

§ 310.3

21 CFR Ch. I (4–1–08 Edition)

Subpart D—Records and Reports

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- 310.533 Drug products containing active ingredients offered over-the-counter (OTC) for human use as an anticholinergic in cough-cold drug products.
- 310.534 Drug products containing active ingredients offered over-the-counter (OTC) for human use as oral wound healing agents.
- 310.536 Drug products containing active ingredients offered over-the-counter (OTC) for use as a nailbiting or thumbsucking deterrent.
- 310.537 Drug products containing active ingredients offered over-the-counter (OTC) for oral administration for the treatment of fever blisters and cold sores.
- 310.538 Drug products containing active ingredients offered over-the-counter (OTC) for use for ingrown toenail relief.
- 310.540 Drug products containing active ingredients offered over-the-counter (OTC) for use as stomach acidifiers.
- 310.541 Over-the-counter (OTC) drug products containing active ingredients offered for use in the treatment of hypophosphatemia.
- 310.542 Over-the-counter (OTC) drug products containing active ingredients offered for use in the treatment of hyperphosphatemia.
- 310.543 Drug products containing active ingredients offered over-the-counter (OTC) for human use in exocrine pancreatic insufficiency.
- 310.544 Drug products containing active ingredients offered over-the-counter (OTC) for use as a smoking deterrent.
- 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.
- 310.546 Drug products containing active ingredients offered over-the-counter (OTC) for the treatment and/or prevention of nocturnal leg muscle cramps.
- 310.547 Drug products containing quinine offered over-the-counter (OTC) for the treatment and/or prevention of malaria.
- 310.548 Drug products containing colloidal silver ingredients or silver salts offered over-the-counter (OTC) for the treatment and/or prevention of disease.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

Subpart A—General Provisions

§ 310.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 et seq., as amended; 21 U.S.C. 321–392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) The term *person* includes individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) *New drug substance* means any substance that when used in the manufacture, processing, or packing of a drug, causes that drug to be a new drug, but does not include intermediates used in the synthesis of such substance.

(h) The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for a drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(i) [Reserved]

(j) The term *sponsor* means the person or agency who assumes responsibility for an investigation of a new drug, including responsibility for compliance with applicable provisions of the act and regulations. The "sponsor" may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new drugs.

(k) The phrase *related drug(s)* includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety, including articles prepared or manufactured by other manufacturers: and any other drug containing a com-

ponent so related by chemical structure or known pharmacological properties that, in the opinion of experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, it is prudent to assume or ascertain the liability of similar side effects and contraindications.

(l) *Special packaging* as defined in section 2(4) of the Poison Prevention Packaging Act of 1970 means packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(m) [Reserved]

(n) The term *radioactive drug* means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product" as defined in §600.3(ee) of this chapter.

[39 FR 11680, Mar. 29, 1974, as amended at 39 FR 20484, June 11, 1974; 40 FR 31307, July 25, 1975; 46 FR 8952, Jan. 27, 1981; 50 FR 7492, Feb. 22, 1985]

§ 310.4 **Biologics; products subject to license control.**

(a) If a drug has an approved license under section 351 of the Public Health Service Act (42 U.S.C. 262 *et seq.*) or under the animal virus, serum, and toxin law of March 4, 1913 (21 U.S.C. 151 *et seq.*), it is not required to have an approved application under section 505 of the act.

(b) To obtain marketing approval for radioactive biological products for human use, as defined in §600.3(ee) of