Bank & Trust Company, all of Kansas City, Kansas.

Board of Governors of the Federal Reserve System, February 21, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–3651 Filed 2–26–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Deletion of an Existing System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice to delete an existing CMS system of records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is deleting an existing system of records titled the ''Privacy Accountability Database (PAD),'' CMS System No. 09–70–0540, established at 67 FR 62482 (October 7, 2002).

EFFECTIVE DATE: The deletion will be effective on February 11, 2008.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is (410) 786–5357. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

SUPPLEMENTARY INFORMATION: The PAD as a Privacy Act system of records is being deleted because the database that supported this collection is obsolete and is no longer active. CMS will continue to track disclosures and will provide the necessary tracking, reporting, and accounting of disclosures to be in compliance with the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996.

Dated: February 20, 2008.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 08–873 Filed 2–26–08; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records titled, ''Medicare Administrative Issue Tracker and Reporting of Operations (MAISTRO) System,'' System No. 09–70–0598. The purpose of the system is to capture and track casework/inquiries pertaining to Medicare Part A and Part B programs. The system will also provide a mechanism for recording data on a national level and will serve as a tool to leverage in performing analysis including identification of systemic trends. MAISTRO will record, track and monitor beneficiary and provider level inquiries & complaints. The system will contain information needed to research the inquiries, such as a beneficiary's health insurance claim number (HICN) or a Provider Identification Number (NPI).

The primary purpose of the system is to collect and maintain information needed to provide a mechanism for CMS' central and regional office to capture, track, manage, report and trend inquiries, complaints and issues related to Fee-for-Service (FFS) programs. Information maintained in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor, consultant or CMS grantee; (2) assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent; (3) facilitate research on the quality and effectiveness of care provided, as well as epidemiological projects; (4) support litigation involving the Agency; and (5) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

EFFECTIVE DATES: CMS filed a new system report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on 2/11/2008. In any event, we will not disclose any information under a routine use until 30 days after publication in the **Federal Register** or 40 days after mailings to Congress, which ever is later. We may defer implementation of this system or on one or more of the routine uses listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture & Strategy Group, Office of Information Services, CMS, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Michele Livingston, Division of Ombudsman Casework and Trends Management, Medicare Ombudsman Group, Office of External Affairs, CMS, 7500 Security Boulevard, Mail Stop S1–20–21, Baltimore, Maryland 21244–1850. The telephone number is 410–786–6340 or contact *Michele.Livingston@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: The CMS Consortium for Financial Management and Fee for Service Operations (CFMFFSO) is responsible for handling casework/inquiries, but not limited to: (1) Coverage and payment policy; (2) audit and reimbursement policy and operations; (3) program integrity and medical review policy; (4) Medicare secondary payer and coordination of benefits; (5) claims-related hearings, appeals and grievances; (6) beneficiary eligibility, enrollment, entitlement, rights and protections, premium billing and collection; and (7) dispute resolution processes to assure the effective administration of the Medicare program. These types of inquiries number in the tens of thousands annually across the 10 CMS Regional Offices.

The Office of the Medicare Ombudsman was established as a result of Section 923 of the Medicare

Modernization Act and is responsible for receiving complaints, grievances and requests for information submitted by individuals entitled to benefits under Part A or enrolled under Part B, or both, with respect to any aspect of the Medicare program and providing assistance with respect to complaints. Over the last year the focus of inquiry tracking has centered on the implementation of Part D reporting.

Although each regional office has developed its own system to track and manage inquiries and complaints, these systems are inconsistent and do not utilize standardized operational procedures or processes to guide how inquiries are addressed or reported. Standardization will improve performance, reduce operating costs, and enable statistical analysis of the workload and trends among inquiries. To address these issues, the following tasks had to be accomplished: (1) Identifying a system to track beneficiary and provider inquiries, complaints and issues specific to FFS operations; (2) Ensuring that casework throughout each region is consistently captured and managed appropriately which ensures the delivery of high quality customer service to Medicare Part A and Part B beneficiaries and providers; and (3) Producing workload data statistics to both account for the work and enable improvement in CMS' policies and procedures.

