U.S. FOOD & DRUG ADMINISTRATION

**U.S. Food and Drug Administration**

# Over-the-Counter (OTC) Monograph M022: Oral Healthcare Drug Products for Over-the-Counter Human Use (Posted October 14, 2022)[1, 2]

## Part A—General Provisions



## Part B—Active Ingredients



## Part C—Labeling



## Part D—Professional Use



SOURCE: 53 FR 2436, Jan. 27, 1988, unless otherwise noted.

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[1] Final Administrative Order (OTC000028), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.
[2] Subsection lettering in § M022.66 was corrected on November 22, 2022.

## Part A—General Provisions

### § M022.1 Scope

An over-the-counter (OTC) oral health care drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1.

### § M022.3 Definitions

As used in this OTC monograph:

(a) Oral health care drug. A drug product applied topically for the proper care of the oral cavity, including the temporary relief of symptoms of the gums, teeth, mouth, and throat, for example, minor irritation of the gums, occasional mouth soreness, or minor sore throat.

(b) Agent for the relief of toothache. An ingredient used for the temporary relief of pain arising as a result of an open tooth cavity.

(c) Anesthetic/analgesic. A substance applied topically to an epithelial surface (e.g., skin or mucous membrane) that relieves pain without necessarily abolishing other sensations (analgesic) or a substance applied topically that completely blocks pain receptors resulting in a sensation of numbness and abolition of response to painful stimuli (anesthetic).

(d) Anhydrous glycerin. An ingredient that may be prepared by heating glycerin United States Pharmacopeia (USP) at 150 °C for 2 hours to drive off the moisture content.

(e) Astringent. An agent that causes contraction of the tissues or arrest of secretions by coagulation of proteins on a cell surface.

(f) Debriding agent/oral wound cleanser. A nonirritating agent which causes or assists in the removal (physically or chemically) of foreign material or devitalized or contaminated tissue from or adjacent to a minor oral wound or a traumatic or infected lesion to expose surrounding healthy tissue and does not delay wound healing.

(g) Demulcent. A bland, inert agent that soothes and relieves irritation of inflamed or abraded surfaces such as mucous membranes.

(h) Dentifrice. A substance used with a toothbrush to clean the accessible surfaces of the teeth. It is an abrasive-containing dosage form for delivering an active ingredient to the teeth.

(i) Mouthwash (oral rinse). A solution used for rinsing the mouth, not necessarily for medicinal purposes.

(j) Oral cavity (mouth). The cavity of the mouth and associated structures, including the cheeks, palate, oral mucosa, glands where ducts open into it, the teeth, and the tongue.

(k) Oral mucosal protectant. An ingredient which is a pharmacologically inert substance which forms an adherent, continuous, flexible, or semirigid coating when applied to the oral mucous membranes. The coating protects the irritated area from further irritation due to the activity of oral structures.

(l) Tooth desensitizer. An ingredient which acts on the dentin to block perception of those stimuli which are usually not perceived by subjects with normal teeth but which are perceived by patients with dental hypersensitivity.

(m) Antiseptic drug. In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

(n) Oral antiseptic. An antiseptic-containing drug product applied topically to the oral cavity to help prevent infection in wounds caused by minor oral irritations, cuts, scrapes, or injury following minor dental procedures.

[53 FR 2436 Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991 and 59 FR 6084, Feb. 9, 1994]

**Part B—Active Ingredients**

**§ M022.12 Anesthetic/analgesics**

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § M022.52(d).

(a) Benzocaine.

(b) Benzyl alcohol.

(c) Butacaine sulfate.

(d) Dyclonine hydrochloride.

(e) Hexylresorcinol.

(f) Menthol.

(g) Phenol preparations (phenol and/or phenolate sodium).

(h) Salicyl alcohol.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

## § M022.14 Astringents

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § M022.54(d).

(a) Alum.

(b) Zinc chloride.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

## § M022.16 Debriding agent/oral wound cleansers

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § M022.56(d).

(a) Carbamide peroxide in anhydrous glycerin.

(b) Hydrogen peroxide.

(c) Sodium bicarbonate.

(d) Sodium perborate monohydrate.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

## § M022.18 Demulcents

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § M022.58(d):

(a) Elm bark.

(b) Gelatin.

(c) Glycerin.

(d) Pectin.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

## § M022.20 Oral mucosal protectants

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § M022.60(d).

