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in compliance with Federal, State, and local law regarding radioactive materials and if the label of the immediate container and shielded container, if any, either separate from or as part of any label and labeling required for radioactive materials by the Nuclear Regulatory Commission or by State or local radiological health authorities bear the following:

(1) The statement ''Rx only'';

(2) The statement ''To be administered in compliance with the requirements of Federal regulations regarding radioactive drugs for research use (21 CFR 361.1)'';

(3) The established name of the drug, if any;

(4) The established name and quantity of each active ingredient;

(5) The name and half-life of the radionuclide, total quantity of radioactivity in the drug product's immediate container, and amount of radioactivity per unit volume or unit mass at a designated referenced time;

(6) The route of administration, if it is for the other than oral use;

(7) The net quantity of contents;

(8) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

(9) The name and address of the manufacturer, packer, or distributor;

(10) The expiration date, if any;

(11) If the drug is intended for parenteral use, a statement as to whether the contents are sterile;

(12) If the drug is for other than oral use, the names of all inactive ingredients, except that:

(i) Trace amounts of harmless substances added solely for individual product identification need not be named.

(ii) If the drug is intended for parenteral use, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust pH or to make the drug isotonic may be declared by name and a statement of their effect; if the vehicle is water for injection, it need not be named. *Provided, however,* That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, the information required by paragraphs (f) (1) and (12) of this section may be placed on the shielded container only.

[40 FR 31308, July 25, 1975, as amended at 40 FR 44543, Sept. 29, 1975; 42 FR 15674, Mar. 22, 1977; 43 FR 14646, Apr. 7, 1978; 46 FR 8955, Jan. 27, 1981; 49 FR 44460, Nov. 7, 1984; 50 FR 8996, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990; 56 FR 10806, Mar. 14, 1991; 67 FR 4907, Feb. 1, 2002]

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

Subpart A—Definitions and Interpretations

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Subpart B—Warning and Caution Statements for Drugs

369.20 Drugs; recommended warning and caution statements.
369.21 Drugs; warning and caution statements required by regulations.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

SOURCE: 39 FR 11745, Mar. 29, 1974, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 369 appear at 69 FR 13717, Mar. 24, 2004.

Subpart A—Definitions and Interpretations

§ 369.1 Purpose of issuance.

The warning and caution statements suggested in subparts B and C of this part, for inclusion in the label or labeling of drugs and devices subject to section 502(d) and (f)(2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are issued for the

purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users. Only section 502(d) of the act requires use of the specific language included in these suggested warning and caution statements. These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law. Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or caution statements where such statements are necessary or desirable for the protection of the user.

§ 369.2 Definitions.

(a) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act.

(b) The terms *drugs* and *devices* are defined in section 201(g) and (k) of the act.

(c) Official compendia are defined in section 201(j) of the act.

§ 369.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).

Drugs exempted from prescription-dispensing requirements under section 503(b)(1)(C) of the act are subject to the labeling requirements prescribed in § 310.201(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 310.201 of this chapter (cross-referenced in the text of this part) are included in subpart B of this part, the inclusion of such drugs in §§ 369.20, 369.21, 369.22 in no way affects the requirements for compliance with § 310.201(a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

§ 369.4 Warnings suggested for drugs by formal or informal statements of policy.

The warning and caution statements included in subpart B of this part in no way affect any warning statement suggested for such drugs or devices by any statement of policy or interpretation in subchapter C of this chapter.

[39 FR 11745, Mar. 29, 1974, as amended at 40 FR 13496, Mar. 27, 1975]

§ 369.6 [Reserved]

§ 369.7 Warnings required by official compendia.

Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in subpart B or subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.

§ 369.8 Warning statements in relation to conditions for use.

The mention in any warning or caution statement included in subparts A, B, and C of this part, of a disease condition does not imply a finding on the part of the Food and Drug Administration that any drug or device is efficacious in such condition; nor is any drug or device bearing labeling referring to such disease condition precluded from regulatory action under the applicable provisions of the act if such claim is considered to be misbranding.

§ 369.9 General warnings re accidental ingestion by children.

Section 369.20 includes under certain items, but not all medicines, the statement: ''Keep this and all medicines out of children's reach. In case of overdose, get medical help or contact a Poison Control Center right away,'' or ''Keep out of reach of children.'' However, in view of the possibility of accidental ingestion of drugs, it is not only suggested but is recommended that one of these statements be used on the label of all drug products.

