U.S. FOOD & DRUG ADMINISTRATION

Overview of Proposed 21 CFR 205

National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

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Office of Drug Security, Integrity, and Response
Office of Compliance
CDER | US FDA

Agenda

- Introduction
- Overview and Definitions
- How to Leave Comments
- Third-Party Logistics Providers (3PLs)
  - Licensure Process
  - Standards
- Wholesale Drug Distributors (WDDs)
  - Licensure Process
  - Standards
- Concluding Remarks

Disclaimer

This presentation is intended only to provide a general overview. It is not intended to be comprehensive nor does it constitute legal advice. Please refer to appropriate guidelines, regulations, or law for specific information.

Additional Resources

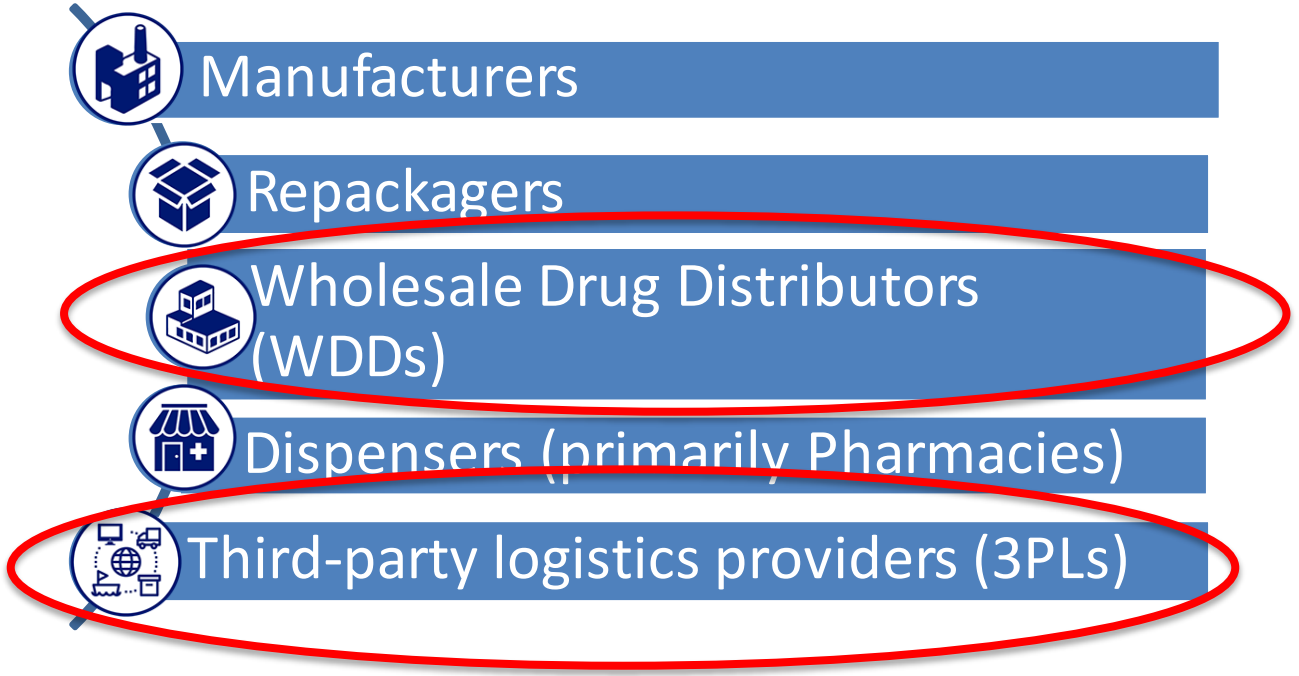
Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website.

Overview and Definitions

The Drug Supply Chain Security Act
DSCSA

- Enacted November 27, 2013.
- **Establishes requirement for national licensure standards for wholesale drug distributors and third-party logistics providers (3PLs).**
- Outlines steps to implement enhanced drug distribution security requirements to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.
- Improves detection and removal of potentially dangerous drugs from the drug supply chain.

Trading Partners under DSCSA



Wholesale Distributor Definitions

Wholesale Distributor

(Section 581(29) of the FD&C Act, as added by DSCSA)

A person (other than a manufacturer, a manufacturer's co-licensed partner, a third party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by the Drug Supply Chain Security Act)

Wholesale Distribution

(Section 503(e)(4) of the FD&C Act)

"…distribution of a drug subject to [503(b), i.e., an Rx drug] … to a person other than a consumer or patient, or receipt of a drug subject to [503(b)] by a person other than the consumer or patient"

Drug

(Section 201(g) of the FD&C Act)

As encompassed in this definition, includes bulk drug substances

3PL Definitions

Third-Party Logistics Provider (3PL)

(Section 581(22) of the FD&C Act, as added by DSCSA)

"…an entity that *provides or coordinates warehousing, or other logistics services* of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, *but does not take ownership of the product*, nor have responsibility to direct the sale or disposition of the product."

Other Logistics Services

(Section 581(22) of the FD&C Act)

See proposed 205.3(i):

Other logistics services include services provided by entities that accept or transfer direct possession of products from that entity's facility within the United States and its territories on behalf of a trading partner (e.g., manufacturer, wholesale distributor, dispenser) but that do not take ownership of the product nor have the responsibility to direct a product's sale or disposition.

Definition of *Product* with Respect to 3PLs

Proposed section 205.3(k) defines *Product* as a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (e.g., capsules, tablets, lyophilized products before reconstitution).

The definition of *product* proposed here is broader and more inclusive than that used for purposes of product tracing detailed in section 582 of the FD&C Act as defined in section 581(13) of the FD&C Act.

DSCSA Authority

Section 583 of the FD&C Act - National Standards for Prescription Drug Wholesale Distributors

Section 583(a) of the FD&C Act, as added by DSCSA, requires that FDA "establish by regulation the standards for the licensing of persons under section 503(e)(1)… including the revocation, reissuance, and renewal of such license."

