the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the draft special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes;'' the notice contains an analysis of the paperwork burden for the draft guidance.

XI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

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

2. In § 870.2360, paragraph (b) is revised to read as follows:

§ 870.2360 Electrocardiograph electrode.

* * * * *

(b) *Classification*. Class II (special controls). The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' See § 870.1(e) for the availability of this guidance document. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 870.9, if it addresses the issues identified in the special controls guidance by following the specific measures recommended in the special controls guidance.

Dated: September 26, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–19580 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–149036–04]

RIN 1545–BG75

Application of Section 6404(g) of the Internal Revenue Code Suspension Provisions; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations for the suspension of interest, penalties, additions to tax, or additional amounts under section 6404(g) of the Internal Revenue Code. The proposed regulations explain the general rules for suspension as well as exceptions to those general rules.

DATES: The public hearing, originally scheduled for October 11, 2007, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Richard A. Hurst of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration), at *Richard.A.Hurst@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION: A notice of public hearing that appeared in the **Federal Register** on Thursday, June 21, 2007 (72 FR 34199), announced that a public hearing was scheduled for October 11, 2007, at 10 a.m., in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under section 6404(g) of the Internal Revenue Code.

The public comment period for these regulations expired on September 19, 2007. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Friday, September 21, 2007, no one has requested to speak. Therefore, the public hearing scheduled for October 11, 2007, is cancelled.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E7–19570 Filed 10–3–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 034–2007]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Bureau of Investigation (FBI), a component agency of the Department of Justice (DOJ), proposes to exempt a new Privacy Act system of records entitled Law Enforcement National Data Exchange (N-DEx) from certain provisions of the Privacy Act. As explained in the proposed rule, the exemption is necessary to avoid interference with the law enforcement functions and responsibilities of the FBI and the N-DEx system. Public comment is invited.

DATES: Comments must be received by November 13, 2007.

ADDRESSES: Address all comments to Joo Chung, Counsel, Privacy and Civil Liberties Office, Office of the Deputy Attorney General, 950 Pennsylvania Avenue, NW., Washington, DC 20530, or facsimile 202–616–9627. To ensure proper handling, please reference the AAG/A Order No. in your correspondence. You may review an electronic version of the proposed rule at *http://www.regulations.gov.* You may also comment via the Internet to the Privacy and Civil Liberties Office at *DOJPrivacy ACTProposedRegulations@usdoj.gov;* or by using the comment form for this regulation at *http://www.regulations.gov.* Please include the AAG/A Order No. in the subject box.

FOR FURTHER INFORMATION CONTACT: Elizabeth Withnell, Assistant General Counsel, Privacy and Civil Liberties Unit, Office of the General Counsel, Federal Bureau of Investigation, (202) 324–3396.

SUPPLEMENTARY INFORMATION: In the notice section of today's **Federal Register**, the FBI proposes a new Privacy Act system of records, the ''Law Enforcement National Data Exchange (N-DEx), FBI–020.'' The N-DEx is a scalable information sharing system, operating under the aegis of the Criminal Justice Information Services (CJIS) Division, which will provide the capability to make potential linkages between crime incidents, criminal investigations, arrests, bookings, incarcerations, and parole and/or probation in order to help solve, deter, and prevent crimes and, in the process, enhance homeland security.

In this rulemaking, the FBI proposes to exempt this Privacy Act system of records from certain provisions of the Privacy Act because the system contains investigatory material compiled for law enforcement purposes.

Regulatory Flexibility Act

This proposed rule relates to individuals, as opposed to small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, the proposed rule will not have a significant economic impact on a substantial number of small entities.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, 5 U.S.C. 801 et seq., requires the FBI to comply with small entity requests for information and advice about compliance with statutes and regulations within FBI jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT**. Persons can obtain further information regarding SBREFA on the Small Business Administration's Web page at *http://www.sba.gov/advo/laws/law_lib.html*.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d), requires that the FBI consider the impact of paperwork and other information collection burdens imposed on the public. There are no current or new information collection requirements associated with this proposed rule.

