

of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

(e) *Prescription-exemption procedure of OTC drug review.* A drug limited to prescription use under section 503(b)(1)(C) of the act may also be exempted from prescription-dispensing requirements by the procedure set forth in § 330.13 of this chapter.

[39 FR 11680, Mar. 29, 1974, as amended at 41 FR 32582, Aug. 4, 1976; 42 FR 4714, Jan. 25, 1977; 42 FR 15674, Mar. 22, 1977]

§ 310.201 Exemption for certain drugs limited by new-drug applications to prescription sale.

(a) The prescription-dispensing requirements of section 503(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to the following drugs subject to new drug applications:

(1) *N*-Acetyl-*p*-aminophenol (acetaminophen, *p*-hydroxy-acetanilid) preparations meeting all the following conditions:

(i) The *N*-acetyl-*p*-aminophenol is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The *N*-acetyl-*p*-aminophenol and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 0.325 gram (5 grains) of *N*-acetyl-*p*-aminophenol per dosage unit, or if it is in liquid form not more than 100 milligrams of *N*-acetyl-*p*-aminophenol per milliliter.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of *N*-acetyl-*p*-aminophenol recommended or suggested in the labeling do not exceed: For adults, 0.65 gram (10 grains) per dose or 2.6

grams (40 grains) per 24-hour period: for children 6 to 12 years of age, one-half of the maximum adult dose or dosage; for children 3 to 6 years of age, one-fifth of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 3 years of age and against use of the drug for more than 10 days, unless such uses are directed by a physician.

(viii) If the article is offered for use in arthritis or rheumatism, the labeling prominently bears a statement that the beneficial effects claimed are limited to the temporary relief of minor aches and pains of arthritis and rheumatism and, in juxtaposition with directions for use in such conditions, a conspicuous warning statement, such as "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".

(2) Sodium gentisate (sodium-2, 5-dihydroxybenzoate) preparations meeting all the following conditions:

(i) The sodium gentisate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The sodium gentisate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 0.5 gram (7.7 grains) of anhydrous sodium gentisate per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of sodium gentisate recommended or suggested in the labeling do not exceed: For adults, 0.5 gram (7.7 grains) per dose of 2.0 grams (31 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations,

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a clear warning statement against administration of the drug to children under 6 years of age and against use of the drug for a prolonged period, except as such uses may be directed by a physician.

(3) Isoamylhydrocupreine and zolamine hydrochloride (N, N-dimethyl-N'-2-thiazolyl-N'-p-methoxybenzyl-ethylenediamine hydrochloride) preparations meeting all the following conditions:

(i) The isoamylhydrocupreine and zolamine hydrochloride are prepared in dosage form suitable for self-medication as rectal suppositories or as an ointment and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The isoamylhydrocupreine, zolamine hydrochloride, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 0.25 percent of isoamylhydrocupreine and 1.0 percent of zolamine hydrochloride.

(v) If the preparation is in suppository form, it contains not more than 5.0 milligrams of isoamylhydrocupreine and not more than 20.0 milligrams of zolamine hydrochloride per suppository.

(vi) The preparation is labeled with adequate directions for use in the temporary relief of local pain and itching associated with hemorrhoids.

(vii) The directions provide for the use of not more than two suppositories or two applications of ointment in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against use of the preparation in case of rectal bleeding, as this may indicate serious disease.

(4) Phenyltoloxamine dihydrogen citrate (N,N-dimethyl-(*a*-phenyl-*O*-toloxy) ethylamine dihydrogen citrate), preparations meeting all the following conditions:

(i) The phenyltoloxamine dihydrogen citrate is prepared, with or without other drugs, in tablet or other dosage

form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The phenyltoloxamine dihydrogen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dose or 264 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 150 milligrams of phenyltoloxamine) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against administration of the drug to children under 6 years of age, except as directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(b) If the article is offered for temporary relief of the symptoms of colds, a statement that continued administration for such use should not exceed 3 days, except as directed by a physician.

(5)-(7) [Reserved]

(8) Dicyclomine hydrochloride (1-cyclohexylhexahydrobenzoic acid, β -diethylaminoethyl ester hydrochloride; diethylaminocarbethoxy-bicyclohexyl hydrochloride) preparations meeting all the following conditions:

(i) The dicyclomine hydrochloride is prepared with suitable antacid and other components, in tablet or other

dosage form for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The dicyclomine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 5 milligrams of dicyclomine hydrochloride per dosage unit, or if it is in liquid form not more than 0.5 milligram of dicyclomine hydrochloride per milliliter.

(v) The preparation is labeled with adequate directions for use only by adults and children over 12 years of age, in the temporary relief of gastric hyperacidity.

(vi) The dosages recommended or suggested in the directions for use do not exceed 10 milligrams of dicyclomine hydrochloride per dose or 30 milligrams in a 24-hour period.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, clear warning statements against:

(a) Exceeding the recommended dosage.

(b) Prolonged use, except as directed by a physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

(c) Administration to children under 12 years of age except as directed by a physician.

(9)–(10) [Reserved]

(11) Hexadenol (a mixture of tetracosanes and their oxidation products) preparations meeting all the following conditions:

(i) The hexadenol is prepared and packaged, with or without other drugs, solvents, and propellants, in a form suitable for self-medication by external application to the skin as a spray, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The hexadenol and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 5 percent by weight of hexadenol.

(v) The preparation is labeled with adequate directions for use by external application in the treatment of minor burns and minor skin irritations.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Use on serious burns or skin conditions or prolonged use, except as directed by a physician.

(b) Spraying the preparation in the vicinity of eyes, mouth, nose, or ears.

(12) Sulfur dioxide preparations meeting all the following conditions:

(i) The sulfur dioxide is prepared with or without other drugs, in an aqueous solution packaged in a hermetic container suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The sulfur dioxide and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 5 grams of sulfur dioxide per 100 milliliters of solution.

(v) The preparation is labeled with adequate directions for use by external application to the smooth skin in the prevention or treatment of minor conditions in which it is indicated.

(vi) The directions for use recommend or suggest not more than two applications a day for not more than 1 week, except as directed by a physician.

(13)–(15) [Reserved]

(16) Tuaminoheptane sulfate (2-aminoheptane sulfate) preparations meeting all the following conditions:

(i) The tuaminoheptane sulfate is prepared, with or without other drugs, in an aqueous vehicle suitable for administration in self-medication as nose drops, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The preparation is packaged with a style of container or assembly suited to self-medication by the recommended route of administration, and delivering not more than 0.1 milliliter of the preparation per drop.

(iii) The tuaminoheptane sulfate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iv) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(v) The tuaminoheptane sulfate content of the preparation does not exceed 10 milligrams per milliliter.

(vi) The preparation is labeled with adequate directions for use in the temporary relief of nasal congestion.

(vii) The dosages recommended or suggested in the directions for use do not exceed the equivalent: For adults, 5 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period; for children 1 to 6 years of age, 3 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period; for infants under 1 year of age, 2 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against use of more than 5 doses daily, and against use longer than 4 days unless directed by a physician.

(b) A clear warning statement to the effect that frequent use may cause nervousness or sleeplessness, and that individuals with high blood pressure, heart disease, diabetes, or thyroid disease should not use the preparation unless directed by a physician.

(17) [Reserved]

(18) Vibesate (a mixture of copolymers of hydroxy-vinyl chlorideacetate, sebacic acid, and modified maleic rosin ester) preparations meeting all the following conditions.

(i) The vibesate is prepared and packaged, with or without other drugs, solvents, and propellants, in a form suitable for self-medication by external application to the skin as a spray, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The vibesate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 13 percent by weight of vibesate.

(v) The preparation is labeled with adequate directions for use by external application as a dressing for minor burns, minor cuts, or other minor skin irritations.

(vi) The labeling bears in juxtaposition with the directions for use clear warning statements against:

(a) Use on serious burns and on infected, deep, and puncture wounds unless directed by a physician.

(b) Spraying the preparation near the eyes or other mucous membranes.

(c) Inhaling the preparation.

(d) Use near open flames.

(e) Puncturing the container or throwing the container into fire.

(19) Pramoxine hydrochloride (4-*N*-butoxyphenyl γ -morpholinopropyl ether hydrochloride) preparations meeting all the following conditions:

(i) The pramoxine hydrochloride is prepared, with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The pramoxine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1.0 percent of pramoxine hydrochloride.

(v) The preparation is labeled with adequate directions for use by external application to the skin for the temporary relief of pain or itching due to minor burns and sunburn, nonpoisonous insect bites, and minor skin irritations.

(vi) The directions for use recommend or suggest not more than four

applications of the preparation per day, unless directed by a physician.

(vii) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Prolonged use.

(b) Application to large areas of the body.

(c) Continued use if redness, irritation, swelling, or pain persists or increases, unless directed by a physician.