[64 FR 13296, Mar. 17, 1999]

§ 369.10 Conspicuousness of warning statements.

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of section 502(c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

Subpart B—Warning and Caution Statements for Drugs

§ 369.20 Drugs; recommended warning and caution statements.

ACETANILID.

Warning—Do not exceed recommended dosage. Overdosage or continued use may result in serious blood disturbances.

ACETOPHENETIDIN CONTAINING PREPARATIONS. (See § 201.309 of this chapter.)

Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS). (See also § 310.201(a)(19) and (23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS FOR EXTERNAL USE (EXCEPT PREPARATIONS FOR OPHTHALMIC USE).

Caution—Do not use in the eyes. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS, ORAL. (See also § 310.201(a)(4) and (a)(24) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

The reference to drowsiness is not required on preparations for the promotion of sleep or on preparations that are shown not to produce drowsiness.

ANTIPYRINE.

Warning—Do not exceed recommended dosage. If skin rash appears, discontinue use and consult physician.

ANTISEPTICS FOR EXTERNAL USE.

Caution—In case of deep or puncture wounds or serious burns, consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs discontinue use and consult physician.

The reference to wounds and burns is not required on preparations intended solely for diaper rash.

ARSENIC PREPARATIONS.

Warning—Frequent or prolonged use may cause serious injury. Do not exceed recommended dosage. Keep out of the reach of children.

BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE, HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE); HYOSCYAMUS, STRAMONIUM, THEIR DERIVATIVES, AND RELATED DRUG PREPARATIONS.

Warning—Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye occurs most frequently), or by children under 6 years of age, unless directed by a physician. Discontinue use if blurring of vision, rapid pulse, or dizziness occurs. Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. If eye pain occurs, discontinue use and see your physician immediately as this may indicate undiagnosed glaucoma.

In the case of scopolamine or scopolamine aminoxide preparations indicated for insomnia, the portion of the above warning that reads ''children under 6 years of age'' should read instead ''children under 12 years of age''.

BORIC ACID (POWDERED, CRYSTALLINE, OR GRANULAR).

Warning—Do not use as a dusting powder, especially on infants, or take internally. Use only as a solution. Do not apply to badly broken or raw skin, or to large areas of the body.

BROMIDES.

Caution—Use only as directed. Do not give to children or use in the presence of kidney disease. If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use and consult physician.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Warning—Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage.

CATHARTICS AND LAXATIVES—IRRITANTS AND OTHER PERISTALTIC STIMULANTS.

Warning—Do not use when abdominal pain, nausea, or vomiting are present. Frequent or prolonged use of this preparation may result in dependence on laxatives.

Mercury preparations should have added to the ''frequent use'' statement, the words ''and serious mercury poisoning''.

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

Caution—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

See also Mineral Oil Laxatives.

CHLORATES: MOUTH WASH OR GARGLE.

Avoid swallowing.

COBALT PREPARATIONS (See also § 250.106 of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age unless directed by physician. Do not use for more than 2 months unless directed by physician.

This warning is not required on articles containing not more than 0.5 milligram of cobalt as a cobalt salt per dosage unit and which recommend administration of not more than 0.5 milligram per dose and not more than 2 milligrams per 24-hour period.

''COUGH-DUE-TO-COLD'' PREPARATIONS. (See also § 310.201(a)(20) of this chapter.)

Warning—Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

COUNTERIRRITANTS AND RUBEFACIENTS.

Caution—Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

See also ''Salicylates'' in this section for additional warnings for preparations containing methyl salicylate.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Caution—Do not apply to large areas of the body.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN DOUCHE PREPARATIONS.

Warning—The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Mix as directed before pouring into douche bag. Do not use more often than twice weekly unless directed by physician.

DENTURE RELINERS, PADS, AND CUSHIONS.

Warning—For temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.

DENTURE REPAIR KITS.

Warning—For emergency repairs only. Long-term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.

DOUCHE PREPARATIONS.

Warning—Do not use more often than twice weekly unless directed by physician.

See also Creosote * * * Douche for additional warning.

DRESSINGS, PROTECTIVE SPRAY-ON TYPE. (See also § 310.201(a) (11) and (18) of this chapter.)

Warning—In case of deep or puncture wounds or serious burns consult physician. If redness, irritation, swelling or pain persists or increases or if infection occurs consult physician. Keep away from eyes or other mucous membranes. Avoid inhaling.

