§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

(1) *Aspirin.* Any aspirin-containing preparation for human use in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following:

(i) Effervescent tablets containing aspirin, other than those intended for pediatric use, provided the dry tablet contains not more than 15 percent aspirin and has an oral LD–50 in rats of 5 grams or more per kilogram of body weight.

(ii) Unflavored aspirin-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 15.4 grains of aspirin per unit dose and that contain no other substance subject to the provisions of this section.

(2) *Furniture polish.* Nonemulsion type liquid furniture polishes containing 10 percent or more of mineral seal oil and/or other petroleum distillates and having a viscosity of less than 100 Saybolt universal seconds at 100 °F., other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (d).

(3) *Methyl salicylate.* Liquid preparations containing more than 5 percent by weight of methyl salicylate, other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(4) *Controlled drugs.* Any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 *et seq.*) and that is in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(5) *Sodium and/or potassium hydroxide.* Household substances in dry forms such as granules, powder, and flakes, containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(6) *Turpentine.* Household substances in liquid form containing 10 percent or more by weight of turpentine shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(7) *Kindling and/or illuminating preparations.* Prepackaged liquid kindling and/or illuminating preparations, such as cigarette lighter fuel, charcoal lighter fuel, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns, which contain 10 percent or more by weight of petroleum distillates and have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(8) *Methyl alcohol (methanol).* Household substances in liquid form containing 4 percent or more by weight of methyl alcohol (methanol), other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(9) *Sulfuric acid.* Household substances containing 10 percent or more by weight of sulfuric acid, except such substances in wet-cell storage batteries, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(10) *Prescription drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with

the provisions of §1700.15 (a), (b), and (c), except for the following:

(i) Sublingual dosage forms of nitroglycerin.

(ii) Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.

(iii) Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams of the equivalent of erythromycin.

(iv) Cyclically administered oral contraceptives in manufacturers' mnemonic (memory-aid) dispenser packages that rely solely upon the activity of one or more progestogen or estrogen substances.

(v) Anhydrous cholestyramine in powder form.

(vi) All unit dose forms of potassium supplements, including individually-wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit-dose packets, containing not more than 50 milliequivalents of potassium per unit dose.

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this §1700.14(a)(10).

(viii) Betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams betamethasone.

(ix) Pancrelipase preparations in tablet, capsule, or powder form and containing no other substances subject to this §1700.14(a)(10).

(x) Prednisone in tablet form, when dispensed in packages containing no more than 105 mg. of the drug, and containing no other substances subject to this §1700.14(a)(10).

(xi)–(xii) [Reserved]

(xiii) Mebendazole in tablet form in packages containing not more than 600 mg. of the drug, and containing no other substance subject to the provisions of this section.

(xiv) Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug and containing no other substance subject to the provisions of this section.

(xv) Colestipol in powder form in packages containing not more than 5 grams of the drug and containing no other substance subject to the provisions of this section.

(xvi) Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.

(xvii) Conjugated Estrogens Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 32.0 mg of the drug and containing no other substances subject to this §1700.14(a)(10).

(xviii) Norethindrone Acetate Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 50 mg of the drug and containing no other substances subject to this §1700.14(a)(10).

(xix) Medroxyprogesterone acetate tablets.

(xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

(xxii) Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.

(xxiii) Sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug.

(11) *Ethylene glycol.* Household substances in liquid form containing 10 percent or more by weight of ethylene glycol packaged on or after June 1, 1974, except those articles exempted by 16 CFR 1500.83, shall be packaged in accordance with the provisions of §1700.15 (a) and (b).

(12) *Iron-containing drugs.* With the exception of: (i) Animal feeds used as vehicles for the administration of drugs, and (ii) those preparations in which iron is present solely as a colorant, noninjectable animal and human drugs providing iron for therapeutic or prophylactic purposes, and containing a total amount of elemental iron, from any source, in a single package, equivalent to 250 mg or more elemental iron in a concentration of 0.025

percent or more on a weight to volume basis for liquids and 0.025 percent or more on a weight to volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c).

(13) *Dietary supplements containing iron.* Dietary supplements, as defined in §1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

(14) [Reserved]

(15) *Solvents for paint or other similar surface-coating material.* Prepackaged liquid solvents (such as removers, thinners, brush cleaners, etc.) for paints or other similar surface-coating materials (such as varnishes and lacquers), that contain 10 percent or more by weight of benzene (also known as benzol), toluene (also known as toluol), xylene (also known as xylol), petroleum distillates (such as gasoline, kerosene, mineral seal oil, mineral spirits, naphtha, and Stoddard solvent, etc.), or combinations thereof, and that have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of §1700.15 (a) and (b).

(16) *Acetaminophen.* Preparations for human use in a dosage form intended for oral administration and containing in a single package a total of more than one gram acetaminophen shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c), except the following—

(i) Effervescent tablets or granules containing acetaminophen, provided the dry tablet or granules contain less than 15 percent acetaminophen, the tablet or granules have an oral LD–50 of 5 grams or greater per kilogram of body weight, and the tablet or granules contain no other substance subject to the provisions of this section.

(ii) Unflavored acetaminophen-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 13 grains of acetaminophen per unit dose and that contain no other substance subject to this §1700.14(a).

(17) *Diphenhydramine.* Preparations for human use in a dosage form intended for oral administration and containing more than the equivalent of 66 mg diphenhydramine base in a single package shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c), if packaged on or after February 11, 1985.

