

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.*

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**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

exemption is being claimed for subsection (d).

(3) *Subsection (d)(1)*. Disclosure of foreign intelligence and counterintelligence information would interfere with collection activities, reveal the identity of confidential sources, and cause damage to the national security of the United States. To ensure unhampered and effective collection and analysis of foreign intelligence and counterintelligence information, disclosure must be precluded.

(4) *Subsection (d)(2)*. Amendment of the records would interfere with ongoing intelligence activities thereby causing damage to the national security.

(5) *Subsections (d)(3) and (4)*. These subsections are inapplicable to the extent exemption is claimed from (d)(1) and (2).

(6) *Subsection (e)(1)*. It is often impossible to determine in advance if intelligence records contained in this system are relevant and necessary, but, in the interests of national security, it is necessary to retain this information to aid in establishing patterns of activity and provide intelligence leads.

(7) *Subsection (e)(2)*. Although this office does not conduct investigations, the collection efforts of agencies that supply information to this office would be thwarted if the agencies were required to collect information with the subject's knowledge.

(8) *Subsection (e)(3)*. To inform individuals as required by this subsection could reveal the existence of collection activity and compromise national security. For example, a target could, once made aware that collection activity exists, alter his or her manner of engaging in intelligence or terrorist activities in order to avoid detection.

(9) *Subsections (e)(4)(G), (H) and (I), and (f)*. These subsections are inapplicable to the extent that this system is exempt from the access provisions of subsection (d).

(10) *Subsection (e)(5)*. It is often impossible to determine in advance if intelligence records contained in this system are accurate, relevant, timely and complete, but, in the interests of national security, it is necessary to retain this information to aid in establishing patterns of activity and providing intelligence leads.

(11) *Subsection (e)(8)*. Serving notice could give persons sufficient warning to evade intelligence collection and anti-terrorism efforts.

(12) *Subsections (g) and (h)*. These subsections are inapplicable to the extent that this system is exempt from other specific subsections of the Privacy Act.

Dated: July 27, 2007.

**Lee J. Lofthus,**  
Assistant Attorney General for  
Administration.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 81

[EPA-R05-OAR-2006-0459; FRL-8450-3]

#### Determination of Attainment, Approval of Designation of Areas for Air Quality Planning Purposes; Indiana; Correction

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correcting amendment.

**SUMMARY:** This document corrects errors in the final rule redesignating LaPorte County, Indiana (LaPorte CO., IN) to attainment for the 8-hour ozone National Ambient Air Quality Standard (NAAQS). In the final approval for the redesignation of this area, EPA inadvertently titled the designation codification table as "OHIO OZONE" instead of "Indiana-Ozone", and inadvertently specified the effective date of this action in the designation table as August 20, 2007, even though the effective date of the final rule was July 19, 2007, as specified in the **DATES** portion of the final rule. This technical correction to the final rule corrects these errors.

**DATES:** *Effective Date:* This final rule is effective on August 8, 2007.

**FOR FURTHER INFORMATION CONTACT:** Edward Doty, Environmental Scientist, Criteria Pollutant Section, Air Programs Branch (AR-18), Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6057, [doty.edward@epa.gov](mailto:doty.edward@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA published a notice of final rulemaking to redesignate LaPorte County, Indiana (LaPorte CO., IN) to attainment of the 8-hour ozone standard on July 19, 2007 (72 FR 39574). In the designation codification table used to revise the 8-hour ozone designation of this area, EPA incorrectly titled the table as "OHIO OZONE." This should have read as "Indiana-Ozone." In the same designation codification table, EPA incorrectly specified the effective date of the redesignation as August 20, 2007. This differed from the actual effective date of the final rule, July 19, 2007, as specified in the **DATES** section of the

final rule. EPA intended to make the redesignation of this area effective upon the date of the publication of the final rule.

#### Correction

For LaPorte County in the final rule published in the **Federal Register** on July 19, 2007 (72 FR 39574), on page 39576 in the codification table, the table title: "OHIO OZONE" is corrected to read "Indiana-Ozone". In the second column of the same codification table, the Date: "8/20/07" is corrected to read "7/19/07". EPA is making changes in 40 CFR 81.315 in order to correct the codification of the 8-hour ozone designation for LaPorte County, Indiana.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because we are merely correcting errors in a previous action. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

#### Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is, therefore, not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)). Because the agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the **SUPPLEMENTARY INFORMATION** section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C 601 et seq.), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and