



21 C.F.R. § 600.3

CODE OF FEDERAL REGULATIONS
TITLE 21—FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER F—BIOLOGICS
PART 600—BIOLOGICAL PRODUCTS: GENERAL
SUBPART A—GENERAL PROVISIONS
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§ 600.3 Definitions.

As used in this subchapter:

- (a) “Act” means the Public Health Service Act (58 Stat. 682), approved July 1, 1944.
- (b) “Secretary” means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.
- (c) “Commissioner of Food and Drugs” means the Commissioner of the Food and Drug Administration.
- (d) “Center for Biologics Evaluation and Research” means Center for Biologics Evaluation and Research of the Food and Drug Administration.
- (e) “State” means a State or the District of Columbia, Puerto Rico, or the Virgin Islands.
- (f) “Possession” includes among other possessions, Puerto Rico and the Virgin Islands.
- (g) “Products” includes biological products and trivalent organic arsenicals.
- (h) “Biological product” means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man:
 - (1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.
 - (2) A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.
 - (3) A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less (or equivalent in weight) of the product, and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized.
 - (4) An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.
 - (5) A product is analogous:
 - (i) To a virus if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.
 - (ii) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum.
 - (iii) To a toxin or antitoxin, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process.

- (i) “Trivalent organic arsenicals” means arsphenamine and its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man.
- (j) A product is deemed “applicable to the prevention, treatment, or cure of diseases or injuries of man” irrespective of the mode of administration or application recommended, including use when intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product.
- (k) “Proper name”, as applied to a product, means the name designated in the license for use upon each package of the product.
- (l) “Dating period” means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.
- (m) “Expiration date” means the calendar month and year, and where applicable, the day and hour, that the dating period ends.
- (n) The word “standards” means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter and which are designed to insure the continued safety, purity and potency of such products.
- (o) The word “continued” as applied to the safety, purity and potency of products is interpreted to apply to the dating period.
- (p) The word “safety” means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.
- (q) The word “sterility” is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests prescribed in § 610.12 of this chapter.
- (r) “Purity” means **relative freedom from extraneous matter in the finished product**, whether or not harmful to the recipient or deleterious to the product. “Purity” includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.
- (s) The word “potency” is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.
- (t) “Manufacturer” means any legal person or entity engaged in the manufacture of a product subject to license under the act; “Manufacturer” also includes any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards.
- (u) “Manufacture” means all steps in propagation or manufacture and preparation of products and includes but is not limited to filling, testing, labeling, packaging, and storage by the manufacturer.
- (v) “Location” includes all buildings, appurtenances, equipment and animals used, and personnel engaged by a manufacturer within a particular area designated by an address adequate for identification.
- (w) “Establishment” includes all locations.
- (x) “Lot” means that quantity of uniform material identified by the manufacturer as having been thoroughly mixed in a single vessel.
- (y) A “filling” refers to a group of final containers identical in all respects, which have been filled with the same product from the same bulk lot without any change that will affect the integrity of the filling assembly.
- (z) “Process” refers to a manufacturing step that is performed on the product itself which may affect its safety, purity or potency, in contrast to such manufacturing steps which do not affect intrinsically the safety, purity or potency of the product.
- (aa) “Selling agent” or “distributor” means any person engaged in the unrestricted distribution, other than by

sale at retail, of products subject to license.

(bb) "Container" (referred to also as "final container") is the immediate unit, bottle, vial, ampule, tube, or other receptacle containing the product as distributed for sale, barter, or exchange.

(cc) "Package" means the immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers. If no package, as defined in the preceding sentence, is used, the container shall be deemed to be the package.

(dd) "Label" means any written, printed, or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle, or wrapper.

(ee) "Radioactive biological product" means a biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(ff) Amendment is the submission of information to a pending license application or supplement, to revise or modify the application as originally submitted.

(gg) Supplement is a request to the Director, Center for Biologics Evaluation and Research, to approve a change in an approved license application.

[[38 FR 32048](#), Nov. 20, 1973, as amended at [40 FR 31313](#), July 25, 1975; [49 FR 23833](#), June 8, 1984; [55 FR 11014](#), March 26, 1990; [61 FR 24232](#), May 14, 1996; [62 FR 39901](#), July 24, 1997]

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