Drug Listing Certification Quick Start Guide

Each drug that was not initially listed or updated during the calendar year must be either updated during that calendar year or certified that the data have not changed since the last update. The period for drug listing certification using the Blanket No Changes Certification Structured Product Labeling (SPL) submission is October 1 through December 31. Outside this window, an update of the listing SPL submission for each National Drug Code (NDC) is required to certify the listing record.

Who must certify and when?

- Certifying drug listings is the responsibility of the registered establishments.
- Private label distributors (PLDs) and contract manufacturers should work together to ensure that all NDCs involved in their business relationships are properly certified.
- U.S. agents, importers, consultants and anyone acting as an authorized agent for a registered establishment may submit drug listing certification SPL files.
- Certification SPL submissions will only be accepted during the registration renewal period of October through December. Outside that window, individual drug listing SPLs must be used to update (or renew) a listing.

What must be certified?

During the reregistration period, October 1 through December 31 each year, every active listing on file with the FDA that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the coming year. This includes all human drug document/product types and marketing categories:

- Finished and unfinished/bulk/API listings
- Approved and unapproved listings
- Rx and OTC listings
- Medical gases, homeopathic, bulk drugs for human drug compounding
- PLD and contractor listings
- Repackaged and relabeled listings

Any NDC for which a listing submission, new or updated, has been received during the calendar year is considered to be up-to-date and does not need to be certified again during the reregistration period (Oct. 1 to Dec. 31).

Veterinary drug listings must be certified annually but follow a different process for certification. Please contact AskCVM@fda.hhs.gov for more information.

What am I certifying?

Certifying an NDC is a statement that all product data have been reviewed and deemed accurate and up-to-date, including:

- All packaging presentations
- Labeling
- Dosage form
- DEA schedule
- Formulation

- Drug listings with a known data deficiency identified by FDA cannot be certified. A full drug listing SPL correcting the error/deficiency must be submitted, which counts as an update and satisfies the certification requirement.
- Discontinued/delisted or expired listings cannot be certified. A full drug listing SPL correcting the error/deficiency must be submitted, which counts as an update and satisfies the certification requirement.

What happens if a product is not certified?
It is expired. Any NDC that has not been updated during the calendar year or certified during the October to December registration renewal period will be considered expired on January 1 of the following year. All expired listings will be inactivated and removed from the NDC Directory and "unfinished drug" download files. The NDC SPL Data Elements (NSDE) file identifies inactivated listings by the inactivation date. Inactivated listings are also communicated to DailyMed.

The only way to reinstate an expired listing is to submit an updated drug listing SPL (with same Set ID as previous version, different Document ID, one higher version number than the most recent submission).

Frequently Asked Questions

What, if any, will be the penalty for noncompliance (other than the drug listing will be designated as expired and reflected as such in the relevant databases)?
A drug that is still actively marketed and sold without being properly listed violates federal regulations.

What happens if I certify a product that has already been certified by someone else?
Certifying the same drug twice or more will have no effect.

What are all the different statuses associated with certifying a drug listing?
- Current: The listing data for this drug are current because the listing information was either submitted or revised in the current calendar year. No certification is needed.
- Certified: This drug listing has already been certified. Certification expiration date is December 31 of the next calendar year.
- Uncertified: This drug listing has not been certified for the next calendar year and is available for certification.
- Pending compliance case: An open listing compliance case exists on this drug and the listing data cannot be certified until the case is closed.
- Completed: Drug is discontinued. The listing data is not available for certification.
- Validation errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.
- Inactivated: The listing data for this drug has been inactivated by FDA and cannot be certified.
- Expired: The listing expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data.

What if my drug has a marketing end date and completed status, does it need to be certified?
No, if the drug has an end marketing date and has completed status, it does not need to be certified.

Do I need to certify my drug if it has a future marketing start date?
Yes.