(18) *Glue removers containing acetonitrile.* Household glue removers in a liquid form containing more than 500 mg of acetonitrile in a single container.

(19) *Permanent wave neutralizers containing sodium bromate or potassium bromate.* Home permanent wave neutralizers, in a liquid form, containing in single container more than 600 mg of sodium bromate or more than 50 mg of potassium bromate.

(20) *Ibuprofen.* Ibuprofen preparations for human use in a dosage form intended for oral administration and containing one gram (1,000 mg) or more of ibuprofen in a single package shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c).

(21) *Loperamide.* Preparations for human use in a dosage form intended for oral administration and containing more than 0.045 mg of loperamide in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c).

(22) *Mouthwash.* Except as provided in the following sentence, mouthwash preparations for human use and containing 3 g or more of ethanol in a single package shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c). Mouthwash products with nonremovable pump dispensers

that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single unit are exempt from this requirement. The term ''mouthwash'' includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

(23) *Lidocaine.* Products containing more than 5.0 mg of lidocaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of §1700.15 (a) and (b).

(24) *Dibucaine.* Products containing more than 0.5 mg of dibucaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of §1700.15 (a) and (b).

(25) *Naproxen.* Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c).

(26) *Ketoprofen.* Ketoprofen preparations for human use and containing more than 50 mg of ketoprofen in a single retail package shall be packaged in accordance with the provisions of §1700.15 (a), (b) and (c).

(27) *Fluoride.* Household substances containing more than the equivalent of 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of §1700.15(a), (b) and (c).

(28) *Minoxidil.* Minoxidil preparations for human use and containing more than 14 mg of minoxidil in a single retail package shall be packaged in accordance with the provisions of §1700.15(a), (b) and (c). Any applicator packaged with the minoxidil preparation and which it is reasonable to expect may be used to replace the original closure shall also comply with the provisions of §1700.15(a), (b) and (c).

(29) *Methacrylic acid.*Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of §1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

(30) *Over-the-Counter Drug Products.* (i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) of this section to be in special packaging, shall be packaged in accordance with the provisions of §1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products approved for OTC marketing based on an application for OTC marketing submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this §1700.14 otherwise applicable to an OTC drug product remains in effect.

(ii) For purposes of this paragraph (30), *active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and *drug product* means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms

are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 (2001) and 21 CFR 314.3 (2000), respectively.)

(31) *Hazardous substances containing low-viscosity hydrocarbons.* All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (*e.g.*, aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners. For purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(32) *Drugs and cosmetics containing low-viscosity hydrocarbons.* All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (*e.g.*, aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads. For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(33) *Imidazolines.* Any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package, must be packaged in accordance with the provisions of § 1700.15(a), (b), and (c).

(b) *Sample packages.* (1) The manufacturer or packer of any of the substances listed under paragraph (a) of this section as substances requiring special packaging shall provide the Commission with a sample of each type of special packaging, as well as the labeling for each size product that will be packaged in special packaging and the labeling for any noncomplying package. Sample packages and labeling should be sent to the Consumer Product Safety Commission, Office of Compliance, 4330 East West Highway, Washington, DC 20207.

(2) Sample packages should be submitted without contents when such contents are unnecessary for demonstrating the effectiveness of the packaging.

(3) Any sample packages containing drugs listed under paragraph (a) of this section shall be sent by registered mail.

(4) As used in paragraph (b)(1) of this section, the term *manufacturer or packer* does not include pharmacists and other individuals who dispense, at the retail or user level, drugs listed under paragraph (a) of this section as requiring special packaging.

(c) *Applicability.* Special packaging standards for drugs listed under paragraph (a) of this section shall be in addition to any packaging requirements of the Federal Food, Drug, and Cosmetic Act or regulations promulgated thereunder or of any official compendia recognized by that act.

(Pub. L. 91–601, secs. 2(4), 3, 5, 85 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92–573, 86 Stat. 1231; 15 U.S.C. 2079(a))

[38 FR 21247, Aug. 7, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1700.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as ''special packaging'' within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with §1700.14.

(a) *General requirements.* The special packaging must continue to function with the effectiveness specifications set forth in paragraph (b) of this section when in actual contact with the substance contained therein. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging. The special packaging must also continue to function with the effectiveness specifications set forth in paragraph (b) of this section for the number of openings and closings customary for its size and contents. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other such relevant factors which establish that, for the duration of normal use, the effectiveness specifications of the packaging would not be expected to lessen.

(b) *Effectiveness specifications.* Special packaging, tested by the method described in §1700.20, shall meet the following specifications:

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) *Ease of adult opening*—(i) *Senior-adult test.* Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of §1700.20(a)(3).

(ii) *Younger-adult test*—(A) *When applicable.* Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of §1700.20(a)(4). The senior-adult panel test of §1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

(B) *Determination of need for metal or aerosol container—(1) Criteria.* A product will be deemed to require metal containers or aerosol form only if:

(*i*) No other packaging type would comply with other state or Federal regulations,

(*ii*) No other packaging can reasonably be used for the product's intended application,

(*iii*) No other packaging or closure material would be compatible with the substance,

(*iv*) No other suitable packaging type would provide adequate shelf-life for the product's intended use, or

(*v*) Any other reason clearly demonstrates that such packaging is required.

(*2*) *Presumption.* In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product,