(a) Compound benzoin tincture, USP XIX.[3]

(b) Benzoin tincture, USP XV.[4]

[56 FR 48302, Sept. 24, 1991]

## § M022.22 Tooth desensitizers

The active ingredient of the product consists of potassium nitrate when used within the dosage limits and in the dosage form established in § M022.62(d).

[56 FR 48302, Sept. 24, 1991]

## § M022.24 Package size limitations

Products containing benzoin preparations identified in § M022.20 should be packaged in well-closed containers in a quantity of 30 milliliters or less.

[56 FR 48302, Sept. 24, 1991]

## § M022.26 Permitted combinations of active ingredients

(a) Any single anesthetic/analgesic active ingredient identified in § M022.12 may be combined with any single astringent active ingredient identified in § M022.14.

(b) Any single anesthetic/analgesic active ingredient identified in § M022.12 may be combined with any single demulcent active ingredient identified in § M022.18.

(c) Any single anesthetic/analgesic active ingredient identified in § M022.12 may be combined with any single oral mucosal protectant active ingredient identified in § M022.20.

(d) Any single anesthetic/analgesic active ingredient identified in § M022.12 may be combined with any generally recognized safe and effective denture adhesive.

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[3] United States Pharmacopeia (USP) XIX (July 1975), is incorporated by reference and is available for inspection at FDA. For further information about inspecting incorporated material, contact druginfo@fda.hhs.gov. Copies may also be available from the publisher, United States Pharmacopeia.
[4] United States Pharmacopeia (USP) XV (December 1955), is incorporated by reference and is available for inspection at FDA. For further information about inspecting incorporated material, contact druginfo@fda.hhs.gov. Copies may also be available from the publisher, United States Pharmacopeia.

(e) Benzocaine identified in § M022.12(a) may be combined with menthol identified in § M022.12(f).

(f) Benzocaine identified in § M022.12(a) may be combined with phenol preparations identified in § M022.12(g).

(g) Oral health care and cough-cold combinations. See § M012.40 of OTC Monograph M012.

(h) Potassium nitrate identified in § M022.22 may be combined with any single anticaries active ingredient identified in § M021.10(a) of OTC Monograph M021.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302 Sept. 24, 1991 and 59 FR 6084, Feb. 9, 1994]

## Part C—Labeling

### § M022.48 Labeling of oral health care drug products

(a) The word physician may be substituted for the word doctor in any of the labeling statements in this OTC monograph.

(b) Indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this OTC monograph, may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

### § M022.52 Labeling of anesthetic/analgesic drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “oral anesthetic," an “oral anesthetic/analgesic," or an “oral pain reliever."

(b) Indications. The labeling of the product states, under the heading “Uses,” any of the phrases listed below:

(1) “For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.”

(2) “For the temporary relief of pain associated with canker sores."

(3) “For the temporary relief of pain due to minor irritation or injury of the mouth and gums."

(4) “For the temporary relief of pain due to minor dental procedures."

(5) “For the temporary relief of pain due to minor irritation of the mouth and gums caused by dentures or orthodontic appliances.”

(6) For products containing benzocaine identified in § M022.12(a) or phenol identified in § M022.12(g) when used as anesthetic/analgesics for teething pain. “For the temporary relief of sore gums due to teething in infants and children 4 months of age and older."

(7) For products containing any ingredient identified in § M022.12 when used in denture adhesive products. “For the temporary relief of pain or discomfort of the mouth and gums due to dentures."

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings":

(1) For all products containing any ingredient identified in § M022.12 labeled with only the indication in § M022.52(b)(1) or with the indication in § M022.52(b)(1) plus any of the indications in §§ M022.52(b)(2), (b)(3), (b)(4), (b)(5), (b)(6), or (b)(7). “If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly."

(2) For all products containing any ingredient identified in § M022.12 labeled with any of the indications §§ M022.52(b)(2), (b)(3), (b)(4), (b)(5), (b)(6), or (b)(7) but not with the indication in § M022.52(b)(1). “Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.”

(3) “Do not exceed recommended dosage.”

(4) For all products containing any ingredient identified in §§ M022.12(a) and (c). “Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other ‘caine' anesthetics.”

(5) For all products labeled with the indication identified in § M022.52(b)(6). “Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your doctor."

(6) For all products containing any ingredient identified in § M022.12 when used in denture adhesive products. “See your dentist as soon as possible.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) For products containing benzocaine identified in § M022.12(a)

(i) For dosage forms other than solid, the product is a 5- to 20-percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 2 to 15 milligrams benzocaine. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(iii) For products intended to be used as teething preparations, the product is a 5- to 20-percent solution or suspension. Apply to the affected area not more than four times daily or as directed by a dentist or doctor. For infants under 4 months of age there is no recommended dosage or treatment except under the advice and supervision of a dentist or doctor.

