

DIVISION 060

PHARMACEUTICAL MANUFACTURERS

Definitions

855-060-0002

(1) "Affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(3) "Illegitimate product" means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

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

(4) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(5) "Pedigree" for the purpose of this division consists of:

(a) "Transaction History" means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) "Transaction Information" must include but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from who ownership is being transferred; and

(J) The business name and address of the person to who ownership is being transferred.

(c) “Transaction Statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with FDA regulations set forth by the Drug Quality and Security Act and includes but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(6) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

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

(c) Potentially the subject of a fraudulent transaction; or

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

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-060-0004

Registration

(1) Any person that manufactures, or contracts for the manufacture of a drug or prescription device that is intended for sale, distribution, dispensing or administration in Oregon must register with the Oregon Board of Pharmacy.

(2) Any person that holds one or more of the following registrations with the Federal Food and Drug Administration (FDA) must register as a Manufacturer.

(a) A New Drug Application number (NDA);

(b) An Abbreviated New Drug Application number (ANDA);

(c) A Labeler Code number (LC) or National Drug Code number (NDC);

(d) An FDA Central File Number (CFN);

(e) An FDA Establishment Identifier number (FEI).

(f) A Biologic License Application (BLA).

(g) An Outsourcing Facility Registration.

(3) A person that is registered with the FDA as a repackager must register as a Manufacturer.

(4) A person **who is a third-party logistics provider as defined in Division 62 or** whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a manufacturer, **but does not take physical possession of a product** must register as a Drug Distribution Agent under **Division 62-OAR 855-062-0005**.

(5) A person who is registered with the FDA as the Agent for a foreign manufacturer must register as a Drug Distribution Agent under **Division 62-OAR 855-062-0005**.

(6) An applicant for a new or renewal of registration must provide all information specified on the form provided by the Board, and pay the fee as specified in OAR 855-110-0007. The applicant must also provide any additional information requested by the Board. An application that does not contain all required information is incomplete and will not be processed.

(7) The registration is non-transferable. Addition or deletion of an owner shall be considered as a change of ownership except where the registrant is a publicly held corporation. A new application for registration and payment of a new registration fee is required when a registrant changes ownership or location. This new application must be submitted to the Board at least 15 days prior to the change.

(8) A person who compounds a drug that is distributed in Oregon not based on a patient specific prescription must register with the Board as a Manufacturer, unless done so pursuant to a Shared Pharmacy Services agreement, as defined in OAR 855-006-0005, between two in-state entities.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155 & 689.305

855-060-0015

Classification of Manufacturers

(1) Class I. A Class I manufacturer is required to employ an Oregon licensed pharmacist or a person approved by the Board who by experience and education possesses the necessary qualifications to supervise manufacturing procedures for United States Pharmacopeia, National Formulary, Accepted Dental Remedies products and including the manufacture of other internal medicines, controlled substances, dangerous external preparations, injectables, products requiring the prescription legend, poisons, and pure (U.S.P. and N.F. chemicals).

(2) Class II. A Class II manufacturer is required to employ personnel with a Bachelor of Science degree or equivalent, but not necessarily a licensed pharmacist to supervise manufacturing procedures **and must comply with 503B manufacturing requirements of 21 USC 353 and is exempted from labeling and research requirements**, which are limited to non-toxic external preparations intended for preventative medication including antiseptics, germicides, detergents, or other agents intended for use in sanitation and not regulated by some other state agency.

(3) Class III. Repackagers or distributors of non-legend drugs will not be required to have a licensed pharmacist in charge, but is required to have competent supervisory personnel.

Stat. Auth.: ORS 689.205

Stats. Implemented: **ORS 689.155**

855-060-0027

Identification of Prescription Drugs

(1) All prescription drug products in tablet or capsule form intended for oral administration will be required to be specifically identified. These drug products, when sold or distributed in Oregon after January 1, 1983, must be marked by the manufacturer with a code imprint identifying the drug product and the manufacturer or distributor of the drug product.

(2) "Code imprint" means an individual symbol, number, company name, words, letters, marking, National Drug Code, or any combination thereof, identifying the drug product and the manufacturer or distributor of the drug product.

(3) Exceptions to the requirement are:

(a) Drug products purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held for resale;

(b)(a) Drug products which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed;

(e)(b) Drug products which are used for experimentation or research purposes;

(d)(c) The Board of Pharmacy, upon application of a manufacturer or distributor, may also exempt a particular drug product from the requirements of this regulation on the grounds that imprinting is not feasible because of such drug product's size, texture, or other unique characteristics.

Stat. Auth.: ORS 475 & ORS 689.205

Stats. Implemented: **ORS 689.155**

855-060-0029

Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated **and illegitimate products** shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315

Stats. Implemented: **ORS 689.155**