Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)

Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers

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FDA Stakeholder Webinar

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Objectives

The purpose of this webinar is:

- to provide an overview of the reporting requirements for wholesale distributors and third-party logistics providers under DSCSA
- to describe who must report to FDA, what information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting to FDA
- to solicit your comments on the draft guidance

Draft Guidance

DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers
(published on 12/9/2014)

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM426126.pdf

Who Must Report (1)

WHOLESALE DISTRIBUTOR

- A person (other than a manufacturer…) engaged in wholesale distribution (as defined in section 503(e)(4))
  - **Wholesale Distribution** is defined as the distribution of a drug… to a person other than a consumer or patient, or receipt of a drug… by a person other than the consumer or patient
  - **Contains a number of exceptions** for example : intracompany distribution, transfers to and from third-party logistics providers and common carriers, distribution of certain drugs in medical convenience kits, IV fluid replenishment and dialysis drugs, medical gases, etc.

Who Must Report (2)

THIRD-PARTY LOGISTICS PROVIDER (3PL)

- Provides or coordinates warehousing, or other logistics services of a product on behalf of a manufacturer, wholesale distributor, or dispenser of a product
- Does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

DUAL ROLES

- Any person or entity that acts as both a wholesale distributor and a 3PL should report according to the relevant requirement for each respective facility.

What Should Be Reported (1)

Wholesale Distributors are required to report identifying information for the facility:

- Name of company
- Address of the facility
- Contact information *(FDA recommendation: email address and telephone number)*
- All trade names that the company does business as (i.e., any other names listed as "dba")

What Should Be Reported (2)

Wholesale Distributors are required to report licensure information for each facility for each State:

- State
- State license number (identification number)

What Should Be Reported (3)

Wholesale Distributors are required to report significant disciplinary actions by any State or Federal agency:

FDA recommendations -

- *For initial report, those that occurred in the 12 months proceeding initial report*
- *Identifying the type of disciplinary action, the date of final disciplinary action, and the state where the disciplinary action occurred*

What Should Be Reported (4)

Wholesale Distributors are requested to report information for each facility:

- Unique Facility Identifier
- Expiration date for each license
- Documents associated with the disciplinary action

What Should Be Reported (5)

3PLs are required to report information for each facility:

- Name of company
- Address of the facility
- All trade names that the company does business as (i.e., any other names listed as “dba”)
- Licensure information for each State
- State
- State license number (identification number)

What Should Be Reported (6)

3PLs are requested to report information for each facility:

- Contact information for each facility
- Unique facility identifier
- Expiration date for each State license
- Information about significant disciplinary actions by any State or Federal agency
- Documents associated with the disciplinary action, such as a consent decree, final State Board ruling, etc.

When to Report (1)

Initial Report to FDA

- Wholesale distributors

  January 1, 2015 – March 31, 2015

- 3PLs

  November 27, 2014 – March 31, 2015

- Newly licensed wholesale distributor and 3PL facilities

  Within 30 days of obtaining a State or Federal license

When to Report (2)

Subsequent Annual Reports

- Wholesale distributors

  January 1 – March 31 each year

- 3PLs

  January 1 – March 31 each year

If a company chooses to update expired licenses during a time frame outside of the annual reporting time period, the company should still report during the defined annual reporting period.

When to Report (3)

Significant Disciplinary Action Reports

- Wholesale distributors

  Within 30 days of the final action

- 3PLs

  Within 30 days of the final action

When to Report (4)

Other Voluntary Reports

- Out of business

  Within 30 days of the business closing

- Voluntary Withdrawal of State License

  Within 30 days

How to Report (1)

Report Format

- (XML) files in a standard Structured Product Labeling (SPL) format

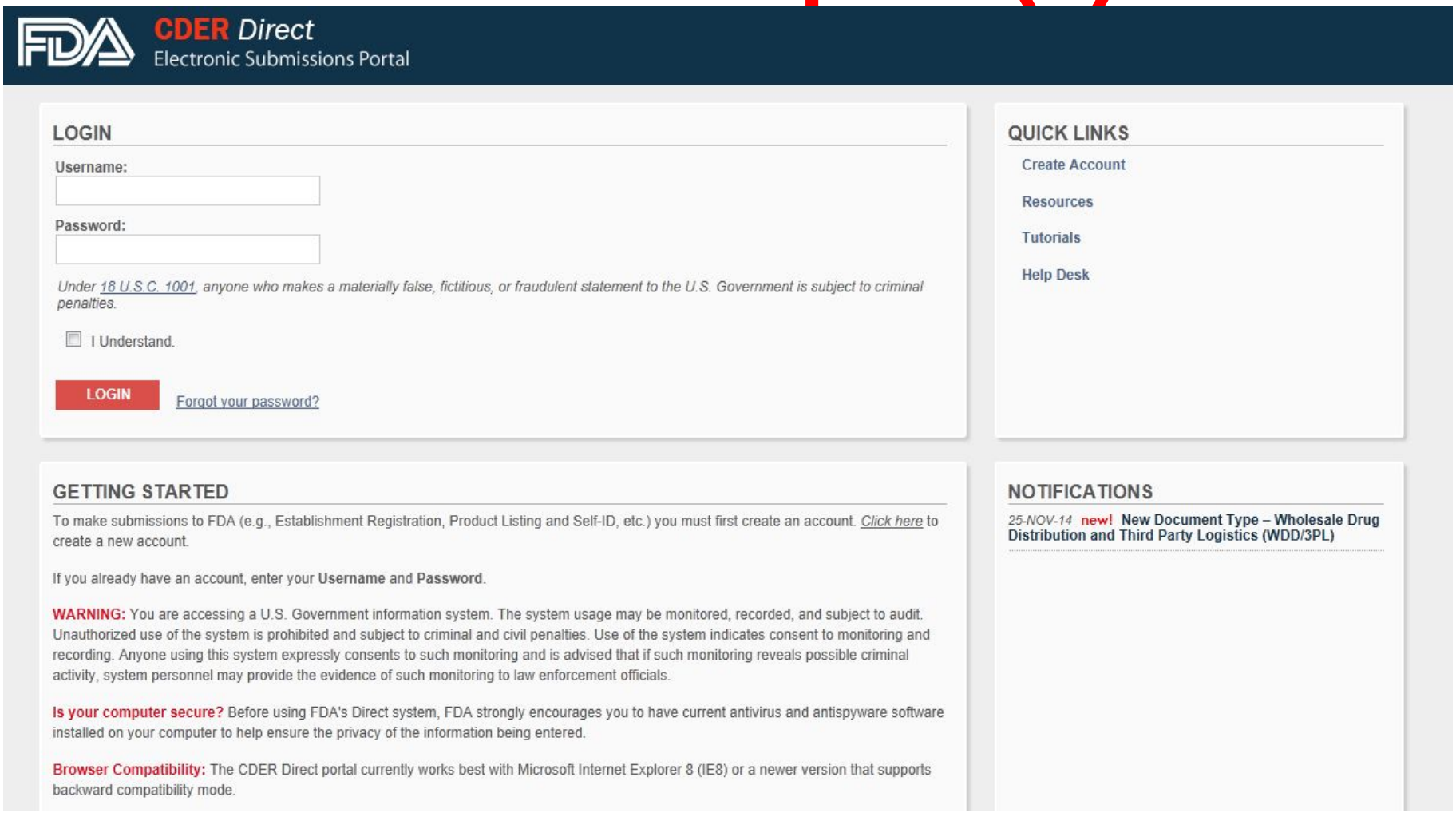
CDER Direct

- Mechanism for reporting
- Link available from FDA webpage:

http://www.fda.gov/wdd3plreporting

- Obtain a user account

How to Report (2)



Public Information

Public Database on FDA Website

- FDA will make the information collected about wholesale distributors publically available.
- FDA plans to make 3PL information publically available.
- FDA plans to make the wholesale distributor and 3PL significant disciplinary action information publicly available to the extent allowable by law.
- FDA's Web site at http://www.fda.gov/wdd3plreporting

Public Comment

Public Docket

- Instructions for how to submit a comment is in the Federal Register notice (79 FR 73083)

https://www.federalregister.gov/articles/2014/12/09/2014-28711/draft-guidance-for-industry-on-drug-supply-chain-security-act-implementation-annual-reporting-by

- Docket No. FDA-2014-D-2083
- Comment by February 9, 2015

Getting Ready for the DSCSA

- Become familiar with the law
- Understand stakeholder responsibilities
- Become familiar with statutory dates of the law
- Check our FDA website - *The DSCSA web page*
  http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm
  - Overview
  - Implementation Plan
  - Links to FDA webinar(s)
  - FDA DSCSA Public Workshop (May 8-9, 2014)
  - Updates

Annual Reporting Webpage

http://www.fda.gov/wdd3plreporting

Send questions to:

wdd3plrequirements@fda.hhs.gov