

concentrations for colloidal oatmeal used in bath additive products and in other dosage forms. Products containing colloidal oatmeal have been formulated in the following dosage forms: Lotion (1 and 10 percent colloidal oatmeal), cleansing cream (8 percent colloidal oatmeal), shampoo (5 percent colloidal oatmeal), and cleansing bars (30, 50, and 51 percent colloidal oatmeal) (Refs. 4, 46, and 47). The agency has calculated the approximate minimum and maximum concentrations of colloidal oatmeal that have been used as follows: For regular colloidal oatmeal, a range of 0.023 to 0.625 percent when used as a tub bath soak (Refs. 29, 34 through 38, and 44), a range of 0.24 to 1.2 percent when used as a foot bath soak (Refs. 30, 31, and 34), a range of 0.24 to 15 percent in aqueous solution when used in a wet pack (Refs. 30, 31, 32, 34, and 45), and a range of 3.75 to 15 percent in aqueous solution when used as a topical lotion (Refs. 30, 32, and 34); for oilated colloidal oatmeal, a range of 0.003 to 0.03 percent when used as a tub bath soak (Refs. 35 and 39 through 43).

With regard to dosage forms, the agency agrees with the comment that colloidal oatmeal as a skin protectant does not need to be dosage-form specific and can be used in a variety of "barrier type" topical dosage forms, except for "cleanser type" topical dosage forms, for which the agency has no data to support use as a skin protectant. Therefore, based on the additional information that has been submitted, the agency is revising the directions for use in § 347.50(d)(2) in this final monograph.

(Comment 16) One comment requested that colloidal oatmeal be included in the skin protectant monograph for the claim: "For prompt temporary relief of itchy, sore, sensitive skin due to * * * hemorrhoidal and genital irritations * * *." The comment provided reports recommending use of colloidal oatmeal baths and creams for rectal itching and other conditions in the genital area (Refs. 50 through 54).

Claims for itching in the genital area (e.g., pruritus vulvae) are included in the rulemaking for OTC external analgesic drug products. A comment to that rulemaking (Ref. 55) specifically requested a claim for colloidal oatmeal for "prompt temporary relief of itchy, sore, sensitive skin due to rashes, eczema/psoriasis, hemorrhoidal and genital irritations, diaper rash, chicken pox, prickly heat, hives, poison ivy/oak, and sunburn." Therefore, the agency will address this comment in the final rule for OTC external analgesic drug products.

The agency concludes that the comment's requested claims for relief of rectal itching and hemorrhoids are similar to the indication (21 CFR 346.50(b)(1)) for OTC anorectal drug products that include protectant active ingredients under 21 CFR 346.14, and to the definition of a protectant drug under 21 CFR 346.3(i) as a drug that provides a physical barrier, forming a protective coating over skin or mucous membranes. Since colloidal oatmeal was not reviewed during any stage of the rulemaking for OTC anorectal drug products, interested parties should provide necessary information to demonstrate that colloidal oatmeal meets the standards of an OTC anorectal protectant active ingredient and petition the agency to include colloidal oatmeal in the final monograph for OTC anorectal drug products (Ref. 56).

(Comment 17) One comment requested that colloidal oatmeal be allowed to be combined with other Category I skin protectants for the treatment of minor irritation and itching caused by insect bites and poisonous plants. The comment cited reports using an oilated colloidal oatmeal bath additive to help treat various dermatoses.

The agency has reviewed the cited studies (Refs. 34, 43, 57, 58, and 59), and finds that these reports support the combination of colloidal oatmeal with mineral oil to treat the irritation, itching, and dryness of various dry skin dermatoses. The agency is including the combination of colloidal oatmeal and mineral oil in new § 347.20(a)(4) for the uses included in new § 347.50(b)(7) of this final monograph. Nevertheless, poison ivy, oak, and sumac are not exclusively dry skin dermatoses; they are characterized by a phase of weeping, oozing exudation. The studies cited by the comment fail to demonstrate the value of adding an additional skin protectant (an oilating component) for the treatment of these conditions in the exudative phase, and also fail to specify how many of the cases of contact dermatitis were due to poisonous plants. In addition, only one case of insect bite was identified in the studies. The agency concludes that the data are insufficient to support the combination of colloidal oatmeal with other skin protectants to treat insect bites and poison ivy, oak, and sumac.

(Comment 18) One comment responded to the agency's request in the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking (54 FR 40808 at 40810) to provide information and directions to support the use of colloidal oatmeal on children under 2 years of age. The comment

stated that most barrier type skin protectant active ingredients have not been restricted to any age group and submitted reports of use of colloidal oatmeal in infants (Refs. 34, 45, 50, 51, and 57). The comment added that the Miscellaneous External Panel had evaluated colloidal oatmeal and placed it in Category I for relief of itching claims with no age restrictions (Ref. 61).

The agency has reviewed the reports submitted by the comment, which described the effective use of colloidal oatmeal on infants and children from 2 months to 18 years of age for various dermatoses associated with dry skin. No adverse effects were reported. The Miscellaneous External Panel (Ref. 61) at its twenty-third meeting concluded that colloidal oatmeal, at all concentrations, is safe and effective for "the symptomatic relief and treatment of itching." Based on the Miscellaneous External Panel's evaluation and the references provided by the comment, the agency is including colloidal oatmeal in the final monograph for use on infants and children under 2 years of age in the same concentrations, dosage forms, and directions for use for adults.

(Comment 19) One comment noted that in the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking the agency proposed (in § 347.50(c)(9)) a specific warning for colloidal oatmeal: "Take special care to avoid slipping when getting into and out of the tub" (54 FR 40808 at 40818). The comment agreed that a warning against slipping is proper and appropriate, but contended that the agency's warning is unnecessarily longer than the warning on its labels, "Take special care to avoid slipping." Furthermore, the comment contended, the reference to entering and leaving the tub may lessen the consumer's perception of need for care during bathing or when bathing a child.

The agency notes that a number of authors have expressed concerns about slipping in the bath tub with oil baths in general, and with colloidal oatmeal baths in particular (Refs. 29, 40, 44, 48, 54, and 62). Two authors (Refs. 29 and 48) recommended use of a mat to reduce the possibility of slipping. Accordingly, the agency has revised the warning, which appears in § 347.50(c)(5) of the final monograph, to read: "When using this product [bullet] to avoid slipping, use mat in tub or shower."

(Comment 20) One comment objected to the highly specific directions for colloidal oatmeal the agency proposed in § 347.50(d)(2) of the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking (54 FR 40808 at 40818). The comment requested that