

DIVISION 60

PHARMACEUTICAL MANUFACTURERS

855-060-0003(T)

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 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).

(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.

(7) A person who is registered as the Agent for a foreign manufacturer under 21 USC 360(2)(i)(1) must register as a Drug Distribution Agent under OAR 855-062-0005.

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155