

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC on July 27, 2007.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 30 AUG 2007

Grand Canyon, AZ, Grand Canyon National Park, Takeoff Minimums and Obstacle DP, Orig
 Phoenix, AZ, Phoenix Deer Valley, RNAV (GPS)-B, Orig-A
 Phoenix, AZ, Phoenix Deer Valley, RNAV (GPS) RWY 25L, Orig-B
 Sylvania, GA, Plantation Airpark, NDB RWY 23, Amdt 2
 Westfield/Springfield, MA, Barnes Muni, ILS OR LOC RWY 20, Amdt 6
 Westfield/Springfield, MA, Barnes Muni, RNAV (GPS) RWY 20, Orig
 Westfield/Springfield, MA, Barnes Muni, GPS RWY 20, Orig-A, CANCELLED
 Lee's Summit, MO, Lee's Summit Municipal, Takeoff Minimums and Obstacle DP, Orig
 Aberdeen/Amory, MS, Monroe County, RNAV (GPS) RWY 18, Orig
 Aberdeen/Amory, MS, Monroe County, RNAV (GPS) RWY 36, Orig
 Aberdeen/Amory, MS, Monroe County, Takeoff Minimums and Obstacle DP, Orig
 Erwin, NC, Harnett County, Takeoff Minimums and Obstacle DP, Orig
 Laconia, NH, Laconia, Muni, NDB RWY 8, Amdt 9
 Laconia, NH, Laconia, Muni, ILS OR LOC RWY 8, Amdt 1
 Laconia, NH, Laconia, Muni, RNAV (GPS) RWY 8, Orig
 Laconia, NH, Laconia, Muni, RNAV (GPS) RWY 26, Orig
 Laconia, NH, Laconia, Muni, GPS RWY 26, Orig-A, CANCELLED
 New York, NY, LaGuardia, ILS OR LOC RWY 4, Amdt 35
 New York, NY, LaGuardia, RNAV (RNP) Z RWY 4, Orig
 New York, NY, LaGuardia, RNAV (RNP) Z RWY 22, Orig

New York, NY, LaGuardia, RNAV (GPS) Y RWY 4, Amdt 2
 New York, NY, LaGuardia, RNAV (GPS) Y RWY 22, Amdt 2
 Sioux Falls, SD, Joss Foss Field, Takeoff Minimums and Obstacle DP, Amdt 7
 Houston, TX, Houston Executive, RNAV (GPS) RWY 18, Orig
 Houston, TX, Houston Executive, RNAV (GPS) RWY 36, Orig
 Houston, TX, Houston Executive, Takeoff Minimums and Obstacle DP, Orig
 Menomonie, WI, Menomonie Municipal-Score Field, RNAV (GPS) RWY 27, Orig
 Menomonie, WI, Menomonie Municipal-Score Field, RNAV (GPS) RWY 9, Orig
 Norfolk, VA, Hampton Roads Executive, NDB RWY 2, Amdt 7
 Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 10, Orig
 Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 28, Orig
 Norfolk, VA, Hampton Roads Executive, GPS RWY 10, Orig-A, CANCELLED
 Norfolk, VA, Hampton Roads Executive, GPS RWY 28, Orig-A, CANCELLED
 Norfolk, VA, Hampton Roads Executive, Takeoff Minimums and Obstacle DP, Amdt 1

Effective 27 SEP 2007

Chicago, IL, Chicago-O'Hare Intl, RNAV (GPS) RWY 32L, Amdt 2A

The FAA published several Amendments in Docket No. 30558, Amdt No. 3225 to Part 97 Of the Federal Aviation Regulations (Vol. 72, FR No. 135, Page 38755; dated Monday, July 16, 2007) under section 97.33, effective 30 August 2007, which is hereby RESCINDED as follows:

Miami, FL, Miami Intl, RNAV (RNP) Y RWY 9, Orig
 Miami, FL, Miami Intl, RNAV (GPS) Z RWY 9, Amdt 1
 Miami, FL, Miami Intl, ILS OR LOC RWY 9, Amdt 10

[FR Doc. E7-15134 Filed 8-7-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 866**

[Docket No. 2007N-0294]

Medical Devices: Immunology and Microbiology Devices: Classification of In Vitro Human Immunodeficiency Virus Drug Resistance Genotype Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying an in vitro human immunodeficiency virus (HIV) drug resistance genotype assay into class II (special controls). The

special control that will apply to this device is the guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." FDA is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule becomes effective September 7, 2007. The classification of this device into class II became effective on September 26, 2001.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:**I. Background**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device.

In accordance with section 513(f)(1) of the act, FDA issued an order on June 27, 2001, classifying into class III the

Visible Genetics, Inc., TRUEGENE HIV Genotyping Kit and OpenGene DNA Sequencing System, because this device was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or to a device which was subsequently reclassified into class I or class II. On July 11, 2001, Visible Genetics, Inc. submitted to FDA a petition requesting classification of the TRUEGENE HIV Genotyping Kit and OpenGene DNA Sequencing System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Visible Genetics, Inc., TRUEGENE HIV Genotyping Kit and OpenGene DNA Sequencing System can be classified in class II with the establishment of special controls. FDA believes that special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish special controls to provide such assurance.