See also Dispensers Pressurized by Gaseous Propellants * * * for additional warnings to be included for products under pressure.

IODINE AND IODIDES (ORAL).

Caution—If a skin rash appears, discontinue use and consult physician.

MERCURY PREPARATIONS FOR EXTERNAL USE.

Warning—Discontinue use if rash or irritation develops or if condition for which used persists. Frequent or prolonged use, or application to large areas may cause serious mercury poisoning.

MINERAL OIL LAXATIVES. (See also § 201.302 of this chapter.)

Caution—Take only at bedtime. Avoid prolonged use. Do not administer to infants or young children, in pregnancy, or to bedridden or aged patients unless directed by physician.

NASAL PREPARATIONS: VASOCONSTRICTORS (PHENYLPROPANOLAMINE).

Caution—Do not exceed recommended dosage.

NUX VOMICA AND STRYCHNINE PREPARATIONS.

''Do not use more than the recommended dosage. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''

OPHTHALMIC PREPARATIONS. (See also § 200.50 of this chapter.)

Boric acid offered for use in the preparation of ophthalmic solutions should bear the statement: Prepare solution by boiling in water. Store in a sterile container. Prepare sufficient for one day's use and discard unused portion.

PHENACETIN-CONTAINING PREPARATION. (See acetophenetidin.)

PHENYLPROPANOLAMINE HYDROCHLORIDE PREPARATIONS, ORAL.

Caution—Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician.

POTASSIUM PERMANGANATE AQUEOUS SOLUTIONS (CONTAINING NOT MORE THAN 0.04 PERCENT POTASSIUM PERMANGANATE). (See § 250.108 of this chapter.)

Warning—For external use on the skin only. Severe injury may result from use internally or as a douche. Avoid contact with mucous membranes.

QUININE AND OTHER CINCHONA DERIVATIVES (EXCEPT FOR USE IN MALARIA).

Caution—Discontinue use if ringing in the ears, deafness, skin rash, or visual disturbances occur.

RESINS, OLEORESINS, AND VOLATILE OILS.

Caution—If nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs, discontinue use and consult physician.

RESORCINOL (NOT THE MONOACETATE) HAIR PREPARATIONS.

Caution—Excessive use of this preparation may temporarily discolor blond, white, or red hair.

SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF AMINOSALICYLIC ACID AND ITS

SALTS). (See also § 201.314 of this chapter.)

''Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away;'' or ''Keep out of reach of children.''

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements is required on the label of all aspirin tablets, but such a statement is not required on the labels of other salicylates clearly offered for administration to adults only.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL). (See also §§ 201.303 and 201.314 of this chapter.)

''Do not use otherwise than as directed. Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.''

If the preparation is a counter-irritant or rubefacient the statement:

Caution—Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

SILVER.

Caution—Frequent or prolonged use of this preparation may result in permanent discoloration of skin and mucous membranes.

SODIUM PERBORATE MOUTHWASH AND GARGLE AND TOOTHPASTE.

Caution—Discontinue use if irritation or inflammation develops, or increases. Avoid swallowing.

SULFONAMIDE NOSE DROPS.

Caution—Do not use if a known allergy to sulfonamide drugs exists.

SULFUR PREPARATION FOR EXTERNAL USE.

Caution—If undue skin irritation develops or increases, discontinue use and consult physician.

THROAT PREPARATIONS FOR TEMPORARY RELIEF OF MINOR SORE THROAT: LOZENGES, TROCHES, WASHES, GARGLES, ETC. (See also § 201.315 of this chapter.)

Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician.

TOOTHACHE PREPARATIONS.

For temporary use only until a dentist can be consulted.

ZINC STEARATE DUSTING POWDERS.

''Keep out of reach of children; avoid inhaling. If swallowed, get medical help or contact a Poison Control Center right away.''

[39 FR 11745, Mar. 29, 1974, as amended at 40 FR 8917, Mar. 3, 1975; 40 FR 13496, Mar. 27, 1975; 41 FR 10885, Mar. 15, 1976; 51 FR 27760, Aug. 1, 1986; 51 FR 35340, Oct. 2, 1986; 52 FR 15893, Apr. 30, 1987; 52 FR 30057, Aug. 12, 1987; 52 FR 47324, Dec. 11, 1987; 53 FR 7093, Mar. 4, 1988; 55 FR 31783, Aug. 3, 1990; 57 FR 58376, Dec. 9, 1992; 59 FR 43412, Aug. 23, 1994; 64 FR 13296, Mar. 17, 1999; 68 FR 18882, Apr. 17, 2003; 68 FR 34293, June 9, 2003]

§ 369.21 Drugs; warning and caution statements required by regulations.