Section 584 of the FD&C Act – National Standards for Third-Party Logistics Providers

Section 584(d) of FD&C Act, as added by DSCSA, requires that FDA "issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section."

21 CFR PART 205
National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

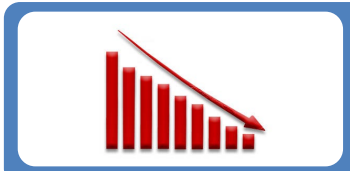
Proposed Rule

The proposed rule, when finalized, will establish the national standards for the licensure of WDDs and 3PLs required under sections 583 and 584 of the FD&C Act, as added by the DSCSA.

Need for Regulation

Provide certainty and clarity to regulated industry

Harmonize requirements and standards for licensure across State lines

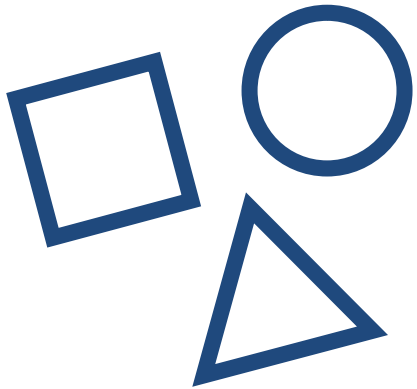


Reduce product diversion

Minimize threats to the legitimate supply chain

Standards Development

To create the standards proposed in the regulations, FDA conducted a comprehensive review of existing State standards for licensure including storing, handling, and holding of prescription drugs, as well as other nationally recognized standards and model rules for wholesale distribution and logistics.



Proposed Effective Dates for National Licensing Standards

	DSCSA Effective Dates	National Licensing Standards Proposed Implementation Dates
WDD	2 years after the regulation is finalized	2 years after the regulation is finalized
3PLs	1 year after the regulation is finalized	FDA does not intend to enforce requirements with respect to the national standards for licensure of 3PLs until 2 years after the regulation is finalized

Preemption/Federalism

- FDA interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the standards and requirements applicable under the regulations promulgated under sections 584 and amended 503(e) of the FD&C Act.

- As of the publication of the proposed rule, FDA has withdrawn the portion of the October 2014 draft guidance, originally titled *The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers,* addressing preemption with respect to WDD/3PL licensure.

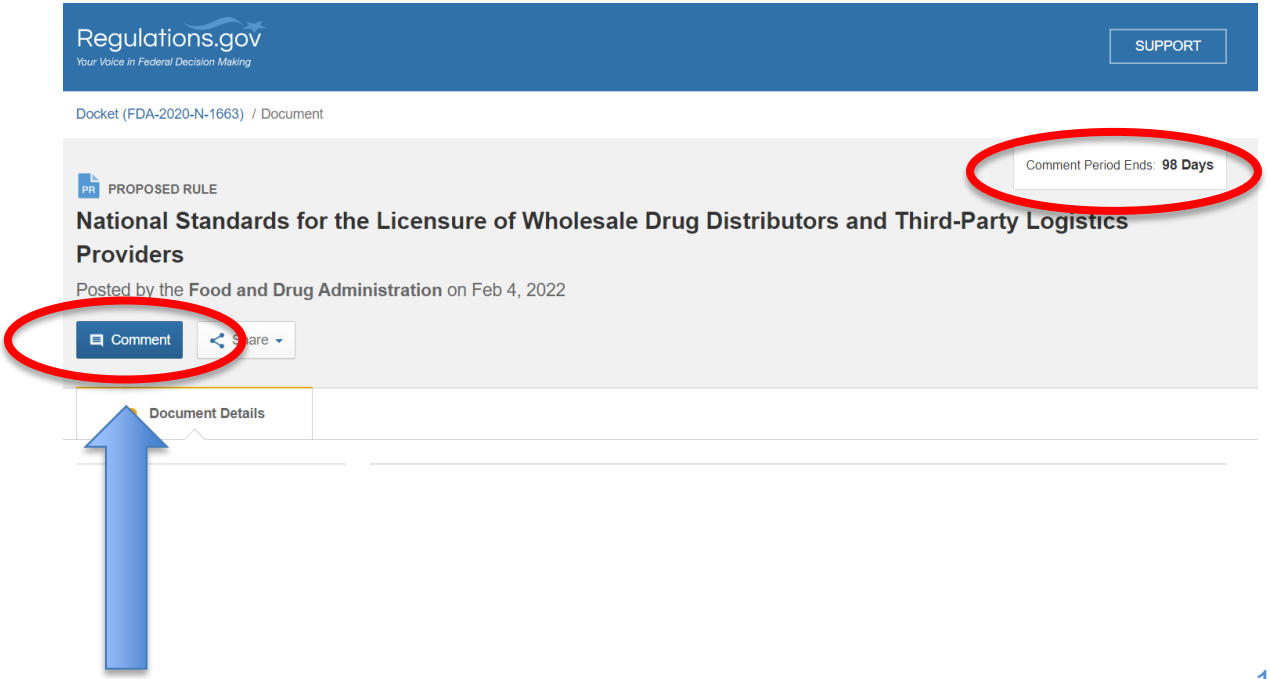
Timing of Preemption

State and local licensure requirements which are inconsistent with the federal requirements (as reflected in this regulation) will be preempted only once this regulation, when finalized, takes effect; until such time, current State and local licensing of WDDs and 3PLs may continue.

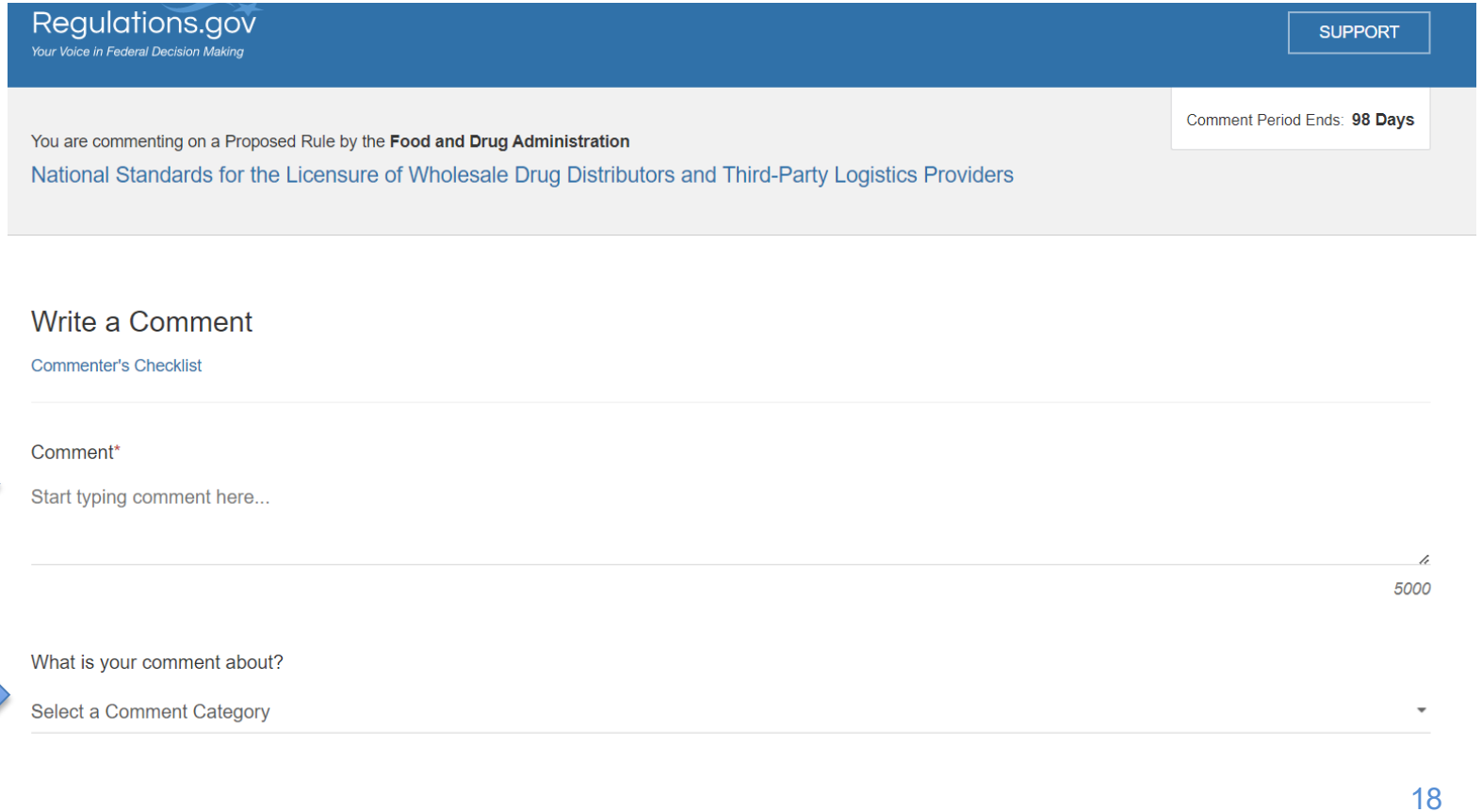
How to Comment on the Proposed Regulations

- Visit https://www.regulations.gov/document/FDA-2020-N-1663-0001 to find the docket for the Proposed Rule on Regulations.gov.

- Click “Comment” button
- Comment period closes at **11:59pm EST** on **June 6, 2022**. Page provides countdown of how many days are left in the comment period