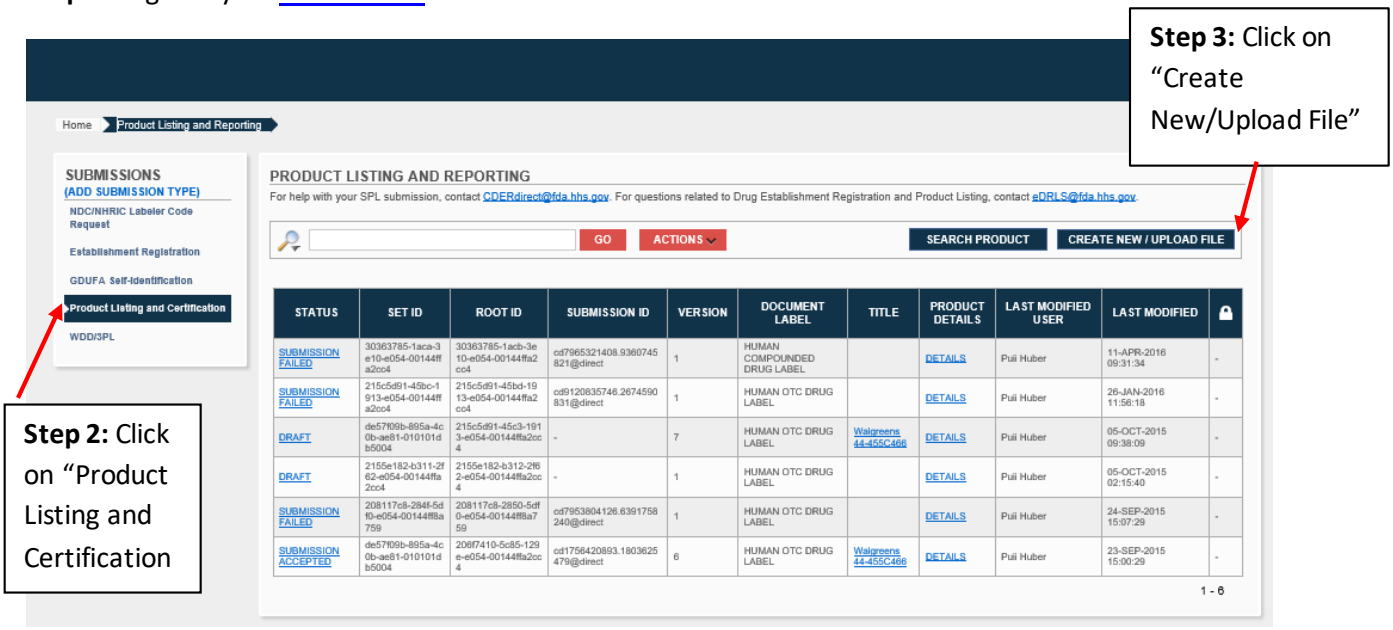
Should I use the same SET ID to update a blanket no changes certification?
If you choose to update a blanket no changes certification with the same SET ID, remember to include all NDCs from the previous version or else they will be replaced by the new version. However, you may add new NDCs to be certified with a new SET ID.

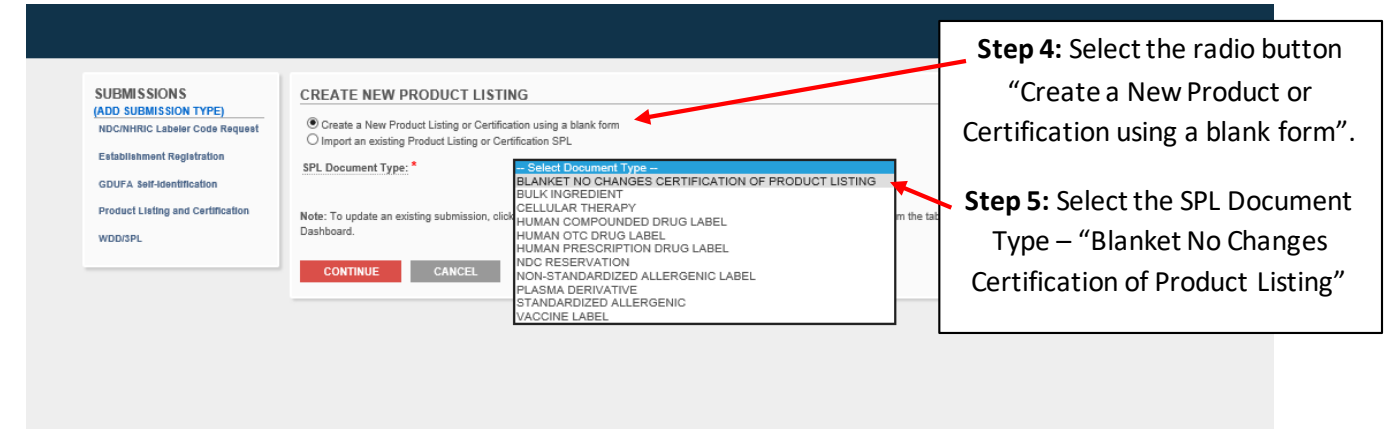
Does this blanket no changes certification renew my establishment registration status?
No, these are two separate renewals. The blanket no changes certification SPL is to certify drug listings only.

