Annual Certification of Drug Product Listings

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FDA/CDER/Office of Compliance

Drug Listing Certification

- *Background – regulatory, problems encountered, new regulatory requirement*
- *Who must certify, what must be certified, and when do they do it?*
- *What will happen if a product is not certified?*
- *What does certification look like (from CDER Direct)?*

Listing Certification Background

To start with, here's what companies are required to do:

Section 510(j)(2)(B) of the Food Drug And Cosmetic Act requires that registrants to delist any discontinued product on file every June or December

Section 510(j)(2)(D) of the Food Drug And Cosmetic Act requires that registrants to send in any material changes to any listing already on file every June or December .

- Established the statutory requirement to keep listings up to date
- Previous version of 21 CFR 207.30 echoed that requirement but also added that if no changes have occurred, no report or update is required.

Listing Certification Background – cont'd

Despite the requirements, here's what companies are actually doing:

- Many companies will list a product initially, then never update again.
  - One time import
  - Don't know about update requirements, or aren't as concerned with keeping all data up to date so long as imports processing, reimbursement, and insurance payments continue.
  - Company may go out of business with no one left to submit discontinuances
- Have to consider non-updated listings as active
  - Electronic listings back to 2010
  - **Paper listings as far back as early to mid 1990's!**

Listing Certification Background - contd

In 2016 – a new 21 CFR 207 was published (August) and implemented (November).

21 CFR 207.57 (b)(2) *For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single "no changes" certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.*

As a result, there is now an annual requirement to update your listing or certify that no changes have occurred, similar to registration requirements.

Listing Certification

Who must certify and when?

A new Certification SPL must be created every year. New set id every year.

Since the ultimate responsibility for submitting product listings lies with the registered establishment, certification of product listings is also the responsibility of the registered establishments.

Private Label Distributors (PLDs) and Contract Manufacturers (CMs) should work together to ensure that all NDCs involved in their business relationships are properly certified.

US Agents, Importers, Consultants, and anyone acting as an authorized agent for a registrant may submit product listing certification SPL files.

Certification SPL submissions will ONLY be accepted during the registration renewal period of October through December. Outside that window, individual product listing SPLs must be used to update (or renew) a listing.

Listing Certification

Who must certify and when? – cont'd

Serialization comes first and must be completed before Certification of product listings.

Manufacturers and repackagers of products subject to the new product identification requirement (see section 581(14) of the FD&C Act) due by November 2018, and who have incorporated the new product identifier (serialization) into their labeling, should NOT certify that their listings are up-to-date during the registration renewal period. Such a change requires that a new and representative sample of labeling incorporating the new product identifier requirements be submitted as an update to listing.

Therefore, If you have the requirement to incorporate the new product identifier this fall, you should plan to submit an update to your SPL listing. Once the SPL has been updated the affected NDC's do not need to be certified.

Listing Certification

Who must certify and when? – cont'd

The FDA will be validating all original Listing SPL's for NDC's attempting to be certified.

2018 BNCCPL SPL Validation will include:

- All 2017 validation rule Highlights

  - Current Establishment Registration

  - source NDC's must be listed

  - All validation rules in reference to product characteristics are included.

- Correct application number included

- DEA schedule is correct

If a single NDC on an SPL (SET ID) fails validation, all the other NDC's on that SPL (SET ID) will not be able to be certified until the error is fixed.

Listing Certification

What must be certified?

At the time of reregistration in the Fall, ***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.*

Includes all human drug document/product types and marketing categories including:

- *Finished and unfinished/bulk/API listings*
- *Approved and unapproved listings*
- *Rx and OTC listings*
- *Medical Gases, Homeopathics, Bulks for human drug compounding*
- *PLD and contractor listings*
- *Repackaged and relabeled listings*

Any NDC Product code 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.

Note: *Veterinary product listings must be certified, but follow a different process for certification.*

Only electronic (SPL) listings can be certified. Any drug last updated in paper prior to June 2009 must first be submitted electronically. (which therefore counts as an update and satisfies the certification requirement!)

Listing Certification

What must be certified? -cont'd

*Certification of an NDC product code is a statement that **all** product data has been reviewed and deemed accurate and up-to-date. Includes but not limited to:*

- *All packaging presentations*
- *Labeling*
- *Dosage Form*
- *DEA Schedule*
- *Formulation*
- *DEA Schedule*

Only electronic (SPL) listings can be certified. Any drug last updated in paper prior to June 2009 must first be submitted electronically. (which therefore counts as an update and satisfies the certification requirement!)

*Product listings with a known data deficiency identified by FDA **cannot** be certified. A full product listing SPL correcting the error/deficiency must be submitted. (which therefore counts as an update and satisfies the certification requirement!)*

*Discontinued/delisted or expired listings **cannot** be certified. A full product listing SPL correcting the error/deficiency must be submitted. (which therefore counts as an update and satisfies the certification requirement!)*

Listing Certification

What happens if a product is not certified?