How to Comment on the Proposed Regulations



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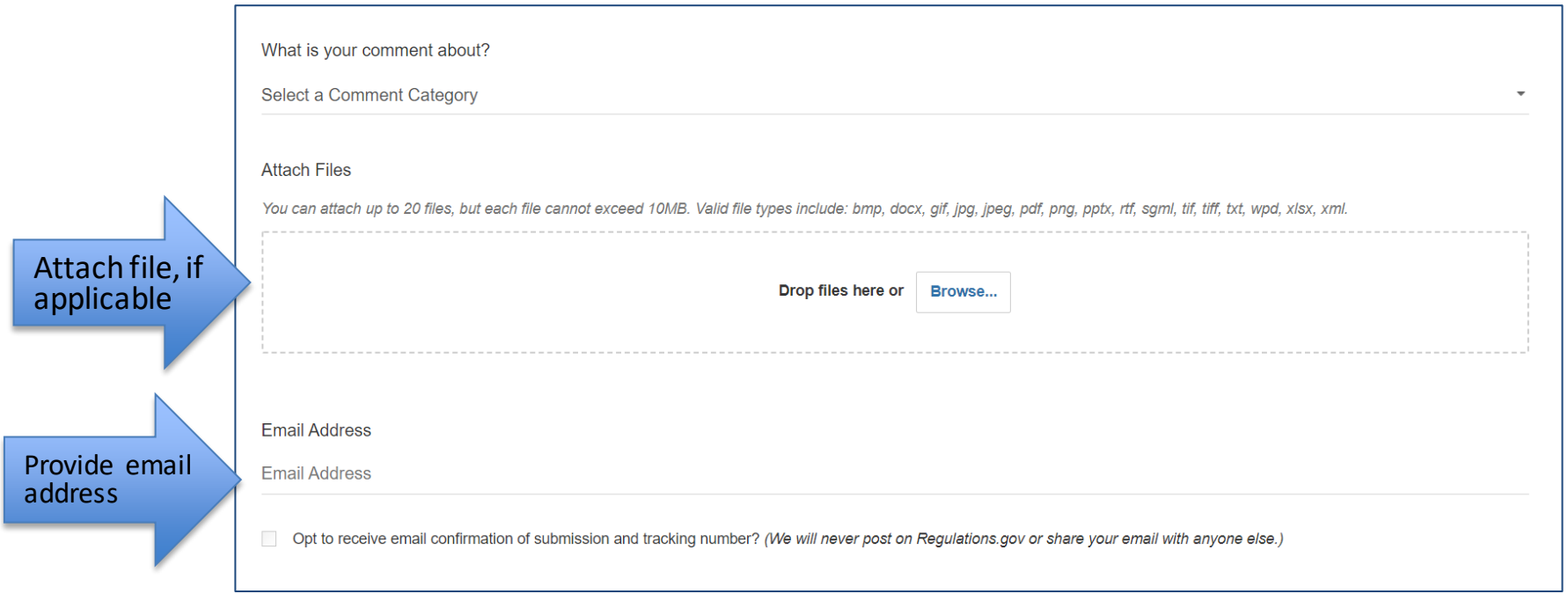
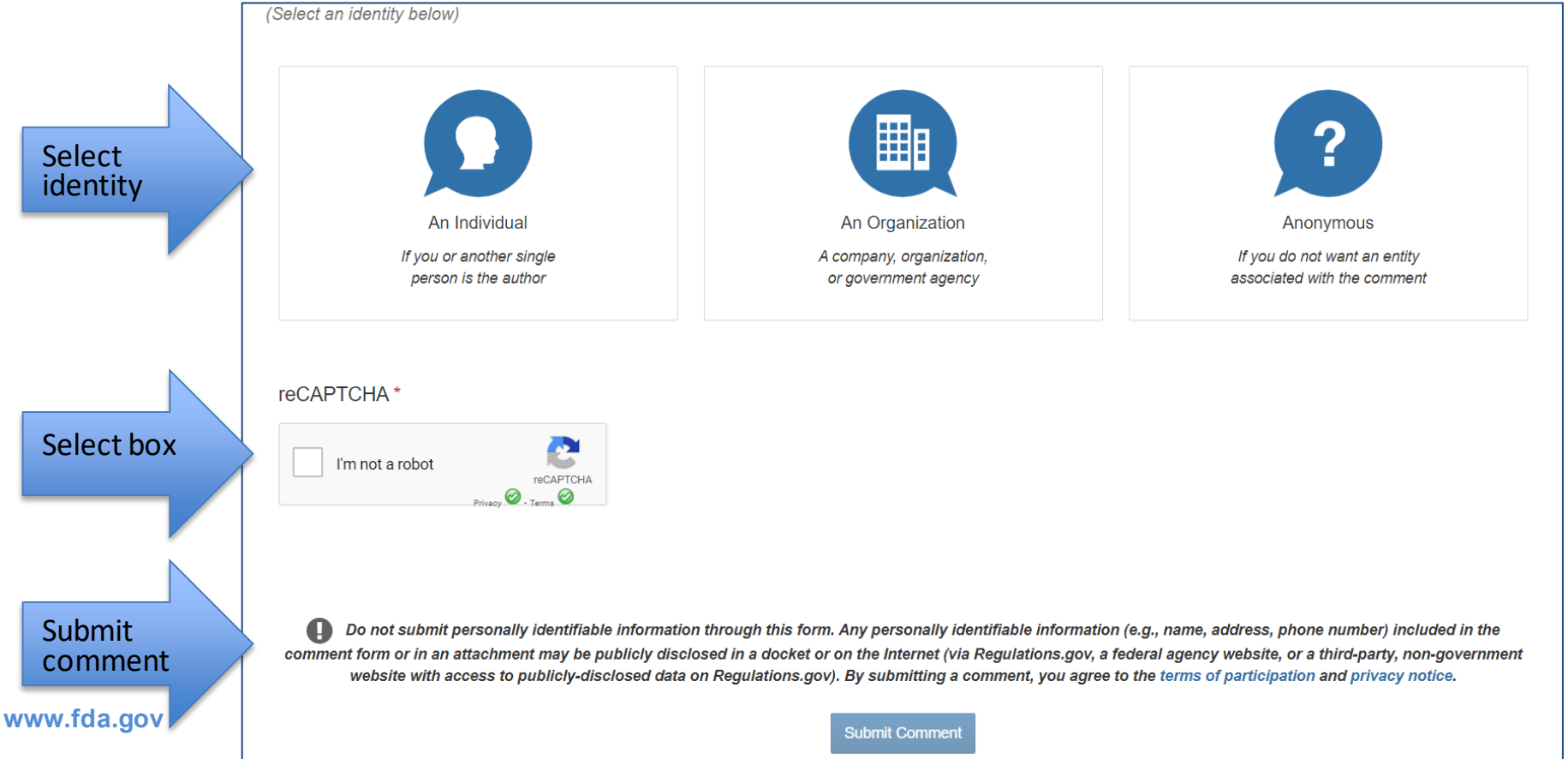
Select comment category from drop down menu

How to Comment on the Proposed Regulations



How to Comment on the Proposed Regulations



Select identity

Select box

Submit comment

www.fda.gov

How to Comment on the Proposed Regulations

- Alternatively, visit https://www.federalregister.gov/documents/search and search for "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers“

- Click “Submit A Formal Comment”
- Also available via FDA’s DSCSA page: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

21 CFR PART 205
National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

Proposed Rule

§ 205.1 Scope

Applies to the licensure of 3PLs in any State and to any entity engaging in wholesale distribution of prescription drugs in any State

§ 205.2 Purpose

To establish standards, terms, and conditions for the licensing of 3PLs and WDDs by State or Federal licensing authorities

§ 205.3 Definitions

Defines key terms

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Third-Party Logistics Providers (3PLs)

3PL
Licensure Requirement

Proposed 21 CFR 205.4

3PL Licensure Requirement

No 3PL may conduct 3PL activities unless each facility of the 3PL is licensed.

A separate is license required for each facility owned, rented, or leased by a 3PL.

Licenses are facility- and owner- specific and are not transferrable.

3PL must maintain its license in readily retrievable manner and permit the license's inspection.