ACETAMINOPHEN (N-ACETYL-*p*-AMINOPHENOL) (See § 310.201(a)(1) of this chapter.)

Warning—Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

If offered for use in arthritis, or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

ALCOHOL RUBBING COMPOUND. (See 26 CFR 182.855(a)(5); The National Formulary, Tenth Edition 1955, pp. 27–28; and section 502(g) of the act).

Warning—For external use only. If taken internally serious gastric distrubances will result.

ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE AND CHLOROTHEN CITRATE PREPARATIONS). (See § 310.201(a)(4) and (a)(24) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

If offered for symptoms of colds, the statement:

Caution—If relief does not occur within 3 days, discontinue use and consult physician.

DICYCLOMINE HYDROCHLORIDE WITH AN ANTACID. (See § 310.201(a)(8) of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age or use for a prolonged period unless directed by physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

DIPHEMANIL METHYLSULFATE FOR EXTERNAL USE. (See § 310.201(a)(22) of this chapter.)

Caution—If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

DRUGS IN DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS. (See also § 310.201(a) (11) and (18) of this chapter.)

The warnings herein shall appear prominently and conspicuously, but in no case may the letters be less than 1/16 inch in height.

If the label of any package is too small to accommodate the warnings, the Commissioner may establish by regulation an acceptable alternative method, e.g., a type size smaller than 1/16 inch in height. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Division of Dockets Management in the form established in part 10 of this chapter.

Warning—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.

In the case of products packaged in glass containers, the word ''break'' may be substituted for the word ''puncture.''

The words ''Avoid spraying in eyes'' may be deleted from the warning in the case of a product not expelled as a spray, or that is intended to be used in the eyes.

In addition to the above warning, the label of a drug packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or hydrocarbon shall bear the following warning:

Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

The warning is not required for the following products:

(a) Products expelled in the form of a foam or cream, which contain less than ten percent propellant in the container;

(b) Products in a container with a physical barrier that prevents escape of the propellant at the time of use;

(c) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation;

(d) Products of a net quantity of contents of less than ½ oz.

DYCLONINE HYDROCHLORIDE. (See § 310.201(a)(23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by physician. Do not use, but consult physician for deep or puncture wounds

or serious burns. Do not use in case of rectal bleeding, as this may indicate serious disease.

HEXADENOL. (See §310.201(a)(11) of this chapter.)

Caution—Do not use for treatment of serious burns or skin conditions or for conditions which persist for prolonged periods. In such cases, consult your physician. Do not spray in vicinity of eyes, mouth, nose, or ears. Do not store above 120 °F.

IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See §201.308 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

''For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice.''

The following warning: Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLHYRDOCUPREINE AND ZOLAMINE HYDROCHLORIDE RECTAL PREPARATIONS FOR EXTERNAL USE (See §310.201(a)(3) of this chapter.)

Warning—Do not use this preparation in case of rectal bleeding, as this may indicate serious disease.

NEOMYCIN SULFATE WITH A VASOCONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROPS).

Caution—Do not exceed recommended dosage. Do not administer to children under 3 years of age unless directed by physician.

PRAMOXINE HYDROCHLORIDE FOR EXTERNAL USE. (See §310.201(a)(19) of this chapter.)

Caution—Do not use in the eyes or nose. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

SODIUM GENTISATE. (See §§201.314 and 310.301(a)(2) of this chapter.)

Warning—Do not use in children under 6 years of age or use for prolonged period unless directed by physician.

''Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

TUAMINOHEPTANE SULFATE NASAL PREPARATIONS. (See §310.201(a)(16) of this chapter.)

Caution—Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness. Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. Do not use for more than 3 or 4 consecutive days unless directed by physician.

VIBESATE PREPARATIONS. (See §310.201(a)(18) of this chapter.)

Caution—Do not use but consult physician for deep or puncture wounds or serious burns. If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130 °Fahrenheit may cause bursting. Never throw container into fire or incinerator.

[39 FR 11745, Mar. 29, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §369.21, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

PARTS 370–499 [RESERVED]