Any NDC product code which has not been updated during the calendar year, or certified during the October to December registration renew period ***will be considered expired*** *on January 1st of the following year.*

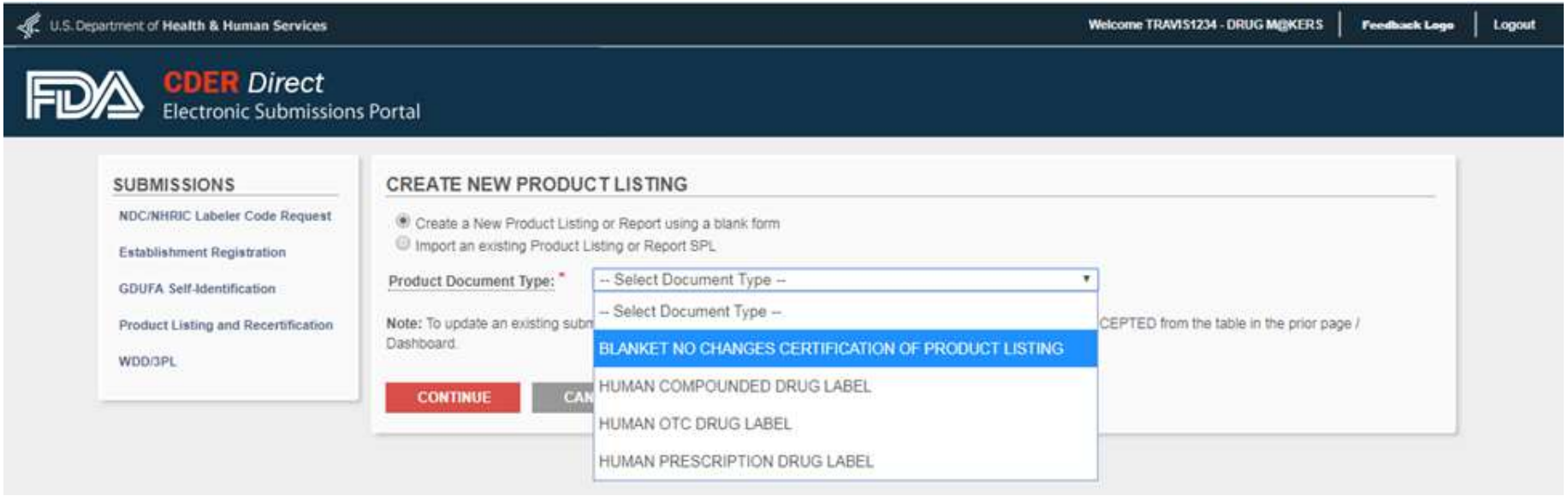
All expired listings will be removed/notated in the NDC Directory and Unfinished Drug download files.

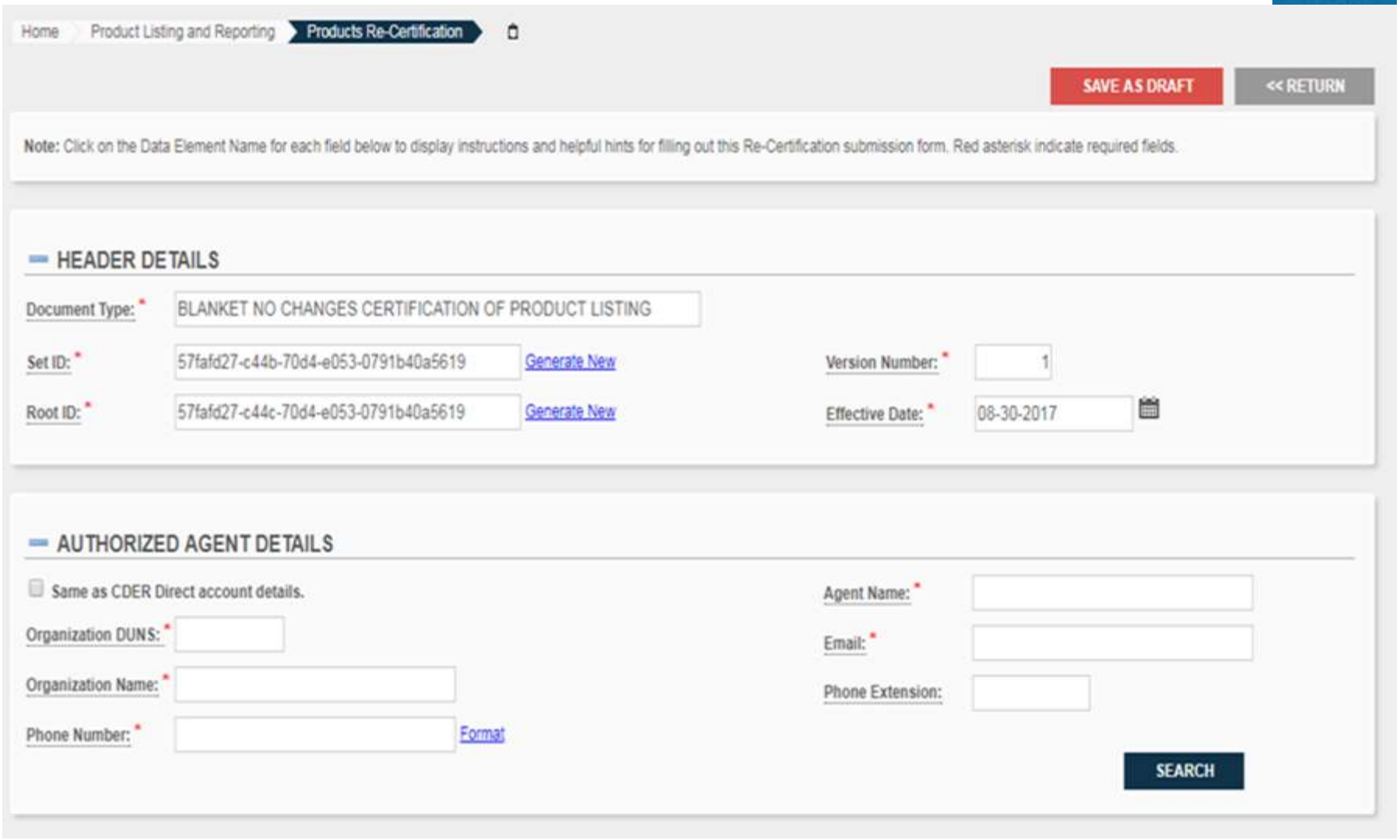
> *The only way to reinstate an expired listing is to submit an updated product listing SPL (with same setID as previous version)*