3PL Licensure Application Requirements

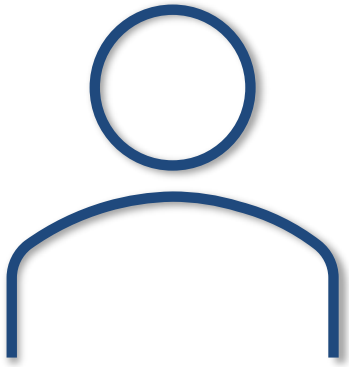
Proposed 21 CFR 205.5

3PL Licensure: General Application Requirements

Applicant Requirements

Applicant must:

- Be ≥18 years old
- Submit required affidavit and application information
- Pay licensing fees



3PL Licensure: General Application Requirements

Licensure Application Information

- Applicant name and title
- 3PL name, facility business address, and telephone number
- All trade or business names used by 3PL within past 7 years

- 3PL facility manager or designated representative name, email address, and telephone number
- Ownership or operation type
- Owner or operator names
- Certain felony convictions

3PL Licensure: General Application Requirements

Licensure Renewal Requirements

To renew a license, the 3PL must:

- Certify that the 3PL has continued to meet all the standards and complied with applicable requirements since the previous license was issued
- Inform licensing authority of any changes to information previously submitted for which a notification was not already submitted

3PL Licensure
Federal Licensure Process

Proposed 21 CFR 205.6

3PL Licensure: Federal Licensure Process

Application Filing and Review

3PL submits application to FDA electronically.

FDA, or Approved Organization (AO) if applicable, conducts licensure review.

- Review of submitted documents
- Facility inspection

Signature and fees

FDA communicates easily correctable deficiencies found in the application or the need for more data or information.

FDA determines whether applicable requirements are met.

3PL Licensure: Federal Licensure Process

License Issuance

- Upon a determination that the 3PL meets the applicable requirements under section 584 of the FD&C Act, and that none of the disqualifying factors listed in proposed section 205.9(a)(1) are present, FDA will issue a license to the 3PL.
- License is effective on date of the issuance of the license certificate.
- License remains valid until date of expiration, unless suspended or revoked.

3PL Licensure
Changes of Information

Proposed 21 CFR 205.7

3PL Licensure

Changes to Information, Location, or Ownership

For a change in the location of a facility at which 3PL activities are conducted, a new license and inspection of the facility is required before commencing 3PL activities at the location.

- Application for a new license must be submitted no later than 90 calendar days prior to beginning operations at the new location.

For a change in the entity engaged in 3PL activities in a facility, a new license is required prior to beginning operations.

- The application for a new license must be submitted no later than 30 calendar days prior to the change of ownership.
- A new inspection may be required.

3PL Licensure
Expiry and Renewal

Proposed 21 CFR 205.8

3PL Licensure

Expiry and Renewal

License Expiration

- 3 years after date issued

License Renewal

- Applications will be accepted within 90 calendar days of expiration

3PL Licensure
Denial, Suspension, Reinstatement, Revocation and Voluntary Termination

Proposed 21 CFR 205.9

3PL Licensure: Negative Licensure Actions

Denial of Application for Licensure

May be initiated by the licensing authority for any of the following reasons:

- Facilities and controls are inadequate to facilitate safe operations
- Methods or procedures do not comply with the requirements for good storage practices
- Personnel do not meet the requirements necessary for good storage practices
- Insufficient information in required written policies and procedures
- Methods or procedures do not comply with the requirements for adequate recordkeeping
- Application contains an untrue statement of material fact
- Failure to permit an adequate opportunity to inspect the facilities, controls, and any records relevant to the application

For renewal applications

- Failure to report any pertinent change of certain required information
- Failure to comply with annual reporting requirements

3PL Licensure: Negative Licensure Actions

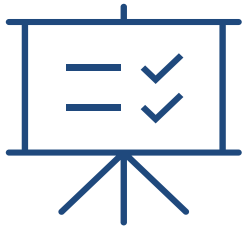
License Suspensions

May be initiated by the licensing authority upon reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure

- After notice and opportunity to request a hearing
- Immediately if the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public heath

3PL Licensure: Negative Licensure Actions

Reinstatement and Revocation After License Suspension



Reinstatement: A previously suspended license may be reinstated upon a 3PL's showing of compliance with requirements and upon such inspection and examination as the licensing authority may require.

Revocation: A 3PL license may be revoked if compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension.

3PL Licensure: Negative Licensure Actions

Procedures

- See § 205.9(a)– Denials of application for licensure
- See § 205.9(b) – Suspension of license after notice and opportunity to request a hearing
- See § 205.9(c) – Immediate suspension of license
- See § 205.9(e) – Revocation of license

3PL Licensure: Other Licensure Actions

Nonrenewal and Voluntary Terminations

Nonrenewal

If a license renewal application is not submitted by the date of expiration of the license, the license will be considered expired.

Voluntary Termination

A 3PL's request for termination must include a notice of intent to discontinue 3PL activities and a waiver of an opportunity for a hearing.

3PL Licensure
Good Storage Practices for 3PL Facilities

Proposed 21 CFR 205.10

3PL Licensure: Facility

General Requirements for Storage and Handling

- Not a personal residence
- Size, construction, and configuration to ensure:
  - Proper storage and distribution
  - Cleaning, maintenance, and proper operation
- Maintained in clean and orderly condition
- Sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions
- Defined designated areas that separate saleable products from products that are unfit for distribution

3PL Licensure: Facility

Adequate Security

- Secure from unauthorized entry
- Access from outside limited, well controlled, and documented
- Outside perimeter of the premises is well lit
- Alarm to detect and notify entry after hours
- Security system that protects against theft and diversion of products

3PL Licensure: Facility

Equipment

- Calibrated and validated at regular intervals
- Appropriate temperature and humidity recording equipment or logs to document proper storage
- Timely alert of any deviations from intended storage conditions

3PL Licensure
Personnel Requirements for Good Storage Practices

Proposed 21 CFR 205.11

3PL Licensure: Personnel

Personnel Requirements

- Must maintain a list of officers, directors, facility managers, designated representatives
- Must include description of duties
- Must include summary of their qualifications

3PL Licensure: Personnel

Facility Manager or Designated Representative Qualification

The facility manager or designated representative must have the necessary education, background, training and experience to perform assigned functions.

3PL Licensure

Facility Manager or Designated Representative

- Serves as the facility manager or designated representative of such facility manager for only one facility at a time
- Is responsible for managing all daily operations of the facility, including those duties delegated to other personnel
- Has adequate authority and resources to effectively manage daily operations

3PL Licensure

Facility Manager or Designated Representative

3PL is prohibited from obtaining or maintaining licensure if the 3PL employs a facility manager or designated representative who has been:

- Convicted of any felony violation of section 301(i) or (k) of the FD&C Act
- Convicted of any violation of 18 U.S.C. 1365 relating to product tampering

3PL Licensure
Written Policies and Procedures

Proposed 21 CFR 205.12

3PL Licensure: Written Policies & Procedures

Requirements

Proposed Section	The 3PL must establish, maintain, and follow written policies and procedures for:
205.12(b)	Personnel
205.12(c)	Receipt, Security, Storage, Inventory, Shipments, Distribution
205.12(d)	Recalled Products
205.12(e)	Preparing for Foreseeable Crises
205.12(f)	Products that are Unfit for Distribution
205.12(g)	Suspect Products
205.12(h)	Illegitimate Products

3PL Licensure
Recordkeeping and Document Maintenance

Proposed 21 CFR 205.13

3PL Licensure: Recordkeeping and Document Maintenance

Maintenance, Availability, and Accuracy of Records and Written Policies and Procedures

Records as outlined in 205.13 must:

- Be readily retrievable and made available to licensing authorities.
- Be securely stored and protected from unauthorized access or modifications.
- Contain only alterations signed and dated by individual who made alteration. Must preserve original information and document reason for alteration.
- Accurately reflect name of 3PL as it appears on the license.

3PL Licensure: Records

Record Retention

3 Years	6 Years
All other records	Records of investigation of suspect and illegitimate products and of destroyed, nonsaleable returned, and recalled drugs

3PL Licensure
List of Trading Partners

Proposed 21 CFR 205.14

3PL Licensure: Records

List of Trading Partners

3PL must provide upon request a list of all trading partners for which the 3PL conducts 3PL activities

- Manufacturers
- WDDs
- Repackagers
- Dispensers

3PL Licensure
Initial and Annual Reporting to FDA

Proposed 21 CFR 205.15

3PL Licensure: Reporting Requirements

Required Information

Information to be reported for each 3PL facility separately licensed:

- A complete list of States by which the 3PL facility is licensed
  - Includes the corresponding identification number and the expiration date of each such license

- Name of company as it appears on the license and full business address

- All trade names or business names under which the 3PL conducts business

3PL Licensure

Reporting Requirements

Timing of reports required to be submitted electronically to FDA	
Initial	Within 30 calendar days of obtaining initial license
Annual	Each calendar year between January 1 and March 31
Significant Disciplinary Action (initial)	Any Significant Disciplinary Actions that occurred in previous 12 months
Significant Disciplinary Action (subsequent)	Within 30 calendar days of a final action taken by a State or Federal licensing authority
Voluntary withdrawal of State License	Within 30 calendar days after such withdrawal Include reasons for withdrawal

3PL Licensure Inspections

Proposed 21 CFR 205.16

3PL Licensure

Inspections

- Physical inspection prior to issuance of initial license
- Routine inspection once every 3 years
- If licensed by State, inspection by State or by a third-party accreditation or service approved by State licensing authority
- If licensed by FDA, inspection by FDA or by organization approved by FDA under proposed section 205.18

3PL Licensure: Inspections

Records Availability

Readily available during inspection	Available within 2 business days of request
Records kept at the inspection site or that can be immediately retrieved electronically	Records kept at a central location apart from the inspection site and not electronically retrievable

3PL
Approved Third-Party Organizations

Proposed 21 CFR 205.17: Use of approved third-party organizations

Proposed 21 CFR 205.18: General qualifications of approved organizations

Proposed 21 CFR 205.19: Process and procedures for approval by the Food and Drug Administration

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Wholesale Drug Distributors

Wholesale Drug Distributor (WDD) Licensure Requirement

Proposed 21 CFR 205.20

Wholesale Drug Distributor Licensure Requirement

WDDs must be licensed

- By the State from which the drug is distributed, or FDA if the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in the regulation, and
- By the State into which the drug is distributed if that State requires such a license

Licensure Term

- 2 years

Renewal Applications

- Can be submitted up to 90 calendar days before date of licensure expiration

Wholesale Drug Distributor Surety Bonds

Proposed 21 CFR 205.21

Wholesale Drug Distributor Licensure General Application Requirements

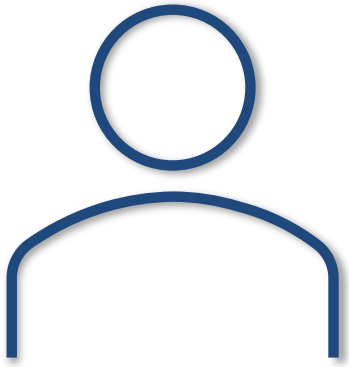
Proposed 21 CFR 205.22

WDD Licensure: General Application Requirements

Applicant Requirements

Applicant must:

- Be ≥18 years old
- Submit required affidavit and application information
- Pay licensing fees



WDD Licensure: General Application Requirements

Surety Bond Requirement

The wholesale distributor must furnish a bond or other equivalent means of security acceptable to the State with an application for licensure.

Proposed § 205.21 describes the requirements for requirements for surety bonds.