(iv) For denture adhesive products the product contains 5 to 20 percent benzocaine. Apply on area of denture that comes in contact with sore gums.

(2) For products containing benzyl alcohol identified in § M022.12(b)

(i) For dosage forms other than solid, the product is a 0.05- to 10-percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 100 to 500 milligrams benzyl alcohol. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(3) For products containing butacaine sulfate identified in § M022.12(c)

(i) The product contains 30 milligrams butacaine sulfate per dosage unit. Adults: Apply (manufacturer should state specific amount of product that contains 30 milligrams butacaine sulfate) to the affected area. Do not apply again for at least 3 hours. Do not use more than three applications in 24 hours unless directed by a dentist or doctor. Children under 12 years of age: Consult a dentist or doctor.

(ii) For denture adhesive products the product contains 30 milligrams butacaine sulfate per dosage unit. Apply on area of denture that comes in contact with sore gums.

(4) For products containing dyclonine hydrochloride identified in § M022.12(d)

(i) For dosage forms other than solid, the product is a 0.05- to 0.10-percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 1 to 3 milligrams dyclonine hydrochloride. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(5) For products containing hexylresorcinol identified in § M022.12(e)

(i) For dosage forms other than solid, the product is a 0.05- to 0.1- percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 2 to 4 milligrams hexylresorcinol. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(6) For products containing menthol identified in § M022.12(f)

(i) For dosage forms other than solid, the product is a 0.04- to 2-percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 2 to 20 milligrams menthol. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(7) For products containing phenol preparations identified in § M022.12(g)

(i) For dosage forms other than solid, the product is an aqueous solution or suspension containing phenol or phenolate sodium equivalent to 0.5 to 1.5 percent phenol

(A) For direct application. Adults and children 2 years of age and older: Apply to the affected area, allow to remain in place for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(B) For use as a mouthwash (oral rinse). Adults and children 12 years of age and older: Gargle or swish around the mouth for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children 6 to under 12 years of age: Apply 10 milliliters to the affected area, gargle, or swish around the mouth for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 6 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product (lozenge or tablet) contains phenol or phenolate sodium equivalent to 10 to 50 milligrams phenol. Adults and children 12 years of age and older: Allow the product (lozenge or tablet) to dissolve slowly in the mouth. May be repeated every 2 hours or as directed by a dentist or doctor. Children 6 to under 12 years of age: Allow product (lozenge or tablet) to dissolve slowly in the mouth. May be repeated every 2 hours, not to exceed 300 milligrams phenol in 24 hours, or as directed by a dentist or doctor. Children under 6 years of age: Consult a dentist or doctor.

(iii) For products intended for use as a teething preparation, the product is an aqueous solution or suspension containing phenol or phenolate sodium equivalent to 0.5 percent phenol. For infants and children 4 months to under 12 years of age: Apply to the affected area. Use up to 6 times daily or as directed by a dentist or doctor.

(iv) For denture adhesive products, the product contains phenol or phenolate sodium equivalent to 0.5 to 1.5 percent phenol. Apply on area of denture that comes in contact with sore gums.

(8) For products containing salicyl alcohol identified in § M022.12(h)

(i) For dosage forms other than solid, the product is a 1- to 6-percent solution or suspension. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains 50 to 100 milligrams salicyl alcohol. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(e) Exemption from the general accidental overdose warning. The labeling for oral health care anesthetic/analgesic drug products containing the active ingredient identified in § M022.12(f) marketed in accordance with § M022.52(d)(6)(ii) is exempt from the requirement in 21 CFR 330.1(g) that the labeling bear the general warning statement “In case of overdose, get medical help or contact a poison control center right away.” The labeling must continue to bear the first part of the general warning in 21 CFR 330.1(g), which states: “Keep out of reach of children.” [highlighted in bold type].

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991, 57 FR 20434, May 13, 1992, and 57 FR 28555, June 25, 1992]

**§ M022.54 Labeling of astringent drug products**

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “oral astringent.”

(b) Indications. The labeling of the product states, under the heading
"Uses,” the following: “For temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.”

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings": For all products containing any ingredient identified in § M022.14. "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly."

