

Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

**SUPPLEMENTARY INFORMATION:**

**Background**

The FAA is redesigning the nation's airspace to reduce the volume of air traffic operations in certain congested areas commonly referred to as "choke-points." As part of this effort, the FAA believes that revising the affected segment of J-180 to reroute it over the new Sawmill, LA, VORTAC will alleviate air traffic congestion in specific "choke-point" areas.

**Public Input**

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on this proposal to the FAA (66 FR 56250). No comments were received in response to the proposal.

**The Rule**

This amendment to 14 CFR part 71 realigns J-180 between the Daisetta, TX, VORTAC and the Little Rock, AR, VORTAC by moving the route eastward over the new Sawmill, LA, VORTAC. This action is necessary to support the national airspace redesign project and reduces air traffic congestion in identified "choke-point" areas.

The FAA has determined that this 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 Department of Transportation (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.

Jet routes are published in paragraph 2004 of FAA Order 7400.9J dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR 71.1. The jet route listed in this document will be published subsequently in the Order.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**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 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 the Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

*Paragraph 2004—Jet Routes*

\* \* \* \* \*

*J-180 [Revised]*

From Humble, TX; Daisetta, TX; Sawmill, LA; Little Rock, AR.

\* \* \* \* \*

Issued in Washington, DC, on June 14, 2002.

**Reginald C. Matthews,**

*Manager, Airspace and Rules Division.*

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**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 73**

**[Docket No. FAA-2002-12100; Airspace Docket No. 02-AGL-5]**

**RIN 2120-AA66**

**Change Using Agency to Restricted Area R-4305; Lake Superior, MN**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends the using agency for Restricted Area R-4305 Lake Superior, MN. Specifically, this action changes the using agency from "USAF, Detachment 1, HQ Air Combat Command (DOSR), Offutt AFB, NE" to "USAF, 55th Wing, Offutt AFB, NE." This rule makes no other changes to R-4305. The FAA is issuing this amendment because the DOSR is no longer in existence.

**EFFECTIVE DATE:** 0901 UTC, August 8, 2002.

**FOR FURTHER INFORMATION CONTACT:**

Steve Rohring, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

**SUPPLEMENTARY INFORMATION:**

**Background**

On February 2, 2002, the United States Air Force (USAF) requested that the FAA take action to change the using agency of R-4305 from "USAF, Detachment 1, HQ Air Combat Command (DOSR), Offutt AFB, NE" to "USAF, 55th Wing, Offutt AFB, NE." This change is needed because the DOSR is no longer in existence and the 55th Wing, Offutt AFB has assumed the responsibility of the using agency for R-4305.

**The Rule**

This amendment to 14 CFR part 73 changes the using agency of R-4305 from "USAF, Detachment 1, HQ Air Combat Command (DOSR), Offutt AFB, NE" to "USAF, 55th Wing, Offutt AFB, NE." No other changes to R-4305 are made by this action.

Since this action simply changes the using agency for the restricted area and does not involve a change in the dimensions or operations requirements of that airspace, notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Section 73.43 of part 73

was republished in FAA Order 7400.8J, dated September 20, 2001.

This 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 it has been determined that this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

#### List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

#### Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

#### PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 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.

#### § 73.43 [Amended]

2. Section 73.43 is amended as follows:

\* \* \* \* \*

*R-4305 Lake Superior, MN [Amended]*

By removing the words “Using Agency. USAF, Detachment 1, HQ Air Combat Command (DOSR), Offutt AFB, NE” and inserting the words “Using Agency. USAF, 55th Wing, Offutt AFB, NE.”

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Issued in Washington, DC, on June 14, 2002.

**Reginald C. Matthews,**  
*Manager, Airspace and Rules Division.*  
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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 352

[Docket No. 78N-0038]

RIN 0910-AA01

#### Sunscreen 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) sunscreen drug products are generally recognized as safe and effective and not misbranded. This amendment updates the monograph to incorporate United States Pharmacopeia (U.S.P.) name changes for four active ingredients included in the monograph. This final rule is part of FDA's ongoing review of OTC drug products.

**DATES:** This final rule is effective September 1, 2002. Submit written or electronic comments by August 19, 2002.

**ADDRESSES:** Submit written or electronic 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:** John D. Lipnicki, 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 May 21, 1999 (64 FR 27666), FDA issued a final monograph for OTC sunscreen drug products (21 CFR part 352). Section 352.10 of that monograph included the active ingredients menthyl anthranilate, octyl methoxycinnamate, octyl salicylate, and phenylbenzimidazole sulfonic acid.

In 2000 (Ref. 1), the U.S.P. proposed (for inclusion in the Third Supplement to U.S.P. 24) name changes for these four ingredients based on names adopted by the United States Adopted Names (USAN) Council. The new names are: Meradimate for menthyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. These name changes became official on March 1, 2001, and were subsequently included in the U.S.P. with an effective date of September 1, 2002 (Ref. 2).

#### II. Naming Process

The Federal Food, Drug, and Cosmetic Act (the act) requires the label of a drug to bear the established name of the drug to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) (21 U.S.C. 352(e)(1)(A)(i)). The established name of the drug is defined as:

(A) the applicable official name designated pursuant to section 508 [of the Act], or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient \* \* \*.

#### 21 U.S.C. 352(e)(3)

Section 508 of the act (21 U.S.C. 358) authorizes FDA to designate an official name for any drug if FDA determines “that such action is necessary or desirable in the interest of usefulness and simplicity” (21 U.S.C. 358(a)). FDA does not, however, routinely designate official names for drug products under section 508 of the act (§ 299.4(e) (21 CFR 299.4(e))). In the absence of designation by FDA of an official name, interested persons may rely on the current compendial name as the established name (§ 299.4(e)).

#### III. The Technical Amendment

FDA has not designated official names for the following active ingredients: Menthyl anthranilate, octyl methoxycinnamate, octyl salicylate, and phenylbenzimidazole sulfonic acid. Thus, their established names are the current compendial names. The U.S.P. has now changed the compendial names to: Meradimate for menthyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. To be consistent with the change in official compendial names, the agency is changing these names in § 352.10 in the