Analysis of Regulatory Impacts

This proposed rule is not a ''significant regulatory action'' within the meaning of Executive Order 12886. Because the economic impact should be minimal, further regulatory evaluation is not necessary. Moreover, the Attorney General certifies that this rule would not have a significant economic impact on a substantial number of small entities, because the reporting requirements themselves are not changed and because it applies only to information on individuals.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, 109 Stat. 48, requires Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments, and the private sector. UMRA requires a written statement of economic and regulatory alternatives for proposed and final rules that contain Federal mandates. A ''Federal mandate'' is a new or additional enforceable duty, imposed on any State, local, or tribal government, or the private sector. If any Federal mandate causes those entities to spend, in aggregate, $100 million or more in any one year the UMRA analysis is required. This proposed rule would not impose Federal mandates on any State, local, or tribal government or the private sector.

Executive Order 13132, Federalism

The FBI has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism. This action will not have a substantial direct effect 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, and therefore will not have federalism implications.

Environmental Analysis

The FBI has reviewed this action for purposes of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4347, and has determined that this action will not have a significant effect on the human environment.

Energy Impact

The energy impact of this action has been assessed in accordance with the Energy Policy and Conservation Act (EPCA), Public Law 94–163, as amended, 42 U.S.C. 6362. This rulemaking is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 28 CFR Part 16

Administrative practices and procedures, Courts, Freedom of Information Act, Government in the Sunshine Act, and the Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 793–78, it is proposed to amend 28 CFR part 16 as follows:

PART 16—[AMENDED]

Subpart E—Exemption of Records Systems Under the Privacy Act

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

Authority: 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 524; 31 U.S.C. 3717, 9701.

2. Section 16.96 is amended to add new paragraphs (t) and (u) as follows:

§ 16.96 Exemption of Federal Bureau of Investigation Systems—limited access.

* * * * *

(t) The following system of records is exempt from 5 U.S.C. 552a(c)(3) and (4); (d)(1), (2), (3) and (4); (e)(1), (2), (3), (5) and (8); and (g) of the Privacy Act:

(1) Law Enforcement National Data Exchange (N-DEx), (JUSTICE/FBI–020).

(2) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(j)(2). Where compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system, or the overall law enforcement process, the applicable exemption may be waived by the FBI in its sole discretion.

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

(1) From subsection (c)(3) because this system is exempt from the access provisions of subsection (d). Also, because making available to a record subject the accounting of disclosures from records concerning him/her would specifically reveal any investigative interest in the individual. Revealing this information may thus compromise ongoing law enforcement efforts. Revealing this information may also permit the record subject to take measures to impede the investigation, such as destroying evidence, intimidating potential witnesses or fleeing the area to avoid the investigation.

(2) From subsection (c)(4) because this system is exempt from the access and amendment provisions of subsection (d).

(3) From subsections (d)(1), (2), (3), and (4), because these provisions

concern individual access to and amendment of investigatory records, compliance with which could alert the subject of an investigation of the fact and nature of the investigation, and/or the investigative interest of the FBI and other law enforcement agencies; interfere with the overall law enforcement process by leading to the destruction of evidence, improper influencing of witnesses, fabrication of testimony, and/or flight of the subject; possibly identify a confidential source or disclose information which would constitute an unwarranted invasion of another's personal privacy; reveal a sensitive investigative or intelligence technique; or constitute a potential danger to the health or safety of law enforcement personnel, confidential informants, and witnesses. Amendment of these records would interfere with ongoing investigations and other law enforcement activities and impose an impossible administrative burden by requiring investigations, analyses, and reports to be continuously reinvestigated and revised.

(4) From subsection (e)(1) because it is not always possible to know in advance what information is relevant and necessary for law enforcement purposes and, in fact, a major tenet of the N-DEx information sharing system is that the relevance of certain information may not always be evident in the absence of the ability to correlate that information with other existing law enforcement data.

