

rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

**DATES:**

*Effective Date:* This rule is effective October 27, 2003.

*Compliance Dates:* The compliance dates are either June 13, 2005, or the date of the first major labeling revision after the effective date of October 27, 2003, whichever occurs first.

*Comment Dates:* Submit written comments by August 27, 2003. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before September 26, 2003, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a document of significant adverse comments in the **Federal Register** and withdraw this direct final rule before September 26, 2003.

**ADDRESSES:** Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 21, 1993 (58 FR 54458), FDA published a final monograph for OTC skin protectant astringent drug products in part 347 (21 CFR part 347), subpart A (the 1993 skin protectant final monograph). In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA published a final rule for OTC skin protectant drug products (the 2003 skin protectant final monograph) and revised the format of part 347. Subpart A was redesignated as "General Provisions," and the astringent active ingredients (§ 347.10) and labeling (§ 347.50) were redesignated as §§ 347.12 and 347.52, respectively.

Two ingredients (colloidal oatmeal and sodium bicarbonate) added to the skin protectant monograph are used as a soak, compress, or wet dressing similar to the astringent active ingredient aluminum acetate. In the 2003 skin protectant final monograph, the agency included a warning about soaking too long (§ 347.50(c)(7)) and included directions for colloidal oatmeal (§ 347.50(d)(2)) and sodium

bicarbonate (§ 347.50(d)(3)) that are shorter than the directions for aluminum acetate (§ 347.52(d)(1)) and that are in the new OTC drug labeling format. In this direct final rule, the agency is adding this warning, shortening the directions for aluminum acetate drug products, and arranging these directions in the new OTC drug labeling format.

Section 201.66(d)(10) (21 CFR 201.66(d)(10)) of the OTC drug labeling rule (64 FR 13254 at 13286, March 17, 1999) 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 requirements of § 201.66(c)(1) through (c)(9) and (d)(1) through (d)(9). The agency stated in that rule 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, March 17, 1999). The 2003 skin protectant final monograph included additional labeling exemptions for certain small packages (lip protectant products) that meet the size criteria established in § 201.66(d)(10). The agency determined that 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).

Consequently, the agency is now including additional labeling exemptions for certain small packages of skin protectant astringent drug products (styptic pencils) that meet the criteria established in § 201.66(d)(10), 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. For the safety profile of styptic pencils, the agency considered the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel). The Panel noted that "In 75 years of marketing styptic pencils there have been [no] reported instances of human toxicity" (47 FR 39412 at 39429, September 7, 1982). (The word "no" was inadvertently left out of the September 7, 1982, publication, and the agency corrected this error in its notice of proposed rulemaking for OTC skin

protectant astringent drug products (54 FR 13490 at 13493, April 3, 1989).) The Panel also stated that aluminum sulfate (the active ingredient in styptic pencils) "has little, if any, cell permeability and exerts its effect on the cell surface." The only side effect the Panel noted was that application of the styptic pencil on a cut may result in some stinging. Thus, these products have an extremely low risk in actual consumer use situations, and the monograph only requires two general warnings (§ 347.50(c)(1)) and no ingredient specific warnings.

The agency also considered the factors listed previously that were the basis for labeling modifications for OTC lip protectant/lip balm drug products. Like those products, styptic pencils are packaged in small amounts, have a high therapeutic index and a favorable public health benefit (stop bleeding), would be used infrequently and on very limited areas of the body to stop bleeding of minor cuts from shaving, require minimal warnings (there is no pregnancy warning because this is a topical product), and have no specified dosage limitation (the directions for use are to apply to the affected area). For these reasons, the agency is including specific labeling provisions for certain small packages of skin protectant astringent drug products (styptic pencils) in this direct final rule.

**II. Description of the Labeling Revisions**

The warning in § 347.50(c)(7), when the colloidal oatmeal or sodium bicarbonate product is labeled for use as a soak, compress, or wet dressing, states: "When using this product [bullet] in some skin conditions, soaking too long may overdry." The agency is adding this warning in new § 347.52(c)(4) for products containing aluminum acetate when labeled for use as a soak, compress, or wet dressing. Our decision to revise the warning set forth in this direct final rule is based upon a finding that bathing can dry the skin out and exacerbate some conditions (as discussed in the 2003 skin protectant final monograph, 68 FR 33362 at 33367). Mandating a warning does not require a finding that any or all of the astringent drug products actually caused an adverse event, and FDA does not so find. Nor does FDA's mandate of a warning repudiate the OTC drug monograph under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that this revised warning is necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are