

amend 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; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

AGL MI E5 Sawyer, MI [New]

Sawyer Airport, MI

(Lat. 46°21'20"N, long. 87°23'34"W)

Tha airspace extending upward from 700 feet above the surface within a 7.1-mile radius of the Sawyer Airport, excluding that airspace within the Marquette, MI, Class E airspace area, and that airspace extending upward from 1,200 feet above the surface within a 34.8-mile radius of the Sawyer Airport.

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Issued in Des Plaines, Illinois on November 13, 1996.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 96–29821 Filed 11–20–96; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Parts 91, 121, 127, and 135

RIN 2120–AG11

[Docket No. 28577; Notice No. 96–4]

Special Flight Rules in the Vicinity of the Rocky Mountain National Park

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; reopening of the comment period and notice of availability of Draft Environmental Assessment (EA).

SUMMARY: This notice announces the reopening of the comment period on a Notice of Proposed Rulemaking (NPRM), which proposes to establish a Special Federal Aviation Regulation to preserve the natural park experience of visitors to Rocky Mountain National Park (RMNP) by preventing any potential adverse noise impact from aircraft-based sightseeing overflights. Following the closing date of the

comment period the FAA prepared a Draft EA concerning alternatives for addressing the potential aviation noise issues at RMNP. This action is being taken to afford the public the opportunity to comment on the Draft EA.

DATES: The comment period is being reopened from November 21, 1996 through December 23, 1996. Comments must be received on or before the December 23, 1996.

ADDRESSES: Comments on this NPRM should be mailed, in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 28577, 800 Independence Avenue, SW., Washington, DC 20591. Comments may also be sent electronically to the Rules Docket by using the following Internet address: nprmcmts@mail.hq.faa.gov. Comments must be marked Docket No. 28577. Comments may be examined in the Rules Docket in Room 915G on weekdays between 8:30 a.m. and 5:00 p.m., except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Neil Saunders, Airspace and Rules Division, ATA–400, Airspace Management Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: 202–267–8783.

SUPPLEMENTARY INFORMATION:

Background

Notice No. 96–4 was placed on immediate display at the Federal Register on May 10, 1996, and published on May 15, 1996 (61 FR 24852). A correction document was published on July 23, 1996 (61 FR 38119) extending the comment period to August 19, 1996. Notice No. 96–4 proposed several methods of preserving the natural park experience of RMNP by restricting aircraft-based sightseeing flights. The NPRM indicated that the FAA would select a viable alternative based on comments received and other pertinent information, identify a proposed alternative for final rulemaking and publish a Draft EA for comment. The Draft EA would evaluate the alternatives identified for detailed study and assess the current conditions and the preferred alternative. The NPRM also indicated that the FAA will evaluate the comments on the Draft EA and prepare a final assessment.

Reopen Comment Period

The comment period on Notice No. 96–4, Special Flight Rules in the Vicinity of the Rocky Mountain National Park closed on August 19, 1996. Following the closing date of the

comment period the FAA prepared a Draft EA that evaluates various alternatives for addressing potential aviation noise issues at RMNP. Consequently, the FAA finds that it is in the public interest to reopen the comment period to allow interested persons the opportunity to comment on the Draft EA. A copy of the Draft EA has been placed in the Docket and is available for review.

Copies of the Draft EA are being circulated to interested parties and the Draft EA is also available on the Internet at the website of the FAA's Office of Environment and Energy: <http://aee.hq.faa.gov/>. Copies may also be obtained by contacting Mr. William J. Marx, Division Manager, ATA–300, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3075.

In addition, after the comment period on the NPRM closed, the Department of Transportation became aware of certain RMNP sound level data. In September 1995, sound level measurements were made at five locations in RMNP on behalf of the NPS. While it is unlikely that this data will provide a basis for a final rulemaking in this matter, we are including it in the Docket for completeness of the record.

Accordingly, the comment period is being reopened and the Draft EA is being made available for comment from November 21, 1996 through December 23, 1996.

Issued in Washington, DC, on November 18 1996.

Harold W. Becker,

Acting Program Director for Air Traffic, Airspace Management.

[FR Doc. 96–29816 Filed 11–18–96; 4:04 pm]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 511 and 514

[Docket No. 96N–0411]

New Animal Drugs for Investigational Use and New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to propose revisions to its

regulations governing new animal drugs for investigational use and new animal drug applications (NADA's). On October 9, 1996, President Clinton signed into law the Animal Drug Availability Act of 1996 (the ADAA). FDA intends to propose revisions to the investigational new animal drug (INAD) and NADA regulations to implement the ADAA. FDA also intends to propose revisions to the INAD and NADA regulations to fulfill its commitment under the National Performance Review to reinvent the regulation of animal drugs. In the President's National Performance Report, "Reinventing the Regulation of Animal Drugs," May 1996, the President announced FDA's proposal to revise its regulations to create a more efficient process for reviewing and approving new animal drugs (NAD's). FDA's proposal for changes in the process for reviewing and approving animal drugs is intended to minimize the regulatory burden upon industry without compromising FDA's ability to ensure that the animal drugs it approves are safe and effective.

DATES: Written comments before January 21, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George A. Mitchell, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1761.

SUPPLEMENTARY INFORMATION:

I. Background

On October 9, 1996, President Clinton signed into law the ADAA. The purpose of the ADAA is to build into the NAD approval process needed flexibility to facilitate more efficient and expeditious approval of NAD's without decreasing FDA's existing authority to ensure that animal drug products are safe for use in animals and for humans who consume food products derived from animals. The ADAA does this, in large part, by redefining substantial evidence, the standard by which FDA determines whether a NAD is effective. The ADAA redefines the term "substantial evidence" to mean:

evidence consisting of one or more adequate and well-controlled investigations, such as—a study in a target species; a study in laboratory animals; any field investigation that may be required under [section 512(d)(3)] and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant; a bioequivalence study; or an in vitro study; by

experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Section 2(e) of the ADAA directs FDA to further define by regulation the term "substantial evidence" and the term "adequate and well-controlled" as it relates to field investigations that alone or along with other studies may establish substantial evidence that a NAD is effective. The ADAA also requires FDA to publish regulations to address dose range labeling. FDA has 6 months from the enactment of the ADAA to publish proposed regulations to further define "adequate and well-controlled" and 12 months to publish proposed regulations to address dose range labeling and further define "substantial evidence."

In the President's National Performance Report, "Reinventing the Regulation of Animal Drugs," May 1996, the President announced FDA's proposal to revise its regulations to create a more efficient process for reviewing and approving NAD's. Historically, FDA has reviewed NADA's using a process that emphasized centralized coordination of an application review. Although this approach has advantages, FDA has found that this approach for processing applications has also resulted in delays. FDA has introduced numerous process changes intended to foster a more streamlined animal drug application review and approval process and reduce the regulatory burden on industry. For example, FDA tested an evaluation process described as direct review. Under direct reviews of sponsors' technical submissions, individuals conducting reviews of technical submissions are responsible for the scientific evaluation and administrative processing of a particular section of a submission and for communicating directly with the appropriate responsible official of the drug sponsor. To implement FDA's reinventing government proposal, FDA intends to propose revisions to its INAD and NADA regulations to reflect such process changes. The proposed changes to the INAD and NADA regulations will also reflect, among other things, CVM's use of presubmission conferences, phased review of data submissions, direct review of sponsors' technical submissions, and sponsor-monitored methods trials.

II. Revisions Under Consideration

The agency intends to propose revisions to the INAD and NADA regulations to further define "substantial evidence" and "adequate and well-controlled," as well as address dose range labeling, as directed by the ADAA. FDA also anticipates proposing revisions to these regulations to implement other aspects of the ADAA, i.e., presubmission conferences, combination animal drugs, Veterinary Feed Directive (VFD) drugs, and feed mill licensing. Finally, FDA intends to propose revisions to the INAD and NADA regulations to implement FDA's reinventing government proposal to reinvent the regulation of animal drugs.

III. Agency Request for Comments

FDA is soliciting comments on all aspects of this advance notice of proposed rulemaking (ANPRM), and specifically requests comments on the following issues:

(1) Further definition of "substantial evidence."

(2) Defining "adequate and well-controlled" as it relates to field investigations.

(3) Regulations to address dose range labeling.

(4) Regulations to implement presubmission conferences.

(5) Regulations to implement the streamlined approval process for certain combination animal drugs.

(6) The content and format of a VFD.

(7) CVM's use of a phased review process for reviewing NADA's.

(8) CVM's use of direct review of sponsors' technical submissions for reviewing NADA's.

(9) CVM's review of manufacturing supplements.

IV. Comments

Interested persons may, on or before January 21, 1997, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Because the ADAA requires FDA to publish regulations within short timeframes, FDA encourages that comments be submitted as soon as possible. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under section 2(e) of the ADAA, sections 201, 501, 502, 503, 512, 701, and 801 of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 321, 351, 352, 353, 360b, 371, and 381), and under the authority of the Commissioner of Food and Drugs.

Dated: November 15, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96-29767 Filed 11-20-96; 8:45 am]

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 203

RIN-1510-AA37

Treasury Tax and Loan Depositories and Payment of Federal Taxes

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice of proposed rulemaking; extension of time for comments.

SUMMARY: On September 30, 1996, the Financial Management Service issued a notice of proposed rulemaking proposing new regulatory text for 31 CFR Part 203 to govern the operation of the Electronic Federal Tax Payment System. The document also proposed to update the rules governing Treasury's investment program. The date for filing comments is being extended at the request of interested commenters. Although the date is to be extended until January 13, 1997, commenters are encouraged to submit comments as soon as possible.

