M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: FEB 24 2004

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0021 and 78N-021P

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. PRC1 and

Charles J. Ganley, M.D.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 24 2004

E. Edward Kavanaugh
The Cosmetic, Toiletry, and
Fragrance Association
1101 17th Street, N.W., Suite 300
Washington, D.C. 20036-4702

RE: Docket Nos. 78N-0021
and 78N-021P
Comment No. PRC1

Dear Mr. Kavanaugh:

This responds to your petition submitted on July 7, 2003, requesting reconsideration and a stay of action of certain Food and Drug Administration (FDA) decisions in the final monograph (FM) for over-the-counter (OTC) skin protectant drug products that was published in the Federal Register on June 4, 2003 (68 FR 33362).

I. PETITIONER'S REQUEST AND FDA'S DECISION

You requested FDA to reconsider its decision to eliminate the terms "helps prevent" and "chafing" from the indications in the FM for OTC skin protectant drug products in 21 CFR part 347 and to amend the FM to include these claims. You also requested FDA to stay any enforcement action on the FM regarding such claims while the agency's decision is pending.

You explained that FDA had included these claims in the tentative final monograph (TFM) for OTC skin protectant drug products, published February 15, 1983 (48 FR 6820), but FDA modified the claims allowed in the FM and deleted the words "helps prevent" and "chafed." You 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 (68 FR 33362 at 33367). However, you contended that the FM did not provide adequate justification or discussion for the elimination of these claims for other skin protectant active ingredients. You indicated that consumers select skin protectant products frequently for their preventative as well as their protective benefits.

FDA has reviewed your petition and arguments. The agency has reconsidered this matter, and for the reasons set forth below, has granted your request in a technical amendment to the skin protectant FM, published in the Federal Register on December 9, 2003

(68 FR 68509) (copy enclosed). Because this decision was made and the technical amendment was published well in advance of the compliance dates of the FM, your request that FDA stay any enforcement action while the decision is pending is moot. The basis for these decisions is set forth below.

II. DISCUSSION

A. Amendment of the FM for OTC Skin Protectant Drug Products

As explained in the technical amendment (68 FR 68509), FDA reevaluated the indications in § 347.50(b)(2) of the FM (21 CFR 347.50(b)(2)) and concurred with your petition that the terms "helps prevent" and "chafed" should be included in the indications, as proposed in the TFM. FDA stated, however, that labeling space may be limited for some OTC skin protectant drug products and all manufacturers may not wish to include this additional language in their products' indications. Therefore, in the technical amendment, FDA amended the indications in § 347.50(b)(2) of the FM and included these additional terms as optional labeling. FDA concluded that the revised labeling provides manufacturers of OTC skin protectant drug products a number of ways to state the indications for these products and does not change the substance of the labeling requirements in the FM.

FDA also stated in the technical amendment that it intends to amend one of the indications in the FM for OTC sunscreen drug products (21 CFR part 352). That amendment will add the optional "prevents" language to the indication for lip protectant drug products in § 352.52(f)(1)(ii) to make that indication comparable to the revisions made in the FM for OTC skin protectant drug products. FDA noted that it will include the revision for OTC sunscreen drug products in a future issue of the Federal Register.

B. Stay of Enforcement Action

The compliance dates for FDA enforcement of the FM for OTC skin protectant drug products are June 6, 2005, for products with annual sales less than $25,000, and June 4, 2004, for all other products subject to that FM. As you are aware, enforcement of § 347.20(d) (combinations of skin protectant and sunscreen active ingredients) was stayed in the FM for OTC skin protectant drug products. We estimate that few, if any, manufacturers of OTC skin protectant drug products that bear the indications included in your petition have relabeled their products as of the date of the technical amendment to the FM. FDA will not consider enforcement of the FM for OTC skin protectant drug products initially introduced or initially delivered for introduction into interstate commerce until after these compliance dates. As we have acted on your petition well in advance of the time when enforcement action will begin, your request to stay these compliance dates is now moot.

III. CONCLUSION

After considering the information you presented, FDA has amended the FM for OTC skin protectant drug products to include the claims "helps prevent" and "chafed" in the indications in § 347.50(b)(2), as you requested. However, FDA denies your request to stay enforcement action on the FM regarding these claims, as enforcement action will not begin until after June 4, 2004, or June 6, 2005 (for products with annual sales less than $25,000).

For the reasons stated above, we grant your petition in part and deny it in part. Any comment that you wish to make on the above information should be submitted in triplicate, identified with the docket and comment numbers shown at the beginning of this letter, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

John M. Taylor III
Associate Commissioner
for Regulatory Affairs

Enclosure

"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

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

products. Although not requested by the petition, FDA is also amending the indications in § 347.50(e)(1)(ii) [for products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10)] and (f)(1)(ii) [for products containing only cocoa butter, petrolatum, or white petrolatum, singly or in combination with each other, and marketed other than as a lip protectant]. FDA is amending these indications so that OTC skin protectant drug products labeled under these sections of the monograph can have comparable labeling to products labeled under § 347.50(b)(2). These amended sections read as follows:

(e)(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" (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)(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".

FDA also intends to amend one of the indications in § 352.52(f)(1)(ii) 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 protect against sunburn and" (optional: "prevent and protect") "chapped lips".

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) in that obtaining public comment is impracticable, unnecessary, and contrary to public interest. The labeling revisions represent a minor change to reinstate language that should not have been excluded from the FM, and to make other labeling in the FM consistent with the labeling proposed in the TFM. In addition, given the imminence of the current compliance dates (see DATES) for the FM, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether the regulation should be modified or revoked.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any 1 year (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this final rule is to revise several monograph indications. These changes provide manufacturers of OTC skin protectant drug products additional options to state the uses in the labeling for their products.

All manufacturers of OTC skin protectant drug products will need to relabel their products as a result of the FM issued on June 4, 2003. Based on the amount of time it takes to relabel products (6 to 10 months, on average) FDA estimates that few, if any, manufacturers have relabeled their products as of the date of this technical amendment to the FM.

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 or brief. 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. PRC1.

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

■ 1. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. 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.* * * *

(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.]

* * * * *

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

(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" (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 guidance published in the Internal Revenue Bulletin.

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

FOR FURTHER INFORMATION CONTACT: David A. Shulman (202) 622–3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections 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.

EFFECTIVE DATE: June 16, 2003.

FOR FURTHER INFORMATION CONTACT: Commander Scott A. Kenney, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE, Suite 3000, Washington Navy Yard, DC 20374–5066, Telephone number: (202) 685–5040.

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