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BY ELECTRONIC MAIL
DrugTrackandTrace@fda.hhs.gov

Ilisa B.G. Bernstein, Pharm.D., J.D.
Acting Director
Deputy Director, Program Operations
Office of Compliance
Food and Drug Administration
Room 5266, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
ilisa.bernstein@fda.hhs.gov

Eleni Z. Anagnostiadis, RPh
Acting Director
Division of Supply Chain Integrity
Office of Drug Security, Integrity and Recalls
Room 4272, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
eleni.anagnostiadis@fda.hhs.gov

Connie T. Jung, RPh, PhD
Associate Director for Policy and Communication
Office of Compliance
Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
connie.jung@fda.hhs.gov

Karen L. Rothschild
Regulatory Counsel
Division of Supply Chain Integrity
Office of Drug Security, Integrity and Recalls
Room 4272, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
karen.rothschild@fda.hhs.gov

Re: Licensure Standards for Wholesale Distributors,
§ 583 of the Drug Supply Chain Security Act, New 21 C.F.R. Part 205

Dear Doctor Bernstein, Doctor Jung, Ms. Anagnostiadis, and Ms. Rothschild:

The Healthcare Distribution Management Association (HDMA) and Health Industry Distributors Association (HIDA) thank you and the Food and Drug Administration (FDA) for the collective efforts to implement Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). One of FDA's obligations in 2015 is to promulgate regulations, within 2 years of the DSCSA's enactment, establishing standards for the licensure of wholesale distributors. §583(a).

These standards shall apply to all State and Federal wholesale distributor licenses issued under the federal Food, Drug and Cosmetic Act (FDC Act) as amended by the DSCSA.

HDMA is the national association representing primary wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

HIDA members deliver medical products and supplies, manage logistics, and offer customer services to more than 294,000 points of care. Medical-surgical products distributors primarily distribute items used in every day medical services and procedures, ranging from gauze and gloves to diagnostic laboratory tests and capital equipment. Their customers include over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the country. For more information, please visit www.hida.org.

HDMA and HIDA have worked for many years to establish strong standards for the licensure of wholesale distributors. We are pleased to provide the attached model regulation for FDA's consideration and review. We propose replacing in its entirety existing 21 C.F.R. Part 205 – Guidelines for State Licensing of Wholesale Prescription Drug Distributors. In its place, the new Part 205 we attach sets out the appropriate standards for federal or state licensure of wholesale distributors. We believe this new Part 205 incorporates all of the DSCSA's requirements as to wholesale distributors and specifically addresses new issues, such as handling of suspect and illegitimate product, mandatory initial inspections for new facilities, fingerprinting, and the approval or certification of third-party inspectors.

This new draft Part 205 is the product of many months of work by HDMA, HIDA and our members. We have, as associations, called upon our long years of expertise in State licensure issues to develop this draft regulation. Ideally, once promulgated as a regulation by FDA, State licensing authorities would adopt new Part 205. In this way, there will be, as the DSCSA contemplates and requires, a single, rigorous and uniform system for the licensure of wholesale distributors of pharmaceuticals.

HDMA and HIDA would very much like to meet with you to review our proposed recommended regulations for the licensure of state wholesale distributors. We will contact you about setting up a convenient time for a meeting.

Sincerely,

Linda Rouse O'Neill
Vice President, Government Affairs
Health Industry Distributors Association

Anita T. Ducca
Vice President, Regulatory Affairs
Healthcare Distribution Management Association

Attachment: HDMA/HIDA Recommendations For New 21 C.F.R. Part 205 – Licensing Of Prescription Drug Wholesale Distributors

9/19/14

HDMA recommends that FDA propose to revise existing 21 C.F.R. Part 205 to read as follows:

21 C.F.R. Part 205 – Licensing Of Prescription Drug Wholesale Distributors

Subpart A – General Provisions
Subpart B – Procedures for Prescription Drug Wholesale Distributor Licensing
Subpart C – Personnel
Subpart D – Facilities, Storage, Handling, and Procedures
Subpart E – Recordkeeping
Subpart F – Inspections
Subpart G – Bond

Subpart A – General Provisions

205.1 Scope and purpose.

(a) This part applies to any individual, partnership, corporation, or other business entity in a State engaging in the wholesale distribution of prescription drugs in interstate commerce. The purpose of this part is to implement the Drug Supply Chain Security Act of 2013 (the DSCSA) by providing standards, requirements, terms, and conditions for the licensing of prescription drug wholesale distributors by State and Federal licensing authorities.

