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 14 CFR part 73 (part 73) to establish R–3203D, Orchard, ID, adjacent to the existing R–3203A, to assist the Idaho Army National Guard's annual training. The proposed restricted area would be effective for a period of time not exceeding three weeks annually. Expansion in the number of gun batteries assigned to field artillery units, along with requirements that each assigned battery accomplish several moves per day to different firing points, has created the need to expand the available restricted airspace, for a period of time each year, to provide for more effective annual training tests. All artillery firing would be directed into existing impact areas located approximately in the center of R–3203A. The restricted area is needed to provide protected airspace to contain projectiles during flight between the surface firing point and entry into the existing restricted area.

The proposed restricted area would be utilized for a period of time not exceeding three weeks per year by the Idaho Army National Guard Field Artillery and would be released to the FAA for public use during the periods when it is not required for military training.

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. Therefore, this proposed regulation: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under 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.

The coordinates for this airspace docket are based on North American Datum 83. Section 73.32 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8G dated September 1, 1999.

Environmental Review

This proposal will be subject to environmental review prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 73

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 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.

§ 73.32 [Amended]

2. Section 73.32 is amended as follows:

* * * * *

R–3203D Orchard Training Area, ID [New]

Boundaries. Beginning at lat. 43°14′00″ N., long. 116°16′30″ W.; at lat. 43°17′51″ N., long. 116°16′25″ W.; at lat. 43°19′02″ N., long. 116°14′45″ W.; at lat. 43°19′02″ N., long. 116°06′36″ W.; at lat. 43°15′58″ N., long. 116°01′12″ W.; at lat. 43°15′00″ N., long. 116°01′00″ W.; at lat. 43°17′00″ N., long. 116°05′00″ W.; at lat. 43°17′00″ N., long. 116°12′00″ W.; to point of beginning.

Designated altitudes. Surface to and including 22,000 feet MSL.

Times of use. As scheduled by NOTAM 24 hours in advance not to exceed three weeks annually.

Controlling agency. FAA Boise ATCT.

Using agency. Commanding General Idaho Army National Guard.

* * * * *

Issued in Washington, DC, on April 14, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–10215 Filed 4–24–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Airspace Docket No. 99–ANM–15]

Proposed Reconfiguration, Revision, and Establishment of Restricted Areas; ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to reconfigure Restricted Area 3202A (R–3202A), Saylor Creek, ID by establishing a High area from FL 180 to FL 290 and a Low area from the surface to, but not including, FL 180 within the existing R–3202A, and to revoke Restricted Areas 3202B and C (R–3202B and R–3202C). Additionally, this action proposes to establish three new Restricted Areas (R–3204A, B, and C) at Juniper Butte, ID. The FAA is proposing these efforts to support the United States Air Force (USAF) rapid-response air expeditionary wing training.

DATES: Comments must be received on or before June 9, 2000.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ANM–500, Docket No. 99–ANM–15, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98055–4056.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–ANM–15.'' The postcard will be date/time stamped and returned to the

commenter. Send comments on environmental and land-use aspects to: Headquarters ACC/DOR Air Combat Command Airspace and Range Management Division, 205 Dodd Blvd, Ste 101, Langley AFB, VA 23665–2789. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded, using a modem and suitable communications software, from the FAA regulations section of the Fedworld electronic bulletin board service (telephone: 703–321–3339) or the **Federal Register**'s electronic bulletin board service (telephone: 202–512–1661).

Internet users may reach the FAA's web page at http://www.faa.gov or the Superintendent of Document's web page at http://www.access.gpo.gov/nara for access to recently published rulemaking documents.

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–8783. Communications must identify the notice number of this NPRM. 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 14 CFR part 73 (part 73) that would reconfigure R–3202A, Saylor Creek, ID by establishing a High area from FL 180 to FL 290 and a Low area from the surface to, but not including, FL 180 within the existing R–3202A, and revoke R–3202B and R–3202C. In addition, this action proposes to establish three new Restricted Areas (R–3204A, from the surface to 100 feet AGL; R–3204B, from 100 feet to, but not including, FL 180; and R–3204C, from FL 180 to FL 290) at Juniper, Butte, ID. The proposed restricted airspace for the Juniper Butte range would be established over 12,000-acres with one 300-acre impact area at the approximate center of the area. The proposed restricted airspace would permit the safe delivery of training ordinances into the proposed R–3204A impact area. This proposal eliminates restricted airspace south of the existing Saylor Creek Range and would result in an overall reduction of restricted airspace. The FAA is proposing these efforts to support the USAF rapid-response air expeditionary wing training.

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. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under 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.

The coordinates for this airspace Docket are based on North American Datum 83. Section 73.32 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8G dated September 1, 1999.

Environmental Review

This proposal will be subject to environmental review prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 73

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—Special Use Airspace

1. The authority citation for 14 CFR part 73 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.

§ 73.32 [Amended]

2. Section 73.32 is amended as follows:

* * * * *

R–3202A Saylor Creek, ID [Revoke]
R–3202B Saylor Creek, ID [Revoke]
R–3202C Saylor Creek, ID [Revoke]
R–3202 Saylor Creek Low, ID [New]

Boundaries: Beginning at lat. 42°53′00″ N., long. 115°42′20′ W.;
at lat. 42°53′00″ N., long. 115°24′15″ W.;
at lat. 42°36′00″ N., long. 115°24′15″ W.;
at lat. 42°36′00″ N., long. 115°42′20″ W.; to point of beginning.
Designated altitudes: Surface to, but not including, FL 180.
Times of use: 0730–2200 local time, Monday through Friday, other times by NOTAM.
Controlling agency: FAA Salt Lake City, ARTCC.
Using agency: USAF, 366th Wing, Mountain Home AFB, ID.

R–3202 Saylor Creek High, ID [New]

Boundaries: Beginning at lat. 42°53′00″ N., long. 115°42′20″ W.;
at lat. 42°53′00″ N., long. 115°24′15″ W.;
at lat. 42°36′00″ N., long. 115°24′15″ W.;
at lat. 42°36′00″ N., long. 115°42′20″ W.; to point of beginning.
Designated altitudes: FL 180 to FL 290.
Times of use: 0730–2200 local time, Monday through Friday, other times by NOTAM.
Controlling agency: FAA Salt Lake City, ARTCC.
Using agency: USAF, 366th Wing, Mountain Home AFB, ID.

R–3204A Juniper Buttes, ID [New]

Boundaries: Beginning at lat. 42°20′00″ N., long. 115°22′30″ W.;
at lat. 42°20′00″ N., long. 115°18′00″ W.;
at lat. 42°19′00″ N., long. 115°17′00″ W.;
at lat. 42°16′35″ N., long. 115°17′00″ W.;
at lat. 42°16′35″ N., long. 115°22′30″ W.; to point of beginning.
Designated altitudes: Surface to 100 feet AGL.
Times of use: 0730–2200 local time, Monday through Friday, other times by NOTAM.
Controlling agency: FAA Salt Lake City, ARTCC.
Using agency: USAF, 366th Wing, Mountain Home AFB, ID.

R–3204B Juniper Buttes, ID [New]

Boundaries: The airspace within a 5 NM radius centered on lat.42°18′00″ N., long. 115°20′00″ W.
Designated altitudes: 100 feet AGL to, but not including, FL 180.
Times of use: 0730–2200 local time, Monday through Friday, other times by NOTAM.
Controlling agency: FAA Salt Lake City, ARTCC.
Using agency: USAF, 366th Wing, Mountain Home AFB, ID.

R–3204C Juniper Buttes, ID [New]

Boundaries: The airspace within a 5 NM radius centered on lat.42°18′00″ N., long. 115°20′00″ W.
Designated altitudes: FL 180 to FL 290.
Times of use: 0730–2200 local time, Monday through Friday, other times by NOTAM.
Controlling agency: FAA Salt Lake City, ARTCC.

Using agency: USAF, 366th Wing, Mountain Home AFB, ID.

* * * * *

Issued in Washington, DC, on April 19, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–10243 Filed 4–24–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 821

[Docket No. 00N–1034]

Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the medical device tracking regulations. The scope of the regulation and certain patient confidentiality requirements must be amended to conform to changes made in section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA). FDA also proposes nonsubstantive revisions to remove outdated references or simplify terminology.

