

Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

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ASO MS E2 Elizabeth City, NC [Corrected]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15'38" long. 76°10'29")

That airspace extending upward from the surface within a 4.1-mile radius of the Elizabeth City CGAS/Regional Airport.

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Issued in College Park, Georgia, May 28, 2003.

Walter R. Cochran,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 347, and 352

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

RIN 0910-AA01

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of the ongoing review of OTC drug products conducted by FDA. The final monograph includes OTC skin protectant drug products for minor cuts, scrapes, burns, chapped skin and lips, poison ivy, poison oak, poison sumac, and insect bites. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on skin protectant drug products for these specific uses that have come to the agency's attention. This final rule amends the regulation that lists nonmonograph active ingredients by adding those OTC skin protectant ingredients that have been found to be

not generally recognized as safe and effective. This final rule also lifts the stay of 21 CFR part 352 (published at 66 FR 67485, December 31, 2001) to amend the final monograph for OTC sunscreen drug products to include sunscreen-skin protectant combination drug products, and then stays § 347.20(d) (21 CFR 347.20(d)) and part 352 until further notice in the **Federal Register**.

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

Compliance Dates: The compliance date for products subject to parts 310 and 347 (21 CFR parts 310 and 347) with annual sales less than \$25,000 is June 6, 2005. The compliance date for all other products subject to parts 310 and 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 is stayed until further notice.

Comment Date: Submit written or electronic comments on specific labeling items discussed in section X of the **SUPPLEMENTARY INFORMATION** section of this document by September 2, 2003.

ADDRESSES: Submit written comments 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: 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 August 4, 1978 (43 FR 34628), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC skin protectant drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class (§ 330.10(a)(6) (21 CFR 330.10(a)(6))).

In the **Federal Register** of February 15, 1983 (48 FR 6820), FDA published the proposed regulation for OTC skin protectant drug products in the form of a tentative final monograph (TFM). In the **Federal Register** of October 3, 1989 (54 FR 40808), the agency published a document to amend the TFM to include OTC drug products for poison ivy, oak,

and sumac and for the treatment and/or neutralization of insect bites. This final rule completes the TFM published on February 15, 1983, and October 3, 1989, amends the final monograph for OTC skin protectant drug products used as astringents in part 347 published on October 21, 1993 (58 FR 54458), and incorporates the name change ("witch hazel") published in the **Federal Register** of June 3, 1994 (59 FR 28767).

In the **Federal Register** of May 10, 1993 (58 FR 27636), the agency issued a final rule establishing that certain active ingredients, including some skin protectant active ingredients, in OTC drug products are not generally recognized as safe and effective or are misbranded. These skin protectant ingredients are listed in § 310.545(a)(18). This final rule adds several ingredients to that section.

On or after 12 months after date of publication in the **Federal Register**, and 24 months after date of publication in the **Federal Register**, for products with annual sales less than \$25,000, except combination products containing skin protectant and sunscreen active ingredients, and for combination products containing skin protectant and sunscreen active ingredients, no OTC drug product that is subject to this final rule and that contains a nonmonograph condition may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application or abbreviated new drug application. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective dates of the final rule must be in compliance with the monographs regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily as soon as possible.

All "OTC Volumes" cited throughout this document refer to information on public display in the Dockets Management Branch (*see ADDRESSES*).

II. The Agency's Conclusions on the Comments

(Comment 1) One comment stated its continuing position that OTC drug monographs are interpretive, as opposed to substantive, regulations.

The agency addressed this issue and reaffirms its conclusions stated in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products (37 FR 9464 at 9471 to 9472, May 11, 1972); in paragraph 3 of the preamble to the TFM for OTC antacid drug products (38