(5) From subsection (e)(2) because application of this provision could present a serious impediment to efforts to solve crimes and improve homeland security in that it would put the subject of an investigation on notice of that fact, thereby permitting the subject to engage in conduct intended to frustrate or impede that activity.

(6) From subsection (e)(3) because disclosure would put the subject of an investigation on notice of that fact and would permit the subject to engage in conduct intended to thwart that activity.

(7) (i) From subsection (e)(5) because many of the records in this system are records contributed by other agencies and the restrictions imposed by (e)(5) would limit the utility of the N-DEx system. All data contributors are expected to ensure that information they share is relevant, timely, complete and accurate. In fact, rules for use of the N-DEx system will require that information be updated periodically and not be used as a basis for action or disseminated beyond the recipient without the recipient first obtaining permission from the record owner/contributor. These rules will be enforced through robust audit procedures. The existence of these rules should ameliorate any perceived concerns about the integrity of the information in the N-DEx system. Nevertheless, exemption from this provision is warranted in order to reduce the administrative burden on the FBI to vouch for compliance with the provision by all N-DEx data contributors and to encourage those contributors to share information the significance of which may only become apparent when combined with other information in the N-DEx system.

(ii) The FBI is also exempting the N-DEx from subsection (e)(5) in order to block the use of a challenge under subsection (e)(5) as a collateral means to obtain access to records in the N-DEx. The FBI has exempted these records from the access and amendment requirements of subsection (d) of the Privacy Act in order to protect the integrity of law enforcement investigations. Exempting the N-DEx system from subsection (e)(5) complements this exemption and will provide the FBI with the ability to prevent the assertion of challenges to a record's accuracy, timeliness, completeness and/or relevance under subsection (e)(5) to circumvent the exemption claimed from subsection (d).

(8) From subsection (e)(8), because to require individual notice of disclosure of information due to compulsory legal process would pose an impossible administrative burden on the FBI and may alert the subjects of law enforcement investigations to the fact of those investigations, when not previously known.

(9) From subsection (g) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Dated: September 25, 2007.

Lee J. Lofthus,

Assistant Attorney General for Administration.

[FR Doc. E7–19458 Filed 10–3–07; 8:45 am]

BILLING CODE 4410–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2007–0835–200740(b); FRL–8475–3]

Approval of Implementation Plans of Kentucky: Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Kentucky State Implementation Plan (SIP) submitted on July 19, 2007. This revision addresses the requirements of EPA's Clean Air Interstate Rule (CAIR), promulgated on May 12, 2005, and subsequently revised on April 28, 2006, and December 13, 2006. EPA is proposing to determine that the SIP revision fully implements the CAIR requirements for Kentucky. Therefore, as a consequence of the SIP approval, EPA will also withdraw the CAIR Federal Implementation Plans (FIPs) concerning sulfur dioxide (SO_2), nitrogen oxides (NO_X) annual, and NO_X ozone season emissions for Kentucky. The CAIR FIPs for all States in the CAIR region were promulgated on April 28, 2006, and subsequently revised on December 13, 2006.

CAIR requires States to reduce emissions of SO_2 and NO_X that significantly contribute to, and interfere with maintenance of, the national ambient air quality standards for fine particulates and/or ozone in any downwind state. CAIR establishes State budgets for SO_2 and NO_X and requires States to submit SIP revisions that implement these budgets in States that EPA concluded did contribute to nonattainment in downwind states. States have the flexibility to choose which control measures to adopt to achieve the budgets, including participating in the EPA-administered cap-and-trade programs. In the SIP revision that EPA is proposing to approve, Kentucky would meet CAIR requirements by participating in the EPA-administered cap-and-trade programs addressing SO_2, NO_X annual, and NO_X ozone season emissions.

In the Final Rules Section of this **Federal Register**, EPA is approving the Commonwealth's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before November 5, 2007.