your account is properly closed. If other employees in your company will need access to your labels, instructions will be provided.

# Additional Resources

- Label System and Approval System (LSAS):
  http://www.fsis.usda.gov/Regulations_&_Policies/Label_Submission_Approval_System/index.asp
- LSAS Industry Webinar: January 23, 2013:
  http://www.fsis.usda.gov/PDF/LSAS_Industry_Webinar_012313.pdf
- Industry User Guide:
  http://www.fsis.usda.gov/PDF/LSAS_Industry_User_Guide_052112.pdf
- LPDD Labeling Guidance:
  http://www.fsis.usda.gov/About_FSIS/labeling_&_consumer_protection/index.asp
- Child Nutrition (CN) Labeling Program:
  http://www.fns.usda.gov/cnd/cnlabeling/default.htm
- Generic Labeling:
  http://www.fsis.usda.gov/Regulations_&_Policies/Generic_Labeling/index.asp

# Additional Resources (Continued)

- LSAS Administrator:

  LSAS@fsis.usda.gov or lynn.yoder@fsis.usda.gov

  or call: (301) 504-0837

- askFSIS:

  http://askfsis.custhelp.com/

- Labeling and Program Delivery Division:

  Office: (301) 504-0878