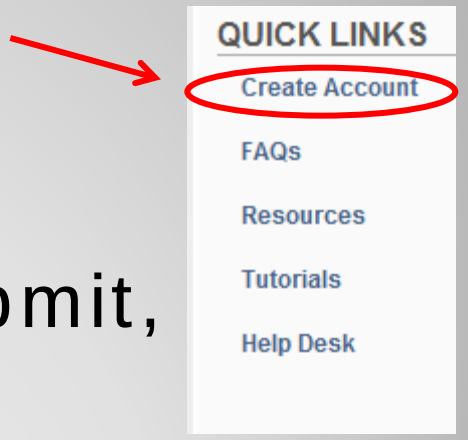
CDER Direct
Electronic Submissions Portal

CDER Direct – Quick Start Guide

Accessing the Application

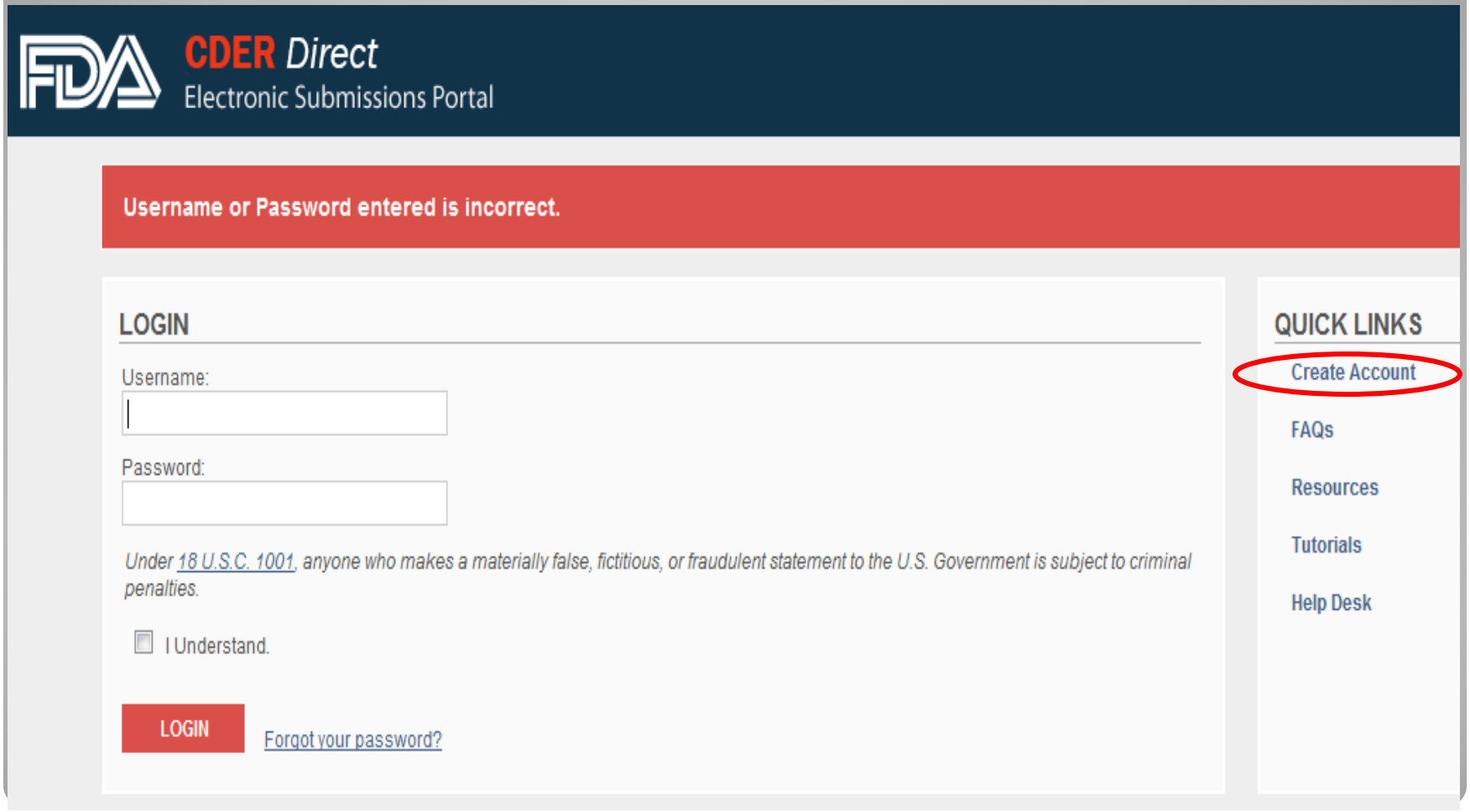
To access CDER Direct, enter direct.fda.gov into IE 8

First Time Users – Select Create Account; enter all the requested user and company information



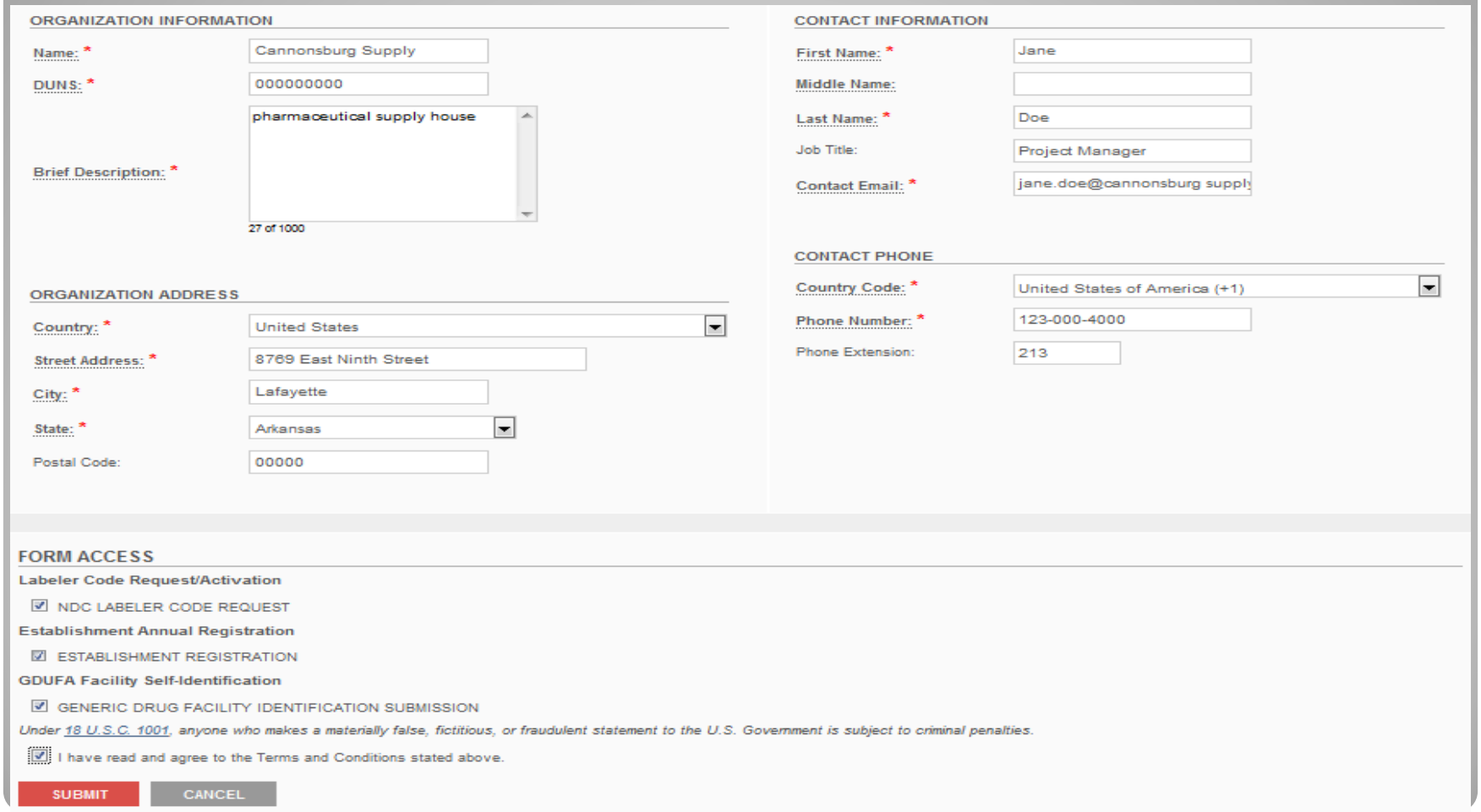
Activating - Once you click submit, you must activate your account within 48 hours.

Login Screen



CDER Direct: direct.fda.gov

Creating Account



CDER Direct: direct.fda.gov

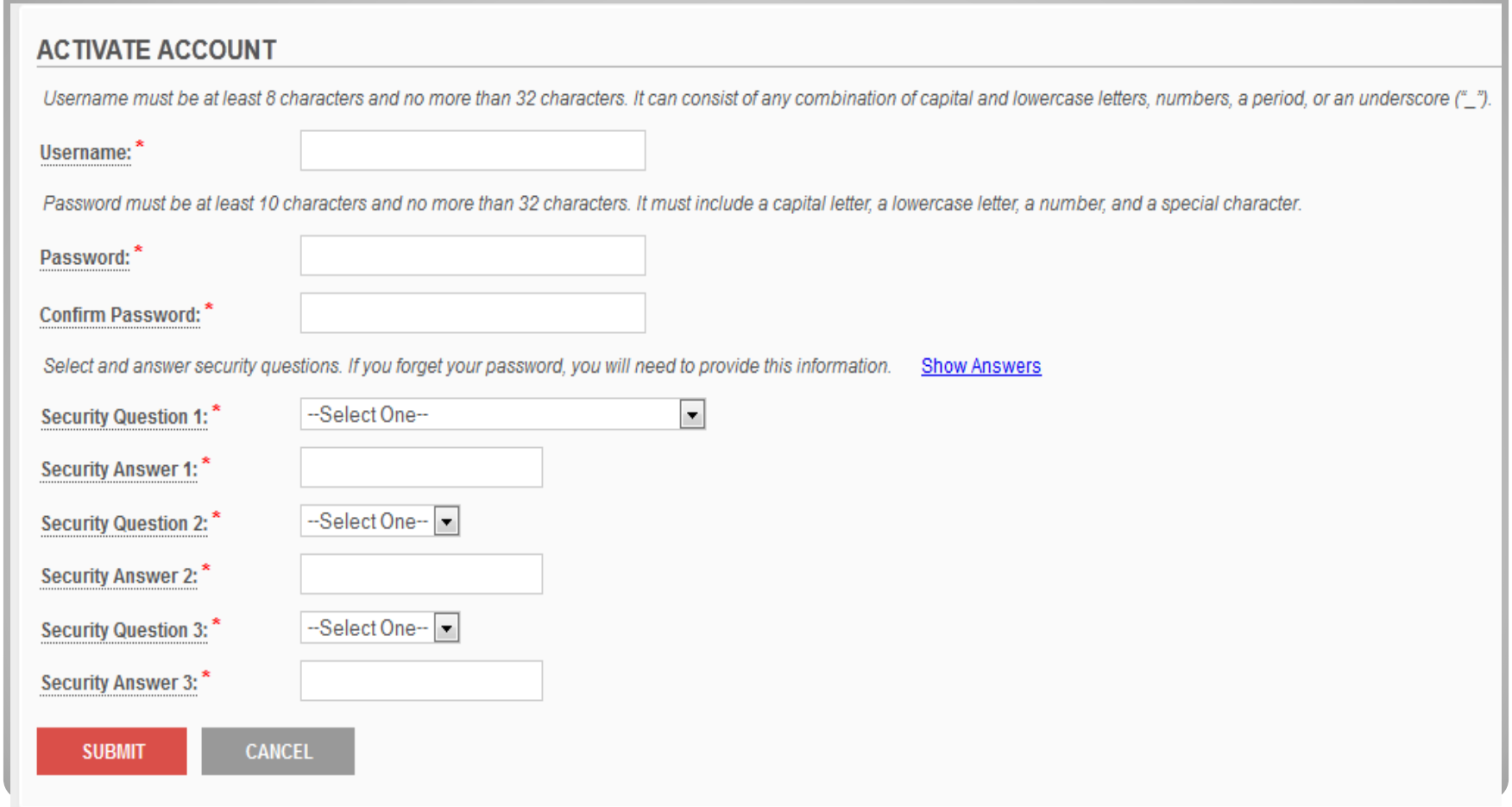
Activating Your Account

To activate your account:

1. Open your email account
2. Open the email from cderdirect@fda.gov.
3. Click on the activation link in the email.
4. Enter a user name and password following the guidelines that appear on the screen
5. Select three security questions and enter the answer to each question.
6. Click **Submit**.

(If you do not receive an email, please check your Spam filters)

Activating Your Account



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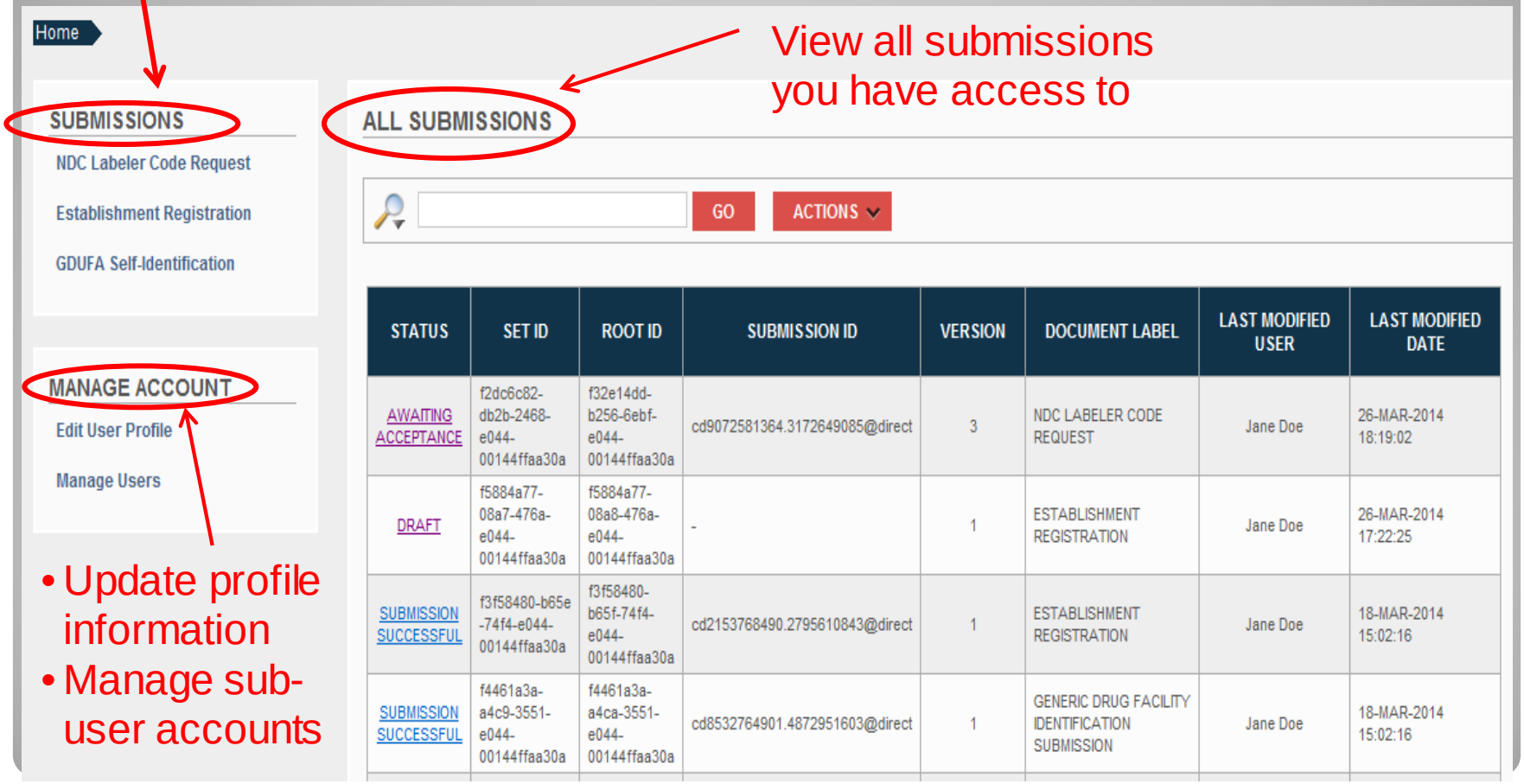
Login Credential Requirements

- Username
  - eight characters including:
    - upper and lower case letters
    - numbers
    - a period or an underscore (“_”)
- Password
  - least ten characters including:
    - an upper and a lower case letter
    - a number
    - a non-alphanumeric character

Using the Home Page

All forms that you have access to

View all submissions you have access to



- Update profile information
- Manage sub-user accounts

CDER Direct: direct.fda.gov

Where do I get more information?

Log on to CDER Direct: direct.fda.gov

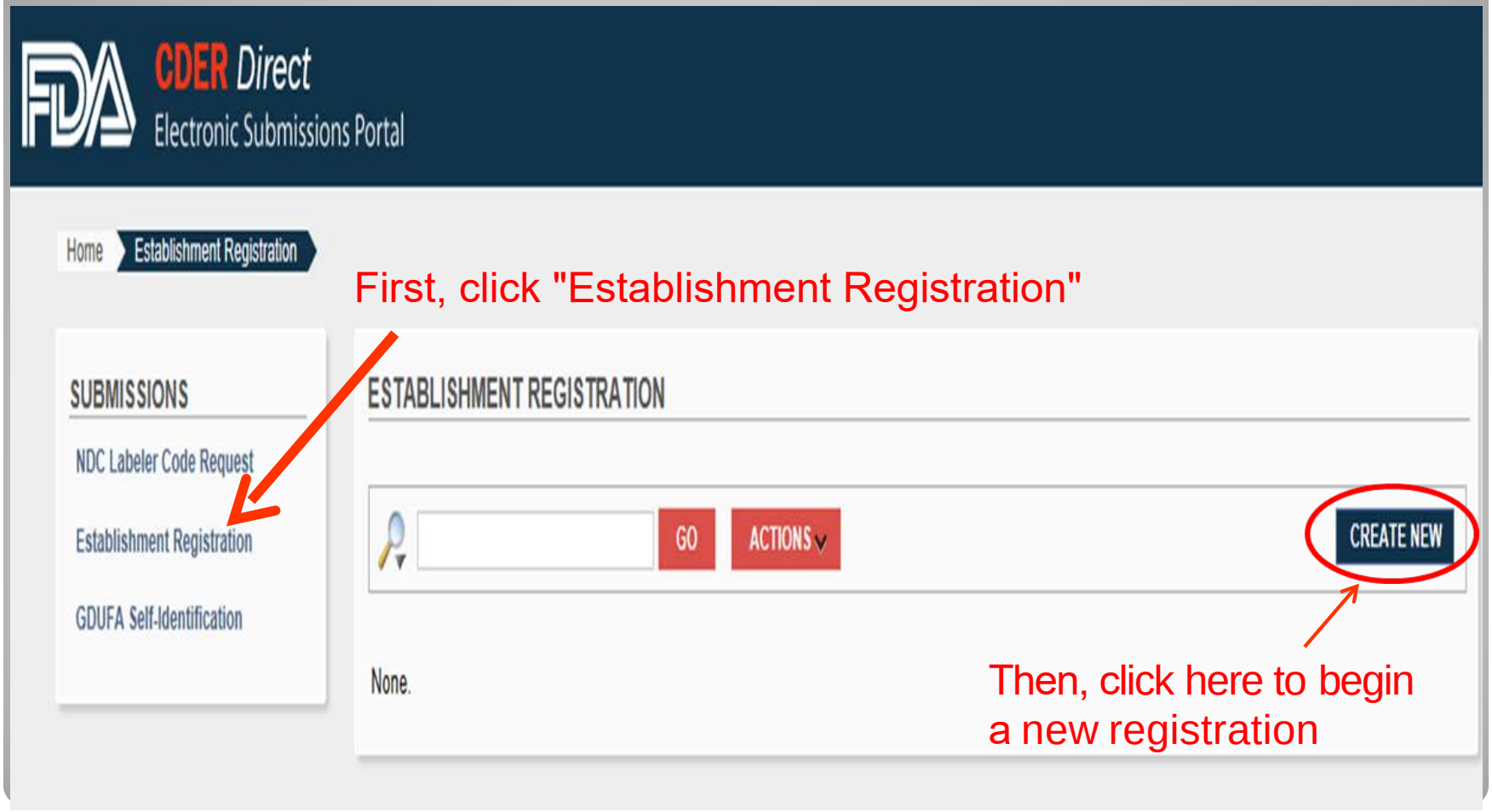
Compatible with the following browsers:

- *IE version 8 and above*
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov

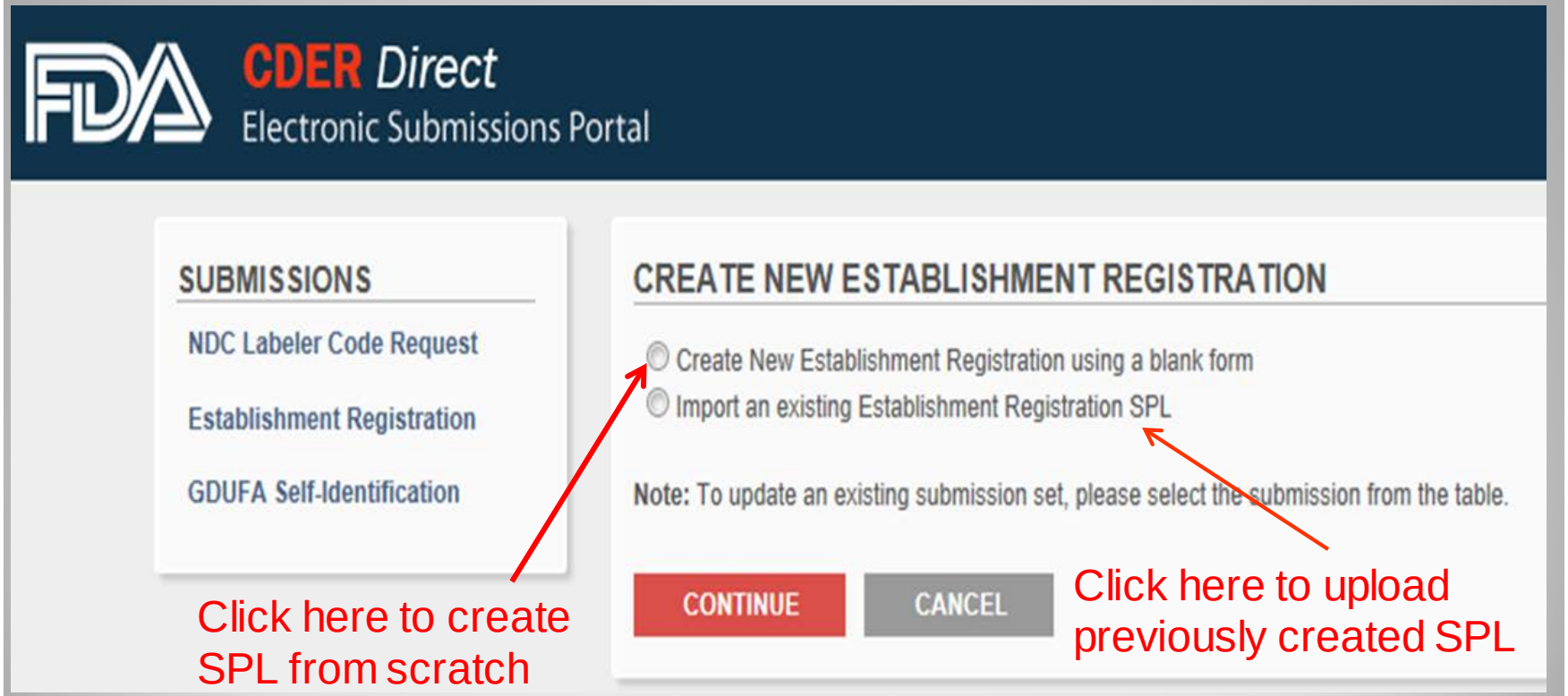
CDER Direct – Establishment Registration

Establishment Registration



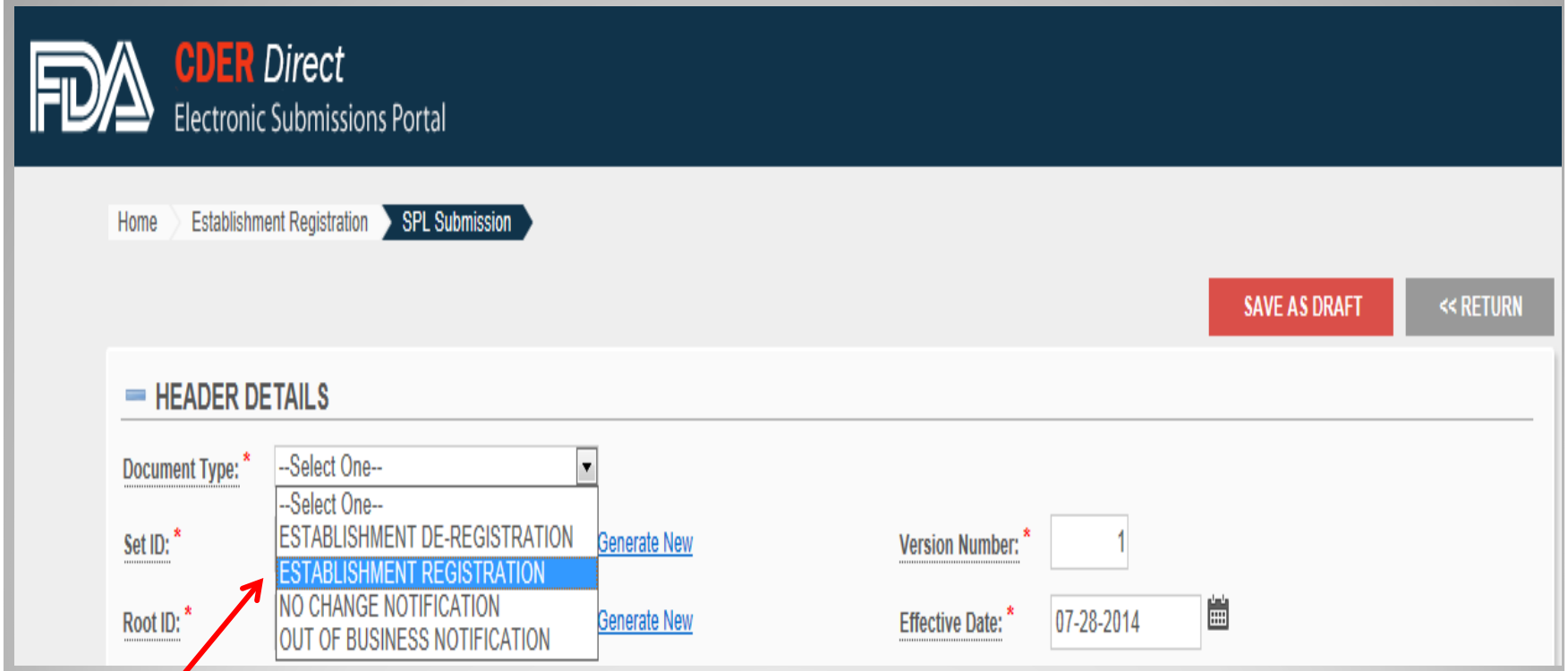
CDER Direct: direct.fda.gov

Establishment Registration



CDER Direct: direct.fda.gov

Establishment Registration



Select "Establishment Registration "