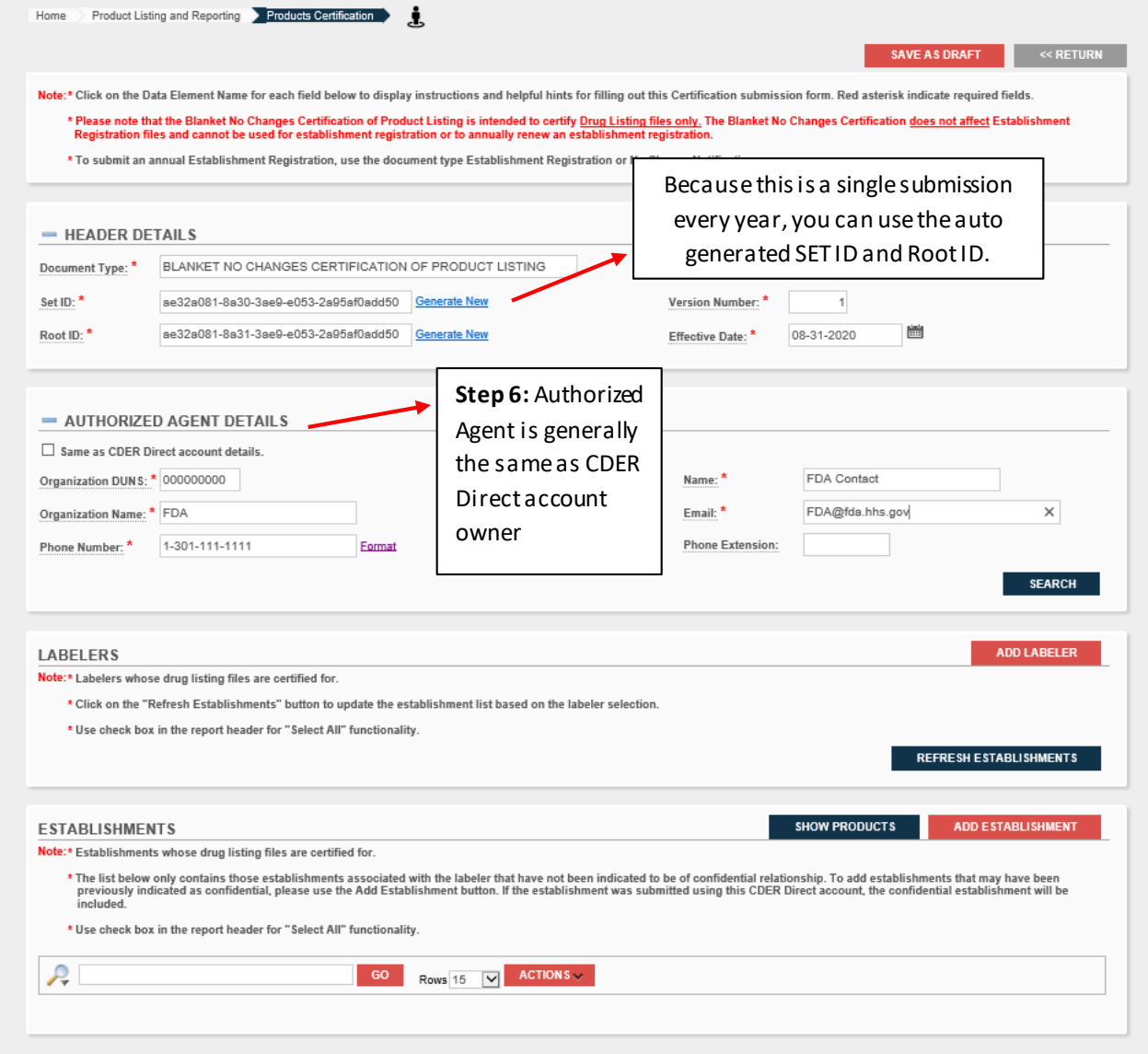
To submit or renew an establishment registration, use the document type Establishment Registration or No Change Notification.

