How to Submit an Establishment Registration

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Electronic Drug Registration and Listing Using CDER DIRECT
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Learning Objectives

- Determine who registers and when
- Create and submit an Establishment Registration

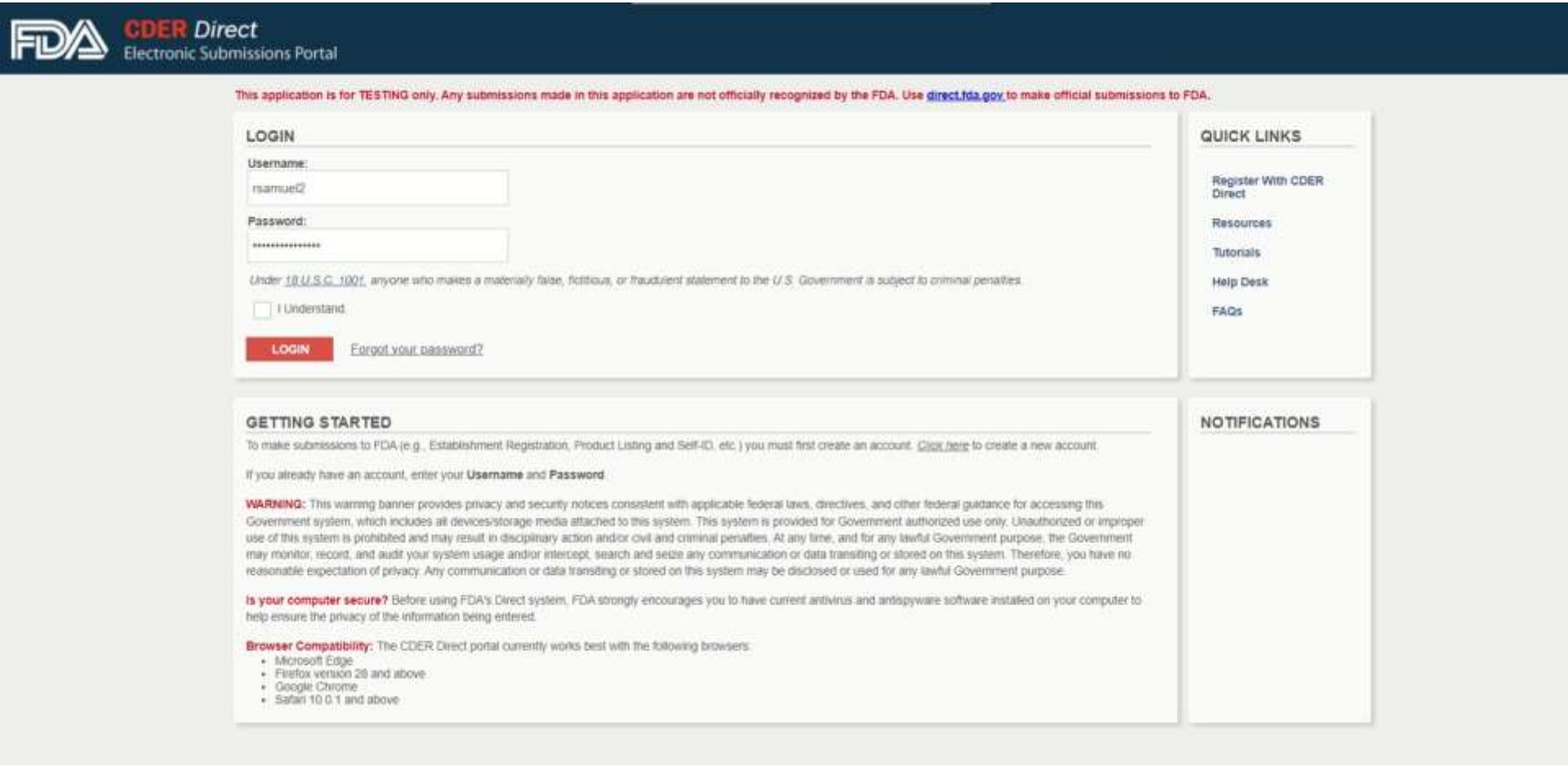
Who Must Register?

- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the United States (21 CFR 207.17).
- Certain exemptions are included under 21 CFR 207.13.

When to Register?

§207.21 When must initial registration information be provided?