205.2 National uniformity.

(a) FDA interprets the national uniformity provisions of the DSCSA so that no State licensing authority may establish standards, requirements, or regulations for the licensure of prescription drug wholesale distributors that are more stringent or less stringent than the requirements set forth in this part. Each license issued by any licensing authority shall meet the standards, terms, and conditions of this part.

(b) Any standards, requirements, or regulations a State licensing authority adopts for the licensure of prescription drug wholesale distributors should include all the requirements of this part without substantive change. Any other or additional standards, requirements, or regulations with respect to prescription drug wholesale distributor licensure a State licensing authority

adopts cannot be inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of this part.

205.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended.

(b) *Affiliate* means a business entity that has a relationship with a second business entity if, directly or indirectly—

(1) one business entity controls, or has the power to control, the other business entity; or

(2) a third-party controls, or has the power to control, both of the business entities.

(c) *Authorized* means —

(1) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510 of the Act;
(2) in the case of a wholesale distributor, having a valid license under State law or sections 582 and 583 of the Act, and complying with the licensure reporting requirements under section 503(e) of the Act;
(3) in the case of a third-party logistics provider, having a valid license under State law or sections 582 and 584 of the Act and complying with the licensure reporting requirements of section 584 of the Act; and
(4) in the case of a dispenser, having a valid license under State law.

(d) *Co-licensed Partner* means an instance in which 2 or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the requirements in this part.

(e) *Designated Representative or Facility Manager* means an individual employed at a wholesale distributor who has appropriate education and/or experience to assume responsibility for positions related to compliance with licensing requirements.

(f) *Dispenser* means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor and does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5) of the Act.

(g) *Distribute* or *Distribution* means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) of the Act or the dispensing of a product approved under section 512(b) of the Act.

(h) *Exclusive Distributor* means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

(i) *Health care entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a ''health care entity'' and a retail pharmacy or wholesale distributor.

(j) *Illegitimate Product* means a product for which credible evidence shows that the product –

(1) is counterfeit, diverted, or stolen;

(2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(3) is the subject of a fraudulent transaction; or

(4) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(k) *Licensing Authority* means, as appropriate, the State agency authorized by State law to issue licenses to prescription drug wholesale distributors or FDA.

(l) *Manufacturer* means, with respect to a product –

(1) a person that holds an application approved under section 505 of the Act or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(2) a co-licensed partner of the person described in subparagraph (1) that obtains the product directly from a person described in this paragraph or paragraph (1) or (3); or

(3) an affiliate of a person described in paragraph (1) or (2) that receives the product directly from a person described in this paragraph or paragraph (1) or (2).

(m)*Person* includes an individual, partnership, corporation, or other business entity.

(n) *Prescription Drug* means a drug for human use subject to section 503(b)(1) of the Act.

(o) *Product* means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582 of the Act, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in 21 C.F.R. 600.3(ee)) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B) of section 581 of the Act, medical gases (as defined in section 575 of the Act), homeopathic drugs marketed in accordance with applicable guidance under the Act, or a drug compounded in compliance with section 503A or 503B of the Act.

(p) *Quarantine* means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

(q) *Repackager* means a person who owns or operates an establishment that repacks and relabels a product or package for:

(1) further sale; or

(2) distribution without a further transaction.

(n) *Suspect Product* means a product for which there is reason to believe that such product—

(1) is potentially counterfeit, diverted, or stolen;

(2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(3) is potentially the subject of a fraudulent transaction; or

(4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(o) *Third-party Logistics Provider* means 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 has responsibility to direct the sale or disposition of the product.

