

whom obesity is refractory to other measures. For purposes of this regulation, a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity.

(c) The Food and Drug Administration is not aware of data providing substantial evidence of the effectiveness of levamfetamine and its salts and regards these preparations as new drugs requiring approved full new drug applications.

(d) In view of the well-documented history of abuse of parenteral amphetamines, the severe risk of drug dependence, and the availability of safer alternative parenteral drugs which are equally effective for recognized non-anorectic indications, the Food and Drug Administration regards parenteral amphetamines as lacking evidence of safety.

(e) Any combination drug containing amphetamine or dextroamphetamine is regarded as a new drug requiring an approved full new drug application as a condition for marketing. Data in new drug applications are required to fulfill the criteria set forth in §300.50 of this chapter governing fixed combination prescription drugs for humans.

(f) New drug applications have been received from persons marketing orally administered single entity amphetamine or dextroamphetamine dosage forms. Any other person who intends to market such drug is required to submit to the Food and Drug Administration an abbreviated application under §314.55 of this chapter.

(g) The labeling conditions for single entity oral dosage forms of amphetamine and dextroamphetamine and their salts are as follows:

(1) The label shall bear the statement "Caution: Federal law prohibits dispensing without prescription".

(2) The drug shall be labeled to comply with all requirements of the act and regulations. The labeling shall bear adequate information for safe and effective use of the drug. The indications for use are:

Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Management of exogenous obesity as short-term (a few weeks) adjunct in a regi-

men of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulation.

[39 FR 11680, Mar. 29, 1974, as amended at 41 FR 10885, Mar. 15, 1976; 55 FR 11578, Mar. 29, 1990]

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §310.504 was removed, effective Apr. 14, 1997.

§ 310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness when inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) Clinical investigations designed to obtain evidence that any aerosol drug preparation containing vinyl chloride as an ingredient, including propellant, is safe and effective for the purpose intended, must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

Food and Drug Administration, HH.

(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

[39 FR 30830, Aug. 26, 1974, as amended FR 11578, Mar. 29, 1990]

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §310.506 was removed, effective 14, 1997.

§ 310.507 Aerosol drug products human use containing 1 trichloroethane.

(a) Trichloroethane has been used in aerosol drug products as a solvent for the active ingredients and to reduce the vapor pressure of the propellant. It is potentially toxic to the cardiovascular system, i.e., can sensitize the heart to epinephrine. At a sufficient large concentration, it is a potent anesthetic agent. Deaths associated with aerosol decongestant products intended to be inhaled and containing trichloroethane have been reported. Most of the deaths resulted from abuse or gross misuse of the preparations.

(b) The Food and Drug Administration finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of trichloroethane in aerosol drug products intended for inhalation either directly or indirectly. Any aerosol drug product containing trichloroethane as a propellant, labeled, represented, or advertised for use by inhalation is a new drug and is subject to regulatory proceedings unless it is the subject of a new drug application approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

(c) Clinical investigations designed to obtain evidence that any aerosol drug product containing trichloroethane as a propellant, labeled, represented, or advertised for use by inhalation either directly or indirectly, is safe and effective for the purposes intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act wh-