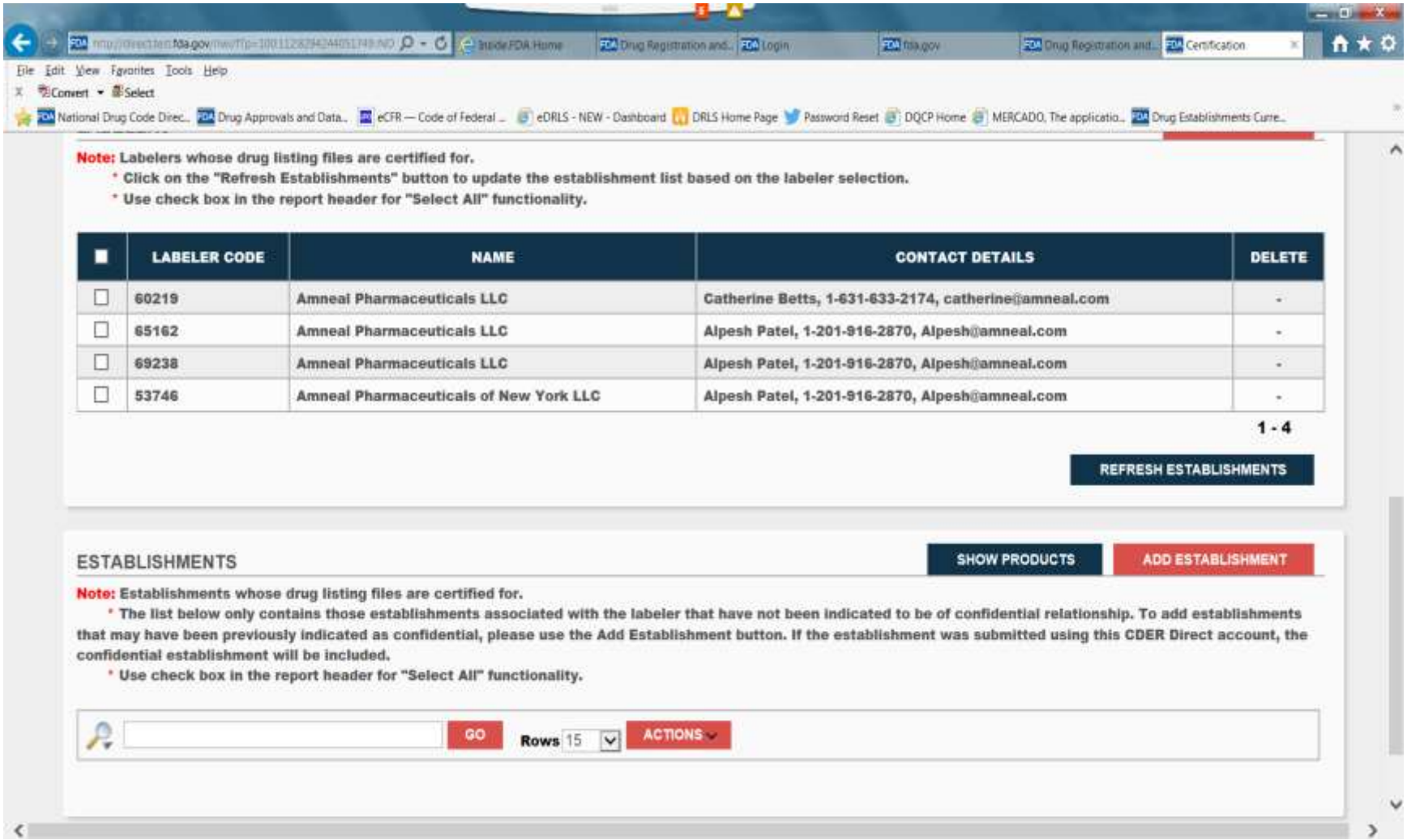
Communication of expired listings to the NDC SPL Data Elements (NSDE) file or DailyMed is planned but as yet has not been worked out with those offices.

