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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket Nos. 78N-0021 and 78N-021P] *Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph;* 68 FR 33362 (June 4, 2003)

The Mentholatum Co. Inc. appreciates the opportunity to comment on the labeling requirements for products formulated and labeled as a lip protectant/lip balm. We submit the following comments for your consideration.

1. We recommend the agency revise § 347.50(a) to include the term "lip protectant" as an alternate statement of identity for products formulated and marketed as a lip protectant/lip balm. We understand that the statement of identity is intended to provide information on the general pharmacological category(ies) of the drug or principal intended action. Consistent with this position and the fact that the agency has distinctly identified products formulated and labeled as lip protectants elsewhere in the final monograph under § 347.3, § 347.50(b)(2)(ii), § 347.50(e), § 347.50(f), and also in combination with sunscreen active ingredients, we feel this term aptly describes the identity of such a product, and provides an option that is easily understood by consumers.

2. We find it somewhat confusing to follow and cross-reference the reduced labeling statements for products formulated and labeled as a lip protectant or lipstick in the final monographs for OTC skin protectant drug products and OTC sunscreen drug products. In the final monograph for OTC sunscreen drug products (64 FR 27666 at 27678), the agency discussed modified (reduced) labeling for lip balm products and stated that it expects to adopt the same modifications when it issues the final monograph for OTC skin protectant drug products.

The amendment to the final monograph for OTC sunscreen drug products (68 FR 33362 at 33380) allows reduced labeling for sunscreen products marketed as a lip protectant or lipstick in § 352.52(c)(2) and § 352.52(d)(4), and for combinations containing a sunscreen and skin protectant marketed as a lip protectant or lipstick in § 352.60(c) and § 352.60(d), without the need to meet the criteria established in § 201.66(d)(10). The final monograph for OTC sunscreen products (64 FR 27666 at 27689) in §352.52(f) additionally addresses reduced labeling for small areas of the face that meet the criteria established in § 201.66(d)(10), including lipstick in §352.52(f)(1)(vi).

However, according to the final monograph for OTC skin protectant drug products § 347.50(e) and the preamble discussion 68 FR 33362 at 33371, reduced labeling for products formulated and labeled as a lip protectant or lip balm appear to only be permitted for products that meet the criteria established in § 201.66(d)(10).

We recommend the same flexibility be allowed in labeling for skin protectants as permitted for sunscreen and sunscreen/skin protectant products marketed as a lip protectants, and that the reduced labeling not be limited to the criteria established in §201.66(d)(10).

3. We also note an inconsistency between labeling permitted for combination sunscreen/skin protectant products versus skin protectant products alone, specifically with interest in products formulated and labeled as a lip protectant/lip balm. The labeling in § 352.60(c) for combination sunscreen/skin protectant products (those identified in § 352.20(b)) need not include the warning for skin protectants in § 347.50(c)(3) which states "Stop use and ask a doctor [bullet] if condition worsens [bullet] symptoms last more than 7 days or clear up and occur again within a few days." Products formulated and labeled as a lip protectant in § 347.50(e)(1)(iii) are allowed reduced labeling, which states, "Stop use and ask a doctor if condition lasts more than 7 days." We understand that § 347.60(c)(1) in the skin protectant monograph allows combinations containing a sunscreen and skin protectant to use the warnings for sunscreen products in § 352.60(c), which does not require the warning in § 347.50(c)(3). We do not understand why products formulated and labeled solely as a lip protectant/lip balm, and not in combination, require inclusion of the warning.

4. We recommend that all packaging for products formulated and labeled as a lip protectant/lip balm (i.e., individual loose stick, blister card, or carton), and not just those that meet the criteria established in § 201.66(d)(10), be allowed to utilize the reduced labeling exemptions established in the final OTC skin protectant and sunscreen monographs for reasons stated by the agency (68 FR 33362 at 33371). The agency concluded that minimal information is needed for the safe and effective use of such products: "Lip protectant/lip balm products are typically packaged in small amounts, applied to limited areas of the body, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings)."

We appreciate your consideration of our comments. If there are any questions, please contact me at 716-677-2500 ext. 1572.

Sincerely,

Joyce L. Miller

Joyce L. Miller
Director, Regulatory Affairs