

FDA modify the directions for use to allow for other concentrations and to address the use of other dosage forms, such as ointments, lotions, and cleansing bars. The comment objected to a specified frequency of use ("once or twice daily") because absorption of active agent seems unlikely to occur.

The agency has reviewed the literature and agrees with the comment that other directions may also provide safe and effective use concentrations. Since a bathtub, foot bath, sitz bath, or infant bath can be used to soak and a compress or wet dressing can be applied as a soak, the agency is including all of these forms of a "soak" in the final monograph. Colloidal oatmeal can also be formulated in other topical products intended for direct application (e.g., ointment, lotion), and the monograph provides directions for these products.

Frequent and prolonged exposure to water may have a drying effect. Authors have different views on recommended frequency and duration of bathing (Refs. 37, 48, and 63 through 67) depending on the condition. The Miscellaneous External Panel noted that bathing can dry the skin out and exacerbate some conditions (Ref. 68). Given the variety of conditions for which colloidal oatmeal preparations may be used, the agency agrees with the comment and is not specifying a frequency of use in the directions but is providing for a warning statement in § 347.50(c)(7) to fully inform consumers.

(Comment 21) One comment inquired whether two high-molecular weight dimethylpolysiloxanes, designated as SF96-350 and SF96-1000, were acceptable active ingredients for skin protectant use. The comment included general safety and toxicity information on silicone products, and stated that dimethicone, a proposed Category I skin protectant ingredient, belongs to the same chemical family as the dimethylpolysiloxanes.

In the notice of proposed rulemaking for OTC skin protectant diaper rash drug products, the agency stated that silicone is a general term, but it is often used to describe dimethicone (55 FR 25204 at 25218). The agency did not classify silicone per se because there are various silicone compounds and because the agency considered dimethicone, the only silicone ingredient for which data were submitted.

The agency notes that the information provided by the comment summarizes the results of chronic and acute toxicity studies and irritation studies for specific classes of silicones. However, no specific information was provided for the individual dimethylpolysiloxanes SF96-350 and SF96-1000. In addition,

no information was provided to describe the chemical structure of these dimethylpolysiloxanes. The agency concludes that the data provided are inadequate to support general recognition of the safety and effectiveness of these ingredients for OTC skin protectant use in this final monograph.

(Comment 22) In the TFM for OTC skin protectant drug products, the agency discussed a submission on 2 percent glycerin and stated that the skin protectant final monograph would not be issued until these data were reviewed by the agency and interested persons provided an opportunity to comment on an agency proposal (48 FR 6820 at 6823). The submission (Ref. 69) contained data on the use of glycerin for the indications of dry skin, minor skin irritation, skin protectant, and chapping and included a double-blind study.

The agency has reviewed the data and determined that the study was inadequately controlled and failed to demonstrate that 2, 10, or 18 percent glycerin is effective for the indication "helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips," as proposed by the agency for 20 to 45 percent glycerin in the TFM for OTC skin protectant drug products (48 FR 6820 at 6832). The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 70). The agency concludes that glycerin at concentrations other than 20 to 45 percent is nonmonograph for use in OTC skin protectant drug products.

(Comment 23) One comment requested the agency to reopen the administrative record to include the ingredient "hard fat," as described in the "National Formulary" (NF) (Ref. 71), as a Category I skin protectant.

In the **Federal Register** of December 19, 1991 (56 FR 65873), the agency agreed with the petition that it would be appropriate to reopen the administrative record and include data and information on "hard fat" in the rulemaking for OTC skin protectant drug products. The agency stated that, based on its action in the rulemaking for OTC anorectal drug products (55 FR 31776), hard fat would be classified as a monograph ingredient in the final skin protectant monograph. Since no adverse comments on hard fat were received in response to this reopening of the administrative record, the agency is including hard fat in § 347.10 at concentrations of 50 to 100 percent as a single active ingredient. Hard fat is also allowed in permitted combinations in § 347.20(a)(1), (a)(2), (b), (c), and (d) of this final monograph. Products containing hard fat may be

labeled for the indications in § 347.50(b)(1), (b)(2)(i), and (b)(2)(ii) and should bear the warnings in § 347.50(c)(1) through (c)(4) and the directions in § 347.50(d)(1). In a future issue of the **Federal Register**, the agency will address claims for hard fat in OTC skin protectant cold sore/fever blister drug products (*see proposed* § 347.50(b)(2)(ii), 55 FR 3362 at 3370).

(Comment 24) One comment requested that lanolin be categorized as an active ingredient in the skin protectant monograph for use as a single ingredient or in combination, as permitted by the monograph. In support of lanolin's safety and effectiveness as a skin emollient, the comment cited animal and human test data submitted to the Miscellaneous External Panel (Ref. 72), Kligman, Grove, and Studemayer (Ref. 73), and the Advisory Review Panel on OTC Ophthalmic Drug Products' (Ophthalmic Panel) Category I classification of lanolin as an ocular emollient for the treatment of conditions involving ocular membranes (43 FR 30002 at 30044 and 30045, May 6, 1980).

The agency has considered lanolin as a protectant or emollient active ingredient in several OTC drug rulemakings. In the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25218 to 25219), the agency determined that the data submitted supported the use of 15.5 percent lanolin as a skin protectant active ingredient only in combination with other skin protectant active ingredients for the treatment and prevention of diaper rash.

In the final rule for OTC ophthalmic drug products (53 FR 7076 at 7090, March 4, 1988), lanolin and anhydrous lanolin were included as monograph conditions at a 1 to 10 percent concentration in combination with one or more oleaginous emollients included in the monograph. In the final rule for OTC anorectal drug products (55 FR 31776 at 31780), lanolin was included as a monograph protectant active ingredient at concentrations of 50 percent and above as a single ingredient or between 12.5 and 50 percent in combinations.

The agency has surveyed the marketplace (Refs. 3, 74, 75, and 76), and found that lanolin is being marketed as a skin protectant both as a single ingredient and in combination with other ingredients. The concentration in two single ingredient products is 37 and 50 percent. In almost all cases, the concentration of the lanolin in the combination products is not provided. Based on the agency's market survey and its previous actions