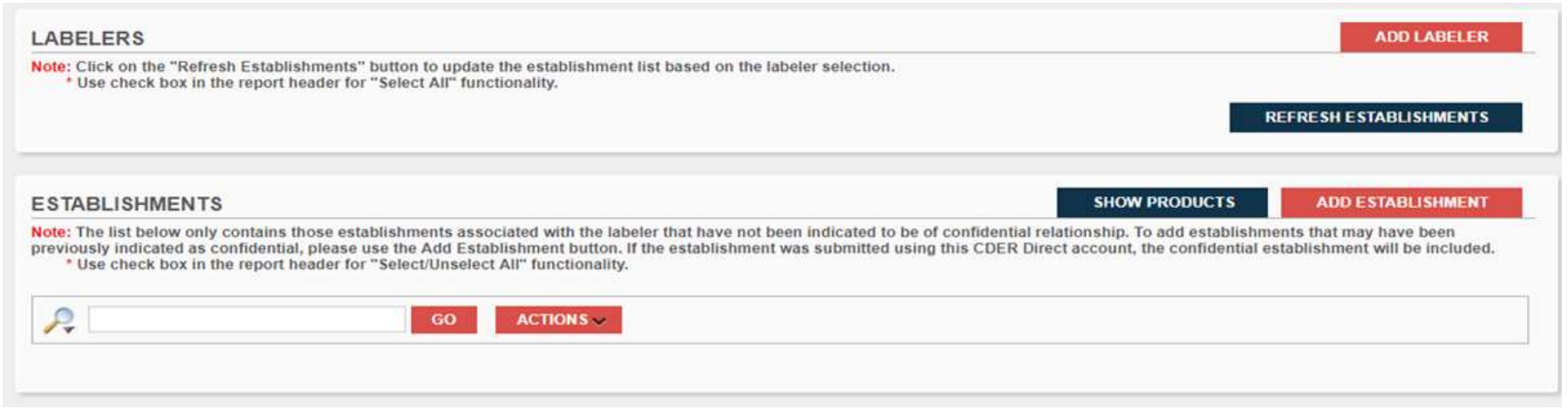
Listing Certification

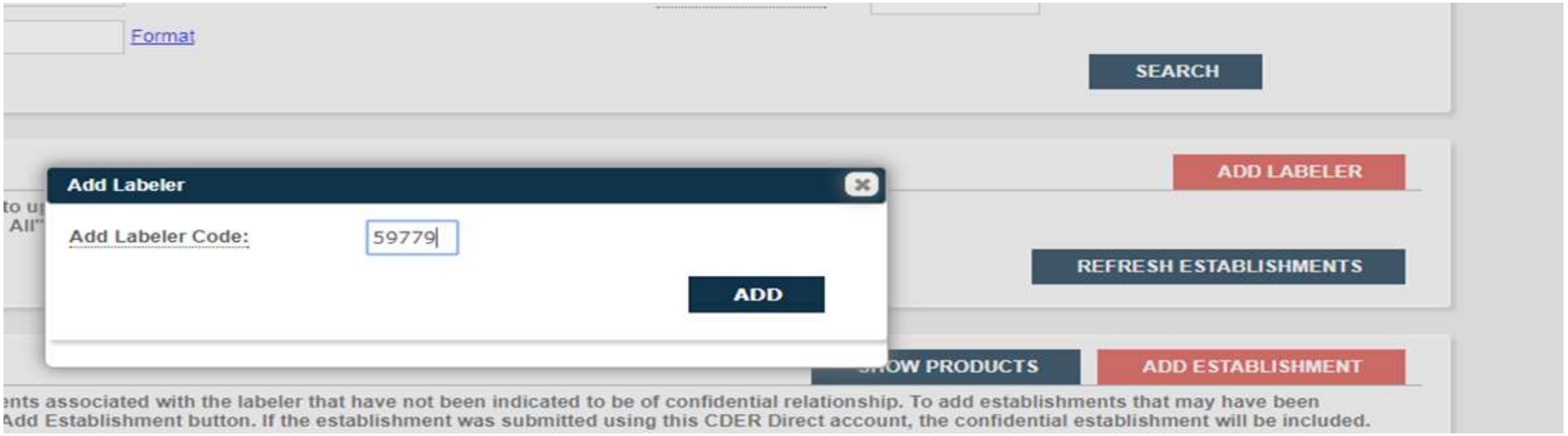
What does certification look like?



