

**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., 389.

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 5000 Class D Airspace.*

\* \* \* \* \*

**AWP CA D Riverside March Field, CA [NEW]**

Riverside March Field, CA  
(Lat. 33°52'50" N., long. 117°15'34" W.)

That airspace extending upward from the surface to and including 4,000 feet MSL within a 5-mile radius of the Riverside March Field. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

\* \* \* \* \*

Dated: Issued in Los Angeles, California, on May 18, 2004.

**John Clancy,**

*Manager, Air Traffic Division, Western-Pacific Region.*

[FR Doc. 04–17531 Filed 7–30–04; 8:45 am]

**BILLING CODE 4910–13–M**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 73**

[Docket No. FAA–2003–15411 Airspace  
Docket No. 02–ANM–15]

**RIN 2120–AA66**

**Proposed Establishment of Restricted Area 4601 A, B, C, and D; Bearpaw, MT**

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

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** This action withdraws a notice proposing to establish four new restricted areas (R–4601 A, B, C, and D) in the vicinity of Bearpaw, MT, as part of a Montana Air National Guard (MANG) training initiative (68 FR 6433; November 17, 2003). This action is

being taken because the MANG has been unable to gain control of the surface area needed for an air-to-ground training range.

**FOR FURTHER INFORMATION CONTACT:** Ken McElroy, Airspace and Rules, Office of System Operations and Safety, ATO–R, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

On November 17, 2003, an NPRM was published in the **Federal Register** proposing to amend Title 14 Code of Federal Regulations (14 CFR) part 73 (part 73) to establish R–4601 A, B, C, and D, in the vicinity of Bearpaw, MT, as part of a MANG training initiative (68 FR 64833). The MANG has been unable to gain control of the surface area needed for an air-to-ground training range.

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

Airspace, Navigation (air).

**Withdrawal of Proposed Rule**

In consideration of the foregoing, the NPRM, FAA Docket No. FAA–2003–15411/Airspace Docket No. 02–ANM–15, as published in the **Federal Register** on November 17, 2003 (68 FR 64833), is hereby withdrawn.

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

\* \* \* \* \*

Issued in Washington, DC, July 23, 2004.

**Reginald C. Matthews,**

*Manager, Airspace and Rules.*

[FR Doc. 04–17406 Filed 7–30–04; 8:45 am]

**BILLING CODE 4910–13–P**

**SECURITIES AND EXCHANGE COMMISSION**

**17 CFR Chapter II**

[Release Nos. 33–8451, 34–50094, 35–27877, 39–2422, IA–2268, IC–26521; File No. S7–31–04]

**List of Rules To Be Reviewed Pursuant to the Regulatory Flexibility Act**

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Publication of list of rules being reviewed.

**SUMMARY:** The Securities and Exchange Commission is today publishing a list of rules it is reviewing pursuant to Section 610 of the Regulatory Flexibility Act. The list is published to provide the public with notice that these rules are

being reviewed by the agency and to invite public comment on them.

**DATES:** Comments should be received on or before September 1, 2004.

**ADDRESSES:** Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/other.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number S7–31–04 on the subject line; or
- Use the Federal eRulemaking Portal (<http://www.regulations.gov>). Follow the instructions for submitting comments.

*Paper Comments*

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number S7–31–04. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/other.shtml>). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

**FOR FURTHER INFORMATION CONTACT:** Anne H. Sullivan, Office of the General Counsel, at 202–942–0954, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

**SUPPLEMENTARY INFORMATION:** The Regulatory Flexibility Act ("RFA"), codified at 5 U.S.C. 600–611, requires agencies every year to review those rules it adopted ten years ago that have a significant economic impact upon a substantial number of small entities. The purpose of the review is "to determine whether such rules should be continued without change, or should be amended or rescinded \* \* \* to minimize any significant economic impact of the rules upon a substantial number of such small entities" (5 U.S.C. 610(a)). The RFA sets forth specific considerations that must be addressed in the review of each rule:

- The continued need for the rule;

- The nature of complaints or comments received concerning the rule from the public;

- The complexity of the rule;
- The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

- The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule (5 U.S.C. 610(c)).

