§ 290.6 Label of a controlled substance dispensed for use in clinical investigations which are “blind.”

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, §290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.” The Spanish version of this is: “Precaucion: La ley Federal prohíbe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada.”

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term emergency situation means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

Sec. 299.3 Definitions and interpretations.

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299.4 Established names for drugs.

299.5 Drugs; compendial name.


Source: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.
Food and Drug Administration, HHS

§ 299.5 Drugs; compendial name.

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium.

(b) The term drug defined in an official compendium means a drug having the identity prescribed for a drug in an official compendium.
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(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.