(p) *Trading Partner* means

(1) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(2) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(q) *Wholesale Distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) intracompany distribution of any drug between affiliates or within a manufacturer;

(2) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a prescription executed in accordance with section 503(b)(1) of the Act;

(5) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) the distribution of a drug by the manufacturer of such drug;

(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(10) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the Act;

(12) salable drug returns when conducted by a dispenser;

(13) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a 'medical convenience kit') if—

(i) the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with section 510(b)(2) of the Act;

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(A) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is—

(A) an intravenous solution intended for the replenishment of fluids and electrolytes;

(B) a product intended to maintain the equilibrium of water and minerals in the body;

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

(14) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas, as defined in section 575 of the Act;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) of the Act and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(r) *Wholesale distributor* means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution.

Subpart B – Procedures for Prescription Drug Wholesale Distributor Licensing

205.20 Prescription drug wholesale distributor license requirement.
Before engaging in the wholesale distribution of prescription drugs in a State, a wholesale distributor must be licensed by the State licensing authority. If the State from which the prescription drug is distributed has not established a licensure requirement, the wholesale distributor must be licensed by FDA pursuant to this part.

205.21 Prescription drug wholesale distributor license application.
To be licensed by a licensing authority, a prescription drug wholesale distributor must submit an application to the licensing authority which contains the following information:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The type of ownership or operation (*e.g.*, partnership, corporation, or sole proprietorship).

(d) The name(s) of the owner and/or operator of the applicant, including:

(i) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
(ii) If a partnership, the name of each partner, and the name of the partnership;
(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and
(iv) If another form of business entity, information comparable to the information set forth in clause iii above.

(e) A list of all licenses and permits issued to the applicant by any other State that authorizes the applicant to purchase, sell, trade or possess prescription drugs.

(f) The name and contact information of the applicant's designated representative or facility manager.

(g) The information required under § 205.31 for the applicant's designated representative or facility manager.

205.22 Action on an initial prescription drug wholesale distributor license application by the licensing authority.

Upon submission of a complete initial license application, payment of any fees required by the licensing authority, posting of bond under § 205.70, and completion of a satisfactory physical inspection under §205.60, the licensing authority shall issue a new license to the prescription drug wholesale distributor applicant within 30 days.

205.23 Applicability to existing licenses.

A wholesale distributor holding an existing license issued by the State licensing authority as of the effective date of this part shall not be required to submit a new application under this part and shall not be required to undergo an initial, mandatory physical inspection under § 205.60. The holder of an existing wholesale distributor license shall submit to the licensing authority the information required by this part upon renewal of its existing license under § 205.24.

205.24 Renewal of wholesale distributor license applications.

The licensing authority shall have procedures in place for the inspection and renewal of existing wholesale distributor licenses every 4 years.

Subpart C – Personnel

205.30 Qualifications for facility manager or designated representative.

The designated representative or facility manager identified in 205.21(f) shall meet the following qualifications:

(a) Is at least 21 years of age;

(b) Has been employed full time for at least 2 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(e) Is serving in the capacity of a designated representative for only one applicant and facility at a time, except

(1) Where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are affiliates; or

(2) Where a licensed wholesale distributor is co-located in the same facility with a third-party logistics provider and such entities are affiliates; or

(3) Where one or more of the wholesale distributor's facilities or third-party logistics provider facilities are within 50 miles of each other, and such entities are affiliates.

(f) Does not have any convictions under Federal, State, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(g) Does not have any felony convictions under Federal, State, or local laws.

205.31 Mandatory background checks and fingerprinting of facility managers or designated representatives.

(a) A wholesale distribution license application shall include the following information for the designated representative or facility manager identified in 205.21(f):

(1) The name of the applicant's designated representative or facility manager for the facility.