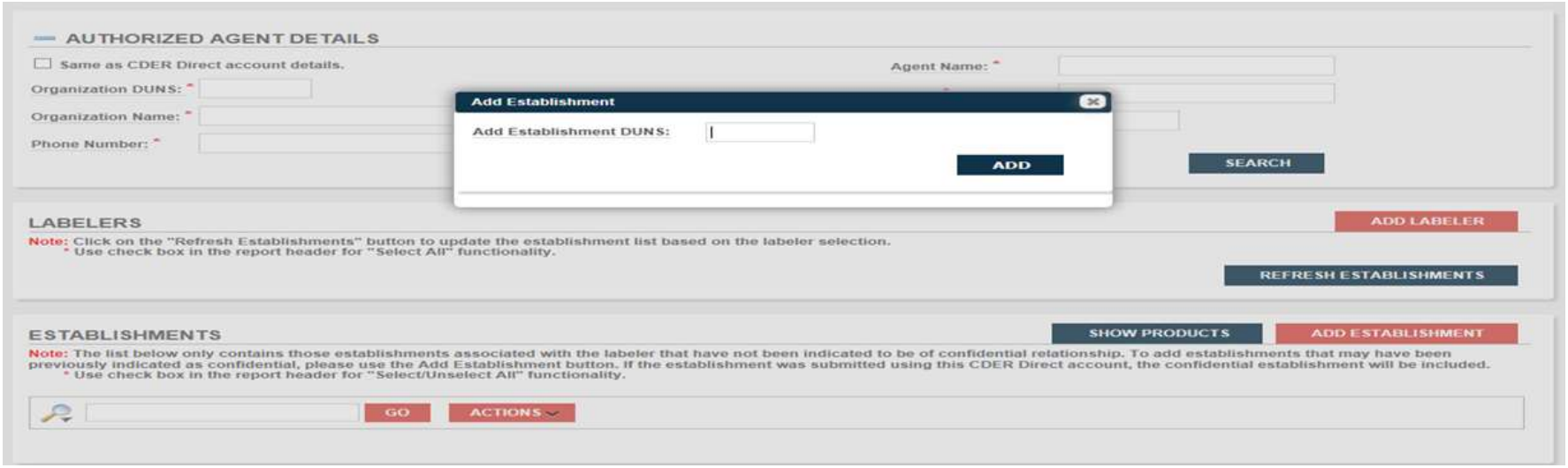

Home
Product Listing and Reporting
Products Re-Certification
SAVE AS DRAFT
<< RETURN
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Re-Certification submission form. Red asterisk indicate required fields.
HEADER DETAILS
Document Type: *
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
Set ID: *
57fafd27-c44b-70d4-e053-0791b40a5619
Generate New
Version Number: *
1
Root ID: *
57fafd27-c44c-70d4-e053-0791b40a5619
Generate New
Effective Date: *
08-30-2017
AUTHORIZED AGENT DETAILS
Same as CDER Direct account details.
Agent Name: *
Organization DUNS: *
Email: *
Organization Name: *
Phone Extension:
Phone Number: *
Format
SEARCH


Inside FDA Home
Drug Registration and...
Login
fda.gov
Drug Registration and...
Certification
File Edit View Favorites Tools Help
Convert
Select
National Drug Code Direc...
Drug Approvals and Data...
eCFR — Code of Federal ...
eDRLS - NEW - Dashboard
DRLS Home Page
Password Reset
DQCP Home
MERCADO, The applicatio...
Drug Establishments Curre...
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.
LABELER CODE
NAME
CONTACT DETAILS
DELETE
60219
Amneal Pharmaceuticals LLC
Catherine Betts, 1-631-633-2174, catherine@amneal.com
65162
Amneal Pharmaceuticals LLC
Alpesh Patel, 1-201-916-2870, Alpesh@amneal.com
69238
Amneal Pharmaceuticals LLC
Alpesh Patel, 1-201-916-2870, Alpesh@amneal.com
53746
Amneal Pharmaceuticals of New York LLC
Alpesh Patel, 1-201-916-2870, Alpesh@amneal.com
1 - 4
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