(d) Directions. The labeling of the product contains the following information under the heading "Directions":

(1) For products containing alum identified in § M022.14(a), the product is a 0.2- to 0.5-percent aqueous solution. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(2) For products containing zinc chloride identified in § M022.14(b), the product is a 0.1- to 0.25-percent aqueous solution. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991]

**§ M022.56 Labeling of debriding agent/oral wound cleanser drug products**

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral debriding agent" or an "oral debriding agent/oral wound cleanser."

(b) Indications. The labeling of the product states, under the heading "Uses," any of the phrases listed below:

(1) "Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth."

(2) "For temporary use in cleansing minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums."

(3) "For temporary use to cleanse canker sores."

(4) Other allowable statements. In addition to the required information specified in §§ M022.56(a), (b), (c), and (d), the labeling of the product may contain any of the following statements, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(i) “Assist in the removal of foreign material from minor oral wounds."

(ii) "Physically removes debris from minor oral wounds.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”: For all products containing any ingredient identified in § M022.16. “Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly."

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) For products containing carbamide peroxide identified in § M022.16(a), the product is a 10- to 15-percent solution in anhydrous glycerin

(i) For direct application. Adults and children 2 years of age and older: Apply several drops directly to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For use as a mouthwash (oral rinse). Adults and children 2 years of age and older: Place 10 to 20 drops onto tongue. Mix with saliva. Swish around in the mouth over the affected area for at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(2) For products containing hydrogen peroxide identified in § M022.16(b), the product is a 3-percent aqueous solution

(i) For direct application. Adults and children 2 years of age and older: Apply several drops to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For use as an oral rinse. Adults and children 2 years of age and older: Mix with an equal amount of warm water. Swish around in the mouth over the affected area for at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(3) For products containing sodium bicarbonate identified in § M022.16(c). Adults and children 2 years of age and older: Prepare a solution by mixing 1/2 to 1 teaspoon in 1/2 glass (4 ounces) of water. Swish around in mouth over affected area for at least 1 minute and then spit out. Use up to four times daily or as directed by a dentist or doctor. Children under 12 should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(4) For products containing sodium perborate monohydrate identified in § M022.16(d). Adults and children 6 years of age and older: Dissolve 1.2 grams of sodium perborate monohydrate in 1 ounce (30 milliliters) of warm water. Use immediately. Swish solution around in the mouth over the affected area or gargle for at least 1 minute and then spit it out. Do not swallow. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Consult a dentist or doctor for use in children under 6 years of age.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991 and 56 FR 65930, Dec. 19, 1991]

**§ M022.58 Labeling of demulcent drug products**

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “oral demulcent.”

(b) Indications. The labeling of the product states, under the heading “Uses," the following: “For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) For all products containing any ingredient identified in § M022.18. “If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly.”

(2) For products containing glycerin identified in § M022.18(c). “Do not use full strength. Dilute with two or three volumes of water.”

(d) Directions. The labeling of the product contains the following information under the heading "Directions":

(1) For products containing elm bark identified in § M022.18(a), the product is 10 to 15 percent elm bark in a solid dosage form. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(2) For products containing gelatin identified in § M022.18(b)

(i) For dosage forms other than solid, the product is a 5- to 10-percent solution or suspension containing a sufficient quantity of gelatin to form a semi-solid state. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains a sufficient quantity of gelatin to form a solid state. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(3) For products containing glycerin identified in § M022.18(c). Adults and children 2 years of age and older: Apply a solution containing glycerin diluted with 2 or 3 parts of water to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(4) For products containing pectin identified in § M022.18(d)

(i) For dosage forms other than solid, the product is a solution or a gel containing a sufficient quantity of pectin to form a semi-solid state. Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) For solid dosage forms, the product contains a sufficient quantity of pectin to form a solid state. Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991 and 56 FR 65930, Dec. 19, 1991]

**§ M022.60 Labeling of oral mucosal protectant drug products**

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral mucosal protectant."

(b) Indications. The labeling of the product states, under the heading "Uses," any of the phrases listed below:

(1) "Forms a coating over a wound."

(2) "Protects against further irritation."

(3) "For temporary use to protect wounds caused by minor irritations or injury."

(4) "For protecting recurring canker sores."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly."

(2) "Do not exceed recommended dosage."