Document Type: *

A *RED* asterisks indicates field is mandatory

State/Province:

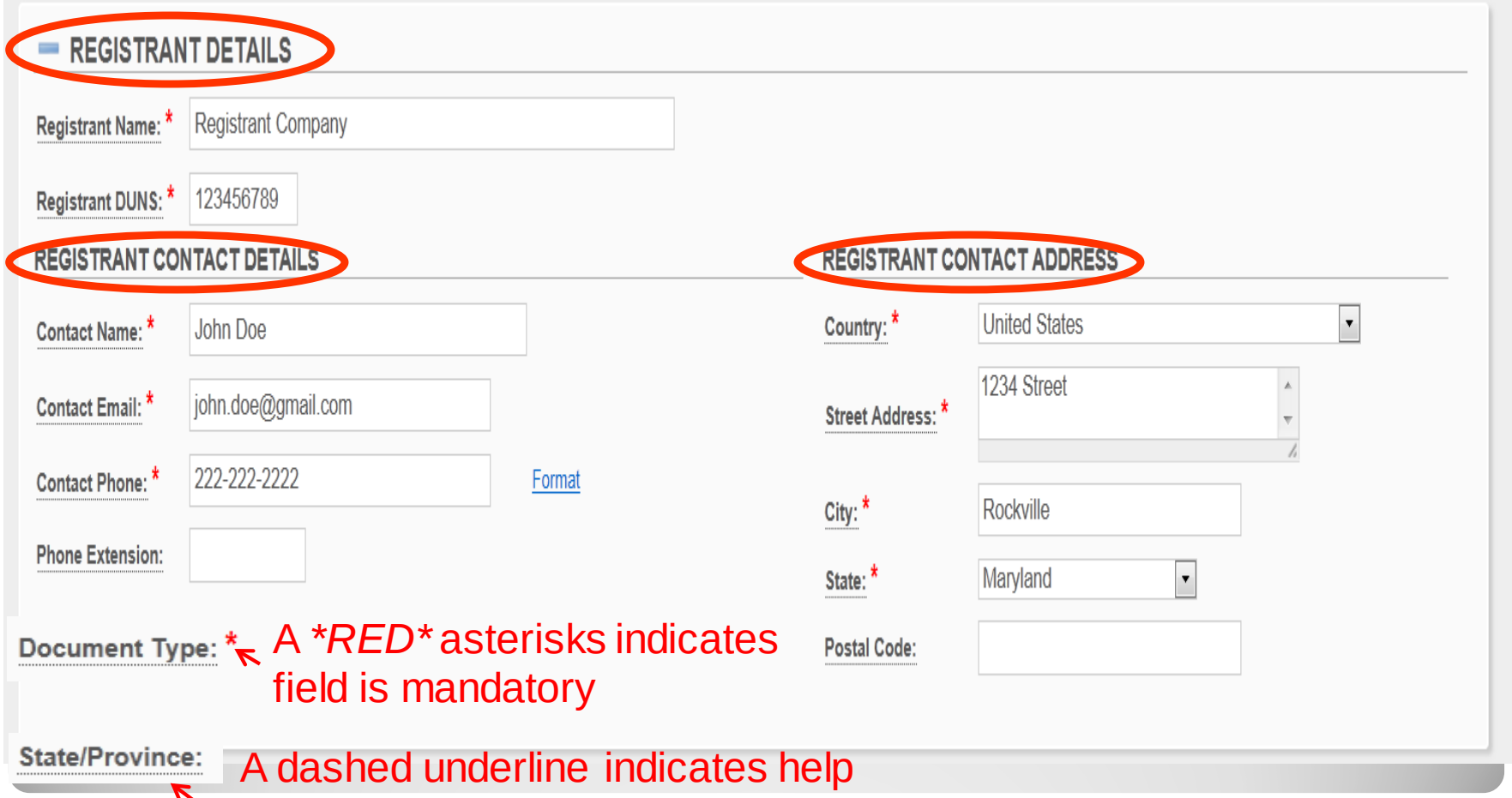
A dashed underline indicates help text if clicked on

CDER Direct: direct.fda.gov

Helpful Hints

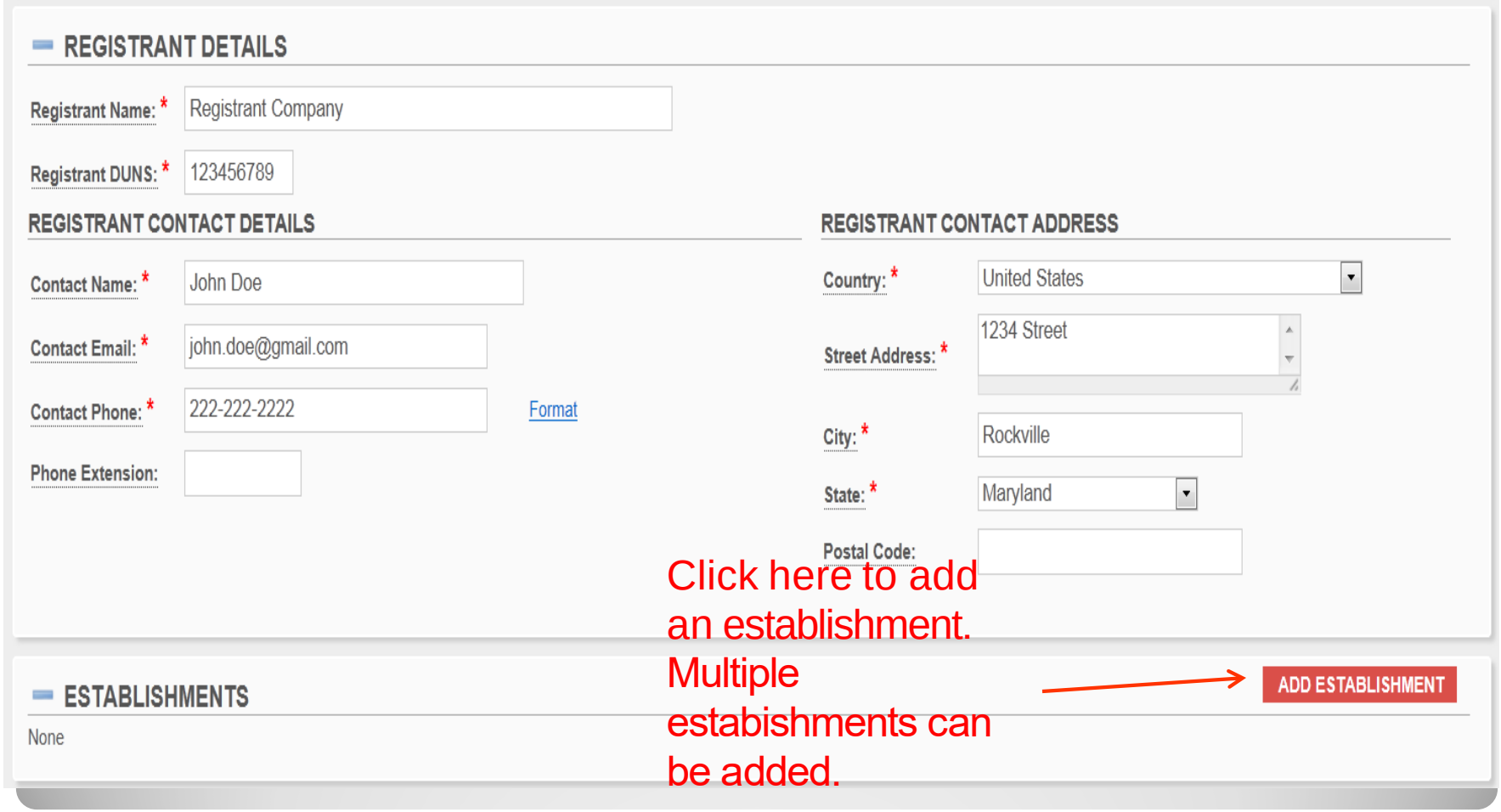
- Document Types
  - Establishment Registration
    - *to register your establishment(s)*
  - No change notification
    - *each year when the information is updated, if there is no change*
  - Out of Business
    - *if the registrant goes out of business*
  - Establishment De-Registration
    - *de-register your establishment(s)*

Establishment Registration



CDER Direct: direct.fda.gov

Establishment Registration



Click here to add an establishment. Multiple estabishments can be added.

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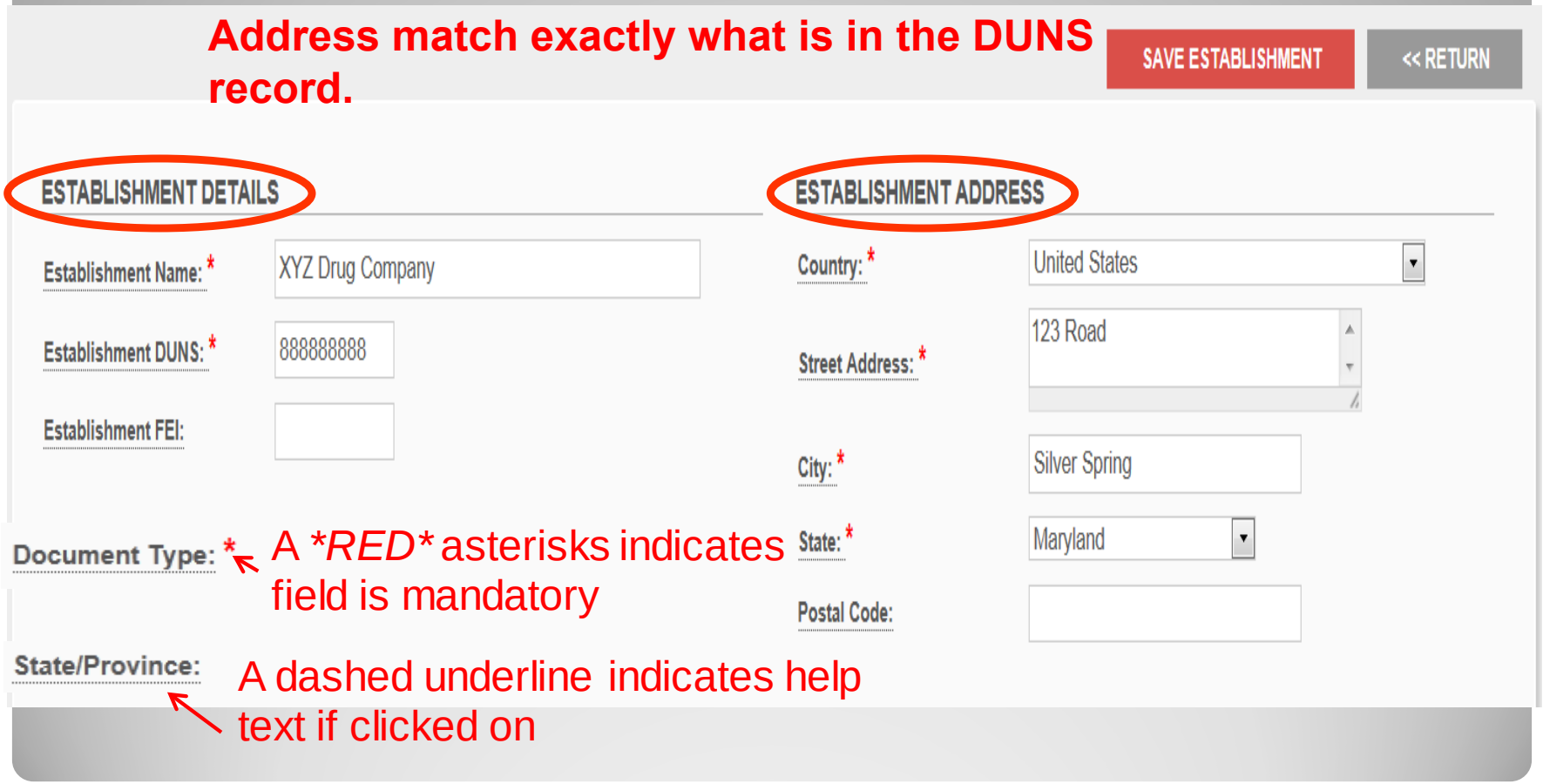
Establishment Registration

Ensure that the Establishment Name and Address match exactly what is in the DUNS record.



