should be used and any or all of the additional indications for sunscreen drug products may be used.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs unless otherwise stated in this paragraph (c).

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(d) and 352.20(b).* The warnings for sunscreen drug products in § 352.60(c) of this chapter are used.

(2) [Reserved]

(d) *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 drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(d) and 352.20(b).* The directions for sunscreen drug products in § 352.60(d) of this chapter are used.

(2) [Reserved]

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 57 FR 27656, June 19, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 348.1 Scope.

(a) An over-the-counter external analgesic 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 part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 348.3 Definitions.

As used in this part:

(a) *Male genital desensitizing drug product.* A drug product applied to the penis to help in temporarily slowing the onset of ejaculation.

(b) [Reserved]

Subpart B—Active Ingredients

§ 348.10 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) *Male genital desensitizers.* (1) Benzocaine, 3 to 7.5 percent in a water-soluble base.

(2) Lidocaine in a metered spray with approximately 10 milligrams per spray.

(b) [Reserved]

Subpart C—Labeling

§ 348.50 Labeling of external 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 follows:

(1) *For products containing any ingredient identified in § 348.10(a).* ''Male genital desensitizer.''

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient identified in §348.10(a).* (i) ''Helps in the prevention of premature ejaculation.''

(ii) ''For temporary male genital desensitization, helping to slow the onset of ejaculation.''

(iii) ''Helps in temporarily'' (select one of the following: ''retarding the onset of,'' ''slowing the onset of,'' or ''prolonging the time until'') followed by ''ejaculation.''

(iv) ''For reducing oversensitivity in the male in advance of intercourse.''

(2) [Reserved]

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

(1) *For products containing any ingredient identified in §348.10(a).* (i) ''Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor.''

(ii) ''Avoid contact with the eyes.''

(iii) ''If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor.''

(2) [Reserved]

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

(1) *For products containing any ingredient identified in §348.10(a)*—(i) *For products containing benzocaine identified in §348.10(a)(1).* ''Apply a small amount to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.''

(ii) *For products containing lidocaine identified in §348.10(a)(2).* ''Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.''

(2) [Reserved]

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 53 FR 7090, Mar. 4, 1988, unless otherwise noted.