

DIVISION 60

PHARMACEUTICAL MANUFACTURERS

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