warnings under the ''Warnings'' heading. (i) ''Do not use on children under 2 years of age.'' (This warning is to be used in place of the warning in paragraph (c)(1)(i) of this section.)

(ii) ''Do not use for diaper rash.''

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

(1) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete's foot, jock itch, and ringworm.* [Select one of the following: ''Clean'' or ''Wash''] ''the affected area and dry thoroughly. Apply'' (the word ''spray'' may be used to replace the word ''apply'' for aerosol products) ''a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.''

(2) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete's foot.* ''To prevent athlete's foot,'' (select one of the following: ''clean'' or ''wash'') ''the feet and dry thoroughly. Apply'' (the word ''spray'' may be used to replace the word ''apply'' for aerosol products) ''a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.''

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

EFFECTIVE DATE NOTE: At 67 FR 52305, Aug. 29, 2000, § 333.250 was amended by revising the introductory texts of paragraphs (b)(1)(i) and (b)(2)(i) and by revising paragraph (b)(2)(ii), effective May 16, 2002. For the convenience of the user, the revised text is set for as follows:

(b) * * *

(1) * * * (i) (Select one of the following: ''Treats,'' ''For the treatment of,'' ''For effective treatment of,'' ''Cures,'' ''For the cure of,'' ''Clears up,'' or ''Proven clinically effective in the treatment of'') ''most'' (select one condition from any one or more of the following groups of conditions:

* * * * *

(2) * * * (i) (Select one of the following: ''Clinically proven to prevent,'' ''Prevents,'' ''Proven effective in the prevention of,'' ''Helps prevent,'' ''For the prevention of,'' ''For the prophylaxis (prevention) of,'' ''Guards against,'' or ''Prevents the recurrence of'') ''most'' (select one of the following: ''Athlete's foot,'' ''athlete's foot (dermatophytosis),'' ''athlete's foot (tinea pedis),''' or ''tinea pedis (athlete's foot)'') ''with daily use.''

(ii) In addition to the information identified in paragraph (b)(2)(i) of this section, the labeling of the product may contain the following statement: ''Clears up most athlete's foot infection and with daily use helps keep it from coming back.''

§ 333.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indication:

(a) *For products containing haloprogin or miconazole nitrate identified in § 333.210 (a) and (c).* ''For the treatment of superficial skin infections caused by yeast (*Candida albicans*).''

(b) [Reserved]

Subpart D—Topical Acne Drug Products

SOURCE: 56 FR 41019, Aug. 16, 1991, unless otherwise noted.

§ 333.301 Scope.

(a) An over-the-counter acne drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

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