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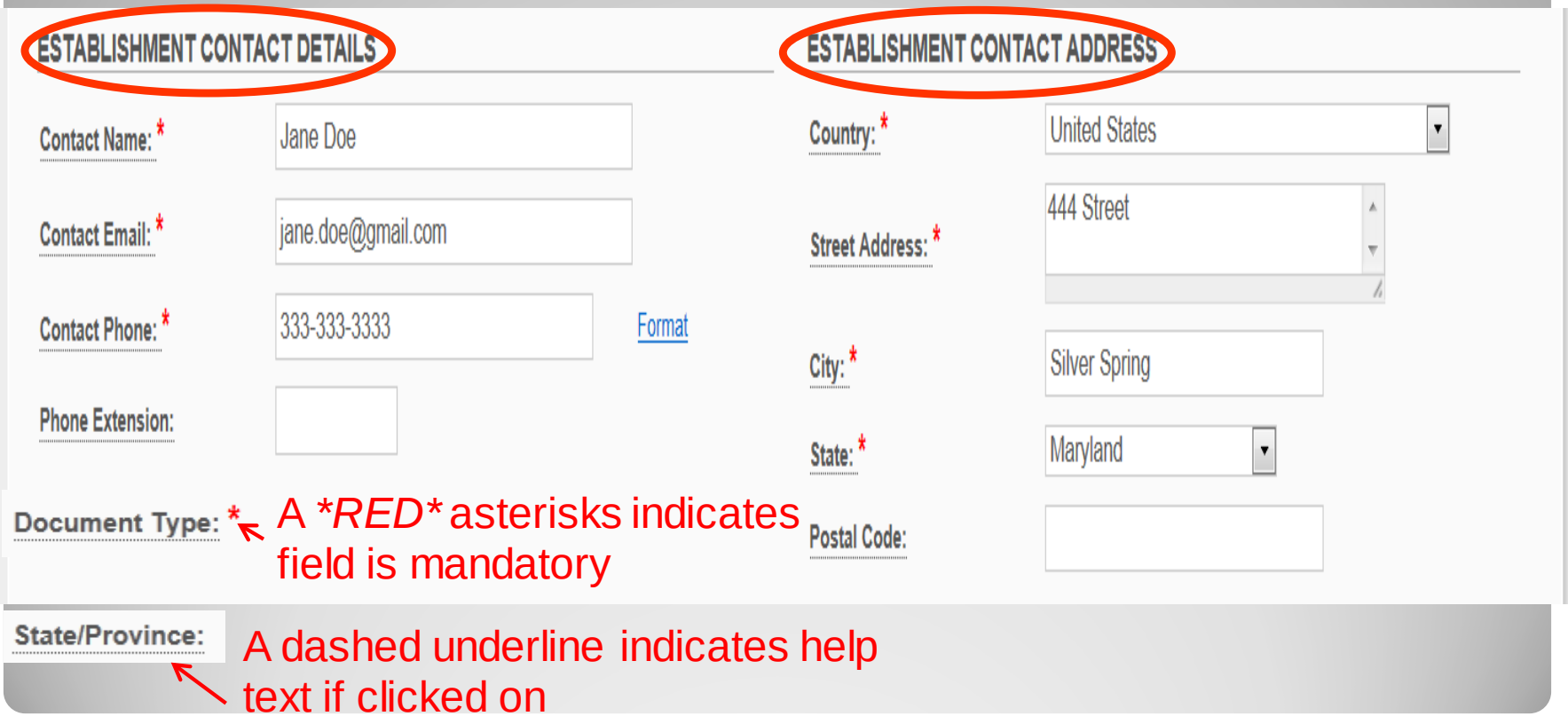
Establishment Registration

Note: This is the contact information for the Establishment, not the Registrant

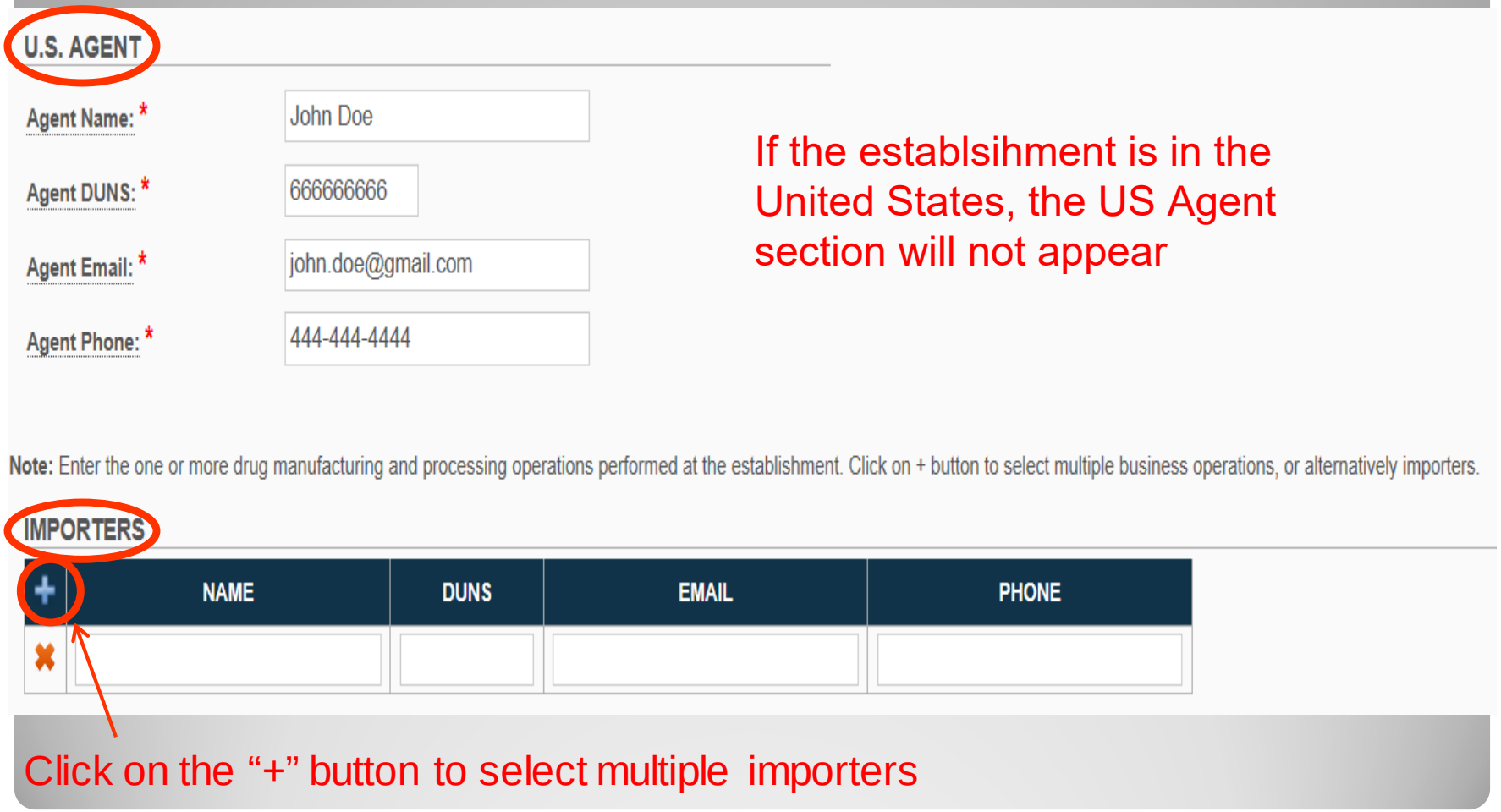


A **RED** asterisks indicates field is mandatory

A dashed underline indicates help text if clicked on

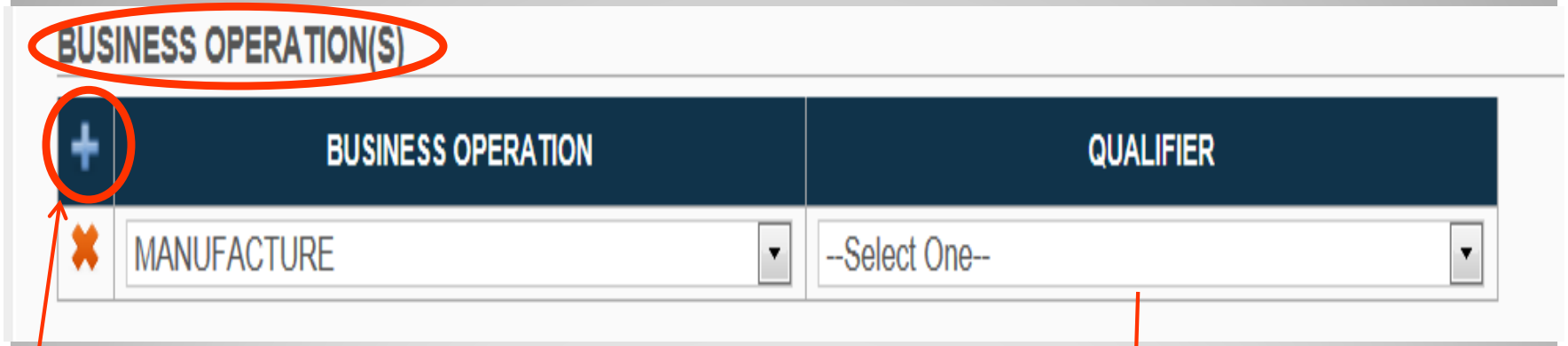
CDER Direct: direct.fda.gov

Establishment Registration



CDER Direct: direct.fda.gov

Establishment Registration



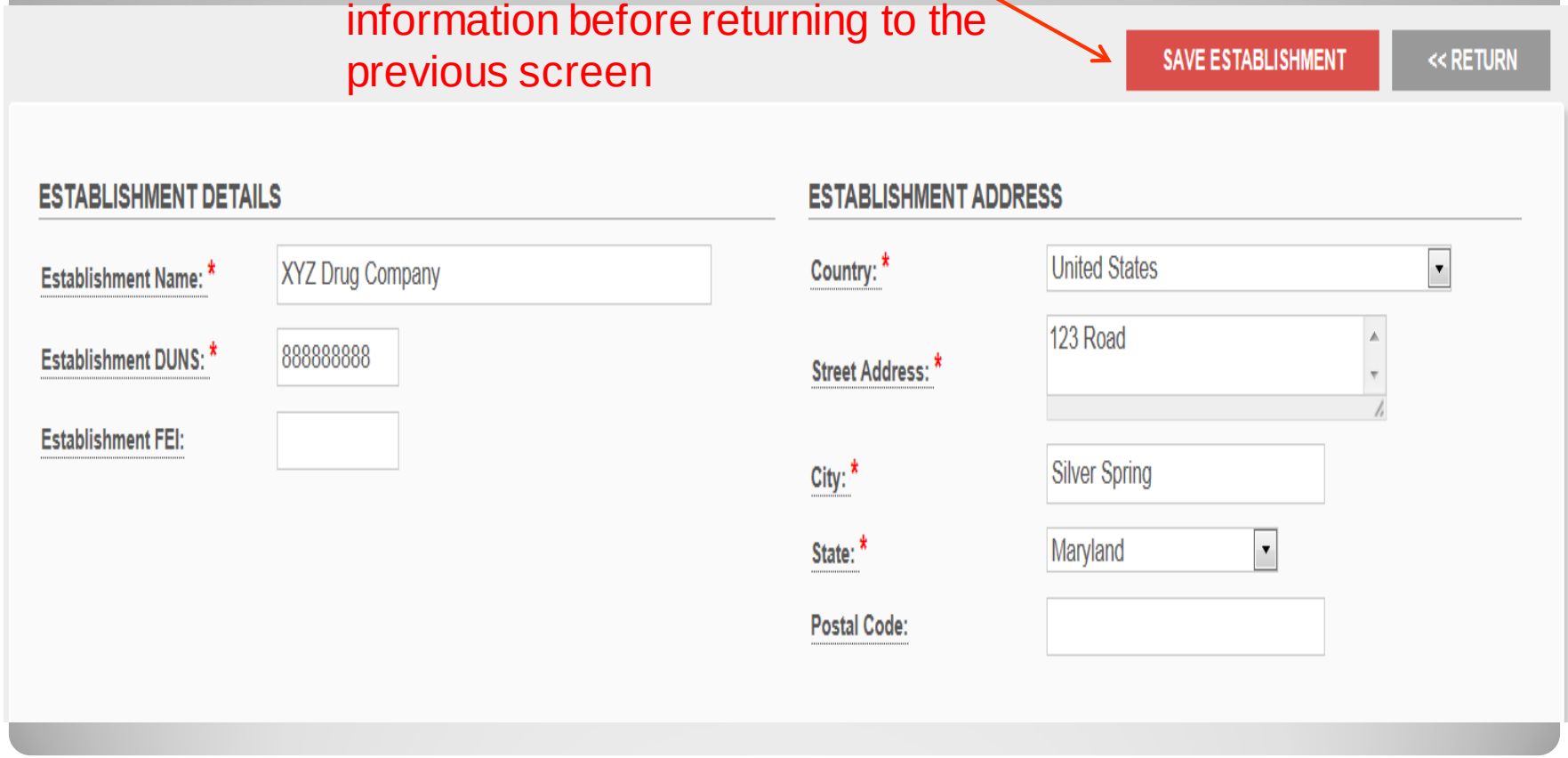
Click on the “+” button to select multiple business operations

Select "Manufactures Human Over-the-Counter Drug Products Produced Under a Monograph"

