

657—20.2 (124,126,155A) Definitions. For the purposes of this chapter, the following definitions apply:

“*Bulk drug substance*” means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

“*Component*” means any ingredient, other than a bulk drug substance, intended for use in the compounding of a drug product, including those ingredients that may not be identifiable in the final product.

“*Compounding*” means preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner’s prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, is to be done pursuant to a prescription. Compounding also includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns pursuant to subrule 20.3(3). Compounding does not include mixing or reconstituting a drug according to the product’s labeling or to the manufacturer’s directions.

“*FDA*” means the Food and Drug Administration of the U.S. Department of Health and Human Services.

“*Manufacturing*” means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the drug’s or device’s container. Manufacturing also includes the promotion, marketing, or preparation from bulk drug substances of commercially available products for resale by pharmacists, practitioners, or other persons.