WAC 246-895-010 Definitions. (1) As used in these regulations, "act" means the Uniform Food, Drug and Cosmetic Act, chapter 69.04 RCW.

(2) The definitions and interpretations contained in the act shall be applicable to such terms used in these regulations.

(3) As used in these regulations:

(a) The term "component" means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in the finished product.

(b) The term "drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(c) The term "active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(d) The term "inactive ingredient" means any component other than an "active ingredient" present in a drug product.

(e) The term "batch" means a specific quantity of a drug or other material that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(f) The term "lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(g) The terms "lot number," "control number," or "batch number" mean any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(h) The term "quality control unit" means any person or organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(i) The term "strength" means:

(i) The concentration of the drug product (for example, w/w, w/v, or unit dose/volume basis); and/or

(ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

(j) The term "fiber" means any particulate contaminant with a length at least three times greater than its width.

(k) The term "nonfiber-releasing filter" means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

(l) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages or labels such substance or device.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-895-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-010, filed 10/10/88; Order 133, § 360-46-010, filed 8/4/77.]