CDER Direct: direct.fda.gov

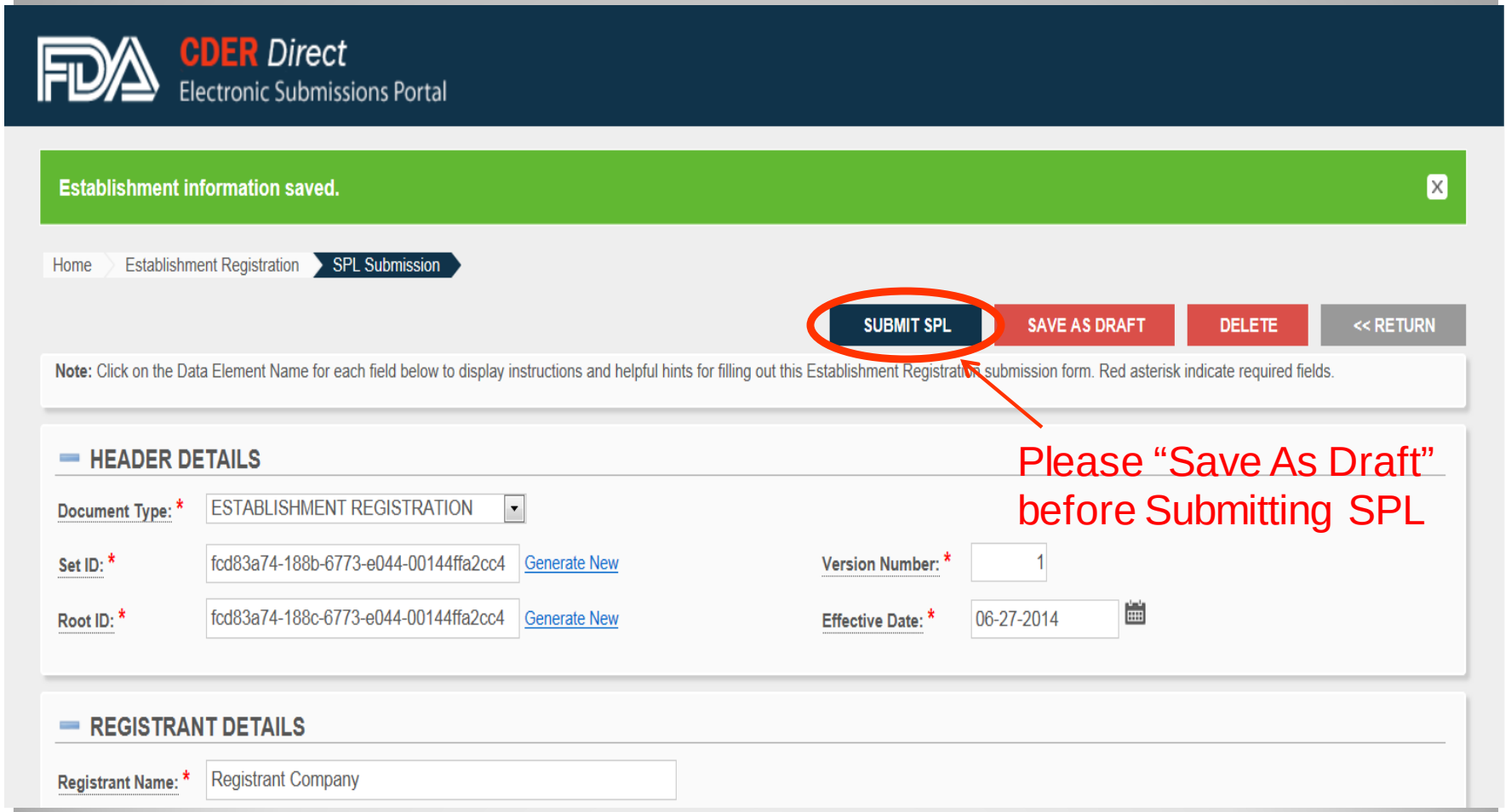
Establishment Registration

Click here to save Establishment information before returning to the previous screen



CDER Direct: direct.fda.gov

Establishment Registration



Please “Save As Draft” before Submitting SPL

CDER Direct: direct.fda.gov

Where do I get more information?

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Compatible with the following browsers:

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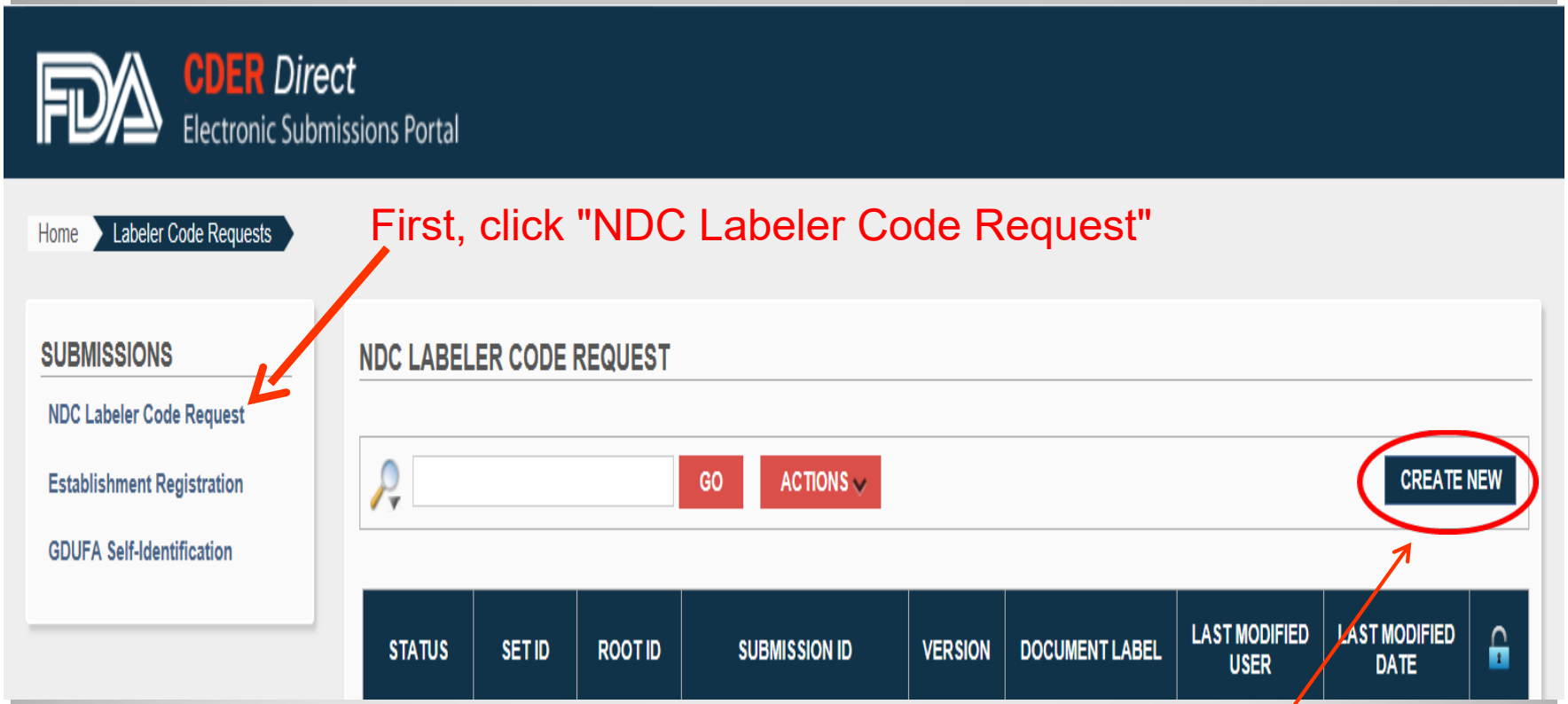
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov

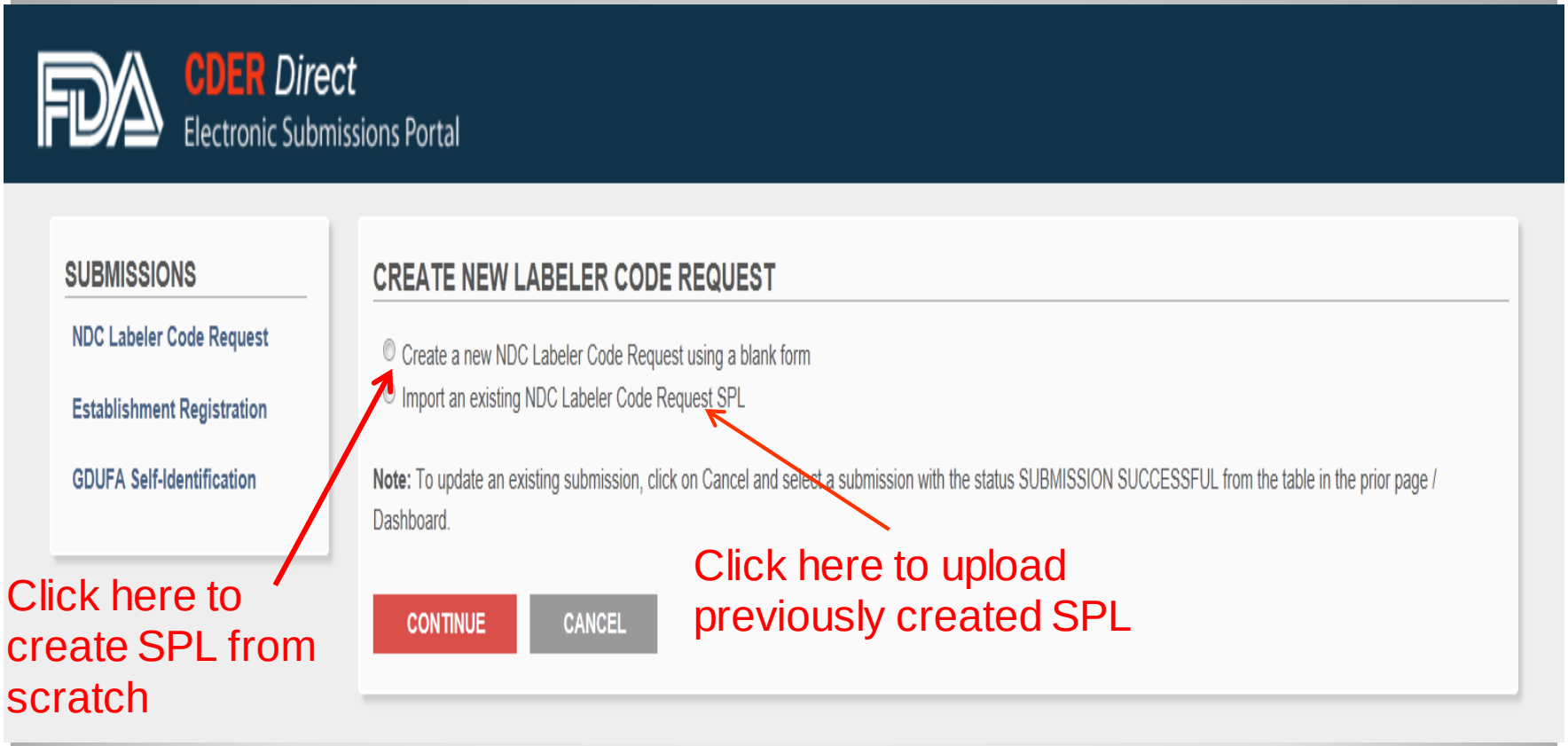
CDER Direct – NDC Labeler Code Request

NDC Labeler Code Request



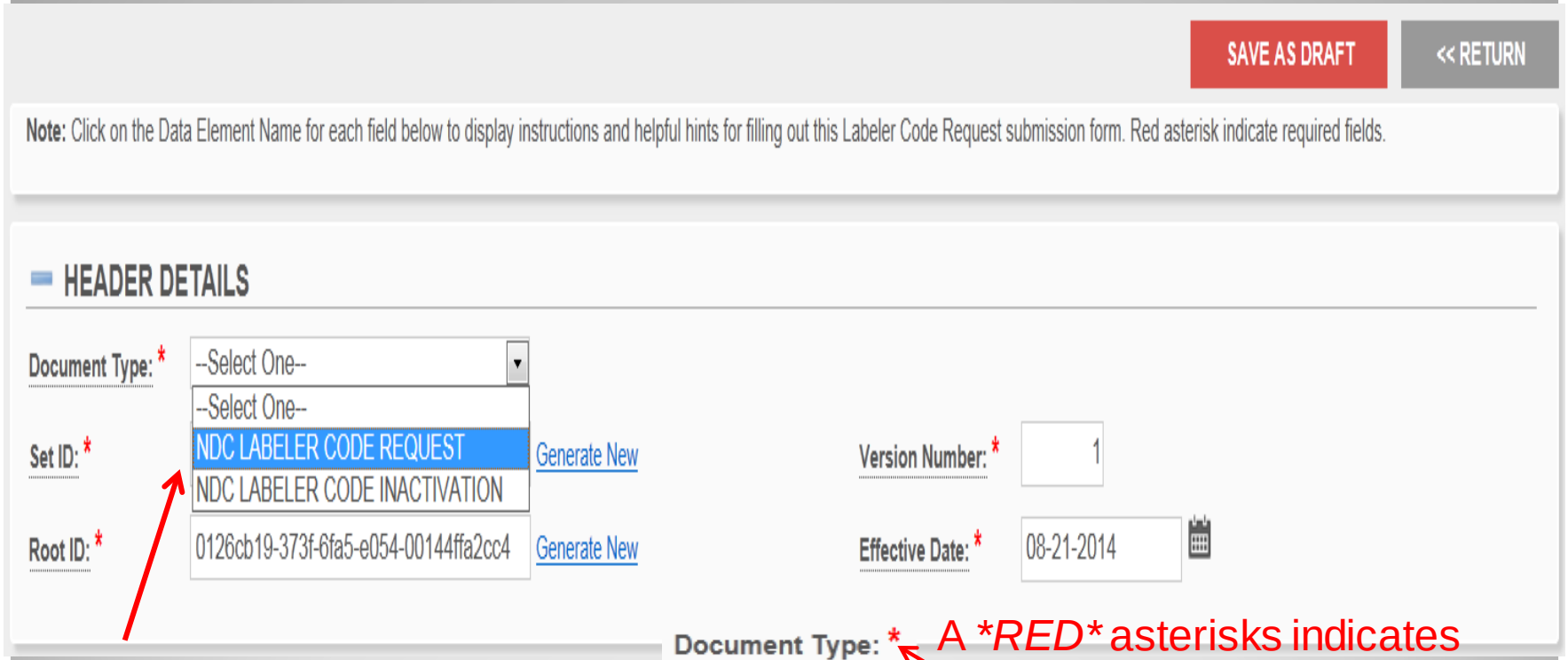
CDER Direct: direct.fda.gov

NDC Labeler Code Request



CDER Direct: direct.fda.gov

NDC Labeler Code Request



Select NDC Labeler Code Request

Document Type: *

A **RED** asterisks indicates field is mandatory

State/Province:

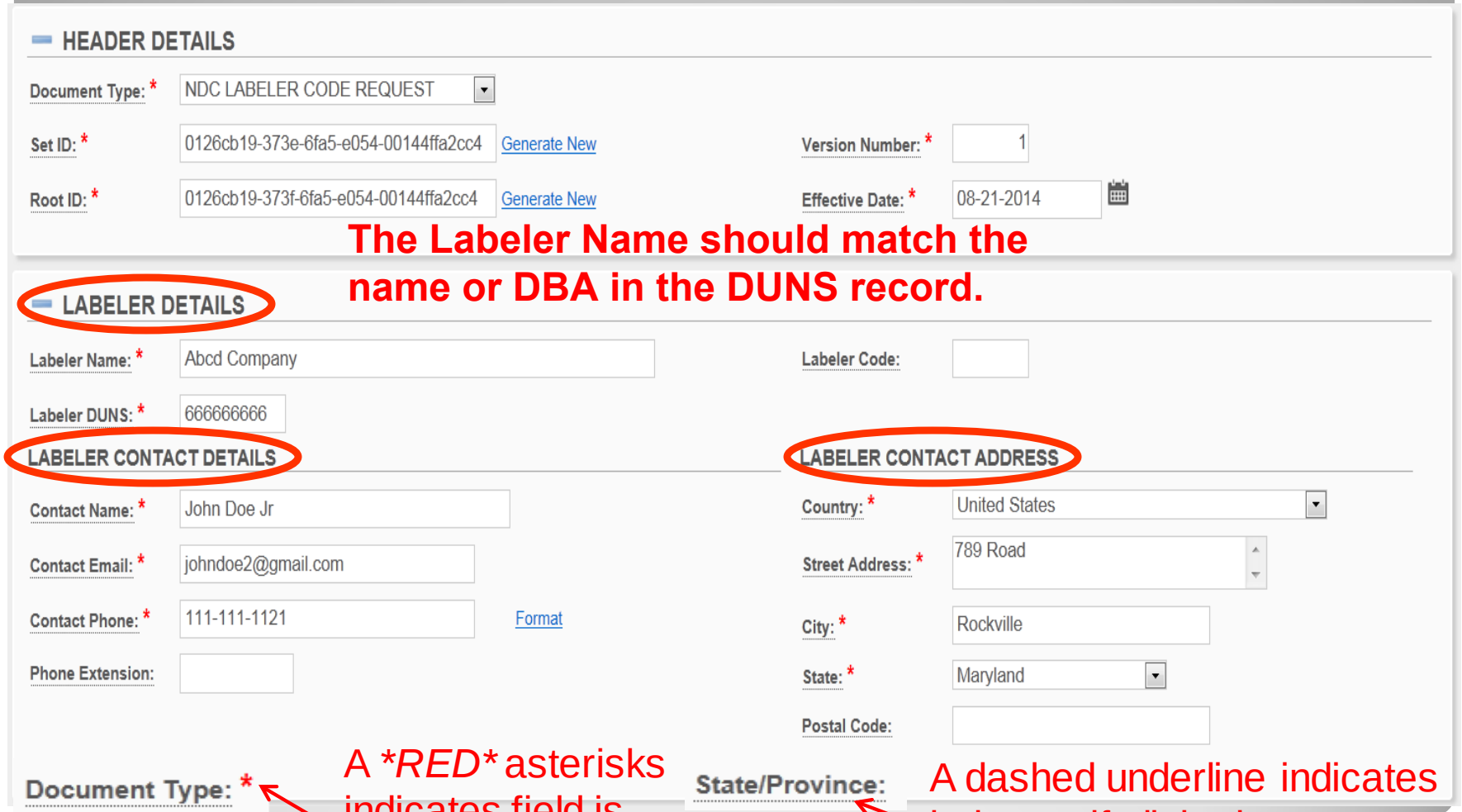
A dashed underline indicates help text if clicked on

CDER Direct: direct.fda.gov

Helpful Hints

- Document Type
  - NDC Labeler Code Request
    - *if you are requesting a labeler code or completing a labeler code process*

NDC Labeler Code Request

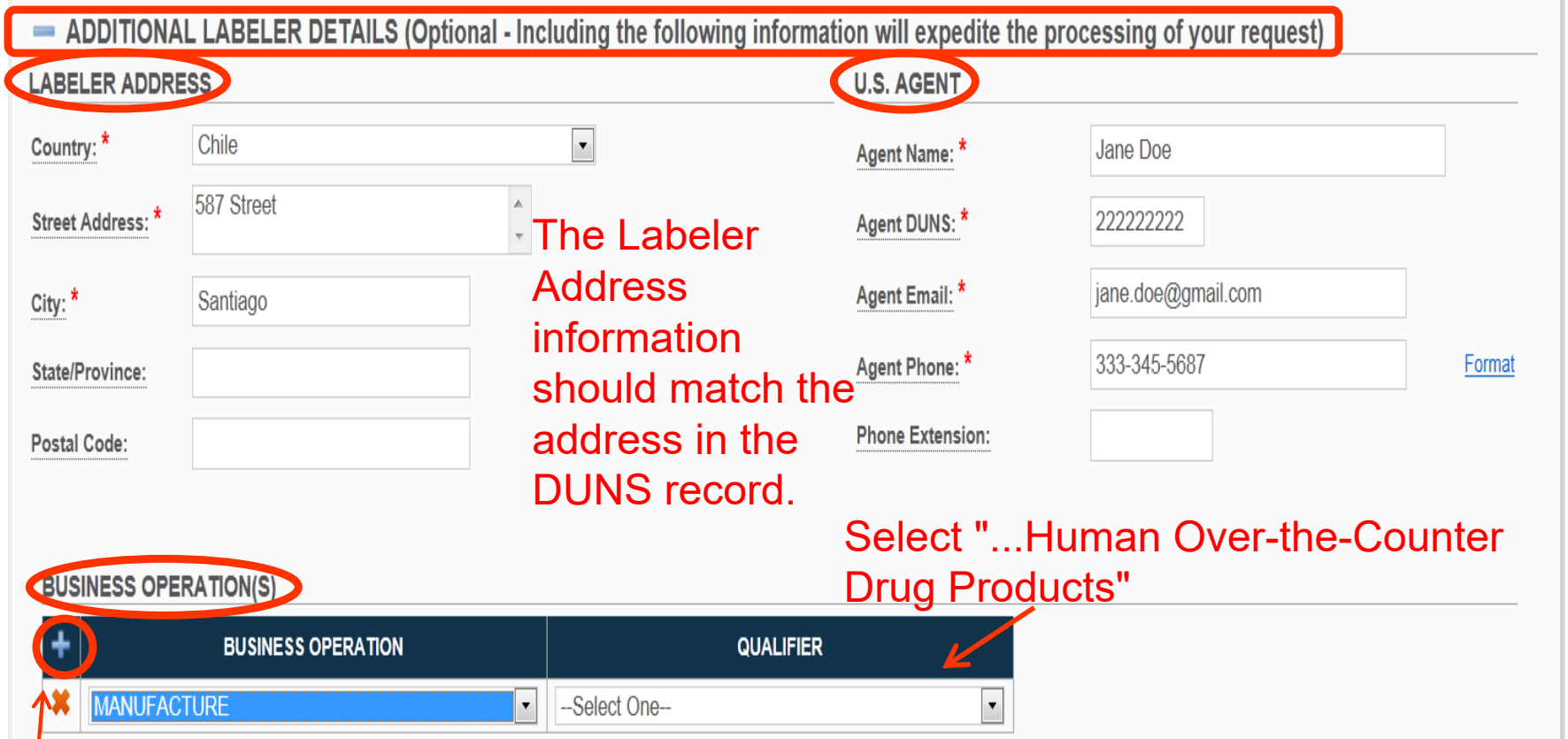


CDER Direct: direct.fda.gov

Helpful Hints

- Labeler Code
  - When first requesting a labeler code
    - ***leave this field blank***
  - When confirming the Labeler Code after you have been assigned a Labeler Code by FDA
    - *enter the 5 digit number assigned by FDA as the NDC Labeler Code*

NDC Labeler Code Request



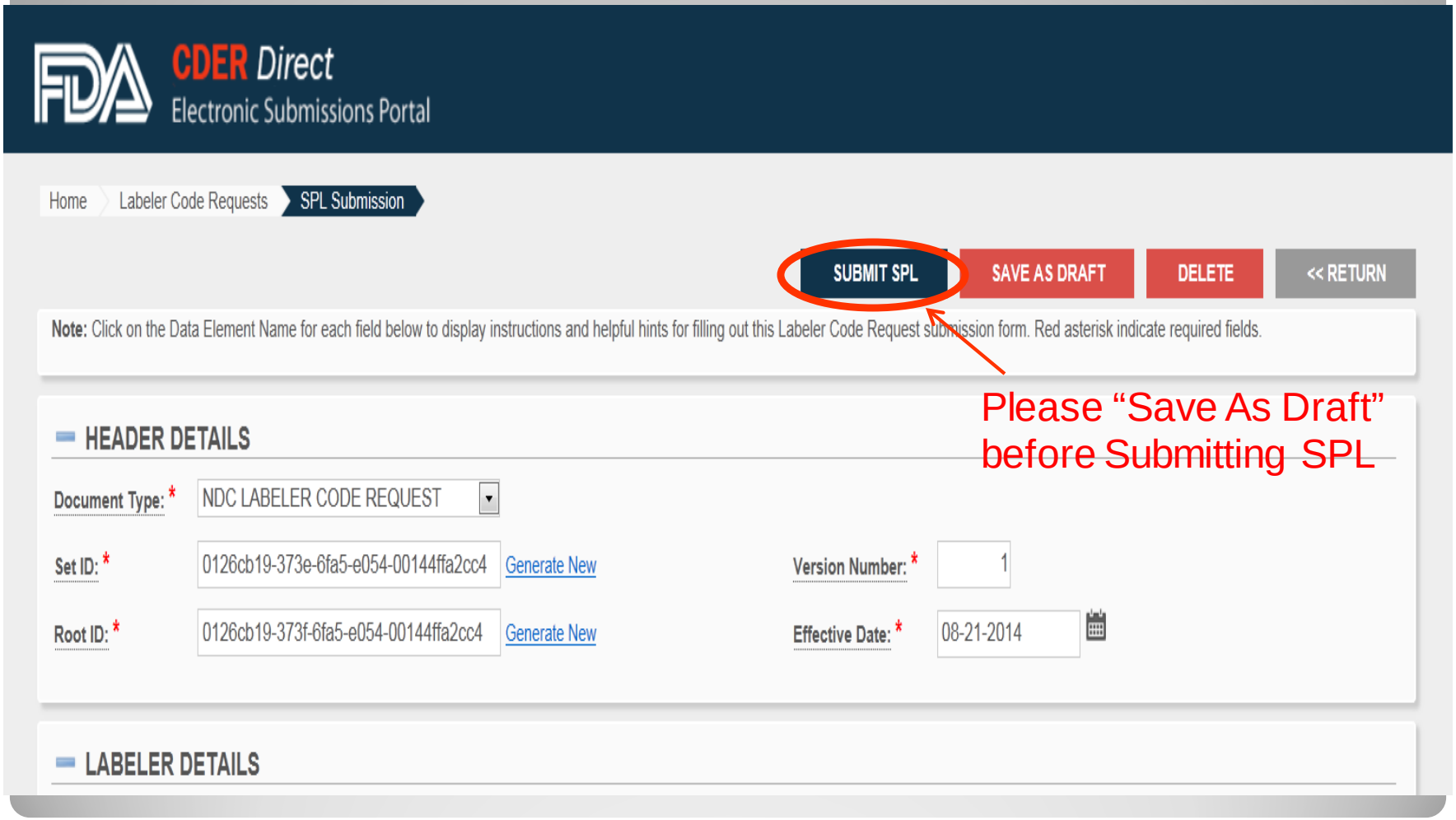
The Labeler Address information should match the address in the DUNS record.

Select "...Human Over-the-Counter Drug Products"

Click on the “+” button to select multiple business operations.

CDER Direct: direct.fda.gov

NDC Labeler Code Request



CDER Direct: direct.fda.gov

Where do I get more information?

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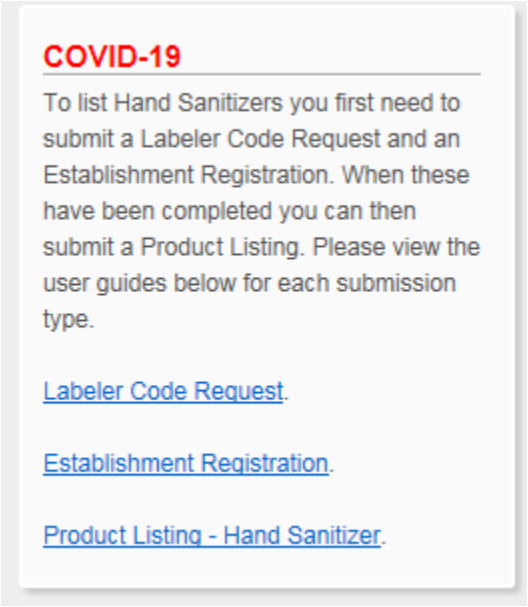
Compatible with the following browsers:

- *IE version 8 and above*
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov

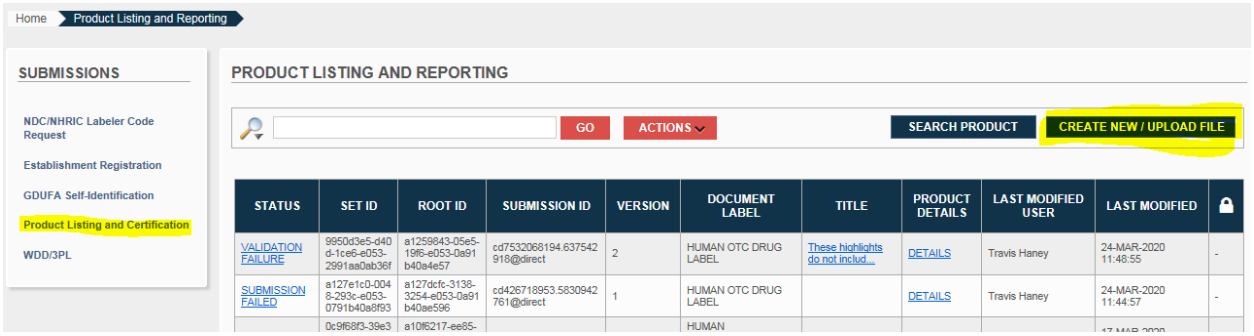
FDA is providing standardized hand sanitizer listing templates that can be used to prepopulate much of the listing data. If you are not currently registered as a drug manufacturing facility and do not already have a labeler code assigned by FDA, please complete an Establishment Registration and Labeler Code Request prior to submitting your Product Listing. For additional instructions on how to submit an Establishment Registration and Labeler Code Request, please review the user guide documents located in CDER Direct after logging into the portal. Please note that this template should not be used by 503B outsourcing or compounding facilities as their requirement for "product reporting" is different than "drug listing".



