

Administration, 15000 Aviation Boulevard, Hawthorne, CA 90261.

Persons interested in being placed on a mailing list for future NPRM's should call the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (CFR) part 71 (part 71) to establish V-584 between the Helena, MT, VORTAC, and the Missoula, MT, VORTAC. This proposed airway would provide a direct route between Helena, MT, and Missoula, MT, during outages of the Drummond VOR. V-584 would also allow for lower enroute altitudes through the mountainous terrain of Montana.

Domestic VOR Federal airways are published in paragraph 6010(a), 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 VOR Federal airway listed in this document would be published subsequently in the order.

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. Therefore, this proposed 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 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 proposed 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).

The Proposed 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, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 FAA Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

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V-584 [New]

From Helena, MT; to Missoula, MT.

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Issued in Washington, DC, August 21, 2003.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 03-22042 Filed 8-27-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N-0346]

Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on declaring botanical ingredients in dietary supplements to incorporate by reference the latest editions of two books. Currently, the regulation incorporates by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code)* 1994. FDA proposes to replace the references to these editions with the 2000 editions of the same books. This action is intended to provide industry with current and more comprehensive references to use in identifying on product labels the common or usual name of each botanical ingredient contained in

dietary supplements. In addition, FDA is proposing to incorporate new statutory restrictions on the use of the word "ginseng" in dietary supplement labeling. Finally, FDA is proposing to make minor wording changes in its regulation on declaring botanical ingredients in dietary supplements. These proposed changes are intended to improve the reader's understanding, consistent with the principles of plain English, or to be more technically accurate, consistent with internationally accepted botanical terminology. This proposed rule is a companion to a direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on this proposed rule by November 12, 2003. See section XI of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: Submit written comments on this companion proposed rule to the Division of Dockets Management (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: Victoria Lutwak, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2375.

SUPPLEMENTARY INFORMATION:

I. Background

A. Rulemaking Process

This proposed rule is a companion to a direct final rule on the same topic published in the final rules section of this issue of the **Federal Register**. The companion proposed rule and its related direct final rule are substantively identical. This proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule is withdrawn because FDA receives significant adverse comments.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments