

period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2003-16504/Airspace Docket No. 03-ACE-88." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, dated September 2, 2003, and effective September 16, 2002, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE IA E5 Greenfield, IA

Greenfield Municipal Airport, IA
(Lat. 41°19'37" N., long. 94°26'45" W.)
Greenfield NDB
(Lat. 41°19'32" N., long. 94°26'40" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Greenfield Municipal Airport and within 2.6 miles each side of the 144° bearing from the Greenfield NDB extending from the 6.4-mile radius to 7.4 miles northwest of the airport.

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

Paul J. Sheridan,
Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 03-30456 Filed 12-8-03; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2003-16079; Airspace Docket No. 03-ACE-71]

Establishment of Class E4 Airspace; and Modification of Class E5 Airspace; Goodland, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a Final rule that was published in the **Federal Register** on Friday, November 14, 2003, (68 FR 64524) [FR Doc. 03-38538]. It corrects an error in the classification of a Goodland, KS Class E airspace area.

DATES: This direct final rule is effective on 0901 UTC, December 25, 2003.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2525.

SUPPLEMENTARY INFORMATION:

History

On Monday, September 22, 2003, the FAA proposed to amend 14 CFR part 71 by establishing a Class E airspace area designated as an extension to the Class E surface area and revising the Class E airspace area extending upward from 700 feet or more above the surface at Goodland, KS (68 FR 55015) [FR Doc. 03-24143]. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received and a Final rule was subsequently published in the **Federal Register** on Friday, November 14, 2003, (68 FR 64524) [FR Doc. 03-28538].

A determination has been made that airspace comprising the extension to the Goodland, KS Class E surface area was necessary and properly established. However, this airspace area was erroneously categorized as an extension to the Class E surface area (E4) when it should have been added to the existing Class E airspace designated as a surface area (E2). This correction has no effect on the dimensions or definition of controlled airspace established by the rule, it merely identifies the extension as part of the basic surface area.

■ Accordingly, pursuant to the authority delegated to me, the Goodland, KS Class E4 airspace, as published in the **Federal Register** on Friday, November 14, 2003, (68 FR 64524) [FR Doc. 03-28538] is corrected as follows:

§71.1 [Corrected]

- 1. On page 64524, column 3, following amendatory instruction 2, revise "Paragraph 6004 Class E airspace areas designated as an extension to Class D or Class E Surface area" to read "*Paragraph 6002 Class E Airspace Designated as Surface Areas.*"
- 2. On page 64524, column 3, following amendatory instruction 2, revise:

“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.

[FR Doc. 03-30459 Filed 12-8-03; 8:45 am]

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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