FDA has created a hand sanitizer drug listing template pursuant to the current WHO guidelines to be used for the duration of the COVID-19 public health emergency. It remains the submitting firm's responsibility to review the suggested data to ensure that the information provided in the drug listing matches the product's formulation and labeling. This template is not *required* to be used during the COVID-19 public health emergency, and a company has discretion whether to utilize this template or a blank Product Listing form instead.

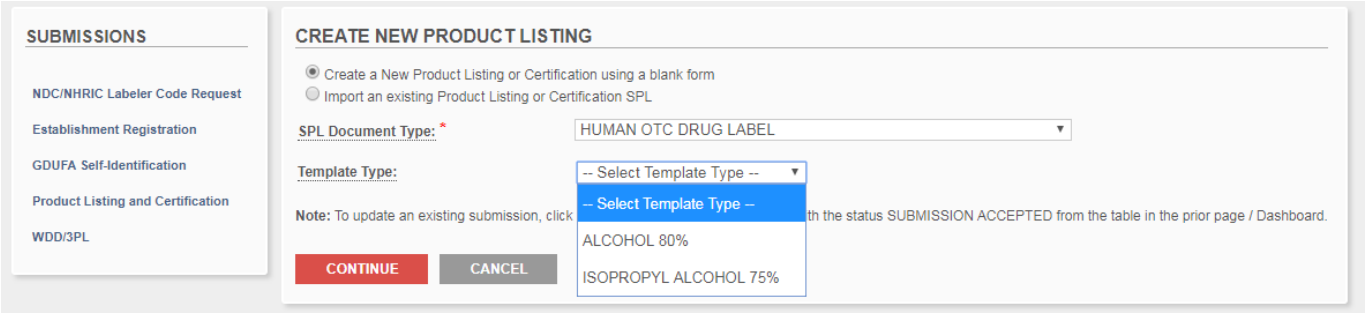
To use the hand sanitizer template, please do the following:

1. Select "Product Listing and Certification" on the left-hand side of the page under the SUBMISSIONS header, and then select CREATE NEW/UPLOAD File.

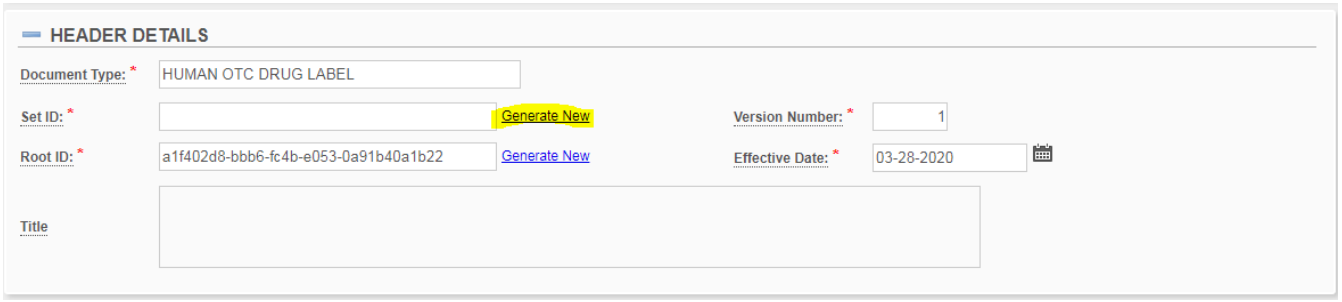


2. Select the “Create a New Product Listing or Certification using a blank form” bubble. Select HUMAN OTC DRUG LABEL as the SPL Document Type. Select “OK” on the popup window that appears to confirm that you would like to use a Hand Sanitizer template. Select the Template Type that best reflects your product.

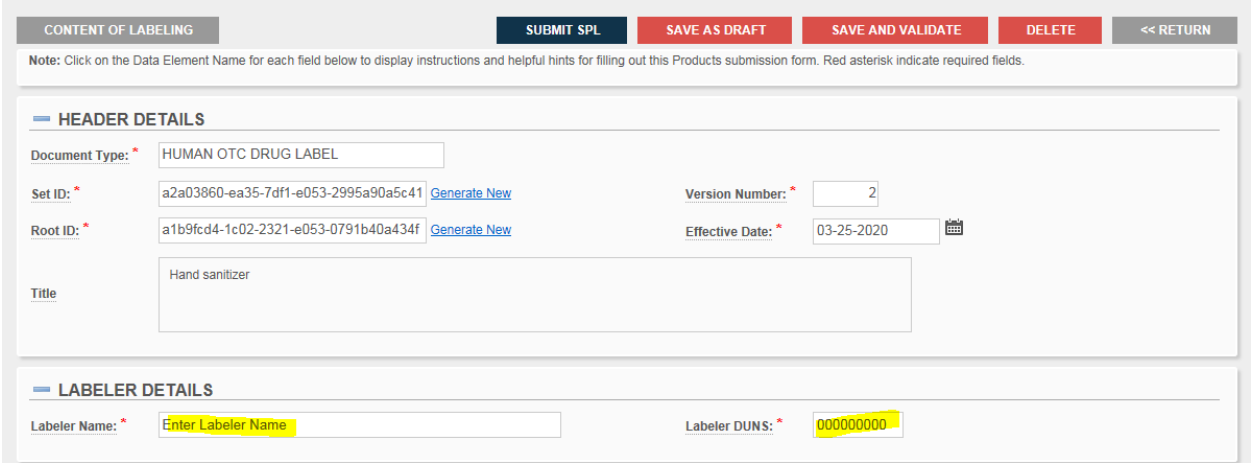
   Please be aware that the list of template options provided in the dropdown only includes formulations pursuant to WHO and FDA’s recent guidance: [Temporary Policy for Preparation of Certain Alcohol Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)] for the duration of pandemic. FDA recommends other active or inactive ingredients are not added. Different or additional ingredients might impact the quality and potency of the product. This template can be used to prepopulate the product listing file.



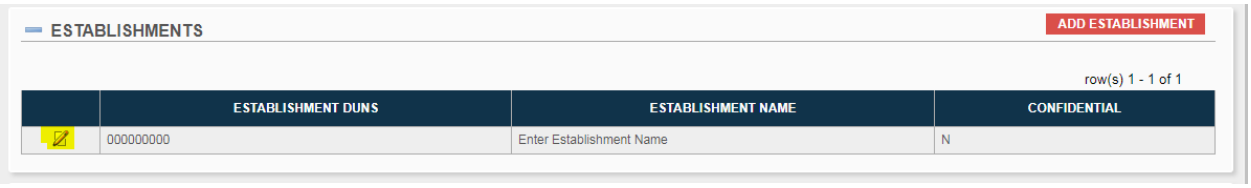
3. Select “Generate New” next to the Set ID field.



4. Enter the Labeler Name and DUNS number that was used in your Labeler Code Request.



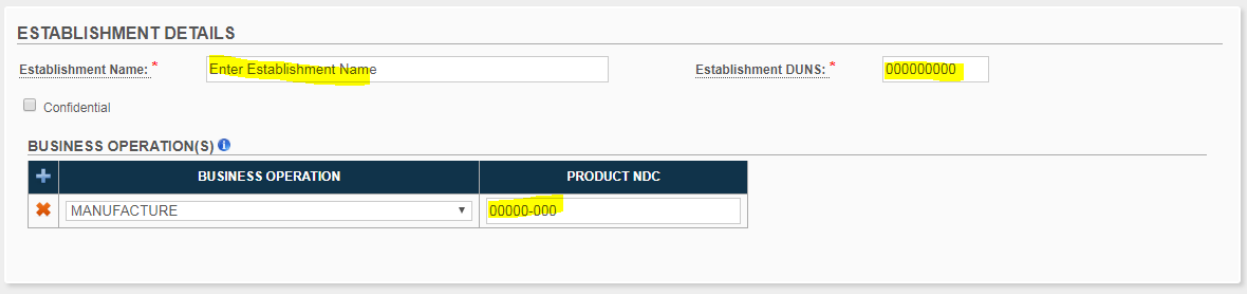
5. Select the Edit Icon next to Establishment DUNS located under the ESTABLISHMENTS header.



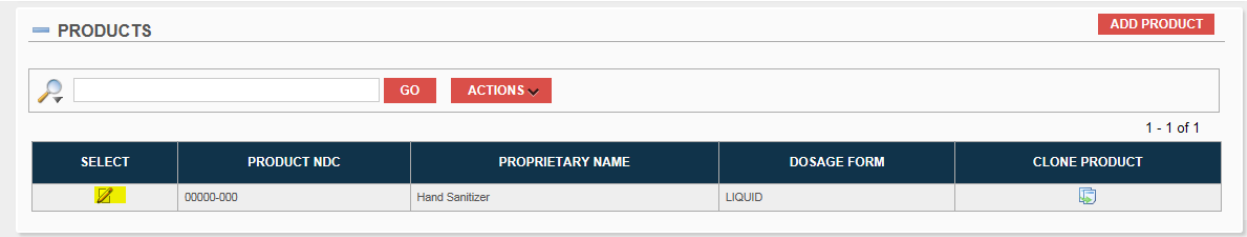
6. Enter the establishment name and DUNS number provided in your establishment registration, followed by the Business Operation(s) performed and the Product NDC.

   Note: The NDC Product Code is the first 2 segments of the NDC. It is the 4- or 5-digit NDC Labeler Code assigned to the company whose name is on the label and the 3- or 4-digit product code segment of the NDC identifying the formulation and dosage form, separated by a hyphen. Examples: 12345-678, 23456-7890.

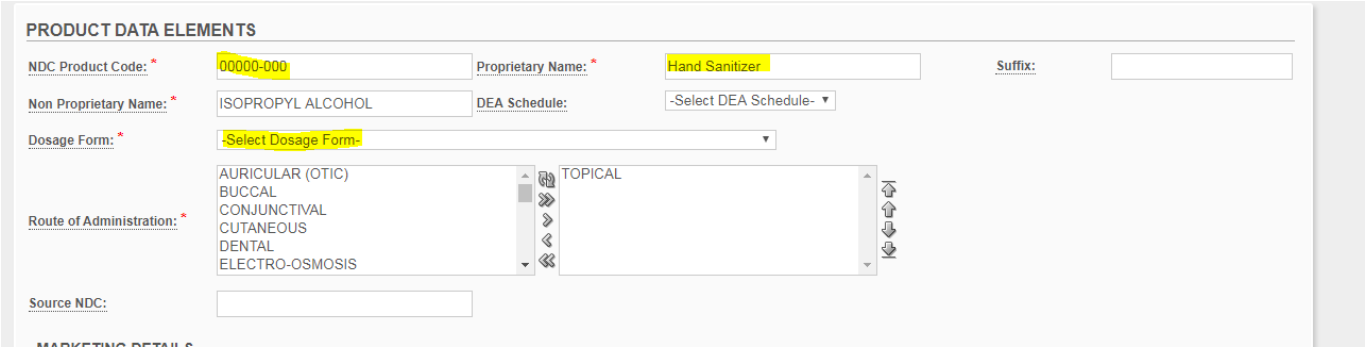
   For more information on NDC and its assignment to drugs visit [Code of Federal Regulations Title 21 Part 207 Subpart C.]



7. Select the Edit icon next to the Product NDC located under the PRODUCTS header.

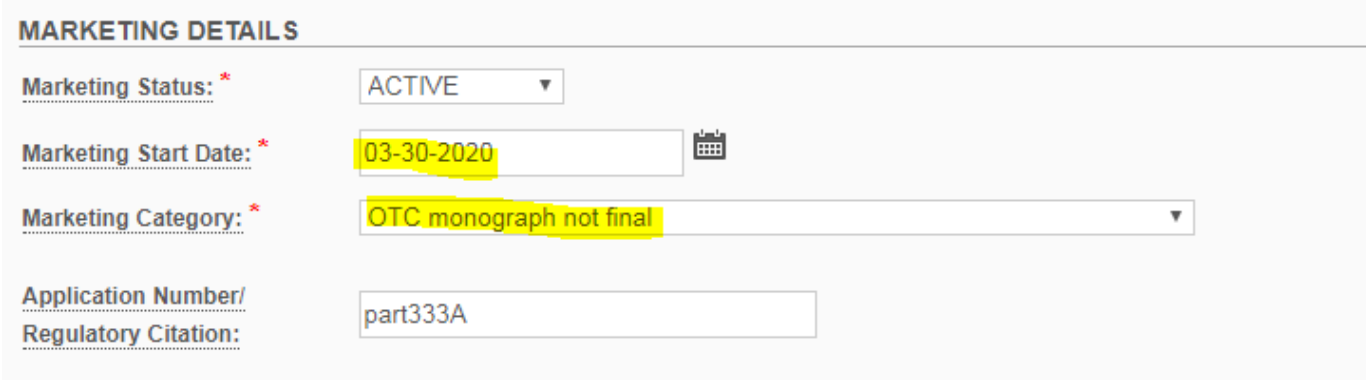


8. Update the Product NDC, Proprietary Name (if any), and Dosage Form of your product. Select OK, on the popup message that will be displayed after selecting a Dosage Form.