DATES: The date for filing comments is extended to and including January 13, 1997.

ADDRESSES: Comments or inquiries may be mailed to Cynthia L. Johnson, Director, Cash Management Policy and Planning Division, Financial Management Service, Room 420, 401 14th Street, S.W., Washington, D.C. 20227.

FOR FURTHER INFORMATION CONTACT: Mark Matolak, Financial Program Specialist; Donald E. Clark, Financial Program Specialist; Cynthia L. Johnson, Director, Cash Management Policy and Planning Division, 401 14th Street, S.W., Washington, D.C. 20227, (202) 874-6590; or Margaret Roy, Principal Attorney, at (202) 874-6680. A copy of the original proposed rule, dated September 30, 1996, is being made available for downloading from the Financial Management Service home page at the following address: <http://www.ustreas.gov/treasury/bureaus/finman/>.

Dated: November 18, 1996.

Russell D. Morris,

Commissioner.

[FR Doc. 96-29771 Filed 11-20-96; 8:45 am]

BILLING CODE 4810-35-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[AD-FRL-5653-2]

List of Industrial Combustion Coordinated Rulemaking Advisory Coordinating Committee Members and Notice of Upcoming Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: List of Industrial Combustion Coordinated Rulemaking (ICCR) Federal Advisory Committee and Work Group members, solicitation of additional Work Group nominations, and notice of upcoming meetings.

SUMMARY: As required by section 9(a)(2) of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, section 9(c), EPA gave notice of the establishment of the ICCR Federal Advisory Committee (hereafter referred to as the Coordinating Committee) in the Federal Register on August 2, 1996 (61 FR 40413). The Coordinating Committee members have been selected and are listed in this document. The Coordinating Committee also has selected Work Group members and the current list of members is announced in this document. Nominations for the Work Groups are still being solicited to ensure adequate representation from each of the stakeholder interest groups on the Work Groups.

The public can follow the progress of the ICCR through attendance at meetings (which will be announced in advance) and by accessing the Technology Transfer Network (TTN), which serves as the primary means of disseminating information about the ICCR.

DATES: The next meeting of the Coordinating Committee is scheduled for January 8 and 9, 1997.

Additional nominations for membership on the work groups must be submitted by December 6, 1996.

Further information on the Coordinating Committee and Work Group meetings may be obtained by accessing the TTN.

ADDRESSES: The Coordinating Committee meeting on January 8 and 9, 1997 will be held at the Holiday Inn Hotel and Suites (formerly Old Colony),

625 First Street, Alexandria, Virginia (703-548-6300).

Nominations for membership on work groups should be submitted to Fred Porter at EPA, Emission Standards Division, Combustion Group, (MD-13), Research Triangle Park, NC 27711.

Inspection of Documents: Docket.

Minutes of the meetings, as well as other relevant materials, will be available for public inspection at U.S. EPA Air and Radiation Docket and Information Center, Docket No. A-96-17. The docket is open for public inspection and copying between 8 a.m. and 4 p.m., Monday through Friday except for Federal holidays, at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), 401 M Street SW, Washington, DC 20460; telephone: (202) 260-7548. The docket is located at the above address in Room M-1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Fred Porter, Sims Roy, or Walt Stevenson, U.S. Environmental Protection Agency, Emission Standards Division, Combustion Group, (MD-13), Research Triangle Park, NC 27711, telephone numbers (919) 541-5251, 541-5263, and 541-5264, respectively.

SUPPLEMENTARY INFORMATION:

Technology Transfer Network (TTN)

The TTN is one of the EPA's electronic bulletin boards. The TTN can be accessed through the Internet or directly by modem. Through the Internet, the TTN may be accessed at: TELNET: [ttnbbs.rtpnc.epa.gov](telnet:ttnbbs.rtpnc.epa.gov) FTP: [ttnftp.rtpnc.epa.gov](ftp:ttnftp.rtpnc.epa.gov) WWW: ttnwww.rtpnc.epa.gov

When accessing the WWW site, select TTN BBS Web from the first menu, then select Gateway to TTN Technical Areas from the second menu, and finally, select ICCR-Industrial Combustion Coordinated Rulemaking from the third menu.

By modem, dial (919) 541-5742 for up to a 14,400 bits-per-second information transfer connection. After logging on to the system, select Gateway to the TTN Technical Areas from the menu and then select ICCR-Industrial Combustion Coordinated Rulemaking from the next menu. Access to the TTN through Telnet will look the same as if you had dialed by modem, so these instructions should be followed for a Telnet connection.

Access to the TTN through FTP is a streamlined approach for downloading files, but is only useful, if the desired filenames are known.