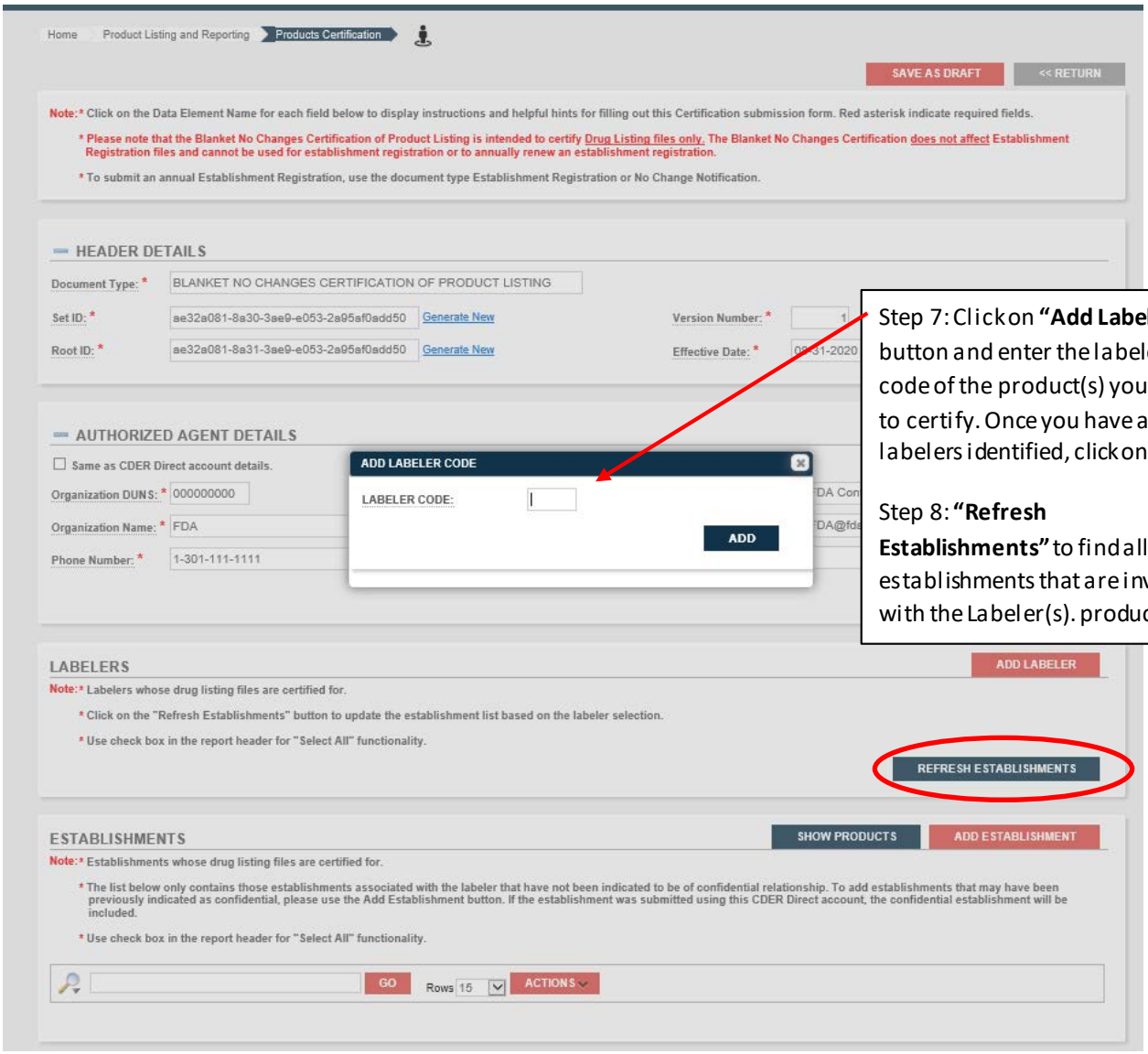
How do you certify drug listings?
If using Xforms for certification, see SPL Xforms. If using CDER Direct for certification, see below.