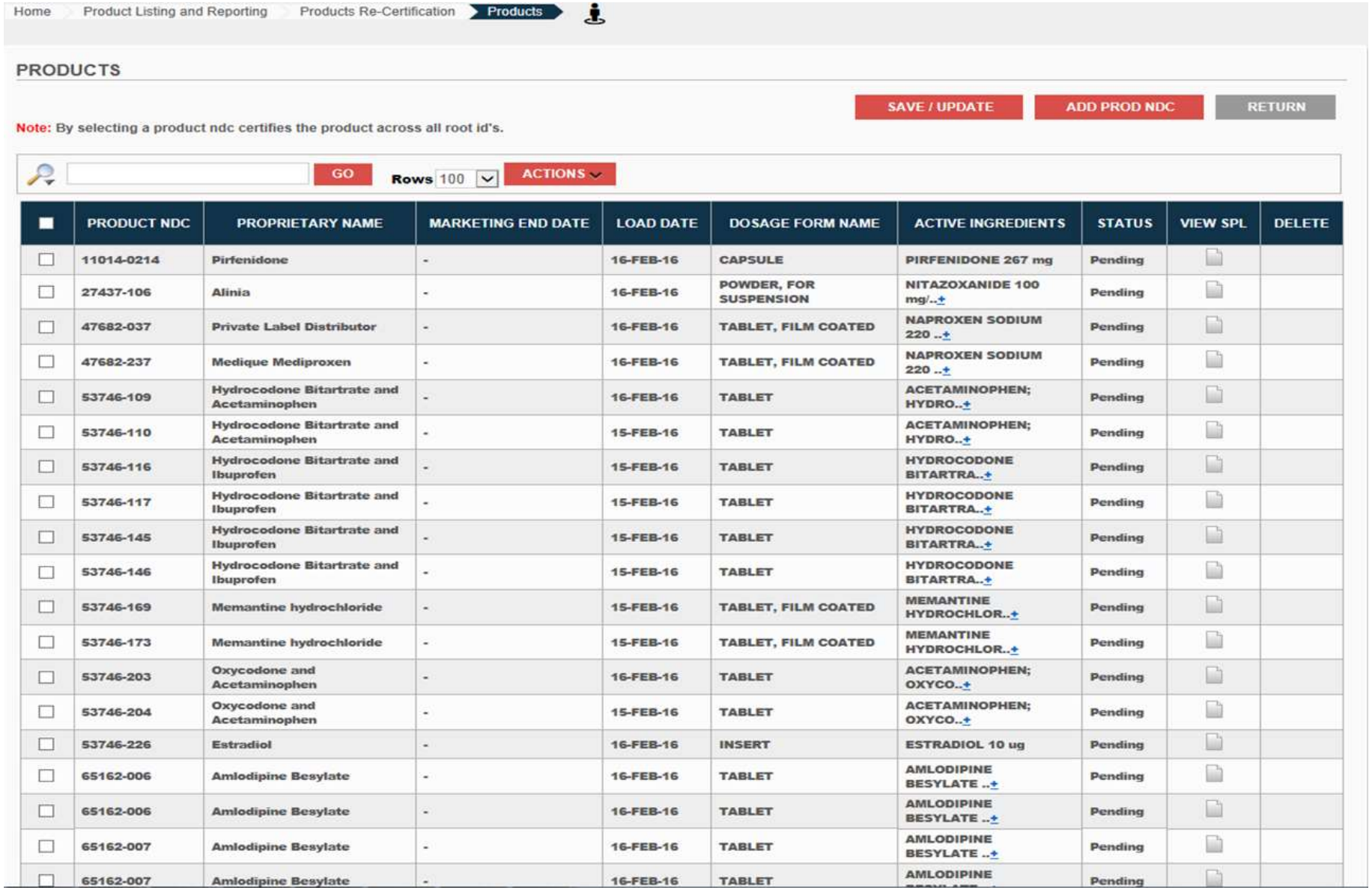

LABELERS
ADD LABELER
Note: Click on the "Refresh Establishments" button to update the establishment list based on the labeler selection.
* Use check box in the report header for "Select All" functionality.
REFRESH ESTABLISHMENTS
ESTABLISHMENTS
SHOW PRODUCTS
ADD ESTABLISHMENT
Note: The list below only 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/Unselect All" functionality.
GO
ACTIONS


Format
SEARCH
Add Labeler
Add Labeler Code:
59779
ADD
ADD LABELER
REFRESH ESTABLISHMENTS
SHOW PRODUCTS
ADD ESTABLISHMENT
nts associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been
Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

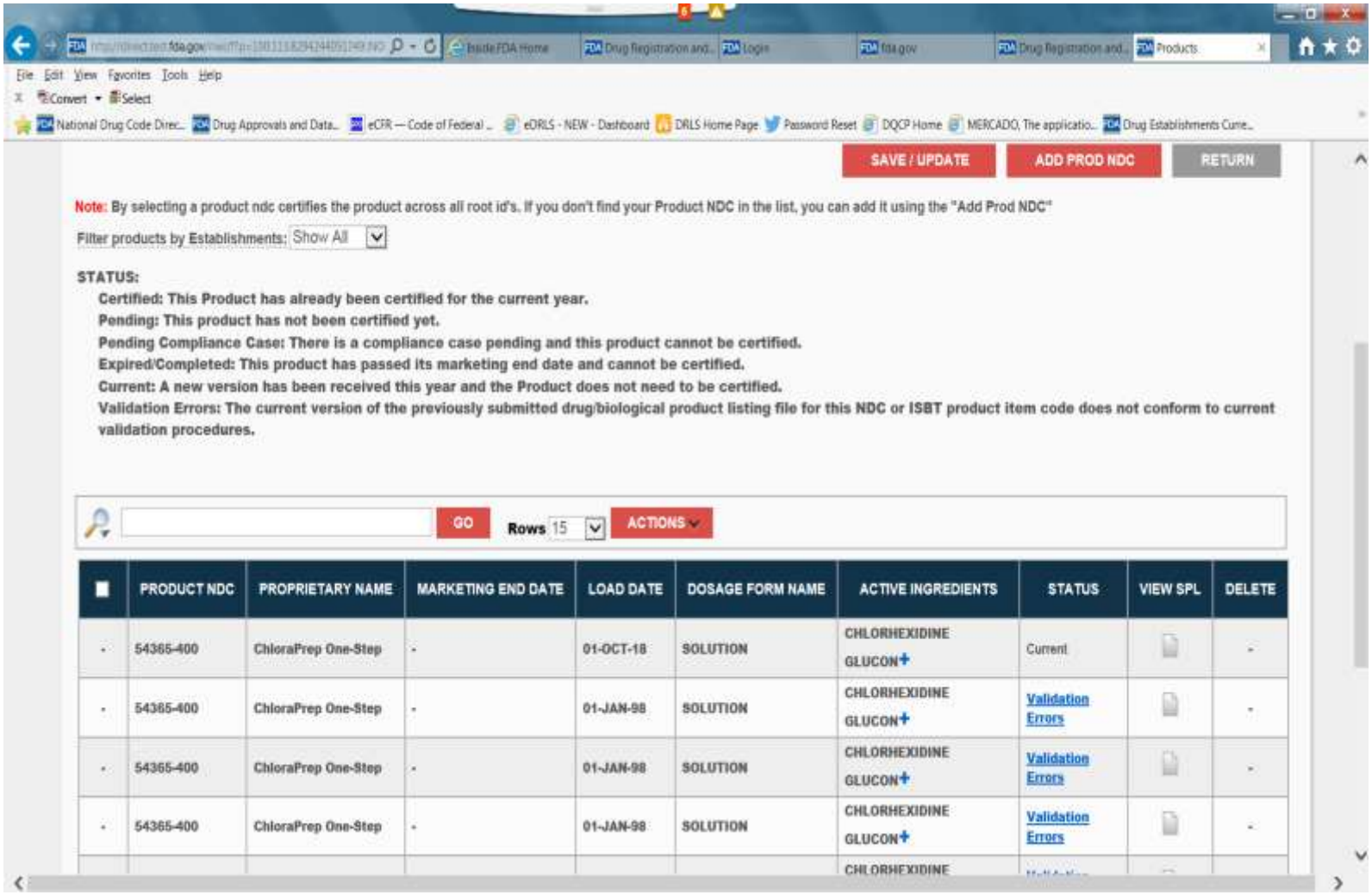
Once the labeler code is manually added, the establishments that are associated with the products listed by the labeler show up under the Establishments. If they are marked confidential in the products listed with this labeler NDC, then the user can click on ADD Establishment to add Establishment.



