

§ 310.502

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drug's use, and a statement of the risks and benefits associated with the drug's use.

(3) A statement comparing the effectiveness of oral contraceptives to other methods of contraception.

(4) A boxed warning concerning the increased risks associated with cigarette smoking and oral contraceptive use.

(5) A discussion of the contraindications to use, including information that the patient should provide to the prescriber before taking the drug.

(6) A statement of medical conditions that are not contraindications to use but deserve special consideration in connection with oral contraceptive use and about which the patient should inform the prescriber.

(7) A warning regarding the most serious side effects of oral contraceptives.

(8) A statement of other serious adverse reactions and potential safety hazards that may result from the use of oral contraceptives.

(9) A statement concerning common, but less serious side effects which may help the patient evaluate the benefits and risks from the use of oral contraceptives.

(10) Information on precautions the patients should observe while taking oral contraceptives, including the following:

(i) A statement of risks to the mother and unborn child from the use of oral contraceptives before or during early pregnancy;

(ii) A statement concerning excretion of the drug in human milk and associated risks to the nursing infant;

(iii) A statement about laboratory tests which may be affected by oral contraceptives; and

(iv) A statement that identifies activities and drugs, foods, or other substances the patient should avoid because of their interactions with oral contraceptives.

(11) Information about how to take oral contraceptives properly, including information about what to do if the patient forgets to take the product, information about becoming pregnant after discontinuing use of the drug, a statement that the drug product has been prescribed for the use of the patient

and should not be used for other conditions or given to others, and a statement that the patient's pharmacist or practitioner has a more technical leaflet about the drug product that the patient may ask to review.

(12) A statement of the possible benefits associated with oral contraceptive use.

(13) The following information about the drug product and the patient package insert:

(i) The name and place of business of the manufacturer, packer, or distributor, or the name and place of business of the dispenser of the product.

(ii) The date, identified as such, of the most recent revision of the patient package insert placed prominently immediately after the last section of the labeling.

(d) *Other indications.* The patient package insert may identify indications in addition to contraception that are identified in the professional labeling for the drug product.

(e) *Labeling guidance texts.* The Food and Drug Administration issues informal labeling guidance texts under §10.90(b)(9) of this chapter to provide assistance in meeting the requirements of this section. A request for a copy of the guidance texts should be directed to the Center for Drug Evaluation and Research, Division of Metabolism and Endocrine Drug Products (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(f) *Requirement to supplement approved application.* Holders of approved applications for oral contraceptive drug products that are subject to the requirements of this section are required to submit supplements under §314.70(c) of this chapter to provide for the labeling required by this section. Such labeling may be put into use without advance approval by the Food and Drug Administration.

[54 FR 22587, May 25, 1989]

§310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. An approved new drug application under

section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

- (1) Aerosol drug products for human use containing 1,1,1-trichloroethane.
- (2) Aerosol drug products containing zirconium.
- (3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.
- (4) Camphorated oil drug products.
- (5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4',5'-tribromosalicylanilide), dibromsalan (DBS, 4', 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3', 4,5'-tetrachlorosalicylanilide (TC-SA)) as an ingredient in drug products.
- (6) Chloroform used as an ingredient (active or inactive) in drug products.
- (7) Cobalt preparations intended for use by man.
- (8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.
- (9) Oral prenatal drugs containing fluorides intended for human use.
- (10) Parenteral drug products in plastic containers.
- (11) Sterilization of drugs by irradiation.
- (12) Sweet spirits of nitre drug products.
- (13) Thorium dioxide for drug use.
- (14) Timed release dosage forms.
- (15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) [Reserved]

[62 FR 12084, Mar. 14, 1997, as amended at 64 FR 401, Jan. 5, 1999]

§ 310.503 Requirements regarding certain radioactive drugs.

(a) On January 8, 1963 (28 FR 183), the Commissioner of Food and Drugs exempted investigational radioactive new drugs from part 312 of this chapter provided they were shipped in complete conformity with the regulations issued by the Nuclear Regulatory Commission. This exemption also applied to investigational radioactive biologics.

(b) It is the opinion of the Nuclear Regulatory Commission, and the Food and Drug Administration that this ex-

emption should not apply for certain specific drugs and that these drugs should be appropriately labeled for uses for which safety and effectiveness can be demonstrated by new drug applications or through licensing under the Public Health Service Act (42 U.S.C. 262 *et seq.*) in the case of biologics. Continued distribution under the investigational exemption when the drugs are intended for established uses will not be permitted.

(c) Based on its experience in regulating investigational radioactive pharmaceuticals, the Nuclear Regulatory Commission has compiled a list of reactor-produced isotopes for which it considers that applicants may reasonably be expected to submit adequate evidence of safety and effectiveness for use as recommended in appropriate labeling. Such use may include, among others, the uses in this tabulation:

Isotope	Chemical form	Use
Chromium 51 ...	Chromate	Spleen scans.
Dodo	Placenta localization.
Dodo	Red blood cell labeling and survival studies.
Do	Labeled human serum albumin.	Gastrointestinal protein loss studies.
Dodo	Placenta localization.
Do	Labeled red blood cells.	Do.
Cobalt 58 or Cobalt 60.	Labeled cyanocobalamin.	Intestinal absorption studies.
Gold 198	Colloidal	Liver scans.
Dodo	Intracavitary treatment of pleural effusions and/or ascites.
Dodo	Interstitial treatment of cancer.
Iodine 131	Iodide	Diagnosis of thyroid functions.
Dodo	Thyroid scans.
Dodo	Treatment of hyperthyroidism and/or cardiac dysfunction.
Dodo	Treatment of thyroid carcinoma.
Do	Iodinated human serum albumin.	Blood volume determinations.
Dodo	Cisternography.
Dodo	Brain tumor localization.
Dodo	Placenta localization.
Dodo	Cardiac scans for determination of pericardial effusions.