(d) Use in the eyes or nose.

(20) Carbetapentane citrate (2-(2-dihydroxyethylaminoethoxy)-ethyl-1-phenylcyclopentyl-1-carboxylate citrate) preparations meeting all the following conditions:

(i) The carbetapentane citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The carbetapentane citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, and application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of carbetapentane citrate per dosage unit; or if it is in liquid form, not more than 1.5 milligrams of carbetapentane citrate per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of cough due to minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 30 milligrams of carbetapentane citrate per dose or 120 milligrams of carbetapentane citrate per 24-hour period; for children 4 to 12 years of age, 7.5 milligrams per dose or 30 milligrams per 24-hour period; for children 2 to 4 years of age, 4.0 milligrams per dose or 16.0 milligrams per 24-hour period.

(vii) The label bears a conspicuous warning to keep the drug out of the reach of children, and the labeling bears, in juxtaposition with the dosage recommendations:

(a) A clear warning statement against administration of the drug to

children under 2 years of age, unless directed by a physician.

(b) Clear warning statements against use of the drug in the presence of high fever or if cough persists, since persistent cough as well as high fever may indicate the presence of a serious condition.

(21) Pamabrom (2-amino-2-methylpropanol-1-8-bromotheophyllinate) preparations meeting all the following conditions:

(i) The pamabrom is prepared with appropriate amounts of a suitable analgesic and with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The pamabrom and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 50 milligrams of pamabrom per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the minor pains and discomforts that may occur a few days before and during the menstrual period.

(vi) The dosages recommended or suggested in the labeling do not exceed 50 milligrams of pamabrom per dose or 200 milligrams per 24-hour period.

(22) Diphemanil methylsulfate (4-diphenylmethylene-1,1-dimethylpiperidinium methylsulfate) preparations meeting all the following conditions:

(i) The diphemanil methylsulfate is prepared, with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The diphemanil methylsulfate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

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(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 2.0 percent of diphepanil methylsulfate.

(v) The preparation is labeled with adequate directions for use by external application to the skin for the relief of symptoms of mild poison ivy, oak, and sumac and other minor irritations and itching of the skin.

(vi) The directions for use recommend or suggest not more than four applications of the preparation per day, unless directed by a physician.

(vii) The labeling bears, in juxtaposition with the directions for use, a clear warning statement, such as: "Caution: If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician."

(23) Dyclonine hydrochloride (4-butoxy-3-piperidinopropiophenone hydrochloride; 4-*n*-butoxy- β -piperidono-propiofenone hydrochloride) preparations meeting all the following conditions:

(i) The dyclonine hydrochloride is prepared, with or without other drugs, in a dosage form suitable for use as a cream or ointment in self-medication by external application to the skin, or rectally, and contains no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The dyclonine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1.0 percent of dyclonine hydrochloride.

(v) The preparation is labeled with adequate directions for use:

(a) By external application to the skin for the temporary relief of pain and itching in sunburn, nonpoisonous insect bites, minor burns, cuts, abrasions, and other minor skin irritations.

(b) [Reserved]

(c) In the prevention or treatment of other minor conditions in which it is indicated.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Continued use if redness, irritation, swelling, or pain persists or increases, unless directed by a physician.

(b) Use in case of rectal bleeding, as this may indicate serious disease.

(c) Use in the eyes.

(d) Prolonged use.

(e) Application to large areas of the body.

(f) Use for deep or puncture wounds or serious burns.

(24) Chlorothen citrate (chloromethapyrilene citrate; *N,N*-dimethyl-*N'*-(2-pyridyl)-*N'*-(5-chloro-2-thenyl) ethylenediamine citrate) preparations meeting all the following conditions:

(i) The chlorothen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The chlorothen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of chlorothen citrate per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 25 milligrams of chlorothen citrate per dose or 150 milligrams of chlorothen citrate per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against administration of the drug to children under 6 years of age or exceeding the recommended dosage, unless directed by a physician, and against driving a car or operating machinery while using

the drug, since it may cause drowsiness.

(b) If the article is offered for the temporary relief of symptoms of colds, a statement that continued administration for such use should not exceed 3 days, unless directed by a physician.