This device is assigned the generic name, "In vitro HIV drug resistance genotype assay." It is identified as an in vitro diagnostic device to be used to detect HIV genomic mutations that confer resistance to specific types of antiretroviral drugs, as an aid in monitoring and treating HIV infection.

FDA has identified the risks to health associated with the use of the in vitro HIV drug resistance genotype assay. These risks include inaccurate detection of resistance mutations present in a patient's viral swarm that can result in continuance of therapies that are no longer appropriate, or changes to new, inadequate therapies. In both cases, the patient's viral load may increase, worsening the clinical prognosis and accelerating the development of drug resistant viruses. Patients may be needlessly subjected to serious, deleterious side effects of inappropriate antiviral drugs. Furthermore, failure of the assay to give any results at all (sequence failure) can deny or delay

beneficial, appropriate therapies, which may also result in high viral loads and their attendant morbidity.

FDA believes that the class II special controls guidance document will aid in mitigating the potential risks to health by providing recommendations on performance characteristics; other considerations such as design controls, statistical methods, and instruments and software; product modification; and labeling. The guidance document also provides recommendations for fulfilling the premarket (510(k)) submission requirements for this device. FDA believes that the class II special controls guidance document, in addition to general controls, addresses the risks to health identified in the previous paragraph and provides reasonable assurance of the safety and effectiveness of the in vitro HIV drug resistance assay. Therefore, on September 26, 2001, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device classification at 21 CFR 866.3950.

Following the effective date of this final classification rule, manufacturers submitting a 510(k) premarket notification for an in vitro HIV drug resistance genotype assay will need to address the issues covered in the special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, before marketing the device, which contains information about the in vitro HIV drug resistance genotype assay they intend to market.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have

federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." FDA concludes that the special controls guidance document contains information collection provisions that are subject to review by the OMB under the PRA and that have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (part 807, subpart E, OMB control number 0910-0120).

VI. References

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Visible Genetics, Inc., dated July 11, 2001.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 866.3950 to subpart D to read as follows:

§ 866.3950 In vitro human immunodeficiency virus (HIV) drug resistance genotype assay.

(a) *Identification.* The in vitro HIV drug resistance genotype assay is a device that consists of nucleic acid reagent primers and probes together with software for predicting drug resistance/susceptibility based on results obtained with these primers and

probes. It is intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs, as an aid in monitoring and treating HIV infection.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." See § 866.1(e) for the availability of this guidance document.

Dated: August 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-15475 Filed 8-7-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 023-2007]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Final Rule.

SUMMARY: On May 8, 2007, at 72 FR 26037, the Department of Justice issued a proposed rule to amend Title 28 of the Code of Federal Regulations, Part 16, to exempt the following new system of records from certain provisions of the Privacy Act: The National Security Division (NSD), "Foreign Intelligence and Counterintelligence Records System (JUSTICE/NSD-001)," which incorporated three previous systems of records of the Office of Intelligence Policy and Review (OIPR). This records system must be exempted from sections of the Privacy Act since, in most cases, disclosure of the existence of records pertaining to an individual would hinder authorized United States intelligence activities by informing that individual of the existence, nature, or scope of information that is properly classified pursuant to Executive Order 12958, as amended, and thereby cause damage to the national security. Further it is necessary to exempt this system to ensure unhampered and effective collection and analysis of foreign intelligence and counterintelligence information and to protect the identities of confidential sources.

EFFECTIVE DATE: This final rule is effective August 8, 2007.

FOR FURTHER INFORMATION CONTACT: GayLa Sessoms, (202) 616-5460 or Mary Cahill (202) 307-1823.

SUPPLEMENTARY INFORMATION: The notice of the proposed rule with invitation to

comment was published in the **Federal Register** on May 8, 2007, at 72 FR 26073. No comments were received. The Department of Justice is exempting JUSTICE/NSD-001 from 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (2), (3), (4)(G), (H), and (I), (5) and (8); (f); (g); and (h).

This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, this order will not have a significant impact on a substantial number of small business entities.

List of Subjects in 28 CFR Part 16

Administrative Practices and Procedures, Courts, Freedom of Information, and Privacy.

■ Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793-78, amend 28 CFR part 16 as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

■ 1. The authority for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 551, 552a, 552b(g), and 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717, and 9701.

■ 2. Section 16. 74 is revised to read as follows:

§ 16.74 Exemption of National Security Division Systems—limited access.

(a) The following system of records is exempted from subsections (c)(3) and (4); (d); (e)(1), (2), (3), (4)(G),(H) and (I), (5) and (8); (f); (g); and (h) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2), (k)(1), (2) and (5): Foreign Intelligence and Counterintelligence Records System (JUSTICE/NSD-001). These exemptions apply only to the extent that information in the system is subject to exemption pursuant to 5 U.S.C. 552a(j)(2), (k)(1), (2), and (5).

(b) Exemptions from the particular subsections are justified for the following reasons:

(1) *Subsection (c)(3).* To provide the target of a surveillance or collection activity with the disclosure accounting records concerning him or her would hinder authorized United States intelligence activities by informing that individual of the existence, nature, or scope of information that is properly classified pursuant to Executive Order 12958, as amended, and thereby cause damage to the national security.

(2) *Subsection (c)(4).* This subsection is inapplicable to the extent that an