DATES: Submit written comments by July 24, 2000. See section IV of this document for the proposed effective date of a final rule based on this document. Submit written comments on the information collection requirements by May 25, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Background

A. The SMDA and Device Tracking Regulations

The Safe Medical Device Act of 1990 (the SMDA) (Public Law 101–629) became law on November 28, 1990. It added mandatory and discretionary device tracking provisions to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) under new section 519(e) (21 U.S.C. 360i(e)).

As added by the SMDA, new section 519(e)(1) mandated the adoption of a method of tracking by any person registered under section 510 of the act (21 U.S.C. 360) and engaged in the manufacture of a device if its failure would be reasonably likely to have serious adverse health consequences and the device was either a permanently implantable device or a life-sustaining or life-supporting device used outside a device user facility. New section 519(e)(2) authorized FDA, in its discretion, to ''designate'' other devices that must be tracked, to protect the public health and safety.

On August 16, 1993, FDA published in the **Federal Register** (58 FR 43442) the final rule setting forth regulations governing the tracking of medical devices, as provided by the SMDA under sections 519(e)(1) and (e)(2) of the act. Elsewhere in the same **Federal Register** (58 FR 43451), FDA published a rule amending the illustrative list of those devices FDA considered subject to tracking under the mandatory criteria under section 519(e)(1) and the list of devices FDA designated as subject to tracking under section 519(e)(2). The final tracking regulations for medical devices, including the amended lists of tracked devices, went into effect on August 29, 1993, and are currently codified in part 821 of title 21 of the Code of Federal Regulations (21 CFR part 821).

B. FDAMA Tracking Provisions

FDAMA (Public Law 105–115) was enacted on November 21, 1997. Section 211 of FDAMA amended the tracking provision in section 519(e)(1) of the act and became effective on February 19, 1998. Unlike the tracking provisions under the SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements and provides that tracking requirements can be imposed only after issuance of an order.

FDAMA authorizes FDA to issue orders that require a manufacturer to adopt a method of tracking a class II or class III device if its failure would be reasonably likely to have serious adverse health consequences, or it is intended to be implanted in the human body for more than 1 year, or it is a life-sustaining or life-supporting device used outside a device user facility. As amended by FDAMA, section 519(e)(2) of the act provides that patients receiving a device subject to tracking may refuse to release, or refuse permission to release, their names, addresses, social security numbers, or other identifying information for tracking purposes.

Section 519(e) of the act, as amended by FDAMA, provides that FDA '' may by order require a manufacturer to adopt a method of tracking.'' Such an order specifies to the manufacturer the class II or class III device(s) to be tracked. FDA interprets the discretion inherent in ''may'' to allow the agency to consider additional relevant factors in determining whether to issue a tracking order for a device that meets the criteria in amended section 519(e)(1) of the act.

The discretionary authority to issue tracking orders, and the three statutory criteria that operate independently of one another in section 519(e)(1) of the act, allow the agency to accomplish the intended purpose of device tracking under FDAMA, as identified by Congress, i.e., to facilitate the recall of dangerous or defective devices, under section 518(e) of the act (S. Rept. 108, 105th Cong., 1st sess. 37 (1997)).

II. Implementation of FDAMA Tracking Authority

A. Public Meeting/Manufacturer Notification

On December 18, 1997, FDA published a **Federal Register** notice (62 FR 66373) announcing the agency's intention to hold a public meeting on January 15, 1997, in Rockville, MD to discuss changes in medical device tracking and postmarket surveillance authorities under FDAMA. In particular, the agency was interested in discussing whether it should consider additional nonbinding factors to supplement the statutory criteria, under FDAMA, in determining whether tracking requirements should be ordered by FDA.

On December 19, 1997, FDA sent letters to manufacturers having responsibilities to track devices under section 519(e) of the act. These letters advised that FDAMA would implement important statutory changes in medical device tracking, which had been authorized previously under the SMDA. The letters noted FDA's December 18, 1997, **Federal Register** notice announcing the public meeting it would conduct on January 15, 1998, to discuss