

FDA's decision to act in this instance need not meet the standard of proof required to prevail in a private tort action (*Glastetter v. Novartis Pharmaceuticals, Corp.*, 252 F. 3d 986, 991 (8th Cir. 2001)). To mandate warnings, or take similar regulatory action, FDA need not show, nor do we allege, actual causation. For an expanded discussion of case law

supporting FDA's authority to require such warnings, *see* the final rule entitled "Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use" (67 FR 72555, December 6, 2002).

IV. Labeling Guidance

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA established a

standardized format and standardized content for the labeling of OTC drug products. Table 1 of this document shows how the warnings proposed in the TFM have been revised in this final rule based on comments received and using the new format in § 201.66. Using the format in § 201.66(c)(4), the warnings in §§ 347.50(c) and 347.52(c) appear as follows:

TABLE 1.—REVISION OF PROPOSED MONOGRAPH WARNINGS TO NEW FORMAT

Skin Protectant Tentative Final Monograph	Skin Protectant Final Monograph
Not to be applied over deep or puncture wounds, infections, or lacerations. Consult a doctor. Do not use on broken skin.	Do not use on <ul style="list-style-type: none"> • deep puncture wounds • serious burns • animal bites • broken skin¹
Avoid contact with the eyes. Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Take special care to avoid slipping when getting into and out of the tub.	When using this product <ul style="list-style-type: none"> • do not get into eyes • keep away from face and mouth to avoid breathing it • in some skin conditions, soaking too long may overdry • to avoid slipping, use mat in tub or shower
If condition worsens or does not improve within 7 days, consult a doctor.	Stop use and ask doctor if <ul style="list-style-type: none"> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days
For external use only.	For external use only ²

¹ Only required for powder products containing kaolin or topical starch. *See* § 347.50(c)(6).

² In bold type on the line immediately following the line for the Warnings heading. *See* § 201.66(c)(5)(i) and (d)(6).

Section 201.66(d)(10) (21 CFR 201.66(d)(10)), which sets forth format and content requirements for OTC drug product labeling, establishes a modified labeling format for small packages that need more than 60 percent of their total surface area available to bear labeling to meet the format requirements of § 201.66(d)(1) through (d)(9). The agency stated in the final rule that established these labeling requirements that it would consider additional approaches for accommodating certain products in their respective monographs, taking into consideration the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population (64 FR 13254 at 13270).

In the final monograph for OTC sunscreen drug products (64 FR 27666 at 27678), the agency discussed modified warnings 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. Accordingly, the agency is establishing additional labeling exemptions for lip balm/lip protectant products that meet the criteria established in § 201.66(d)(10). The specifications for products formulated and labeled as a lip

protectant or lip balm that meet the criteria established in § 201.66(d)(10) are in § 347.50(e) of the skin protectant final monograph. In making this determination for lip protectant/lip balm products, the agency considered a number of factors that were discussed in the final rule that established the new OTC drug product labeling format in § 201.66 (64 FR 13254 at 13270). These factors include the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. 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 benefit, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings). For these reasons, the agency has concluded that minimal information is needed for the safe and effective use of such products.

The agency is also including in this final rule some modified labeling requirements in § 347.50(f) of the final monograph for products containing only cocoa butter, petrolatum, or white

petrolatum singly or in combination with each other when marketed other than as a lip protectant or lip balm. In making this decision for cocoa butter, the agency considered the factors discussed in the previous paragraphs and the Panel's recommendations on cocoa butter. The Panel stated in its safety evaluation of cocoa butter (43 FR 34628 at 34635) that "No reports regarding the safety of cocoa butter have been specifically identified. However, the Panel recognizes that its safety has been established by its wide and continuous use in pharmaceutical products and cosmetics. Clinical and marketing experience has confirmed that cocoa butter is safe in the dosage range used as a skin protectant." Thus, these products have an extremely low risk in actual consumer use situations. In addition, the agency has considered the OTC uses for this ingredient as providing temporary protection of minor cuts, scrapes, burns, and chapped or cracked skin and lips. Application to these areas for these uses will likely be infrequent and to limited areas of the body. In making this decision for petrolatum and white petrolatum, the agency considered the factors discussed in the previous paragraphs, the Panel's recommendations, and the evidence and data described in section II., comment