- (a) Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment.
- (b) Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.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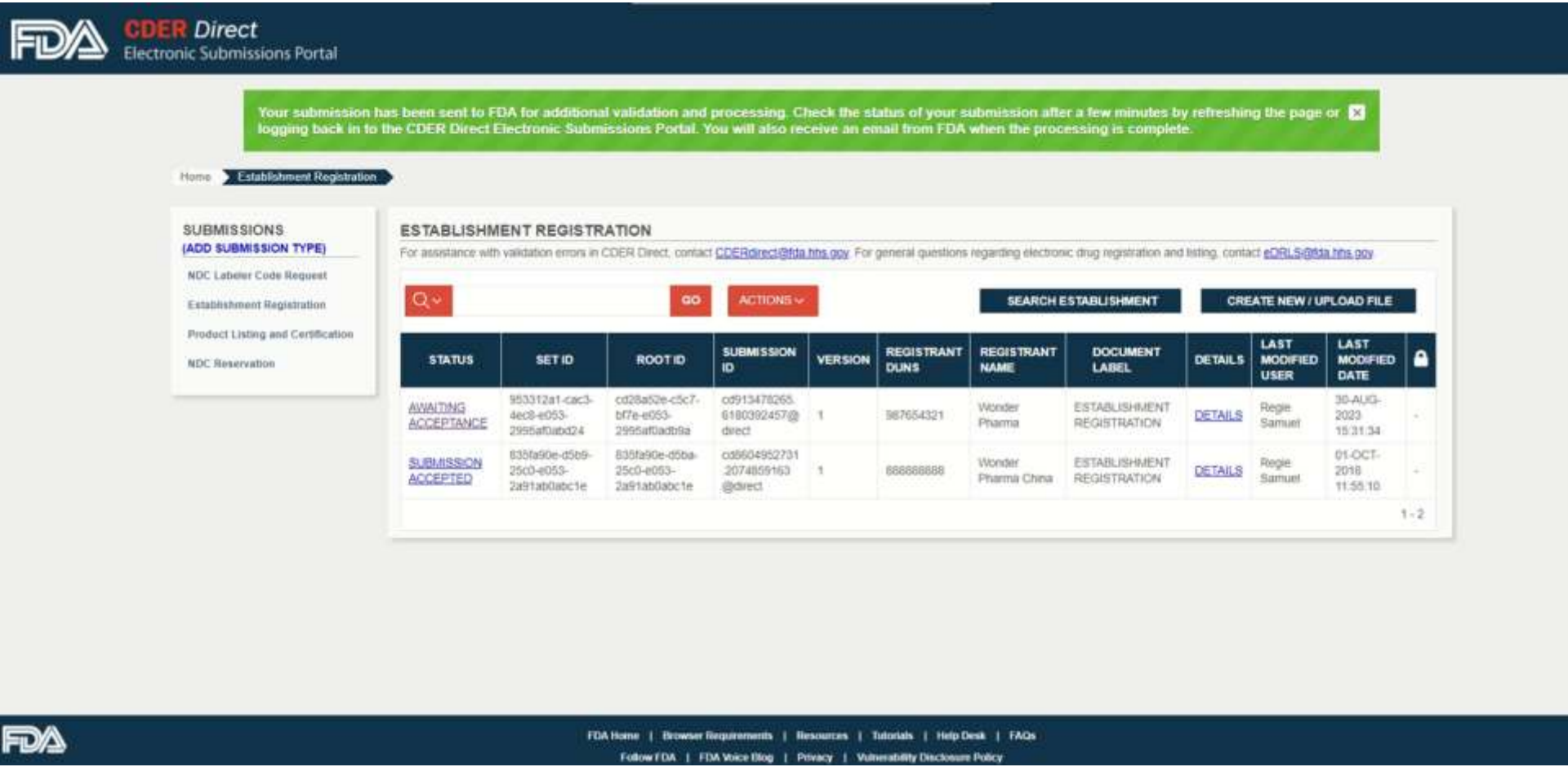
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GO
ACTIONS
SEARCH ESTABLISHMENT
CREATE NEW / UPLOAD FILE
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
REGISTRANT DUNS
REGISTRANT NAME
DOCUMENT LABEL
DETAILS
LAST MODIFIED USER
LAST MODIFIED DATE
AWAITING ACCEPTANCE
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ESTABLISHMENT REGISTRATION
DETAILS
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SUBMISSION ACCEPTED
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Registration Certificates

Challenge Question

Who should not register as a drug establishment?

A. Repackagers

B. Private Label Distributors

C. Contract Manufacturers

D. Manufacturers

Summary

- Register on time – it's easy!
- You can manage multiple establishment locations on one Establishment Registration
- Ensure your DUNS information is up-to-date with D&B
- Firms that are solely Private Label Distributors should not register as a drug establishment

U.S. FOOD & DRUG ADMINISTRATION

Thank You for Registering!

Contact Us:

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