WDD Licensure: General Application Requirements

Licensure Application Information

- Applicant name and title
- WDD name, full business address, and telephone number
- All trade or business names used by WDD within past 7 years
- Ownership or operation type
- Owner or operator names

- Name, email address, and telephone number of the designated representative or facility manager for the WDD
- Certain felony convictions
- Certain citations or disciplinary actions within past 7 years

WDD Licensure: General Application Requirements

Licensure Renewal Requirements

To renew a license, the WDD must submit:

- Certification that the WDD has continued to meet all the standards and complied with the requirements in 21 CFR Part 205 subpart C since the previous license was issued
- Information about any changes to information previously submitted for which a notification was not already submitted

WDD Licensure: General Application Requirements

Licensure Availability

- WDD must maintain its license in readily retrievable manner.
- WDD must permit inspection:
  - By any official, agent, or employee of the licensing authority.
  - By any Federal, State, or local agency engaged in enforcement of laws relating to the distribution of prescription drugs.

Wholesale Drug Distributor Licensure
Federal Licensure Process

Proposed 21 CFR 205.23

WDD Licensure: Federal Licensure Process

Application Filing and Review

WDD submits application to FDA electronically.

- Required application information and surety bond
- Preferred approved organization for inspection (if applicable)
- Applicant signature
- Fees

FDA communicates easily correctable deficiencies found in the application or the need for more data or information.

WDD Licensure: Federal Licensure Process

License Issuance

- Upon a determination that the WDD meets the applicable requirements under sections 503(e)(1) and 583 of the FD&C Act, FDA will issue a license to the WDD.
- License is effective on date of the issuance of the license certificate.
- License remains valid until date of expiration, unless suspended or revoked.

Wholesale Drug Distributor Licensure Changes to Information

Proposed 21 CFR 205.24

WDD Licensure

Changes to Information, Location, or Ownership

For a change in the location of a WDD at which wholesale distribution occurs, an inspection of the new facility is required prior to commencing wholesale distribution at the location.

For a change to the person engaged in wholesale distribution, a new license is required prior to beginning operations.

A new inspection of the WDD will be performed at a reasonable time.

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Wholesale Distributor Licensure
Key Personnel

Proposed 21 CFR 205.25

WDD Licensure

Key Personnel (21 CFR 205.3(g))

Responsible for managing operations of the wholesale distributor:

- Principal
- Owner
- Director
- Officer of the wholesale distributor
- Designated representatives
- Individuals authorized to enter areas where prescription drugs held and are likely to handle prescription drugs as part of their responsibilities

WDD Licensure: Key Personnel

Prohibited Persons

- Convicted of any felony for violating section 301(i) or (k) of the FD&C Act
- Convicted of any felony violation of 18 U.S.C. 1365 relating to product tampering
- Cited on 2 or more occasions within 7 years for violating section 583 or section 503(e) of FD&C Act, or State requirement for licensure that presents threat of serious adverse health consequences or death to humans

WDD Licensure: Key Personnel

Qualifications

All key personnel must have the necessary education, background, training and experience to perform assigned functions.

WDD Licensure: Key Personnel

Grounds for Denying Licensure Application

If applicant or key personnel:

- Delayed or impeded inspection,
- Omitted material information of furnished false or fraudulent information in an application, or
- Subject to licensure suspension or revocation for currently or previously held license for manufacture or distribution of any drugs.

WDD Licensure: Key Personnel

List of Personnel & Written Policies and Procedures

List of Personnel	Written Policies and Procedures
Must maintain a list of officers, directors, facility managers, designated representatives, and other key personnel in charge of wholesale distribution.	Must establish written policies and procedures designed to ensure qualifications of key personnel are met, maintained, and documented.
Must include description of duties and summary of their qualifications.	Must identify personnel who are responsible for: •Implementing and maintaining facility personnel requirements, •Complying with all licensure and reporting requirements, and •Ensuring key personnel receive initial and regular training.
Must be available for review by State or Federal licensing authority.	Must be available for review by State or Federal licensing authority.

WDD Licensure: Key Personnel

Facility Manager or Designated Representative

- Serves as the facility manager for only one facility at a time
- Actively involved in and responsible for managing daily operations
- Responsible for all facility manager duties that are delegated to other personnel at facility
- Must submit full set of fingerprints for purposes of conducting local and national criminal background checks

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Wholesale Drug Distributor Licensure Storage and Handling of Prescription Drugs for Wholesale Distribution

Proposed 21 CFR 205.26

WDD Licensure: Facility

Systems and Processes

Any wholesale distributor's facility that is also licensed or registered as another trading partner (such as a 3PL) and operating from the same address must have separate systems and processes in place for their separate functions.

WDD Licensure: Facility

Suitability for Storage and Handling

- Not a personal residence
- Size, construction, and configuration to ensure:
  - Proper distribution
  - Cleaning, maintenance, and proper operation
- Maintained in clean and orderly condition
- Sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions
- Defined designated areas that separate saleable prescription drugs from prescription drugs that are unfit for distribution

WDD Licensure: Facility

Adequate Security

- Secure from unauthorized entry
- Access from outside limited, well controlled, and documented
- Outside perimeter of the premises is well lit
- Entry where drugs are held limited to key personnel
- Security system that protects against theft and diversion of prescription drugs and accidental or unsanctioned modifications to data

WDD Licensure: Facility

Equipment

- Facility must have equipment that ensures prescription drugs are properly stored, including:
  - Cold storage
  - Refrigerators
  - Temperature and humidity devices
  - Air handling units
- Must be maintained in good repair
- Must be suitable for distribution of prescription drugs
- Facility assessments must be regularly conducted and documented

WDD Licensure: Facility

Equipment

Establish written procedures to ensure that equipment is installed, maintained, and repaired by qualified individuals following written procedures

Equipment calibrated and validated at regular intervals

Use:

- Manual, electromechanical, or electronic temperature and humidity recording equipment or logs must be used to document proper storage
- Monitoring equipment must immediately alert of any deviations from required storage conditions

WDD Licensure: Facility

Written Policies and Procedures

Establish, maintain, and follow written policies and procedures for:

- Authorized trading partners
- Facility and equipment maintenance management
- Transportation
- Examination of Shipping Containers
- Storage and Handling
- Disposition of Prescription Drugs
- Preparation for Foreseeable Crises

WDDs not limited to establishing written policies and procedures for the stated functions in proposed section 205.26(c).