9. Enter the Marketing Start Date of your product and then select “OTC monograph not final” for the Marketing Category. Select OK, on the popup message that will be displayed after changing the Marketing Category.

Regulatory Citation: Please note, that your selection of the Marketing Category "OTC monograph not final" and Regulatory Citation "part333A" represents an affirmation that the drug included in this product listing satisfies all regulatory requirements under this OTC monograph. If any change occurs to the drug formulation represented in this listing, please ensure that the product conforms to all relevant requirements outlined under part333A of the OTC monograph.



10. Review the Ingredients in the INGREDIENTS SECTION.

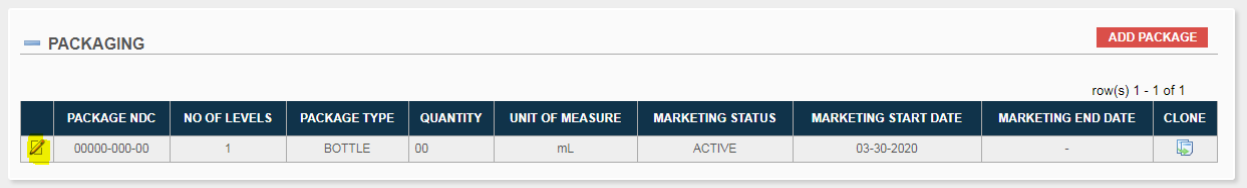
Note: For formulation, refer to Item 1 on the guidance document : [Temporary Policy for Preparation of Certain Alcohol Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)]
According to the guidance document, other active or inactive ingredients should not be added. Different or additional ingredients may impact the quality and potency of the product.

	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE
	ALCOHOL	3K9958V90M	80 mL	ACTIB
	WATER	059QF0KO0R		IACT
	GLYCERIN	PDC6A3C0OX	1.45 mL	IACT
	HYDROGEN PEROXIDE	BBX060AN9V	0.125 mL	IACT

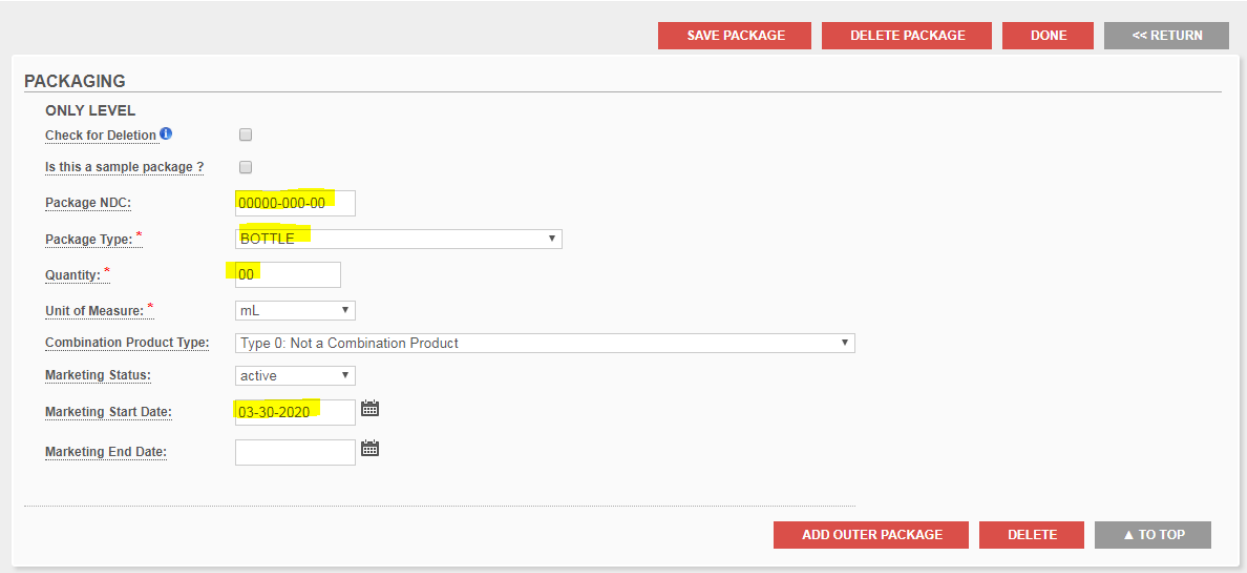
11. Select the Edit Icon next to the Package NDC located in the PACKAGING region.

    Package NDC: Enter the full 10-digit code separated by a hyphen. The third segment, the package code, identifies package sizes and types. Depending on the firm's NDC configuration, the package code can be 1- or 2-digits. Different package sizes and types are required to be identified with different package codes. Details concerning all packaging configurations must be included in the packaging section.

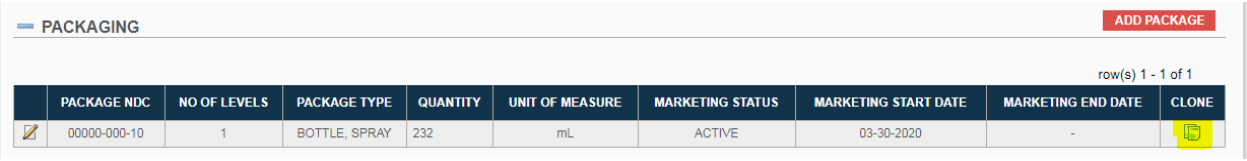
    Examples: 12345-678-01, 23456-7890-1



12. Update the Package NDC, Package Type, Quantity, and Marketing Start Date and then select the Save Package button at the top of the page.

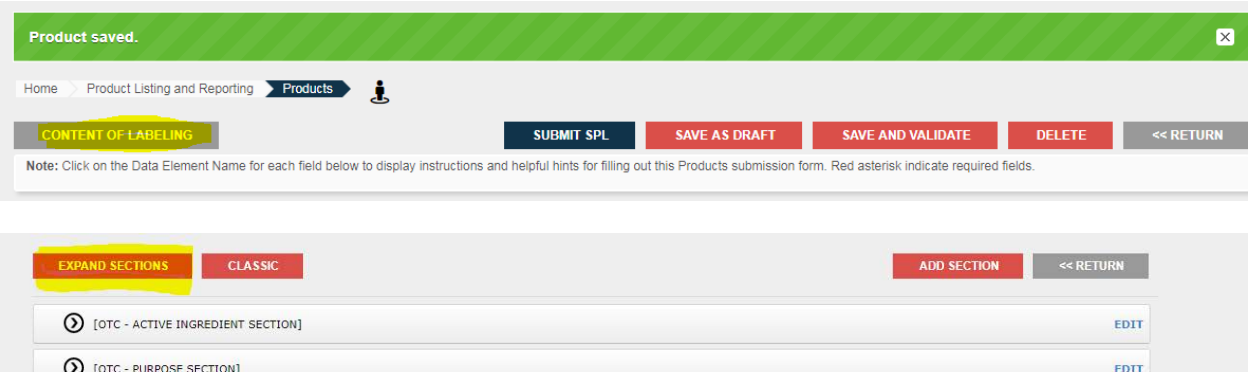


Note: If you have multiple packages for the product, you can select the "Clone" icon to create an additional package and make any additional changes by following the instructions provided in step 12.



When all packages have been added, select SAVE PRODUCT.

13. Select Content of Labeling at the top of the page and the Expand Sections icon.

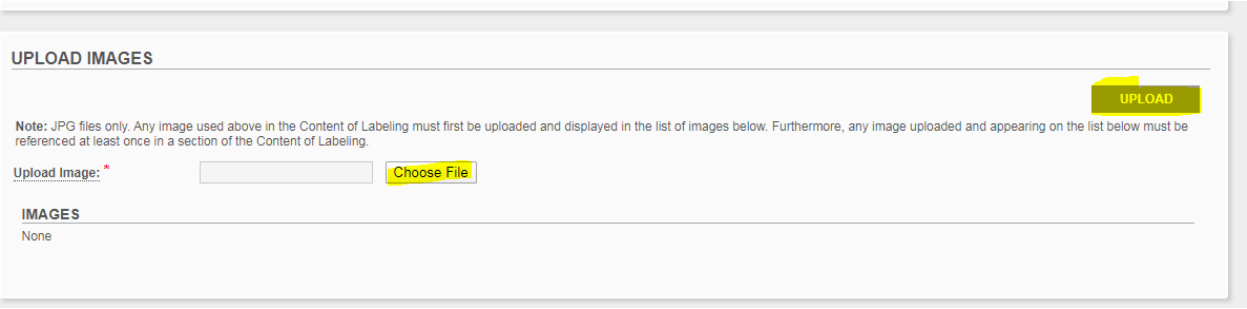


14. Review all sections to ensure that all sections are complete and accurate. If any changes are required, select the Edit icon for that section.

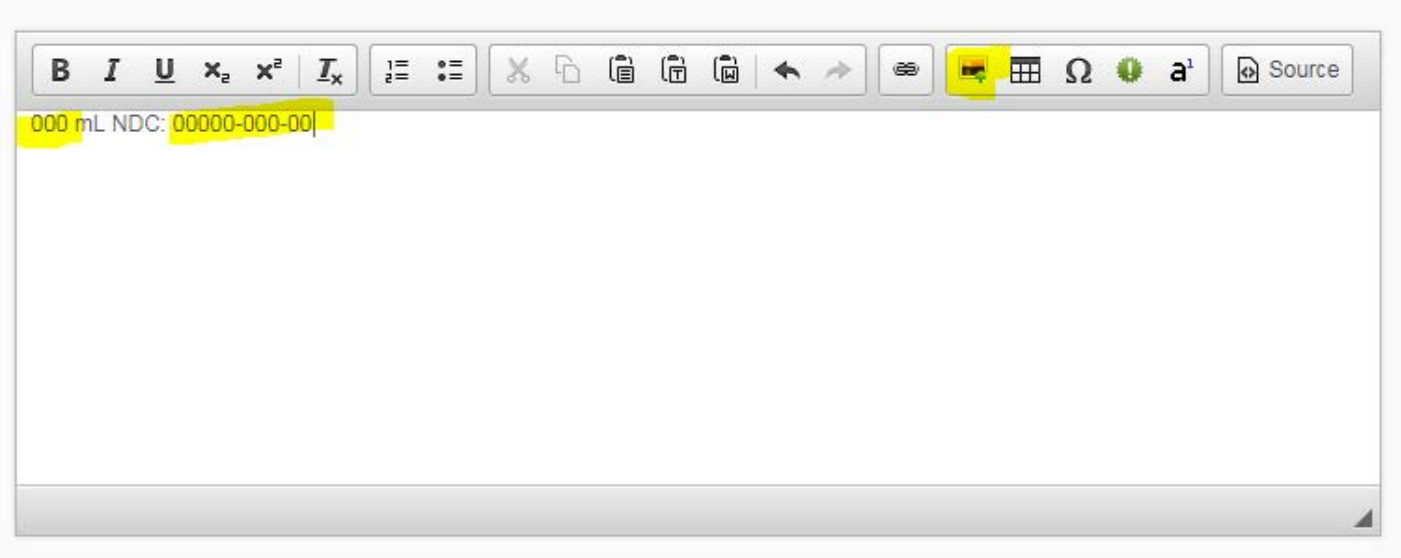
15. Scroll to the last section titled, Package Label. Principal Display Panel section, and select edit.

16. In the Upload Images region, select Choose File and select the package label for your product and then select upload. Repeat this step for each package previously entered.

Note: Both the front and back images of the packaging should be included.



17. Add the Package Quantity, Package NDC and then select “Insert an image Icon” in the Content editor region

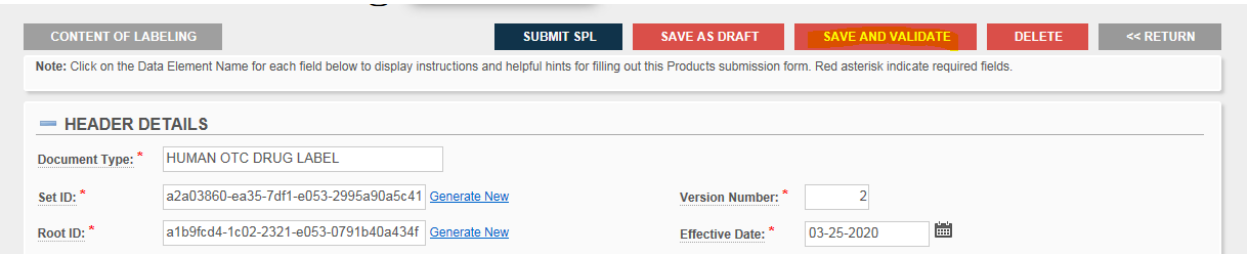


18. Select the Image Name for the package and then add image text that accurately describes the image. Select OK when finished. Repeat this process for all packages uploaded and included in the listing.

    Note: The file name must contain only alphanumeric characters. No special characters can be used.

19. When finished, select Apply

20. Review your submission for completeness and accuracy and then Select Save and Validate. If Validation Passes, proceed to the final step. If Validation Fails, then correct any errors before Saving, and attempt to Validate the file again.



21. If your submission Passed Validation, proceed with sending the submission to the FDA by selecting SUBMIT SPL. The submission processing takes approximately 15 minutes to complete. When the process is completed, you will receive a confirmation email indicating whether the submission was accepted or failed, and the status associated with the submission will update in the CDER Direct dashboard to either Submission Accepted or Submission Failed. If Submission Failed, go to the highlighted error to fix. If you need assistance preparing your submission, email cderdirect@fda.hhs.gov with a screen capture of your error(s).