

only the uses that have been established and listed in this paragraph (b), 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 in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r).* The labeling states “temporarily protects minor: [bullet]<sup>1</sup> cuts [bullet] scrapes [bullet] burns”.

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—(i).* The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked skin” (which may be followed by: “and lips”). This statement may be followed by the optional statement: “helps protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps protect lips from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(3) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* The labeling states “dries the oozing and weeping of poison: [bullet] ivy [bullet] oak [bullet] sumac”.

(4) *For products containing colloidal oatmeal identified in § 347.10(f).* The labeling states “temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: ‘[bullet] rashes’ ‘[bullet] eczema’ ‘[bullet] poison ivy, oak, or sumac’ ‘[bullet] insect bites’].”

(5) *For products containing sodium bicarbonate identified in § 347.10(o).* The labeling states “temporarily protects and helps relieve minor skin irritation and itching due to: [bullet] poison ivy, oak, or sumac [bullet] insect bites”.

(6) *For products containing topical starch identified in § 347.10(q).* The labeling states “temporarily protects and helps relieve minor skin irritation”.

(7) *For products containing the combination of ingredients in § 347.20(a)(4).* The labeling states

“temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: ‘rashes’ or ‘eczema’].” [If both conditions are used, each is preceded by a bullet.]

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

(1) “For external use only” in accord with § 201.66(c)(5)(i) of this chapter. For products containing only mineral oil in § 347.10(l) or sodium bicarbonate in § 347.10(o), this warning may be omitted if labeling for oral use of the product is also provided.

(2) “When using this product [bullet] do not get into eyes”.

(3) “Stop use and ask a doctor if [bullet] condition worsens [bullet] symptoms last more than 7 days or clear up and occur again within a few days”.

(4) For products labeled according to § 347.50(b)(1) or (b)(2): “Do not use on [bullet] deep or puncture wounds [bullet] animal bites [bullet] serious burns”.

(5) For products containing colloidal oatmeal identified in § 347.10(f) when labeled for use as a soak in a tub. “When using this product [bullet] to avoid slipping, use mat in tub or shower”.

(6) For powder products containing kaolin identified in § 347.10(j) or topical starch identified in § 347.10(q)—(i) “Do not use on [bullet] broken skin”.

(ii) “When using this product [bullet] keep away from face and mouth to avoid breathing it”.

(7) For products containing colloidal oatmeal identified in § 347.10(f) or sodium bicarbonate identified in § 347.10(o) when labeled for use as a soak, compress, or wet dressing. “When using this product [bullet] in some skin conditions, soaking too long may overdry”.

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading “Directions”:

(1) *For products labeled according to § 347.50(b)(1), (b)(2), (b)(3), (b)(5), or (b)(6).* The labeling states “apply as needed”.

(2) *For products containing colloidal oatmeal identified in § 347.10(f)—(i) For products requiring dispersal in water.* The labeling states “[bullet] turn warm water faucet on to full force [bullet] slowly sprinkle” (manufacturer to insert quantity to be used) “of colloidal oatmeal directly under the faucet into the tub or container [bullet] stir any colloidal oatmeal settled on the bottom”.

(A) *For products used as a soak in a bath.* The manufacturer must provide adequate directions to obtain a solution

containing a minimum of 0.007 percent colloidal oatmeal or 0.003 percent colloidal oatmeal in the oilated form for a tub bath, sitz bath, or infant bath, or a minimum of 0.25 percent colloidal oatmeal for a foot bath. “For use as a soak in a bath: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin”.

(B) *For products used as a compress or wet dressing.* The manufacturer must provide adequate directions to obtain a solution containing a minimum of 0.25 percent colloidal oatmeal. “For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use”.

(ii) *For topical products intended for direct application.* The labeling states “apply as needed”.

(3) *For products containing sodium bicarbonate identified in § 347.10(o).* The labeling states “[bullet] adults and children 2 years of age and over:”

(i) The labeling states “For use as a paste: [bullet] add enough water to the sodium bicarbonate to form a paste [bullet] apply to the affected area of the skin as needed, or as directed by a doctor”.

(ii) The labeling states “For use as a soak in a bath: [bullet] dissolve 1 to 2 cupfuls in a tub of warm water [bullet] soak for 10 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin”.

(iii) The labeling states “For use as a compress or wet dressing: [bullet] add sodium bicarbonate to water to make a mixture in a container [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use”.

(iv) Any of the directions in paragraphs (d)(3)(i), (d)(3)(ii), or (d)(3)(iii) of this section shall be followed by the statement: “[bullet] children under 2 years: ask a doctor”.

(4) *For products containing aluminum hydroxide gel identified in § 347.10(b).* The labeling states “[bullet] children under 6 months: ask a doctor”.

(5) *For products containing glycerin identified in § 347.10(h).* The labeling states “[bullet] children under 6 months: ask a doctor”.

(6) *For products containing zinc acetate identified in § 347.10(s).* The labeling states “[bullet] children under 2 years: ask a doctor”.

<sup>1</sup> See § 201.66(b)(4) of this chapter for definition of bullet symbol.