(2) The Personal Information Statement for the designated representative or facility manager which shall include the following information:

(i) The individual's places of residence for the past 7 years;
(ii) The individual's date and place of birth;
(iii) The individual's occupations, positions of employment, and offices held during the past 7 years;
(iv) The principal business and address of any business, corporation, or other organization in which each such office of the individual was held or in which each such occupation or position of employment was carried on;
(v) Whether the individual has been, during the past 7 years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;
(vi) Whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any Federal or State law regulating the possession, control, or distribution of

prescription drugs or criminal violations, together with details concerning any such event;

(vii) A description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude or related to the qualifications, functions or duties of that individual in connection with the operation of the wholesale distributor, of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the licensing authority a copy of the final written order of disposition; and

(viii) A photograph of the designated representative or facility manager for the facility taken within the previous year. Such photograph shall be submitted to the licensing authority with only the wholesale distributor's initial application or, in the case of a wholesale distributor holding an existing license as of the effective day of this part, with the first renewal application; and

(3) The fingerprints of the designated representative or facility manager for the facility. Fingerprints of the individual shall be submitted to the licensing authority with only the initial application or, in the case of a wholesale distributor holding an existing license as of the effective day of this part, with the first renewal application an already licensed wholesale distributor submits under this part;

(b) In order to facilitate the criminal background check of the facility manager or designated representative, the applicant, during the wholesale distributor license application process, shall submit a set of fingerprints collected pursuant to the standards determined by the FBI procedures and the licensing authority. The fingerprints shall be used by the local jurisdiction to search the state criminal repository and shall be sent to the Federal Bureau of Investigation for searching the federal criminal history files. Nothing in this section shall prohibit an applicant or licensing authority from utilizing a third-party service to collect fingerprints.

(c) If the facility manager or designated representative identified in a licensed wholesale distributor's application changes, the wholesale distributor shall report to the licensing authority within 30 days the information specified in subsections (a) and (b), including a photograph of the individual taken within the previous year and a set of fingerprints.

Subpart D– Facilities, Storage, Handling, and Procedures

205.40 Prescription drug wholesale distributor facilities.

Any facility at which a wholesale distributor stores, warehouses, handles, holds, offers, markets, or displays prescription drugs shall:

(a) Be of suitable size and construction to facilitate cleaning, security, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a holding area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, adulterated, suspect, or illegitimate or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

205.41 Holding of prescription drugs in wholesale distributor facilities.

A wholesale distributor shall:

(a) Store all prescription drugs at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, except that if no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected; and

(b) Utilize appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs to document the proper storage of prescription drugs.

205.42 Examination of incoming and outgoing prescription drugs in wholesale distributor facilities.

A wholesale distributor shall:

(a) Upon receipt, visually examine each outside shipping container for identity and damage. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to contents; and

(b) Inspect each outgoing shipment for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been visibly damaged in storage or obviously held under improper conditions.

205.43 Returned, damaged, and outdated prescription drugs.

A wholesale distributor shall:

(a) Separate from other prescription drugs any prescription drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or illegitimate until the wholesale distributor causes them to be destroyed or returns them to the supplier;

(b) Quarantine suspect product until it can be investigated and either verified as not illegitimate or determined to be illegitimate; and

(c) Destroy or return to the supplier any prescription drug if the conditions under which it has been returned to the wholesale distributor cast doubt on the drug's safety, identity, strength, quality, or purity, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

205.44 Written policies and procedures.

(a) Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(b) Wholesale distributors shall include the following in their written policies:

(1) A procedure for identification, quarantine, handling, and investigation of suspect and illegitimate product, including notifications to FDA and trading partners where required under the DSCSA;

(2) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate;

(3) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the FDA or other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(4) A procedure to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(5) A procedure to implement §205.43, including written documentation of the disposition of outdated, damaged, deteriorated, misbranded, adulterated, or illegitimate prescription drugs. This documentation shall be maintained for two years after disposition of the outdated, damaged, deteriorated, misbranded, adulterated, or illegitimate drugs; and

(6) A procedure for the capture and transmission of transaction information, transaction history, and transaction statement for each transaction consistent with the requirements of section 582(c) of the Act.

205.45 Responsible persons.

A wholesale distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subpart E – Recordkeeping

205.50 Wholesale distributor records.

(a) A wholesale distributor shall:

(1) Capture the transaction information, transaction history, and transaction statement for each transaction consistent with the requirements of section 582(c)(1)(A)(v)(I) of the Act, and maintain such information, history, and statement for not less than 6 years after the date of the transaction;

(2) Keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation; and

(3) Keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

(b) Records described in this section that are kept at the inspection site shall be readily available for inspection by the licensing authority upon request within 2 business days of a request the licensing authority.

