

in the rulemakings for OTC diaper rash, anorectal, and ophthalmic drug products, the agency is including lanolin in the final skin protectant drug products monograph as a single ingredient and in combination with certain other skin protectant active ingredients, depending on the labeled use of the product. The use concentration included in the final monograph is 12.5 to 50 percent in accord with the concentration of marketed single ingredient skin protectant drug products and the concentration used in anorectal protectant combination drug products. The use concentration of 15.5 percent proposed in § 347.10(o) for OTC diaper rash skin protectant drug products (55 FR 25204 at 25232) will be addressed in the final rule for those drug products.

(Comment 25) One comment submitted data (Refs. 77 through 89), including two clinical studies by Kaplan (Refs. 77, 78, 80, 81, and 84), in support of reclassifying LYCD from Category III to Category I as a wound healing aid. The first Kaplan study (Ref. 77) has been published (Ref. 90). The comment also submitted data included earlier in the rulemaking for OTC anorectal drug products and transcripts of meetings of the Hemorrhoidal Panel (Ref. 87).

The ingredient LYCD was reviewed by both the Hemorrhoidal Panel and the Topical Analgesic Panel. Neither panel found LYCD to be effective. The agency determined that the data were inadequate to support the use of LYCD in the final rule for OTC anorectal drug products (58 FR 46746, September 2, 1993).

The agency has reviewed the wound healing studies (Refs. 77, 78, 80, 81, and 84) submitted to this rulemaking for OTC skin protectant drug products and determined that the studies are inadequate to include LYCD as a wound healing aid in this final monograph. The agency's detailed comments and evaluations of the nonconfidential data are on file in the Dockets Management Branch (Refs. 91 and 92).

The agency also informed the company that additional information is needed on the chemical and physical characterization of LYCD before a final classification can be made and suggested the company provide information to establish a compendial monograph for the ingredient (Ref. 93). The company submitted information, both nonconfidential (Refs. 88 and 89) and confidential, but it also was not adequate. The agency's detailed comments on the information are on file in the Dockets Management Branch (Refs. 94 and 95).

(Comment 26) The agency has included in the rulemaking for OTC

skin protectant drug products several submissions (Refs. 96, 97, and 98) for drug products containing mineral oil that were originally submitted to the Miscellaneous External Panel for review. One submission (Ref. 96) did not contain any data on mineral oil as an individual ingredient and the other submissions (Refs. 97 and 98) were discussed in the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25220 to 25221). The agency concluded that the ingredient's physical properties were sufficient, along with the Category I findings of two other panels (Hemorrhoidal and Ophthalmic Panels), to support the effectiveness of mineral oil in § 347.10(p) of the skin protectant diaper rash TFM (55 FR 25204 at 25232) for diaper rash claims proposed in § 347.50(b)(5). In this final monograph for OTC skin protectant drug products, mineral oil in the first concentration listed in § 347.10(l) (50 to 100 percent) may be labeled for the claims listed in § 347.50(b)(1) and (b)(2). In addition, mineral oil in the second concentration listed in § 347.10(1) (30 to 35 percent) when combined with colloidal oatmeal may be labeled for the claims listed in § 347.50(b)(7).

(Comment 27) One comment urged FDA to consider a single statement of identity for the ingredient petrolatum because of its multi-purpose uses in OTC drug products. The comment suggested the term "protectant."

Petrolatum is generally recognized as safe and effective in two other OTC drug final monographs: Ophthalmic (part 349 (21 CFR part 349)) and anorectal (21 CFR part 346). The statement of identity for ophthalmic use is "lubricant" or "emollient (lubricant) eye ointment" (see § 349.65(a)).

The agency previously considered a related issue in the proposed rulemaking for OTC anorectal drug products (see comment 39, 53 FR 30756 at 30771) and determined that a comment's suggested statement of identity (topical protectant and lubricant) did not make it clear that such a product could be used anorectally and thus did not fully satisfy the requirements of § 201.61(b). The agency believes that the same is true of the currently suggested statement of identity "protectant." Thus, the agency is not adopting a single statement of identity for the ingredient petrolatum and is using "skin protectant" as the statement of identity for drug products containing petrolatum included in this final monograph (part 347).

(Comment 28) One comment argued that petrolatum should be exempt from the "directions for use" proposed in § 347.50(d), citing petrolatum's long

history of consumer use, efficacy, and safety and contending that petrolatum meets the requirements for such exemption under § 201.116 (21 CFR 201.116).

The agency disagrees. Section 201.116 allows for exemption from section 502(f)(1) of the act which requires adequate directions for use, if adequate directions for common uses are known to the ordinary individual. While some individuals may know that petrolatum may be applied as needed, the agency believes that not all people who use this drug would know that it can be applied on an as needed basis. Therefore, the agency is requiring the standard direction in § 347.50(d)(1) for products that contain petrolatum.

(Comment 29) One comment contended that petrolatum should be exempt from the warnings proposed in the TFM (48 FR 6820 at 6832 to 6833). The comment argued that sufficient evidence to exempt these warnings is provided by the universal use of petrolatum over many decades for a wide variety of topical indications, the clinical and marketing experience over this long period of extensive and universal use, the Panel conclusion that "large amounts of petrolatum are essentially nontoxic when ingested * * *" (43 FR 34628 at 34639), the results of a long-term chronic feeding study by Oser et al. (Ref. 99) as demonstrating safety on ingestion, and the fact that petrolatum is regulated as an approved direct food additive (under § 172.880 (21 CFR 172.880)) and is listed in the Food Chemicals Codex (Ref. 100).

Although the comment suggested a revision, it agreed in principle with the warning "Not to be applied over deep or puncture wounds, infections, or lacerations. Consult a doctor." A second comment requested, in the interest of brevity, clarity, and conservation of scarce label space, that the warning be shortened to read: "Do not apply over deep or puncture wounds or infections."

The agency discussed the importance of each of the proposed warnings in comments 25 through 31 of the TFM (48 FR 6820 at 6828 to 6830) and stated that these warnings are necessary for petrolatum used as a skin protectant. In comment 31 of the TFM, however, the agency proposed not to require the "For external use only warning" for all products (including those containing petrolatum) formulated as lip balms. The agency is finalizing that proposal in this document.