The Commission, as a matter of policy, reviews all rules which it publishes for notice and comment to assess not only their continued compliance with the RFA, but also to assess generally their continued utility. When the Commission implemented the Act in 1980, it stated that it "intend[ed] to conduct a broader review [than that required by the RFA], with a view to identifying those rules in need of modification or even rescission." Securities Act Release No. 6302 (Mar. 20, 1980), 46 FR 19251. The list below is therefore broader than that required by the RFA (and may include rules that do not have a substantial impact on a significant number of small entities). Where the Commission has previously made a determination of a rule's impact on small businesses, the determination is noted on the list.

Pursuant to the RFA, the rules and forms listed below are being reviewed by the staff of the Commission during 2004. The rules are grouped according to which Division or Office of the Commission will review each rule:

### Rules and Forms To Be Reviewed by the Division of Corporation Finance

#### 1. Safe Harbor for Public Announcement of Unregistered Offerings

*Citation:* 17 CFR 230.135c.

*Authority:* 15 U.S.C. 77a *et seq.*

*Description:* The rule created a safe harbor for certain company announcements regarding exempt offerings or unregistered offshore offerings.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 33-7053, which was approved by the Commission on April 19, 1994. Any comments to the proposing release were considered at that time. The amendments were designed to minimize costs to small business issuers, without sacrificing important concerns of investors.

### Rules and Forms To Be Reviewed by the Divisions of Corporation Finance and Market Regulation

#### 2. Exemptive Relief and Simplification of Filing Requirements for Debt Securities To Be Listed on a National Securities Exchange

*Citation:* 17 CFR 240.3a12-11, 240.12d1-2

*Authority:* 15 U.S.C. 77a *et seq.*, 15 U.S.C. 78a *et seq.*

*Description:* These rules were adopted to reduce regulatory distinctions between debt securities listed on a national securities exchange and those traded in the over-the-counter market by exempting listed debt securities from restrictions on borrowing and from most of the proxy and information statement rules.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 34-34922, which was approved by the Commission on November 1, 1994. Any comments to the proposing release were considered at that time. The rules were designed to decrease costs and compliance burdens on small entities.

#### 3. Municipal Securities Disclosure

*Citation:* 17 CFR 240.15c2-12

*Authority:* 15 U.S.C. 77a *et seq.*, 15 U.S.C. 78a *et seq.*, 15 U.S.C. 79q, 15 U.S.C. 79t, 15 U.S.C. 80a *et seq.*

*Description:* These rules prohibit the underwriting and subsequent recommendation of securities for which adequate information is not available.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 34-34961, which was approved by the Commission on November 10, 1994. Any comments to the proposing release were considered at that time. The rules were drafted to decrease costs and compliance burdens on small entities.

#### 4. Limited Partnership Roll-up Transactions

*Citation:* 17 CFR 240.3b-11, 240.14a-15, 240.14e-7

*Authority:* 15 U.S.C. 77a *et seq.*, 15 U.S.C. 78a *et seq.*

*Description:* These rules were adopted to implement provisions of the Limited Partnership Rollup Reform Act of 1993.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in

conjunction with the adoption of Release No. 33-7113, which was approved by the Commission on December 1, 1994. Any comments to the proposing release were considered at that time. The rules were drafted to decrease costs and compliance burdens on small entities.

### Rule To Be Reviewed by the Division of Investment Management

#### 5. Rule 486

*Citation:* 17 CFR 230.486

*Authority:* 15 U.S.C. 77a *et seq.*, 15 U.S.C. 78a *et seq.*, 15 U.S.C. 79t, 15 U.S.C. 80a *et seq.*

*Description:* Rule 486 under the Securities Act of 1933 establishes procedures for post-effective amendments to registration statements filed by closed-end interval funds.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 33-7083, which was approved by the Commission on August 17, 1994. The Commission stated that proposed Rule 486 would have no significant economic impact on any small entity.

### Rules and Forms To Be Reviewed by the Division of Market Regulation

#### 6. Customer Account Statements

*Citation:* 17 CFR 240.11Ac1-3

*Authority:* 15 U.S.C. 77a *et seq.*, 15 U.S.C. 78a *et seq.*, 15 U.S.C. 79q, 79t, 15 U.S.C. 80a *et seq.*

*Description:* The rule requires enhanced disclosure of payment for order flow practices on customer confirmations, and account statements, as well as upon opening new accounts.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 34-34902, which the Commission approved on October 27, 1994. Any comments to the proposing release were considered at that time.

#### 7. Notice of Assumption or Termination of Transfer Agent Services

*Citation:* 17 CFR 17Ad-16

*Authority:* 15 U.S.C. 78a *et seq.*

*Description:* The rule requires a registered transfer agent to provide written notice to a registered securities depository when terminating or assuming transfer agent services on behalf of an issuer or when changing its name or address.