Step 1: Log into your CDER Direct Account






Home
Product Listing and Reporting
Products Certification
SAVE AS DRAFT
<< RETURN
Note:* Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Certification submission form. Red asterisk indicate required fields.
* Please note that the Blanket No Changes Certification of Product Listing is intended to certify Drug Listing files only. The Blanket No Changes Certification does not affect Establishment Registration files and cannot be used for establishment registration or to annually renew an establishment registration.
* To submit an annual Establishment Registration, use the document type Establishment Registration or
Because this is a single submission every year, you can use the auto generated SET ID and Root ID.
HEADER DETAILS
Document Type: * BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
Set ID: * ae32a081-8a30-3ae9-e053-2a95af0add50 Generate New
Root ID: * ae32a081-8a31-3ae9-e053-2a95af0add50 Generate New
Version Number: * 1
Effective Date: * 08-31-2020
Step 6: Authorized Agent is generally the same as CDER Direct account owner
AUTHORIZED AGENT DETAILS
Same as CDER Direct account details.
Organization DUNS: * 000000000
Organization Name: * FDA
Phone Number: * 1-301-111-1111 Format
Name: * FDA Contact
Email: * FDA@fda.hhs.gov
Phone Extension:
SEARCH
LABELERS
ADD LABELER
Note:* Labelers whose drug listing files are certified for.
* Click on the "Refresh Establishments" button to update the establishment list based on the labeler selection.
* Use check box in the report header for "Select All" functionality.
REFRESH ESTABLISHMENTS
ESTABLISHMENTS
SHOW PRODUCTS
ADD ESTABLISHMENT
Note:* Establishments whose drug listing files are certified for.
* The list below only contains those establishments associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been previously indicated as confidential, please use the Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.
* Use check box in the report header for "Select All" functionality.
GO
Rows 15
ACTIONS