Subpart F – Inspections

205.60 Mandatory initial inspections and regular inspections.

(a) The licensing authority shall not issue a new wholesale distribution license under this part unless the wholesale distributor applicant has completed a satisfactory inspection of the facility identified in the initial application. The licensing authority shall undertake a physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the submission of the initial application of the facility, which shall not exceed 30 days from date of receipt of a complete initial application.

(b) The licensing authority shall inspect an already licensed wholesale distributor at renewal. The licensing authority shall conduct an inspection within 30 days of receipt of the wholesale distributor's renewal application. However, the wholesale distributor's existing license shall remain in force and effective even if the licensing authority cannot initiate inspection within 30 days. In lieu of conducting an inspection at the time of renewal of a wholesale distributor license, the licensing authority may accept the inspection of a wholesale distributor conducted by another licensing authority.

(c) Any inspection the licensing authority or its approved third-party accreditation or inspection service undertakes shall be completed within 14 days.

205.61 Scope of physical inspection.

The inspection shall be limited to determining if the wholesale distributor applicant is in substantial compliance with the requirements of this part, or,

consistent with § 205.2, with the comparable wholesale distribution licensure requirements, standards, and regulations of the State licensing authority.

205.62 Duties of inspector.

The inspector shall:

(a) Initiate an inspection of the wholesale distributor identified in the application during normal business hours by showing appropriate identification to the designated representative or facility manager identified in the application and stating that the purpose of the inspection is to conduct a physical inspection under the DSCSA;

(b) Examine the wholesale distributor's facility;

(c) Examine the methods for receiving, holding, and distributing prescription drugs;

(d) Inspect any records required to be kept pursuant to section 582(c) of the Act;

(e) Determine if the wholesale distributor applicant is in substantial compliance with the requirements of this part, or, consistent with § 205.2, with the comparable wholesale distribution licensure requirements, standards, and regulations of the State licensing authority;

(f) Conduct the inspection in accordance with FDA procedures applicable to the conduct of establishment inspections, including, but not limited to, the Investigations Operations Manual (IOM), Chapter 5- Establishment Inspection, the Regulatory Procedures Manual (RPM), and Field Management Directives;

(g) Conduct a closing interview with the wholesale distributor, share any shortcoming observed in the course of inspection, and provide the wholesale distributor with the opportunity to respond and correct the shortcoming before the conclusion of the inspection;

(h) Provide a written copy of the inspectional findings to the wholesale distributor within 5 business days, to which the wholesale distributor may provide a written response within 10 business days of receipt; and

(i) Submit an inspection report and any wholesale distributor response to the licensing authority following the FDA- prescribed format defined in FDA's IOM and in accordance with the timeframes of FDA's IOM, RPM, and Field Management Directives.

205.63 Duties of prescription drug wholesale distributor.

Prescription drug wholesale distributors shall permit authorized licensing authority personnel to enter and inspect their premises and delivery vehicles, and to review their records and written operating procedures required to be maintained pursuant to the DSCSA and this part, at reasonable times and in a reasonable manner, to the extent permitted by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale distributors' premises and delivery vehicles.

205.64 Third-party accreditation or inspection service.

(a) A licensing authority may approve a third-party accreditation or inspection service for purposes of conducting inspections described in § 205.61.

(b) To be approved, the third-party accreditation or inspection service must submit an application to the licensing authority containing the information and certifications set forth in § 205.65.

205.65 Approving an applicant as a third-party accreditation or inspection service.

(a) To be approved as a third-party accreditation or inspection service by the licensing authority, the applicant:

(1) Must be a legally constituted entity;

(2) Must not engage in the design, manufacture, promotion, or sale of articles regulated under the Act; and

(3) Must operate in accordance with generally accepted professional and ethical business practices.