Once the establishment is added click on Show Products to view the products associated with the DUNS


Home
Product Listing and Reporting
Products Re-Certification
Products
PRODUCTS
SAVE / UPDATE
ADD PROD NDC
RETURN
Note: By selecting a product ndc certifies the product across all root id's.
GO
Rows 100
ACTIONS
PRODUCT NDC
PROPRIETARY NAME
MARKETING END DATE
LOAD DATE
DOSAGE FORM NAME
ACTIVE INGREDIENTS
STATUS
VIEW SPL
DELETE
11014-0214 Pirfenidone - 16-FEB-16 CAPSULE PIRFENIDONE 267 mg Pending
27437-106 Alinia - 16-FEB-16 POWDER, FOR SUSPENSION NITAZOXANIDE 100 mg/.. Pending
47682-037 Private Label Distributor - 16-FEB-16 TABLET, FILM COATED NAPROXEN SODIUM 220 .. Pending
47682-237 Medique Mediproxen - 16-FEB-16 TABLET, FILM COATED NAPROXEN SODIUM 220 .. Pending
53746-109 Hydrocodone Bitartrate and Acetaminophen - 16-FEB-16 TABLET ACETAMINOPHEN; HYDRO.. Pending
53746-110 Hydrocodone Bitartrate and Acetaminophen - 15-FEB-16 TABLET ACETAMINOPHEN; HYDRO.. Pending
53746-116 Hydrocodone Bitartrate and Ibuprofen - 15-FEB-16 TABLET HYDROCODONE BITARTRA.. Pending
53746-117 Hydrocodone Bitartrate and Ibuprofen - 15-FEB-16 TABLET HYDROCODONE BITARTRA.. Pending
53746-145 Hydrocodone Bitartrate and Ibuprofen - 15-FEB-16 TABLET HYDROCODONE BITARTRA.. Pending
53746-146 Hydrocodone Bitartrate and Ibuprofen - 15-FEB-16 TABLET HYDROCODONE BITARTRA.. Pending
53746-169 Memantine hydrochloride - 15-FEB-16 TABLET, FILM COATED MEMANTINE HYDROCHLOR.. Pending
53746-173 Memantine hydrochloride - 15-FEB-16 TABLET, FILM COATED MEMANTINE HYDROCHLOR.. Pending
53746-203 Oxycodone and Acetaminophen - 16-FEB-16 TABLET ACETAMINOPHEN; OXYCO.. Pending
53746-204 Oxycodone and Acetaminophen - 15-FEB-16 TABLET ACETAMINOPHEN; OXYCO.. Pending
53746-226 Estradiol - 16-FEB-16 INSERT ESTRADIOL 10 ug Pending
65162-006 Amlodipine Besylate - 16-FEB-16 TABLET AMLODIPINE BESYLATE .. Pending
65162-006 Amlodipine Besylate - 16-FEB-16 TABLET AMLODIPINE BESYLATE .. Pending
65162-007 Amlodipine Besylate - 16-FEB-16 TABLET AMLODIPINE BESYLATE .. Pending
65162-007 Amlodipine Besylate - 16-FEB-16 TABLET AMLODIPINE Pending

Validation Errors



SAVE / UPDATE | ADD PROD NDC | RETURN

Note: By selecting a product ndc certifies the product across all root id's. If you don't find your Product NDC in the list, you can add it using the "Add Prod NDC"

Filter products by Establishments: Show All

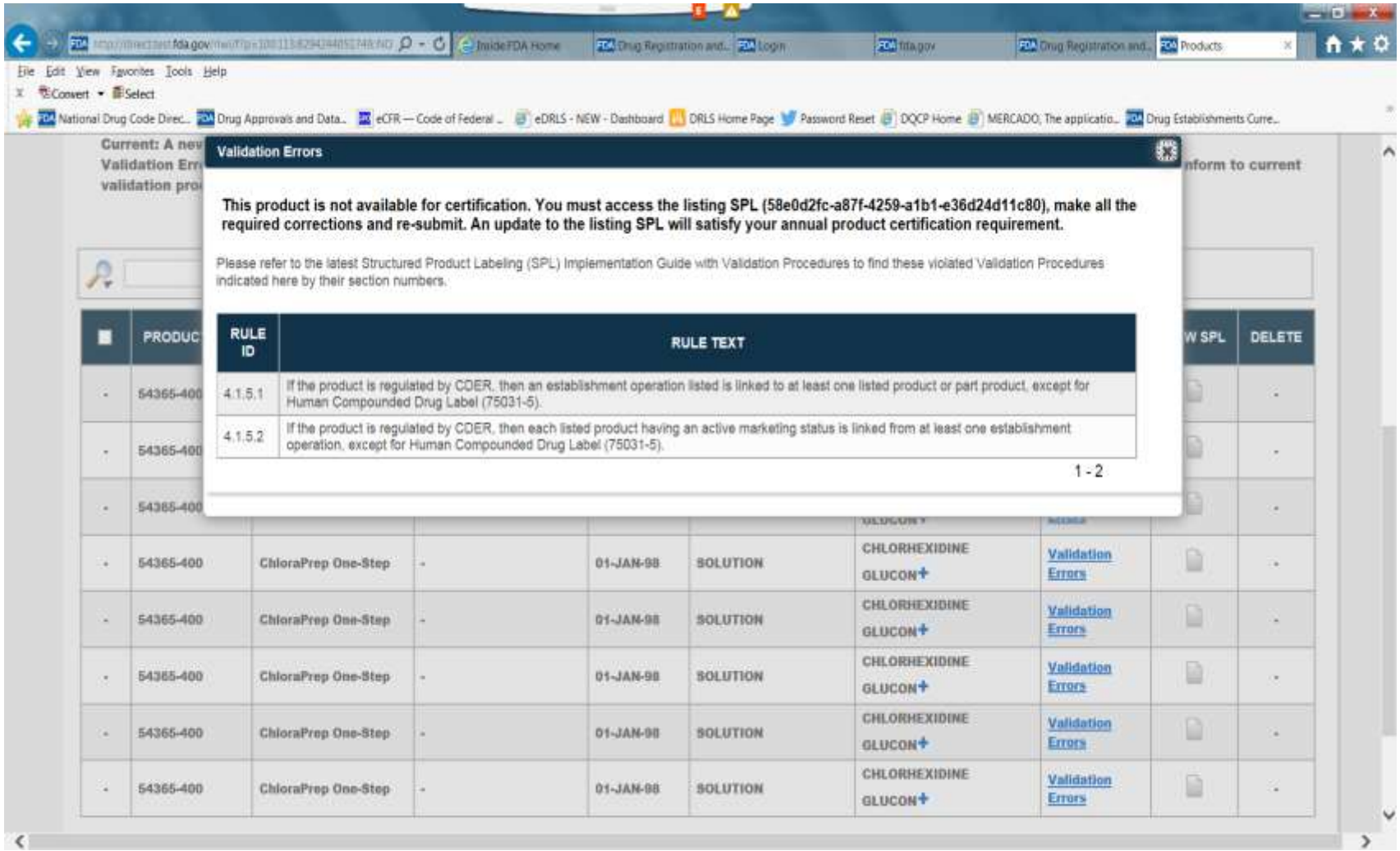
STATUS:

Certified: This Product has already been certified for the current year.
Pending: This product has not been certified yet.
Pending Compliance Case: There is a compliance case pending and this product cannot be certified.
Expired/Completed: This product has passed its marketing end date and cannot be certified.
Current: A new version has been received this year and the Product does not need to be certified.
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.

GO | Rows 15 | ACTIONS

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
-	54365-400	ChloraPrep One-Step	-	01-OCT-18	SOLUTION	CHLORHEXIDINE GLUCON+	Current		-
-	54365-400	ChloraPrep One-Step	-	01-JAN-98	SOLUTION	CHLORHEXIDINE GLUCON+	Validation Errors		-
-	54365-400	ChloraPrep One-Step	-	01-JAN-98	SOLUTION	CHLORHEXIDINE GLUCON+	Validation Errors		-
-	54365-400	ChloraPrep One-Step	-	01-JAN-98	SOLUTION	CHLORHEXIDINE GLUCON+	Validation Errors		-
						CHLORHEXIDINE			

Validation errors identified



Listing Certification
Summary

- ***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.*
- *Certification SPLs are only submitted during the annual re-registration period October – December*
- *Products that are not certified will be considered expired and removed from publication*
- *Products that are expired, delisted, or have a listing deficiency or "validation errors" cannot be certified and must be updated with a full product listing SPL*
- *Products under the category of Unapproved Drug for use in Drug Shortage cannot be certified*
- Manufacturers and repackagers of products subject to the new product identification requirement (see section 581(14) of the FD&C Act) due by November 2018, and who have incorporated the new product identifier (serialization) into their labeling, should NOT certify that their listings are up-to-date during the registration renewal period. Such a change requires that a new and representative sample of labeling incorporating the new product identifier requirements be submitted as an update to listing.

Listing Certification

Questions?

Thank you