

FR 31260, November 12, 1973); and in paragraph 1 of section I of the preamble to the TFM in the present proceeding (48 FR 6820 at 6821).

(Comment 2) One comment requested that the definition of "skin protectant" be reworded to add a primary effect of skin protectants, i.e., temporary relief of the effects of harmful or annoying stimuli and to include the word "product". The agency agrees and is revising the definition of "skin protectant" in § 347.3(d).

(Comment 3) Four comments opposed the agency's "exclusivity policy," which limits the indications used in OTC drug product labeling to the "specific words and phrases" approved by FDA in a final OTC drug monograph.

After these comments were submitted, the agency published a final rule in the **Federal Register** of May 1, 1986 (51 FR 16258) changing its labeling policy (§ 330.1(c)(2) (21 CFR 330.1(c)(2))) for stating the indications for use of OTC drug products. That policy was revised and discussed in the **Federal Register** of March 17, 1999 (64 FR 13254 at 13270 to 13271, and 13294). The final rule in this document is subject to that new labeling policy.

(Comment 4) Three comments disagreed with the agency's position of prohibiting cosmetic claims from appearing in any portion of the labeling that is required by an OTC drug monograph and the agency's view that this type of labeling could be misleading (see 48 FR 6820 at 6823). One comment noted its support for the distinction made by the agency between "drug" and "cosmetic" claims for the same ingredient. Two comments cited current agency regulations in § 701.3(d) (21 CFR 701.3(d)) regarding the combined label declarations of active drug ingredients and cosmetic ingredients and requested that cosmetic indications be allowed to be stated in a manner that is not false or misleading, without regard to their position on the label.

The agency has revised its labeling requirements for OTC drug products by adding § 201.66 (21 CFR 201.66) and amending § 701.3(d) since stating its position on drug-cosmetic labeling in the TFM. Section 701.3(d) now requires separate listing of the active drug ingredients and the cosmetic ingredients where a cosmetic product is also an OTC drug product. FDA does not review and approve cosmetic terminology in OTC drug monographs. Under the new OTC drug product labeling format in § 201.66, the "Drug Facts" area of a product's labeling only contains the indication(s) for the drug part of the product. Thus, manufacturers are not allowed to commingle drug and

cosmetic claims within this specific area of the labeling. However, there are no specific restrictions on commingled information outside of the "Drug Facts" area of a product's labeling. The agency's position is that if commingled drug and cosmetic labeling information is confusing or misleading, the product's labeling may be misleading within the meaning of the Federal Food, Drug, and Cosmetic Act (the act) and the product misbranded under sections 502(a) or 602(a) of the act (21 U.S.C. 352(a) or 362(a)). The agency will review the labeling of affected products on a case-by-case basis.

(Comment 5) Several comments suggested that limiting the statement of identity to one term ("skin protectant") is too restrictive, requested other equally descriptive appropriate terms, and asked for distinct statements of identity for each indication proposed in the monograph, e.g., "minor cut protectant."

The agency does not find it necessary to have distinct statements of identity for each use of a skin protectant drug product. The statement of identity is intended to provide information on the "general pharmacological category(ies) of the drug or the principal intended action(s) of the drug" (see § 201.61(b) (21 CFR 201.61(b))). This position is consistent with the statement of identity proposed by the agency as "external analgesic" for all drug products that provide relief of pain and itching caused by a number of conditions (48 FR 5852 at 5868, February 8, 1983) and as "analgesic (pain reliever)" for all drug products that relieve pain due to various conditions (53 FR 46204 at 46211, November 16, 1988).

The agency concurs with one comment's suggestion of adding the dosage form to the statement of identity, i.e., "skin protectant (dosage form)." The *United States Pharmacopeia (USP)* lists a number of dosage forms that might be used for OTC topical drug products (Ref. 1). From a marketplace survey (Refs. 2, 3, and 4), the agency finds that the most widely used dosage forms for OTC skin protectant drug products are lotions, creams, ointments, and gels. The examples of dosage forms listed in the statement of identity in § 347.50(a) of this final monograph are not all inclusive and depend on products' historical marketing as skin protectants.

(Comment 6) One comment questioned the agency's statement that the term "soothes" is a cosmetic claim in the context of skin protectant products (48 FR 6820 at 6828).

The agency considers claims such as "temporarily protects" and "helps

relieve" to be more informative than "soothes" in conveying to consumers that a drug product provides therapeutic action. The term "soothes" may appear elsewhere in the product's labeling.

(Comment 7) Several comments contended that the indications proposed were too restrictive and omitted indications recommended by the Panel. The comments suggested additional labeling claims.

The agency agrees with some of the comments' suggestions for the indications in § 347.50(b)(2). While the agency wishes to emphasize the "protectant" function of these ingredients, they may also help provide some relief for chapped or cracked skin and lips. Therefore, the agency is allowing manufacturers to add, at their option, the words "and helps relieve" after the word "protects" in the indications in § 347.50(b)(2). The agency also agrees that the words "cold" and "wind" are informative to consumers, and possibly easier to understand than the word "windburned." Accordingly, the agency has made this revision in an optional labeling statement.

The agency considers other suggested claims to be better represented in the agency's proposed indications.

The agency is deleting "sunburn" from the indication proposed in § 347.50(b)(1) because the agency has reexamined the data and determined that they do not support a "protection of sunburn" claim for these ingredients. The "sunburn" claim proposed in the TFM originated from the Panel when it recommended the use of "skin protectant active ingredients for symptoms of dryness: 'For symptoms of chapping, peeling or scaling' (optional, any or all of the following) 'due to minor burns, sunburn, windburn, scrapes, abrasions, or cracked lips'" (see 43 FR 34628 at 34648). The Panel also recommended that the ingredients allantoin, cocoa butter, dimethicone, glycerin, petrolatum, and shark liver oil be included in the monograph as active ingredients for symptoms of dryness. Of these ingredients, petrolatum was the only one that the Panel discussed effectiveness for sunburn (43 FR 34628 at 34639). The Panel stated that "the use of petrolatum as an emollient has been well accepted for dry skin conditions, especially with flaking skin such as sunburn, and chapping" (43 FR 34628 at 34639).

The Panel's claim was revised in the TFM to a shortened "drug" claim that stated: "For the temporary protection of minor cuts, scrapes, burns, and sunburn" (see 48 FR 6820 at 6832). The agency did not include peeling or scaling claims in the TFM (48 FR 6820