“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]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

RIN 0910–AA01

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

AGENCY: Food and Drug Administration, HHSS.

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.

ADDITIONAL: 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. Rachenow, 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 final monograph (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”.
- (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 from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

- (i) The labeling states (optional: “helps prevent”) “chafed or cracked skin” (optional: “and lips”). This statement may be followed by the additional language in their product labeling as follows:
- (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 from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]


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 “help’s 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:

- (i) The labeling states (optional: “help’s prevent”) “temporarily protects” (optional: “and helps relieve”) “chafed” (optional: “and lips”). This statement may be followed by the optional statement: “help’s 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: “help’s prevent”) “temporarily protects” (optional: “and helps relieve”) “chapped or cracked lips”. This statement may be followed by the optional statement: “help’s protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

- (iii) For products formulated as a lip protectant. The labeling states (optional: “help’s prevent”) “temporarily protects” (optional: “and helps relieve”) “chaffed” (optional: “chapped or cracked skin” (optional: “and lips”). This statement may be followed by the optional statement: “help’s 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...
These amended sections read as follows:

Under these sections of the monograph skin protectant drug products labeled amending these indications so that OTC indication state:

Because the final monograph for OTC skin protectant drug products, in a future issue of the Federal Register, may be limited to:

prevent and protect chapped lips

chapped skin

FDA also intends to amend one of the indications in § 352.52(f)(1)(iii) to add the optional “prevents” language to be comparable to the other labeling revisions being made above. FDA intends to propose that the revised indication state:

For a lip protectant product, the heading and the indication required by § 201.66(c)(4) may be limited to: “Use [in bold type] helps prevent minor cuts and burns” or “Use [in bold type] helps” (optional: “prevent and”) “chapped skin” or “Use [in bold type] helps protect minor cuts and burns and” (optional: “prevent and”) “chapped skin.”

Because the final monograph for OTC sunscreen drug products in part 352 is currently stayed, FDA intends to propose this revision in an amendment of that monograph, in a future issue of the Federal Register.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

For the reasons stated in the previous paragraphs and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Rather, the labeling statements are a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see ADDRESSES). Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum of not more than five pages. Received comments may be seen in the Division of Dockets Management...
between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Reference
The following reference is on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. PRCl.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 347 is amended as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

§ 347.50 Labeling of skin protectant drug products.

(i) The authority citation for 21 CFR part 347 continues to read as follows:


(ii) Section 347.50 is amended by revising paragraphs (b)(2), (e)(1)(ii), and (f)(1)(ii) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

(b) Indications. * * *

(i) The heading and the indication required by § 347.10(a), (d), (e), (g), (h), (i), (k), (l), and (m)—The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) “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 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.] * * * * *

(e) Products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10) of this chapter. * * *

(i) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] helps” (optional: “prevent and”) “protect” (optional: “and relieve”) “chapped lips”. If both optional terms are used, the indication may be limited to: “Use [in bold type] helps prevent, protect, and relieve chapped lips”.

(f) Products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), singly or in combination with each other, and marketed other than as a lip protectant. (1) * * *

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] helps protect minor cuts and burns” or “Use [in bold type] helps” (optional: “prevent and”) “protect chapped skin” or “Use [in bold type] helps protect minor cuts and burns and” (optional: “prevent and protect”) “chapped skin”.

* * * * *

Dated: December 1, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–30394 Filed 12–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9094]

RIN 1545–BC01

Return of Partnership Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document contains final and temporary regulations that were published in the Federal Register on November 10, 2003 (68 FR 63733), that authorize the Commissioner to provide exceptions to the requirements of section 6301(a) of the Internal Revenue Code for certain partnerships by Treasury.

EFFECTIVE DATE: This correction is effective November 5, 2003.


SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations are under section 6031 of the Internal Revenue Code.

Need for Correction

As published, these final and temporary regulations (TD 9094) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 9094), which were the subject of FR Doc. 03–28190, is corrected to read as follows:

On page 63734, Authority Citation, column 1, the language “Section 1.6031(a)–1T also issued under” is corrected to read “Section 1.6031(a)–1T is also issued under”.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 03–30524 Filed 12–8–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) has determined that USS PINCKNEY (DDG 91) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.


FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy