

mid-air collision potential for aircraft operating in the vicinity of NAS JRB Carswell Field, Fort Worth, TX. The intended effect of this proposal is to provide adequate controlled airspace for aircraft operating in the vicinity of NAS JRB Carswell Field, Fort Worth, TX.

The coordinates for this airspace docket are based on North American Datum 83. Designated Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9F, dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation 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 that require frequent and routine amendments to keep them operationally current. It, therefore—(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 rule, when promulgated, will not have a significant 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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR 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 the Federal Aviation Administration Order 7400.9F, *Airspace Designations and Reporting Points*, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 5000 Class D airspace areas.

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ASW TX D Fort Worth NAS JRB (Carswell Field), TX [Revised]

Fort Worth, NAS JRB Carswell Field, TX

(Lat. 32°46'09"N., long. 97°26'30"W.)

Carswell ILS Localizer North

(Lat. 32°47'19"N., long. 97°26'28"W.)

Carswell TACAN

(Lat. 32°46'18"N., long. 97°26'22"W.)

Carswell ILS Localizer South

(Lat. 32°45'08"N., long. 97°26'27"W.)

That airspace extending upward from the surface to and including 3,000 feet MSL within a 4.5-mile radius of NAS JRB Carswell Field and within 1 mile each side of the Carswell ILS Localizer north course extending from the 4.5-mile radius to 6.5 miles north of the airport and within 1.3 miles each side of the 359° radial of the Carswell TACAN extending from the 4.5-mile radius to 6.5 miles north of the airport and within 1 mile each side of the Carswell ILS Localizer south course extending from the 4.5-mile radius to 6.5 miles south of the airport and within 1.3 miles each side of the 182° radial of the Carswell TACAN extending from the 4.5-mile radius to 6.5 miles south of the airport excluding that airspace east of long. 97°24'00"W.

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Issued in Fort Worth, TX on September 14, 1999.

Robert N. Stevens,

*Acting Manager, Air Traffic Division,
Southwest Region.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 212

[Docket No. 99N-4063]

Current Good Manufacturing Practices for Positron Emission Tomography Drug Products; Preliminary Draft Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of preliminary draft regulations.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of preliminary draft regulations on current good manufacturing practices (CGMP's) for positron emission tomography (PET) drug products. FDA is developing CGMP's for PET drugs in accordance with the Food and Drug Administration Modernization Act of 1997 (Modernization Act). These preliminary draft regulations are being made available to allow full discussion of

them at an upcoming public meeting on the regulation of PET drugs.

DATES: A public meeting on PET drug matters will be held on September 28, 1999. Submit written comments on or before October 13, 1999.

ADDRESSES: A copy of the preliminary draft regulations will be on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the preliminary draft regulations may be obtained from the Drug Information Branch (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573, and the Center for Drug Evaluation and Research's Fax-on-Demand system at 301-827-0577 or 800-342-2722. An electronic version of the preliminary draft regulations is available on the Internet at “http://www.fda.gov/cder/fdama” under “Section 121—PET (Positron Emission Tomography).” Submit written comments to the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT:

Tracy A. Roberts, Center for Drug Evaluation and Research (HFD-336), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0093.

SUPPLEMENTARY INFORMATION:

The President signed the Modernization Act (Public Law 105-115) into law on November 21, 1997. Section 121(c)(1)(A)(ii) of the Modernization Act directs FDA to establish within 2 years after enactment appropriate CGMP requirements for PET drugs.

Section 121(c)(1)(B) of the Modernization Act requires FDA to consult with patient advocacy groups, professional associations, manufacturers, and other interested persons as the agency develops PET drug CGMP requirements and approval procedures. To that end, the agency has conducted public meetings on PET drug matters and has established a public docket.

In accordance with section 121 of the Modernization Act, FDA has developed preliminary draft CGMP requirements for PET drug products. In accordance with 21 CFR 10.40(f)(4) and 10.80(b)(2), FDA has decided to make available to the public these preliminary draft CGMP regulations to facilitate discussion at the public meeting on PET drug matters to be held on September 28, 1999, from 9 a.m. to 4 p.m., at the Holiday Inn, Gaithersburg, MD (Goshen Room). Subsequently, FDA will issue a proposed rule on CGMP's for PET drug

products and will invite comments on the proposed rule.

Interested persons may, on or before October 13, 1999, submit to the Dockets Management Branch (address above) written comments on the preliminary draft regulations. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The preliminary draft regulations and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

(Authority: 21 U.S.C. 321 *et seq.*)

Dated: September 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-24592 Filed 9-21-99; 8:45 am]

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OFFICE OF NATIONAL DRUG CONTROL POLICY

21 CFR Part 1401

RIN 3201-ZA02

Freedom of Information Act

AGENCY: Office of National Drug Control Policy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of National Drug Control Policy proposes this rule to comply with the Electronic Freedom of Information Act. The proposed rule defines records as defined in the Act, establishes an electronic reading room, institutes an expedited process for handling requests and conforms to the statutory time limitations for a response.

DATES: Submit comments on or before November 22, 1999.

ADDRESSES: Send comments to Executive Office of the President, Office of National Drug Control Policy, Office of Legal Counsel, Attention General Counsel, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Daniel R. Petersen, (202) 395-6745.

SUPPLEMENTARY INFORMATION: This proposed rule is not a major rule for the purposes of Executive Order 12866. As required by the Regulatory Flexibility Act, ONDCP certifies that this proposed rule would not have a significant impact on small business entities.

List of Subjects in 21 CFR Part 1401

Freedom of information, Organization and functions (Government agencies).

For the reasons stated in the preamble, the Office of National Drug

Control Policy proposes to revise 21 CFR part 1401 to read as follows:

PART 1401—PUBLIC AVAILABILITY OF INFORMATION

Sec.

1401.1 Purpose.

1401.2 The Office of National Drug Control Policy—organization and functions.

1401.3 Definitions.

1401.4 Access to information.

1401.5 How to request records.

1401.6 Expedited process.

1401.7 Prompt response.

1401.8 Extension of time.

1401.9 Appeals.

1401.10 Fees to be charged—general.

1401.11 Fees to be charged—miscellaneous provisions.

1401.12 Fees to be charged—categories of requesters.

1401.13 Waiver or reduction of fees.

Authority: 5 U.S.C. 552.

§ 1401.1 Purpose.

The purpose of this part is to prescribe rules, guidelines and procedures to implement the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552.

§ 1401.2 The Office of National Drug Control Policy—organization and functions.

(a) The Office of National Drug Control Policy (ONDCP) was created by the Anti-Drug Abuse Act of 1988, 21 U.S.C. 1501 *et seq.*, and reestablished under 21 U.S.C. 1701 *et seq.* The mission of ONDCP is to coordinate the anti-drug efforts of the various agencies and departments of the Federal government, to consult with States and localities and assist their anti-drug efforts, to conduct a national media campaign, and to annually promulgate the National Drug Control Strategy.

(b) ONDCP is headed by the Director of National Drug Control Policy. The Director is assisted by a Deputy Director of National Drug Control Policy, a Deputy Director for Supply Reduction, a Deputy Director for Demand Reduction, and a Deputy Director for State and Local Affairs.

(c) Offices within ONDCP include Chief of Staff, and the Offices of Legal Counsel, Strategic Planning, Legislative Affairs, Programs Budget and Evaluation, Supply Reduction, Demand Reduction, Public Affairs, State and Local Affairs, and the Financial Management Office.

(d) The Office of Public Affairs is responsible for providing information to the press and to the general public. If members of the public have general questions about ONDCP that can be answered by telephone, they may call the Office of Public Affairs at (202) 395-6618. This number should not be used

to make FOIA requests. All oral requests for information under FOIA will be rejected.

§ 1401.3 Definitions.

For the purpose of this part:

(a) All the terms defined in the Freedom of Information Act apply.

(b) *Commercial-use request* means a request from or on behalf of one who seeks information for a cause or purpose that furthers the commercial, trade or profit interests of the requester or the person or institution on whose behalf the request is made. In determining whether a requester properly belongs in this category, ONDCP will consider the intended use of the information.

(c) *Direct costs* means the expense actually expended to search, review, or duplicate in response to a FOIA request. For example, direct costs include 116% of the salary of the employee performing work and the actual costs incurred while operating equipment.

(d) *Duplicate* means the process of making a copy of a document. Such copies may take the form of paper, microform, audio-visual materials, or machine-readable documentation. ONDCP will provide a copy of the material in a form that is usable by the requester.

(e) *Educational institution* means preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education that operates a program or programs of scholarly research.

(f) *Noncommercial scientific institution* means an institution that is not operated on a commercial basis as that term is defined above, and that is operated solely for the purpose of conducting scientific research not intended to promote any particular product or industry.

(g) *Records* and any other terms used in this part in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained in any format, including electronic format.

(h) *Representative of the news media* means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. News is information about current events or information that would be of interest to the public. Examples of the news media include television or radio stations that broadcast to the public at large and publishers of news periodicals that