*Prior Commission Determination Under 5 U.S.C. 601:* A Final Regulatory

Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 in conjunction with the adoption of Release No. 34–35039, which the Commission approved on December 1, 1994. No comments concerning regulatory flexibility matters were received.

The Commission invites public comment on both the list and on the rules to be reviewed. The Commission particularly solicits public comment on whether the listed rules affect small businesses in new or different ways than when they were first adopted.

Dated: July 27, 2004.

By the Commission.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04–17459 Filed 7–30–04; 8:45 am]

BILLING CODE 8010–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 310 and 341

[Docket No. 2004N–0289]

RIN 0910–AF34

#### **Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for Over-the-Counter Nasal Decongestant Drug Products**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to remove the indication “for the temporary relief of nasal congestion associated with sinusitis” and to prohibit use of the terms “sinusitis” and “associated with sinusitis” elsewhere on the labeling. This proposal is part of FDA’s ongoing review of OTC drug products.

**DATES:** Submit written or electronic comments on the document and comments on the agency’s economic impact determination by November 1, 2004. See sections V and X of this document for the proposed effective and compliance dates of any final rule that may publish based on this proposal.

**ADDRESSES:** You may submit comments, identified by [Docket No. 2004N–0289 and/or RIN number 0910–AF34], by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include [Docket No. 2004N–0289 and/or RIN number 0910–AA01] in the subject line of your e-mail message.

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Michael T. Benson, 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**

###### *A. Advance Notice of Proposed Rulemaking*

In the **Federal Register** of September 9, 1976 (41 FR 38312), the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended the following as one of 13 labeling indications for OTC nasal decongestant drug products: “For temporary relief of nasal congestion associated with sinusitis.” (See 41 FR 38312 at 38422.) The Panel recommended 13 indications for OTC nasal decongestant drug products (41 FR 38312 at 38403 to 38404). Only one of these indications involved the term

“sinusitis,” i.e., “For temporary relief of nasal congestion associated with sinusitis.” The Panel did not provide any explanation for this indication in its general discussion of OTC nasal decongestants (41 FR 38312 at 38396 to 38397) or in its Category I labeling discussion.

##### *B. Tentative Final Monograph*

In the **Federal Register** of January 15, 1985 (50 FR 2220), FDA concurred with the Panel’s recommendation and proposed a similar indication in the tentative final monograph for OTC nasal decongestant drug products. That indication in proposed § 341.80(b)(1) (50 FR 2220 at 2238) stated: “For the temporary relief of nasal congestion due to the common cold (cold), hay fever” (which may be followed by any of the following: “(allergic rhinitis),” “or other upper respiratory allergies,” or “or other upper respiratory allergies (allergic rhinitis)”) “or associated with sinusitis.”

##### *C. Final Monograph*

In the **Federal Register** of August 23, 1994 (59 FR 43386), FDA published a final monograph with a similar indication included in

§ 341.80(b)(1)(iii). The complete indication for OTC nasal decongestant drug products in § 341.80(b)(1) states:

(Select one of the following: “For the temporary relief of nasal congestion” or “Temporarily relieves nasal congestion”) (which may be followed by any of the following in paragraphs (b)(1)(i), (ii), and (iii) of this section):

(i) “due to” (select one of the following: “the common cold” or “a cold”).

(ii) “due to” (select one of the following: “hay fever,” “hay fever (allergic rhinitis),” “hay fever or other upper respiratory allergies,” or “hay fever or other upper respiratory allergies (allergic rhinitis)”); and

(iii) “associated with sinusitis.”

## **II. Sinusitis**

### *A. General Discussion*

Sinusitis is characterized by inflammation of the paranasal passages (Ref. 1). Primary care providers and subspecialists often recommend antibiotics for the management of acute sinusitis and chronic sinusitis because these conditions often have a bacterial etiology (Refs. 1 through 4). Other nasal diseases may have symptoms similar to those of sinusitis. These include allergic and nonallergic rhinitis, the common cold or influenza, Wegener’s granulomatosis, acquired and congenital immunodeficiency diseases, nasal polyposis, sarcoidosis, fungal sinusitis, or neoplasm (Refs. 1 and 3). Further, sinusitis and asthma often occur together in the same person. As many as 40 to 70 percent of people with asthma