

mile. The amendment at Dexter Municipal Airport, MO, will provide additional controlled airspace for aircraft operation under IFR, include the NDB and coordinates in the text header and comply with the criteria of FAA Order 7400.2D. The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, 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.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. 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 final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications

received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the 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-related 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.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 00-ACE-31." The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial 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) if promulgated, will not have a significant economic impact, positive or negative, 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).

Accordingly, 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 Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Dexter, MO [Revised]

Dexter Municipal Airport, MO
(Lat 36°46'39" N., long. 89°56'28" W.)
Dexter NDB
(Lat 36°47'18" N., long. 89°56'27" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Dexter Municipal Airport and within 2.6 miles each side of the 183° bearing from the Dexter NDB extending from the 6.4-mile radius to 7.4 miles south of the NDB.

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Issued in Kansas City, MO, on September 20, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00-24933 Filed 9-28-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00-ACE-30]

Amendments to Class E Airspace; Moberly, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments

SUMMARY: This action amends Class E airspace area at Omar N. Bradley Airport, Moberly, MO. A review of the Class E airspace area for Omar N. Bradley Airport indicates it does not comply with the criteria for 700 feet Above Ground Level (AGL) airspace required for diverse departures as specified in FAA Order 7400.2D. The

Class E airspace has been enlarged to conform to the criteria of FAA Order 7400.2D.

In addition, the Nondirectional Radio Beacon (NDB) Standard Instrument Approach Procedures (SIAPs) have been cancelled, therefore the extensions to the southeast and northwest can be eliminated.

The intended effect of this rule is to provide additional controlled Class E airspace for aircraft operating under Instrument Flight Rules (IFR), eliminate the extensions to the southeast and northwest and comply with the criteria of FAA Order 7400.2D.

DATES: Effective date: 0901 UTC, January 25, 2001.

Comments for inclusion in the Rules Docket must be received on or before November 29, 2000.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Operations and Airspace Branch, Air Traffic Division, ACE-530, DOT Regional Headquarters Building, Federal Aviation Administration, Docket Number 00-ACE-30, 901 Locust, Kansas City, MO 64016.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Operations and Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 revises the Class E airspace at Moberly, MO. A review of the Class E airspace for Omar N. Bradley Airport, MO, indicates it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2D. The criteria in FAA Order 7400.2D for an aircraft to reach 1200 feet AGL is based on a standard climb gradient of 200 feet per mile plus the distance from the Airport Reference Point (ARP) to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The amendment at Omar N. Bradley Airport, MO, will provide additional controlled airspace for aircraft operating under IFR, eliminate the extensions to the southeast and

northwest and comply with the criteria of FAA Order 7400.2D. The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, 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.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. 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.

Comment Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the

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-related 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.

Commenters wishing the FAA to acknowledge their receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 00-ACE-30." The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial 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) if promulgated, will not have a significant economic impact, positive or negative, 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, 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 Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Moberly, MO [Revised]

Moberly, Omar N. Bradley Airport, MO
(Lat 39°27'50" N., long. 92°25'40" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Omar N. Bradley Airport.

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Issued in Kansas City, MO, on September 20, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.
[FR Doc. 00–24932 Filed 9–28–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0044]

RIN 0910–AB97

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Partial Stay of Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of compliance.

SUMMARY: The Food and Drug Administration (FDA) is announcing a partial stay of compliance for the final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body for certain dietary supplement products. Dietary

supplement products that were labeled, or for which labeling had been printed, on or before January 6, 2000, the publication date of the final rule, are eligible for the stay. This action is in response to two petitions for stay and reconsideration.

DATES: This rule is effective October 30, 2000. Submit written comments by October 30, 2000. Submit written comments on the information collection provisions of this final rule by October 10, 2000. Notifications of products that are eligible for the stay of compliance may be submitted to FDA at any time following the effective date of this rule; it is to manufacturers' advantage to submit such notifications as soon as possible, as only products for which FDA has received a notification qualify for the stay.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions of this final rule to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 725 K St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. Send notifications of products that are eligible for the stay of compliance to Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Compliance and Enforcement (HFS–810), 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 6, 2000 (65 FR 1000), FDA published a final rule entitled “Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body” (hereinafter referred to as “the final rule”). In the final rule, FDA established regulations to define the types of statements that may be made without prior FDA review about the effects of dietary supplements on the structure or function of the body (structure/function claims), and to distinguish these claims from claims that a product treats, prevents, cures, diagnoses, or mitigates disease (disease claims).

In the preamble to the final rule, FDA stated that the final rule would become effective on February 7, 2000, approximately 30 days after publication. FDA also stated that any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, would be expected to be in compliance as of the effective date, February 7, 2000. However, small businesses that marketed a product as of January 6, 2000, the date of publication of the final rule, would have an additional 17 months (until July 7, 2001) to bring existing claims (i.e., claims already in the product's labeling on January 6, 2000) for those products into compliance. For all other products that were on the market as of January 6, 2000, FDA allowed an additional 11 months beyond the effective date (until January 7, 2001) to bring existing claims for those products into compliance.

II. Petitions for Reconsideration and Stay of Action

FDA received one petition under § 10.35 (21 CFR 10.35) for stay of the 30-day effective date and one petition under 21 CFR 10.33 for stay and reconsideration of part of the implementation plan in the final rule. A petition for stay submitted jointly by the Council for Responsible Nutrition (CRN) and the Consumer Healthcare Products Association (CHPA) (Docket No. 99N–0044/PSA1) (Ref. 1) (hereinafter referred to as the “joint petition”) requested that FDA stay its 30-day effective date for “pipeline” products, i.e., products that were labeled, or for which labeling had been printed, but that had not yet been marketed when the final rule was published on January 6, 2000. The joint petition requested that such products be given the 11 or 17 months for compliance afforded to products that were being marketed as of the publication date of the final rule. The joint petition stated that in the nearly 2 years between publication of the proposed and final rules, dietary supplement manufacturers and distributors had relied on the criteria and examples of acceptable structure/function claims in the proposed rule to develop marketing strategies, manufacture products, and design and produce labeling. The petition stated that in many cases, this reliance had involved a significant investment of resources.

The joint petition further stated that the implementation of the final rule will involve, among other things, package redesign, redesign of websites and