(d) Directions. The labeling of the product contains the following information under the heading "Directions": For products containing compound benzoin tincture or benzoin tincture identified in § M022.20(a) and (b), the product is compound benzoin tincture, USP XIX[5] or benzoin tincture, USP XV.[6] Adults and children 6 months of age and older: Dry the affected area. Saturate a cotton applicator with medication. Apply the undiluted medication directly to the affected area. Do not use more often than every 2 hours. Children under 6 months of age: Consult a dentist or doctor.

[56 FR 48302, Sept. 24, 1991]

[5] See footnote 3
[6] See footnote 4

## § M022.62 Labeling of tooth desensitizer drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a (insert dosage form, e.g., “toothpaste” or “dental gel”) “for” (select one of the following: “sensitive” or "hypersensitive”) “teeth.”

(b) Indications. The labeling of the product states, under the heading “Uses,” any of the phrases listed below:

(1) "Helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.”

(2) “Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.”

(c) Warnings. The labeling of the product contains the following warning under the heading "Warnings.” “Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor.”

(d) Directions. The labeling for products containing potassium nitrate identified in § M022.22, as a 5 percent dentifrice, contains the following information under the heading “Directions”: Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Children under 12 years of age: Consult a dentist or doctor.

[56 FR 48302, Sept. 24, 1991]

## § M022.66 Labeling of combination drug products

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each active ingredient in the combination drug product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs, unless otherwise stated below.

(b) Indications. The labeling of the product states, under the heading “Uses," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC monographs, unless otherwise stated in § M022.66(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC monographs or listed in § M022.66(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act relating to misbranding and the prohibition in section 301(d) of the FD&C Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act. In addition to the required information identified above in § M022.66, the labeling of the combination drug product may contain any of the “other allowable statements" (if any) that are identified in the applicable OTC monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) For permitted combinations identified in § M022.26(c). Any or all of the indications in §§ M022.52(b)(2), (b)(3), (b)(4), (b)(5), and (b)(6) should be used.

(2) For permitted combinations identified in § M022.26(g). The indications in § M012.85(b)(4) of OTC Monograph M012 should be used.

(c) Directions. The labeling of the product states, under the heading “Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC monographs, unless otherwise stated in § M022.66(c). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991 and 59 FR 6084, Feb. 9, 1994]

**Part D—Professional Use**

**§ M022.92 Active ingredients – Antiseptics**

Povidone-iodine provided to health professionals (but not to the general public).

[59 FR 6084, Feb. 9, 1994]

## § M022.95 Professional labeling

(a) The labeling of products containing oral health care anesthetic/ analgesic active ingredients identified in § M022.12 provided to health professionals (but not to the general public) may contain the following indication: “For the temporary relief of pain associated with" (select one or more of the following conditions: “tonsilitis," "pharyngitis," “throat infections," “Vincent’s infection," or “stomatitis.")

(b) The labeling of products containing dyclonine hydrochloride identified in § M022.12(d) provided to health professionals (but not to the general public) may contain the following indications:

(1) “For the temporary relief of discomfort in patients with an excessive gag reflex when having impressions of the teeth made or during intraoral radiography."

(2) “For use as a preinjection topical anesthetic on the oral mucosa.”

(c) The labeling of products containing oral health care debriding agent/oral wound cleanser active ingredients identified in § M022.16 provided to health professionals (but not to the general public) may contain the following indication: “For temporary use in the cleansing of gum irritation due to erupting teeth (teething)."

(d) The labeling of aqueous products containing povidone-iodine identified in § M022.11 provided to health professionals (but not to the general public) may contain the following:

(1) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral antiseptic," or an "antiseptic" (select one of the following: "rinse," "gargle," or "rinse and gargle").

(2) Indications. The labeling of the product states under the heading "Indications," the following: "For preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction."

(3) Directions. The labeling of the product contains the following information under the heading "Directions:" For products containing povidone-iodine identified in § M022.11, the final product to be applied is a 0.5 percent aqueous solution. Manufacturers may also market a more concentrated solution provided that it contains adequate directions to dilute the product to a 0.5 percent aqueous solution. "Apply 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse for 30 seconds and then spit out. Wait 2 minutes, and apply another 10 to 20 milliliters of solution to the operative site. Instruct the patient to rinse again for 30 seconds and then spit out. With a standard syringe and a blunt, angulated needle, irrigate the operative site and the surrounding gingival mucosa for 1 minute with 10 to 20 milliliters of the solution. Instruct the patient to spit out the solution after the irrigation procedure."

[53 FR 2436, Jan. 27, 1988, as amended by 56 FR 48302, Sept. 24, 1991 and 59 FR 6084, Feb. 9, 1994]