(b) To be approved as a third-party accreditation or inspection service, the applicant must state in its application that it shall:

(1) Certify that reported information from an inspection accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with the Act, and recommendations made during an inspection or at an inspection’s closing meeting;

(2) Limit work to that for which competence and capacity are available;

(3) Treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret

information, except such information may be made available to the licensing authority; and

(4) Promptly respond and attempt to resolve within 10 business days complaints regarding any activities for which it is approved as a third-party accreditation or inspection service.

(c) To be approved as a third-party accreditation or inspection service, the applicant must demonstrate the following to the licensing authority:

(1) The applicant shall have sufficient personnel, with the necessary education, training, skills and experience to review records and perform inspections of prescription drug wholesale distributors.

(2) The applicant shall demonstrate that its personnel are knowledgeable in:

(i) The Act, as amended by the DSCSA;
(ii) The regulations implementing these statutes, particularly this part, and any applicable guidance;
(iii) The prescription drug wholesale distribution licensure requirements, standards, and regulations of the State licensing authority, if applicable; and
(iv) FDA's IOM, RPM, and Field Management Directives concerning inspections.

(d) To be approved by the licensing authority as a third-party accreditation or inspection service, the applicant shall have:

(1) Established, documented, and executed policies and procedures to ensure that inspections are performed by qualified personnel, and should maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the performance of inspections;

(2) Available to its personnel clear, written instructions for duties and responsibilities with respect to inspections;

(3) Identified personnel who are qualified in all of the disciplines necessary for inspection of prescription drug wholesale distributors;

(4) Identified at least one individual who is responsible for providing supervision over inspections and who has sufficient authority and competence to assess the quality and acceptability of inspection reports; and

(5) Identified at least one individual who is sufficiently knowledgeable, competent, impartial, and independent to timely review appeals made by inspected wholesale distributors pursuant to subsection (i) that arise from inspections conducted by the approved third-party accreditation or inspection service.

(e) A third-party accreditation or inspection service must have sufficient infrastructure in order to promptly inspect prescription drug wholesale distributor license applicants and be able to complete the inspection in a timely manner, which shall not exceed 14 days.

(f) The third-party accreditation or inspection service must have physical security and safeguards for protecting trade secret and confidential commercial or financial information.

(g) The third-party accreditation or inspection service may not contract its inspectional duties to another party.

(h) To be approved by a licensing authority as a third-party accreditation or inspection service, the applicant shall:

(1) Complete an FDA-sanctioned training program in DSCSA standards and requirements and inspectional requirements;

(2) Conduct a satisfactory inspection under FDA's observation; and

(3) Promptly submit audit reports of inspected wholesale distributors to the licensing authority.

(i) A third-party accreditation or inspection service shall have procedures in place for the timely resolution of disputes arising during and from inspections, including, but not limited to, complaints of timeliness, competency, inspectional findings, access, and scope. The written procedures shall allow a wholesale distributor to make a written appeal of any such dispute, with appeal first to an independent supervisor within the third-party accreditation or inspection service. If the independent supervisor denies the wholesale distributor's appeal in whole or in part, a wholesale distributor may then make a written appeal of such dispute to the licensing authority. The third-party accreditation or inspection service and licensing authority shall resolve such appeals and disputes in a timely manner which shall not exceed 30 days.

(j) An approved third-party accreditation or inspection service shall renew its approval or accreditation with the licensing authority every 4 years.

Subpart G – Bond

205.70 Bond requirement.

(a) An applicant that is not a government owned and operated wholesale distributor, for the issuance or renewal of a wholesale distributor license shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the licensing authority. The purpose of the surety bond is to secure payment of any administrative fine imposed by the licensing authority and any cost recovery ordered pursuant to the DSCSA and this section.

(b) For purposes of subsection (a), the licensing authority may accept a surety bond less than $100,000 if the annual gross receipts of the previous tax year for the wholesale distributor is $10,000,000 or less, in which case the surety bond shall be $25,000.

(c) Notwithstanding subsection (b), the licensing authority may require a bond up to $100,000 for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the DSCSA.

(d) The licensing authority may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(e) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subsection (a) for all licensed sites under common control.

(f) If a wholesale distributor can provide evidence that it possesses the required surety bond in a State, the requirement for a surety bond in another State shall be waived.