30, 2002, and effective September 16, 2002, which is incorporated by reference in 14 CFR part 71.1. The Class E designations listed in this document will be published subsequently in the Order.

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.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E2 airspace and amends Class E5 airspace at Waycross, GA.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact 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

■ In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.9K, 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.

* * * * *

ASO GA E2 Waycross, GA [New]

Waycross-Ware County Airport, GA
(Lat. 31°14′57″ N, long. 82°23′43″ W)
Waycross VORTAC
(Lat. 31°16′10″ N, long. 82°33′23″ W)

Within a 4.1-mile radius of the Waycross-Ware County Airport, within 1.2 miles each side of the 099° radial from the Waycross VORTAC, extending from the 4.1-mile radius to 4.7 miles west of the airport.

* * * * *

ASO GA E5 Waycross [Revised]

Waycross-Ware County Airport, GA
(Lat. 31°14′57″ N, long. 82°23′43″ W)
WIKET NDB
(Lat. 31°19′32″ N, long. 82°23′53″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Waycross-Ware County Airport, and within 4 miles west and 8 miles east of the 003° bearing from the WIKET NDB extending from the 6.6-mile radius to 16 miles north of the WIKET NDB; excluding that airspace within the Alma, GA, Class E airspace area.

* * * * *

Issued in College Park, Georgia on May 27, 2003.

Walter R. Cochran,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 03–14068 Filed 6–3–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2003–14673; Airspace Docket No. 03–ASO–2]

Establishment of Class E2 Airspace; Elizabeth City, NC; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the final rule (FAA–2003–14673; 03–ASO–2), which was published in the **Federal Register** on May 23, 2003 (68 FR 28128), establishing Class E2 airspace at Elizabeth City, NC. This action corrects an error in the legal description for the Class E2 airspace at Elizabeth City CGAS/Regional Airport, NC.

EFFECTIVE DATE: Effective 0901 UTC, July 10, 2003.

FOR FURTHER INFORMATION CONTACT: Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

SUPPLEMENTARY INFORMATION:

Background

Federal Register Document 03–12816, Docket No. FAA–2003–14673; Airspace Docket 03–ASO–2, published on May 23, 2003, (68 FR 28128), establishes Class E2 airspace at Elizabeth City CGAS/Regional Airport, NC. An error was discovered in the legal description, describing the Class E2 airspace area. The name of the airport should be changed from Elizabeth City CGAS/ Municipal Airport to Elizabeth City CGAS/Regional Airport. This action corrects the error.

Designations for Class E airspace areas designated as surface areas are published in Paragraph 6002 of FAA Order 7400.9k, dated August 30, 2002, and effective September 16, 2002, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Need for Correction

As published, the final rule contains an error which incorrectly identifies the name of the airport. Accordingly, pursuant to the authority delegated to me, the legal description for the Class E2 airspace area at Elizabeth City, NC, incorporated by reference at § 71.1, 14 CFR 71.1, and published in the **Federal Register** on May 23, 2003, (68 FR 28128), is corrected by making the following correcting amendment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

■ In consideration of the foregoing, the Federal Aviation Administration corrects the adopted amendment, 14 CFR part 71, by making the following correcting amendment:

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 [Corrected]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation

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.

* * * * *

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.

* * * * *

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

Walter R. Cochran,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 03–14071 Filed 6–3–03; 8:45 am]

BILLING CODE 4910–13–M

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 TFMs 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