CDER Direct Drug Listing 101- The Basics

Drug Listing

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THE
BASICS

Agenda

- Who must list
- When to list
- How to submit a Drug Listing SPL using CDER Direct
- Summary
- Do’s & Don’ts
- Helpful Resources

“Who”

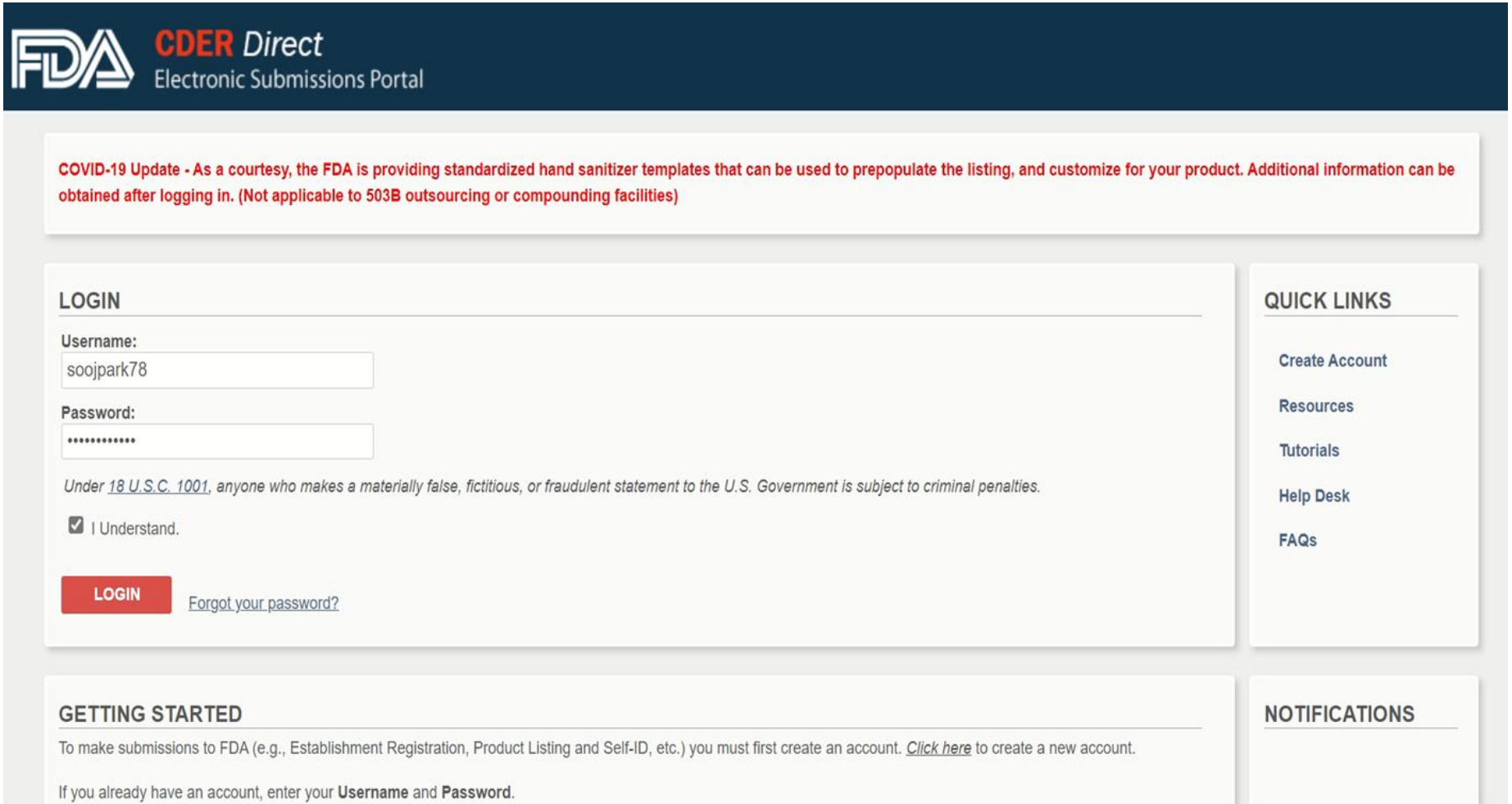
- Unless exempt, ALL registrants must list all drugs manufactured for commercial distribution
- Contract manufactures (CMO) must list under their own labeler code
- CMO who manufacture for private label distributors (PLD) must also list for PLDs, using the PLD’s labeler code. PLDs may list their own products as an authorized agent.

“When”

- Initial- Listing information must be submitted within 3 days of the initial registration.
- Updates- You can update any changes to the listing every June and December, preferably ASAP.
- Annual listing certification- Accepted updates to the listing certifies your listing for the calendar year and the next calendar year.

How to submit a Drug Listing SPL using CDER Direct

https://direct.fda.gov/


CDER Direct
Electronic Submissions Portal
COVID-19 Update - As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product. Additional information can be obtained after logging in. (Not applicable to 503B outsourcing or compounding facilities)
LOGIN
Username:
soojpark78
Password:
Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
I Understand.
LOGIN
Forgot your password?
QUICK LINKS
Create Account
Resources
Tutorials
Help Desk
FAQs
GETTING STARTED
To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. Click here to create a new account.
If you already have an account, enter your Username and Password.
NOTIFICATIONS

Summary

- Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S and their representative labeling
- Listing data is also used by the public including healthcare providers and other organizations in academia and industry
- Have a standard operation procedure or system in place to verify the accuracy of listing at least twice a year

WE WANT DRUG LISTING INFORMATION TO BE ACCURATE, COMPLETE AND UP TO DATE!

Drug Listing

Do's

- Registrants must list all drugs they manufacture
- Check listings at a minimum every June and December for accuracy
- Private Label Distributors (PLDs) may list own drug
- Include the complete supply chain under Establishments
- Include Inactive ingredients

Don’ts

- Don’t list Non-Drugs with CDER
- Don’t make assumptions
- Don’t omit data to pass automated validations
- Don’t include multiple email addresses when requesting for assistance

Helpful resources

- Electronic Drug Registration and Listing instructions
- Strength Conversion in Drug Listing
- OTC Active Ingredients
- Electronic Code of Federal Regulations
- edrls@fda.hhs.gov