SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 300—GENERAL

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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.

(3) *Investigational New Drug (IND).* An IND is as defined in §312.3 of this chapter.

(4) *Known serious adverse event.* A serious adverse event (as defined in §312.32 of this chapter) is considered ''known'' if the manufacturer or sponsor is aware of it.

(5) *Manufacturer or sponsor.* A manufacturer or sponsor is the person who:

(i) Meets the definition of ''sponsor'' in §312.3 of this chapter for the eligible investigational drug;

(ii) Has submitted an application for the eligible investigational drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; or

(iii) Is other than a contract manufacturer acting on behalf of a manufacturer or sponsor, producing the eligible investigational drug provided to an eligible patient on behalf of the persons described in paragraph (a)(5)(i) or (ii) of this section.

(b)(1) Except as described in paragraph (b)(2) of this section, a manufacturer or sponsor of an eligible investigational drug shall submit to the Food and Drug Administration (FDA), no later than March 31 of each year, an annual summary of any use of eligible investigational drugs supplied to any eligible patient under section 561B of the Federal Food, Drug, and Cosmetic Act for the period of January 1 through December 31 of the preceding year.

(2) For a manufacturer or sponsor of an eligible investigational drug that has supplied an eligible patient with an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act between the period from enactment of section 561B (May 30, 2018) and December 31, 2022, the manufacturer or sponsor shall submit to FDA a first annual summary covering that period no later than March 31, 2023.

(c) For each eligible investigational drug, the annual summary must include:

(1) *The name of the eligible investigational drug and applicable IND number.* The name and IND number of the eligible investigational drug supplied by the manufacturer or sponsor for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(2) *Number of doses supplied.* The total number of doses supplied by the manufacturer or sponsor to eligible patients for use under section 561B of the Federal Food, Drug, and Cosmetic Act. Each dose of an eligible investigational drug supplied for an eligible patient shall be counted as a dose supplied.

(3) *Number of patients treated.* The total number of eligible patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under section 561B of the Federal Food, Drug, and Cosmetic Act. An eligible patient treated more than one time or with multiple doses of an eligible investigational drug shall be counted as a single patient.

(4) *Use for which the eligible investigational drug was made available.* A tabular summary identifying the diseases or conditions for which the eligible investigational drug was made available for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(5) *Any known serious adverse events and outcomes.* A tabular summary of any known serious adverse events, including resulting outcomes, experienced by patients treated with the eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(d) Annual summaries submitted pursuant to this section shall be submitted in an electronic format that FDA can process, review, and archive, and shall be sent directly to a designated point of contact for submissions made under section 561B of the Federal Food, Drug, and Cosmetic Act. The annual summaries must be submitted to the designated point of contact and shall not be submitted to a particular investigational new drug application. FDA will specify the designated point of contact for submission of the annual summary on FDA's website, as described at *https://www.fda.gov*.

PART 310—NEW DRUGS

Subpart A—General Provisions

Sec.

310.3 Definitions and interpretations.