

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Aurora Municipal-Al Potter Field Airport.

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Issued in Kansas City, MO, on April 8, 2003.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2003-14868; Airspace Docket No. 2003-ANE-103]

Amendment to Class E Airspace; Windsor Locks, Bradley International Airport, CT

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action revises the Class E Airspace area at Windsor Locks, Bradley International Airport, CT (BDL) to provide for adequate controlled airspace for those aircraft using Instrument Approach Procedures to the airport.

DATES: Effective 0901 UTC, July 10, 2003.

Comments for inclusion in the Rules Docket must be received on or before May 19, 2003.

ADDRESSES: Send comments on the rule to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket number, FAA-2003-14868/Airspace Docket No. 2003-ANE-103, at the beginning of your comments. You may also submit comments on the Internet at <http://dms.dot.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person at the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527) is located on the plaza level of the Department of Transportation NASSIF Building at the street address stated above.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, New England Region, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA

01803-5299. Call the Manager, Airspace branch, ANE-520, telephone (781) 238-7520, fax (781) 238-7596, to make prior arrangements for your visit.

FOR FURTHER INFORMATION CONTACT:

David T. Bayley, Air Traffic Division, Airspace Branch, ANE-520, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7552; fax (781) 238-7596.

SUPPLEMENTARY INFORMATION: This action revises the extensions to the controlled airspace in the vicinity of Bradley International Airport, Windsor Locks, CT. Amendments to existing standard Instrument Approach Procedures (SIAPs) and implementation of new Area Navigation (RNAV) procedures have eliminated the need for controlled airspace extending upward from the surface on each side of the Bradley Vortac 314° radial extending to the northwest. This action also widens the controlled airspace extending to the southwest of the Bradley International Airport, Windsor Locks, CT. This extension of protected airspace is defined using the CHUPP Non-Directional Beacon (NDB) instead of referencing the Bradley Vortac coordinates. The intended effect of this rule is to provide appropriate controlled Class E airspace for aircraft operating under Instrument Flight Rules (IFR) at Bradley International Airport, CT.

Class E airspace designations for airspace areas extending upward from the surface designated as an extension to a Class C surface area are published in Paragraph 6003 of FAA Order 7400.9K, dated August 8, 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 this Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment, and, therefore, issues it as a direct final rule. 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. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative

comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a direct final rule, and was not preceded by a notice of proposed rulemaking, interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications must identify both docket numbers. All communications received on or before the closing date for comments will be considered, and this rule may be amended to withdrawn in light of the comments received. Factual information that supports for commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Agency Findings

This rule does not have federalism implications, as defined in Executive Order No. 13132, because it does not have a substantial direct effect 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, the FAA has not consulted with state authorities prior to publication of this rule.

The FAA has determined that this regulation is non-controversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (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 these routine matters will only affect air traffic procedures and air navigation. It is certified that these proposed rules will not have 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

■ Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

■ 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.

■ 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:

Subpart E—Class E Airspace

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Paragraph 6003 Class E airspace areas designated as an extension to a Class C surface area

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ANE CT E3 Windsor Locks, CT [Revised]

Windsor Locks, Bradley International Airport, CT

(Lat. 41°56'20"N, long. 72°41'00"W)

CHUPP NDB

(Lat. 41°52'39"N, long. 72°45'58")

That airspace extending upward from the surface within 2.9 miles on each side of the 225° bearing from the CHUPP NDB extending from the 5-mile radius of the Bradley International Airport to 8.6 miles southwest of the airport. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Issued in Burlington, MA, on April 10, 2003.

Thomas R. Davidson,

Manager, Air Traffic Division, New England Region.

[FR Doc. 03–9506 Filed 4–16–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket Nos. 93N–0182 and 82N–0166]

RIN 0910–AA01

Labeling for Oral and Rectal Over-the-Counter Drug Products Containing Aspirin and Nonaspirin Salicylates; Reye's Syndrome Warning

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend its regulations to revise the Reye's syndrome warning required for oral and rectal over-the-counter (OTC) human drug products containing aspirin and to require a warning on OTC drug products containing nonaspirin salicylates as active ingredients. The revised warning will inform consumers of the symptoms of Reye's syndrome and advise that aspirin and nonaspirin salicylate drug products should not be given to children or teenagers who have or are recovering from chicken pox or flu-like symptoms. This final rule also finalizes FDA's notice of proposed rulemaking to require a Reye's syndrome warning for orally administered OTC drug products for relief of symptoms associated with overindulgence in food and drink (overindulgence drug products) that contain bismuth subsalicylate that published in the **Federal Register** of May 5, 1993 (58 FR 26886). FDA is issuing this final rule after considering public comment on the agency's notices of proposed rulemaking and all relevant data and information that have come to the agency's attention.

DATES:

Effective Date: This final rule is effective April 19, 2004.

Compliance Dates: The compliance date for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales greater than \$25,000 is April 19, 2004. The compliance date for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales less than \$25,000 is April 18, 2005. The compliance date for OTC drug products containing aspirin and nonaspirin salicylates as an active ingredient and marketed under a new drug application (NDA) or abbreviated

new drug application (ANDA) is October 18, 2004. The compliance dates for all other OTC drug products containing aspirin and nonaspirin salicylates as an active ingredient and marketed under an OTC drug monograph (for internal analgesic, antipyretic, and antirheumatic drug products, or for menstrual drug products) will be established when the final monographs for those drug products are published in a future issue of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ida I. Yoder, 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 5, 1993 (58 FR 26886), FDA published a notice of proposed rulemaking to require a Reye's syndrome warning for OTC overindulgence drug products that contain bismuth subsalicylate (the May 1993 proposed rule). The proposed warning stated: "Children and teenagers who have or are recovering from chicken pox, flu symptoms, or flu should NOT use this product. If nausea, vomiting, or fever occur, consult a doctor because these symptoms could be an early sign of Reye syndrome, a rare but serious illness." The agency did not propose this warning for OTC antidiarrheal drug products that contain bismuth subsalicylate because bismuth subsalicylate was not a proposed monograph ingredient for that use at that time.

This warning was intended to inform consumers of the earliest recognizable symptoms of Reye's syndrome and advise that OTC overindulgence drug products containing bismuth subsalicylate should not be used during the period when children or teenagers have, or are recovering from, the flu or chicken pox. The agency mentioned that it was considering revising the Reye's syndrome warning currently required for products containing aspirin in § 201.314(h)(1) (21 CFR 201.314(h)(1)) to be the same as the proposed warning for products containing bismuth subsalicylate.

In the **Federal Register** of October 20, 1993 (58 FR 54228), FDA published a notice of proposed rulemaking to revise the Reye's syndrome warning required for OTC drug products containing aspirin to be consistent with the proposed warning for OTC overindulgence drug products containing bismuth subsalicylate (the October 1993 proposed rule). The