SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 300—GENERAL

Subpart A [Reserved]

Subpart B—Combination Drugs

Subpart C—Substances Generally Prohibited From Drugs

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AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 360b, 360bbb-0a, 371.

Subpart A [Reserved]

Subpart B—Combination Drugs

§ 300.50 Fixed-combination prescription drugs for humans.

The Food and Drug Administration's policy in administering the new-drug, antibiotic, and other regulatory provisions of the Federal Food, Drug, and Cosmetic Act regarding fixed combination dosage form prescription drugs for humans is as follows:

(a) Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. Special cases of this general rule are where a component is added:

(1) To enhance the safety or effectiveness of the principal active component; and

(2) To minimize the potential for abuse of the principal active component.

(b) If a combination drug presently the subject of an approved new-drug application has not been recognized as effective by the Commissioner of Food and Drugs based on his evaluation of the appropriate National Academy of Sciences-National Research Council panel report, or if substantial evidence of effectiveness has not otherwise been presented for it, then formulation, labeling, or dosage changes may be proposed and any resulting formulation may meet the appropriate criteria listed in paragraph (a) of this section.

(c) A fixed-combination prescription drug for humans that has been determined to be effective for labeled indications by the Food and Drug Administration, based on evaluation of the NAS-NRC report on the combination, is considered to be in compliance with the requirements of this section.

[40 FR 13496, Mar. 27, 1975, as amended at 64 FR 401, Jan. 5, 1999]

Subpart C—Substances Generally Prohibited From Drugs

§ 300.100 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human drugs as propellants in self-pressurized containers is generally prohibited except as provided by § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

Subpart D—Annual Summary Reporting Requirements.

SOURCE: 87 FR 56276, Sept. 14, 2022, unless otherwise noted.

§ 300.200 Annual summary requirements under the Right to Try Act.

(a) Definitions: The following definitions of terms apply only to this section:

(1) *Eligible investigational drug.* An eligible investigational drug is as defined in section 561B(a)(2) of the Federal Food, Drug, and Cosmetic Act.

(2) *Eligible patient.* An eligible patient is as defined in section 561B(a)(1) of the Federal Food, Drug, and Cosmetic Act.