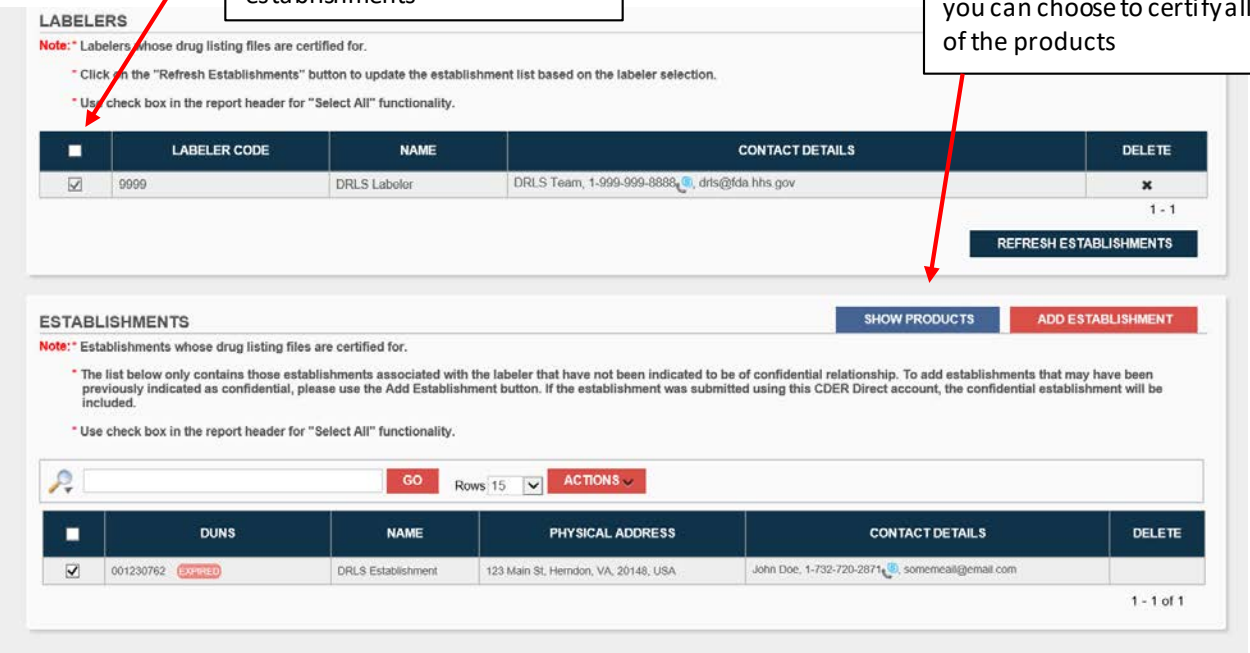


Step 7: Click on **"Add Labeler"** button and enter the labeler code of the product(s) you wish to certify. Once you have all the labelers identified, click on

Step 8: **"Refresh Establishments"** to find all the establishments that are involved with the Labeler(s). products.

Step 9: Select the checkbox to choose all the establishments or just choose specific establishments

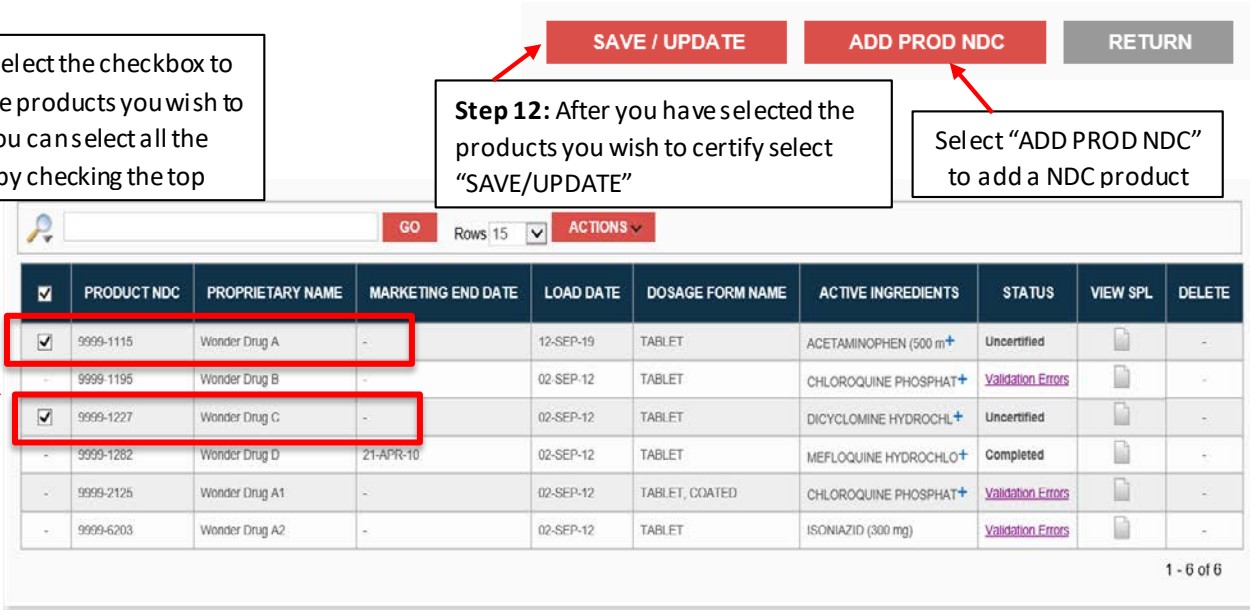
Step 10: Once you have your establishments marked you should select "Show Products". This will result in a list of products where you can choose to certify all or any of the products



Step 11: Select the checkbox to choose the products you wish to certify. You can select all the products by checking the top

Step 12: After you have selected the products you wish to certify select "SAVE/UPDATE"

Select "ADD PROD NDC" to add a NDC product



Step 13: Submit SPL