WDD may wish to establish written policies and procedures pertaining to other aspects of wholesale distribution and staffing of their facilities.

WDDs responsible for contractor compliance.

WDD must ensure that contractor abides by applicable written policies and procedures.

Written policies and procedures must clearly describe responsibilities of the WDD and any contractors used to fulfill the WDD's duties.

Wholesale Drug Distributor Licensure Establishment and Maintenance of Records of The Distribution of Prescription Drugs

Proposed 21 CFR 205.27

WDD Licensure: Records

Required Records

Documents pertaining to distribution

- Storage & Handling
- Security
- Inventory
- Transport
- Shipping

Documents related to compliance

- Written Policies & Procedures
- Instructions
- Contracts
- Data
- Inspection Reports
- Any Other Compliance Documentation

Records of the distribution of prescription drugs

- Invoices
- Purchase Orders
- Packing Slips
- Shipping Records
- Any Other Records of Distribution

WDD Licensure: Records

Record Retention

3 Years	6 Years
All other records	Records of investigation of suspect and illegitimate products and of destroyed, nonsaleable returned, and recalled drugs

Wholesale Drug Distributor Licensure Inspections

Proposed 21 CFR 205.28

WDD Licensure

Inspections

- Physical inspection prior to issuance of initial license
- If licensed by State, inspection by State or by a third-party accreditation or service approved by State licensing authority
- If licensed by FDA, inspection by FDA or by organization approved by FDA under proposed section 205.32
- Routine inspection once every 3 years

WDD Licensure: Inspections

Records Availability

Readily available during inspection	Available within 2 business days of request
Records kept at the inspection site or that can be immediately retrieved electronically	Records kept at a central location apart from the inspection site and not electronically retrievable

Wholesale Drug Distributor Licensure Reporting Requirements

Proposed 21 CFR 205.29

WDD Licensure: Reporting Requirements

Required Information

Information to be reported for each WDD:

- A complete list of States where the WDD is licensed
  - Includes the corresponding identification number and the expiration date of each such license
- Name of company as it appears on the license and full business address, and contact information for the facility manager or designated representative of the WDD
- All trade names or business names under which the WDD conducts business
- Any significant disciplinary actions taken against the WDD license related to the distribution of prescription drugs

WDD Licensure

Reporting Requirements

Timing of reports required to be submitted electronically to FDA	
Initial	Within 30 calendar days of obtaining initial license
Annual	Each calendar year between January 1 and March 31
Significant Disciplinary Action (initial)	Any Significant Disciplinary Actions that occurred in 12 months prior to obtaining licensure
Significant Disciplinary Action (subsequent)	Within 30 calendar days after a final action taken by a State or Federal licensing authority
Closure of facility (facility has ceased operations)	Within 30 calendar days after facility has stopped operating as a WDD
Voluntary withdrawal of State License	Within 30 calendar days after such withdrawal Include any reasons for withdrawal

Wholesale Drug Distributor Licensure Denial, Suspension, Reinstatement, Revocation, and Voluntary Termination Notice and opportunity to request a hearing

Proposed 21 CFR 205.30

WDD Licensure: Negative Licensure Actions

Denial of Application for Licensure

May be initiated by the licensing authority for any of the following reasons:

- Methods or procedures inadequate to preserve the safety, identity, strength, quality, or purity of the prescription drug
- Facilities and controls inadequate to preserve the safety, identity, strength, quality, or purity of the prescription drug
- Methods or procedures do not comply with the requirements for good storage practices
- Personnel do not meet the requirements necessary for good storage practices
- Insufficient information in required written policies and procedures
- Methods or procedures do not comply with the requirements for adequate recordkeeping
- Application contains an untrue statement of material fact
- Failure to permit an adequate opportunity to inspect the facilities, controls, and any records relevant to the application

For renewal applications

- Failure to report to the licensing authority any pertinent change of certain required information
- Failure to report to the FDA any of the requirements for annual reporting

WDD Licensure: Negative Licensure Actions

License Suspensions

May be initiated by the licensing authority upon reasonable belief that the licensee has failed to comply with any of the standards for receiving and maintaining licensure

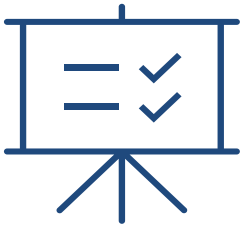
After notice and opportunity to request a hearing if the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety

Immediately if the nature of the noncompliance at issue would reasonably be expected to cause an imminent threat to public health

Proposed § 205.30

WDD Licensure: Negative Licensure Actions

Reinstatement and Revocation After License Suspension



Reinstatement: A previously suspended license may be reinstated upon a WDD's showing of compliance with requirements and upon such inspection and examination as the licensing authority may require.

Revocation: A WDD license may be revoked if compliance is not demonstrated or achieved to the licensing authority's satisfaction within the time period indicated in the notice of suspension.

WDD Licensure: Negative Licensure Actions

Procedures

See § 205.30(a)– Denials of application for licensure

See § 205.30(b) – Suspension of license after notice and opportunity to request a hearing

See § 205.30(c) – Immediate suspension of license

See § 205.30(e) – Revocation of license

WDD Licensure: Other Licensure Actions

Nonrenewal and Voluntary Terminations

Nonrenewal

If a license renewal application is not submitted by the date of expiration of the license, the license will be considered expired.

Voluntary Termination

A WDD's request for termination must include a notice of intent to discontinue prescription drug wholesale distribution and a waiver of an opportunity for a hearing.

Wholesale Drug Distributor
Use of Approved Third-Party Organizations

Proposed 21 CFR 205.31: Use of approved third-party organizations
Proposed 21 CFR 205.32: General qualifications of approved organizations
Proposed 21 CFR 205.33: Process and procedures for approval by the Food and Drug Administration

FDA Resources

- Proposed Rule: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers - Notice of Availability
  https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics
- DSCSA Main Webpage

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm
- DSCSA Regulatory Documents (i.e., regulations, guidances, federal register notices, pilot programs)

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm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