(25) [Reserved]

(26) Methoxyphenamine hydrochloride (β -(*o*-methoxyphenyl)-isopropyl-methylamine hydrochloride; 1-(*o*-methoxyphenyl)-2-methylamino-propane hydrochloride) preparations meeting all the following conditions:

(i) The methoxyphenamine hydrochloride is prepared with appropriate amounts of a suitable antitussive, with or without other drugs, in a dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The methoxyphenamine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 3.5 milligrams of methoxyphenamine hydrochloride per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of cough due to minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 35 milligrams of methoxyphenamine hydrochloride per dose or 140 milligrams of methoxyphenamine hydrochloride per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The label bears a conspicuous warning to keep the drug out of the reach of children, and the labeling bears, in juxtaposition with the dosage recommendations:

(a) A clear warning statement against administration of the drug to children under 6 years of age, unless directed by a physician.

(b) A clear warning statement to the effect that frequent or prolonged use may cause nervousness, restlessness, or drowsiness, and that individuals with

high blood pressure, heart disease, diabetes, or thyroid disease should not use the preparation unless directed by a physician.

(c) A clear warning statement against use of the drug in the presence of high fever or if cough persists, since persistent cough as well as high fever may indicate the presence of a serious condition.

(27) Biphenamine hydrochloride (β -diethylaminoethyl-3-phenyl-2-hydroxybenzoate hydrochloride) preparations meeting all the following conditions:

(i) The biphenamine hydrochloride is prepared in a form suitable for use as a shampoo and contains no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The biphenamine hydrochloride meets its professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1 percent of biphenamine hydrochloride.

(v) The preparation is labeled with adequate directions for use for the temporary relief of itching and scaling due to dandruff.

(vi) The label bears a conspicuous warning to keep the drug out of the reach of children.

(28) Tyloxapol (an alkylaryl polyether alcohol) and benzalkonium chloride ophthalmic preparations meeting all the following conditions:

(i) The tyloxapol and benzalkonium chloride are prepared, with other appropriate ingredients which are not drugs limited to prescription sale under the provisions of section 503(b)(1) of the act, as a sterile, isotonic aqueous solution suitable for use in self-medication on eye prostheses.

(ii) The preparation is so packaged as to volume and type of container as to afford adequate protection and be suitable for self-medication with a minimum risk of contamination of the solution during use. Any dispensing unit is sterile and so packaged as to maintain sterility until the package is opened.

(iii) The tyloxapol, benzalkonium chloride, and other ingredients used to prepare the isotonic aqueous solution

meet their professed standards of identity, strength, quality, and purity.

(iv) An application pursuant to section 505(b) of the act is approved for the drug.

(v) The preparation contains 0.25 percent of tyloxapol and 0.02 percent of benzalkonium chloride.

(vi) The label bears a conspicuous warning to keep the drug out of the reach of children and the labeling bears, in juxtaposition with the dosage recommendations, a clear warning that if irritation occurs, persists, or increases, use of the drug should be discontinued and a physician consulted. The labeling includes a statement that the dropper or other dispensing tip should not touch any surface, since this may contaminate the solution.

(29) [Reserved]

(b) [Reserved]

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Subpart D—Records and Reports

§ 310.303 Continuation of long-term studies, records, and reports on certain drugs for which new drug applications have been approved.

(a) A new drug may not be approved for marketing unless it has been shown to be safe and effective for its intended use(s). After approval, the applicant is required to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds under section 505(e) of the act for suspending or withdrawing approval of the application. Some drugs, because of the nature of the condition for which they are intended, must be used for long periods of time—even a lifetime. To acquire necessary data for determining the safety and effectiveness of long-term use of such drugs, extensive animal and clinical tests are required as a condition of approval. Nonetheless, the therapeutic or prophylactic usefulness of such drugs may make it inadvisable in the public interest to delay the avail-

ability of the drugs for widespread clinical use pending completion of such long-term studies. In such cases, the Food and Drug Administration may approve the new drug application on condition that the necessary long-term studies will be conducted and the results recorded and reported in an organized fashion. The procedures required by paragraph (b) of this section will be followed in order to list such a drug in § 310.304.

(b) A proposal to require additional or continued studies with a drug for which a new drug application has been approved may be made by the Commissioner on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter. Prior to issuance of such a proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. All requirements for special studies, records, and reports will be published in § 310.304.

[39 FR 11680, Mar. 29, 1974, as amended at 41 FR 4714, Jan. 25, 1976; 42 FR 15674, Mar. 22, 1977]

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

(a) *Scope.* FDA is requiring manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences associated with the use of their drug products. Any person subject to the reporting requirements of paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

(b) *Definitions.* The following definitions of terms apply to this section:—

Adverse drug experience. Any adverse event associated with the use of a drug in humans, whether or not considered