

**“ACE KS E4 Goodland, KS**

Renner Field-Goodland Municipal Airport,  
KS

(Lat. 39°22'14"N., long. 101°41'56"W.)

Goodland VORTAC

(Lat. 39°23'16"N., long. 101°41'32"W.)

That airspace extending upward from the surface within 2.4 miles each side of the Goodland VORTAC 164° radial extending from the 4.1-mile radius of Renner Field-Goodland Municipal Airport to 7 miles southeast of the VORTAC.” to read:

**“ACE KS E2 Goodland, KS**

Renner Field-Goodland Municipal Airport,  
KS

(Lat. 39°22'14"N., long. 101°41'56"W.)

Goodland VORTAC

(Lat. 39°23'16"N., long. 101°41'32"W.)

Within a 4.1-mile radius of Renner Field-Goodland Municipal Airport and within 2.4 miles each side of the Goodland VORTAC 164° radial extending from the 4.1-mile radius of the airport to 7 miles southeast of the VORTAC.”

Issued in Kansas City, MO, on November 24, 2003.

**Paul J. Sheridan,**

*Acting Manager, Air Traffic Division, Central Region.*

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**BILLING CODE 4910-13-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 347

[Docket Nos. 78N-0021 and 78N-021P]

RIN 0910-AA01

#### Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products. This amendment revises several of the indications for OTC skin protectant drug products to provide additional labeling claims that should not have been excluded from the final monograph (FM).

**DATES:** *Effective Date:* This rule is effective June 4, 2004.

*Compliance Dates:* The compliance date for products subject to part 347 (21

CFR part 347) with annual sales less than \$25,000 is June 6, 2005. The compliance date for all other products subject to part 347 is June 4, 2004. The compliance date for combination products containing skin protectant and sunscreen active ingredients in § 347.20(d) and for all products subject to part 352 was stayed until further notice at 68 FR 33362, June 4, 2003.

*Comment Date:* Submit written or electronic comments by February 9, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (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:

Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA issued a FM for OTC skin protectant drug products in part 347. Section 347.50(b)(2) of that FM includes the following indications for OTC skin protectant drug products:

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—(i)* The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked skin” (which may be followed by: “and lips”). This statement may be followed by the optional statement: “helps protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps protect lips from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

Shortly after FDA issued the FM, an industry national trade association submitted a petition (“The petition,” Ref. 1) requesting FDA to amend the FM to permit the terms “helps prevent” and “chafed” in the indications in § 347.50(b)(2). The petition stated that FDA had included these terms in the indication in this section proposed in the tentative final monograph (TFM) (February 15, 1983, 48 FR 6820 at 6832), which stated: “Helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips.”

The petition noted that the preamble to the FM contained a discussion of a study using nonmonograph concentrations of glycerin (less than 20 percent) that were found to be inadequate to support the indication that had been proposed in the TFM (see 68 FR 33362 at 33367). The petition added that the FM did not provide adequate justification or discussion for the elimination of this claim for other skin protectant active ingredients. The petition stated that skin protectant products are selected frequently for their preventative as well as their protective benefits. The petition requested FDA to reconsider its decision not to include the terms “helps prevent” and “chafed” in the indications in § 347.50(b)(2) of the FM.

##### II. FDA's Conclusions on the Petition

FDA has reevaluated the indications in § 347.50(b)(2) of the FM and concurs with the petition that these terms should have remained in these indications, as proposed in the TFM. However, because labeling space may be limited for some OTC skin protectant drug products and all manufacturers of these products may not wish to include this additional language in their products' indications, FDA is including these additional terms as optional labeling in the indications in § 347.50(b)(2). Including these additional terms as labeling options will enable those manufacturers who wish to include these terms in product labeling to do so, but will not require all manufacturers of these products to have to include the terms if they do not wish to do so. Accordingly, in this final rule, FDA is amending § 347.50(b)(2) to read as follows:

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—(i)* The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked skin” (optional: “and lips”). This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

FDA concludes that this revised labeling provides manufacturers a number of ways to state the indications for these OTC skin protectant drug