

DIVISION 60

PHARMACEUTICAL MANUFACTURERS

855-060-0004

Registration

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

(2) A 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).

(3) An NDA or ANDA holder that contracts with a third-party for the manufacture of its product and does not take physical possession of the product must register as a manufacturer if it is responsible or otherwise accountable to the FDA for the manufacture of the drug, otherwise it must register as a Drug Distribution Agent under OAR 855-062-0005;

(4) A private label manufacturer or distributor selling under its own labeler code that does not take physical possession of the product must register as a manufacturer if it is responsible or otherwise accountable to the FDA for the manufacture of the drug, otherwise it must register as a Drug Distribution Agent under OAR 855-062-0005.

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

(6) A person whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a registered manufacturer, but does not take physical possession of a product must register as a Drug Distribution Agent under OAR 855-062-0005, however a person that is registered with the Board as a manufacturer does not also need to register as a Drug Distribution Agent.

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

(8) 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.

(9) The registration is non-transferable. Addition or deletion of an owner shall be considered as a change of ownership except where the applicant 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 within 15 days.

(10) Notwithstanding any of the above sections, a person who compounds a drug, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006-0005, who does not otherwise qualify as a manufacturer, does not need to register with the Board as a manufacturer.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.305