When complete, the MAISTRO system will provide a mechanism for CMS' central and regional office to capture, track, manage, report and trend inquiries, complaints and issues related to Fee-for-Service. Additionally, the goal of MAISTRO is to provide an easy to use system that will provide consistency when tracking, resolving, and reporting FFS inquiries, complaints and issues on a national level such that trends, workloads and systemic issues can be identified and managed appropriately across the consortium.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

Authority for maintenance of this system is given under § 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law (Pub. L.) 108–173).

B. Collection and Maintenance of Data in the System

For purposes of this SOR, the system contains information on Medicare beneficiaries, providers and other individuals who have made inquiries concerning the fee-for-service program. The system contains information such as a beneficiary's name, address data, health insurance claim number (HICN), demographic information (gender, date of birth), provider name, address data and provider identification number (NPI), provider organization information, contact person information, employer identification numbers, and certain optional data such as Social Security Numbers and other provider identifiers used by these health care providers.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions Routine Uses

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release MAISTRO information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both individually identifiable and non-individually-identifiable data may be disclosed under a routine use.

We will only disclose the minimum personal data necessary to achieve the purpose of MAISTRO. CMS has the following policies and procedures concerning disclosures of information that is maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason the data are being collected; e.g., to collect and maintain information needed to provide a mechanism for CMS' central and regional office to capture, track, manage, report and trend inquiries, complaints and issues related to Fee-for-Service (FFS).

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record;

b. Remove or destroy at the earliest time all individually-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or CMS grantees that have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing a CMS function relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant, or grantee whatever information is necessary for the contractor, consultant, or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant, or grantee from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To assist another Federal or state agency, agency of a state government, an agency established by state law, or its

fiscal agent pursuant to agreements with CMS to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

Other Federal or state agencies in their administration of a Federal health program may require MAISTRO information for the purposes of collecting and maintaining information needed to capture, track, manage, report and trend inquiries, complaints and issues related to Fee-for-Service (FFS).

Other Federal or state agencies, in their administration of a Federal health program, may require MAISTRO information in order to support evaluations and monitoring of Medicaid claims information of beneficiaries, including proper reimbursement for services provided.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The MAISTRO data will provide for research or support of evaluation projects and a broader, longitudinal, national perspective of the status of Medicaid beneficiaries. CMS anticipates that researchers may have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicaid beneficiaries and the policies that govern their care.

4. To assist the Department of Justice (DOJ), court or adjudicatory body when:

a. The Agency or any component thereof, or

b. Any employee of the Agency in his or her official capacity, or

c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court, or adjudicatory body involved.

5. To support a CMS contractor that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste, and abuse.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or CMS grantee whatever information is necessary for the contractor or CMS grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

6. To support another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in a program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

Other agencies may require MAISTRO information for the purpose of combating fraud, waste, and abuse in such Federally-funded programs.

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Dated: February 20, 2008.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NUMBER: 09–70–0598

SYSTEM NAME:

''Medicare Administrative Issue Tracker and Reporting of Operations (MAISTRO) System,'' HHS/CMS/OEA.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

For purposes of this SOR, the system contains information on Medicare beneficiaries, providers and other individuals who have made inquiries concerning the fee-for-service program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains information such as a beneficiary's name, address data, health insurance claim number (HICN), demographic information, (gender, date of birth), provider name, address data and provider identification number (NPI), provider organization information, contact person information, employer identification numbers, and certain optional data such as Social Security Numbers and other provider identifiers used by these health care providers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of this system is given under § 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law (Pub. L.) 108–173).

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the system is to collect and maintain information needed to provide a mechanism for CMS' central and regional office to capture, track, manage, report and trend inquiries, complaints and issues related to Fee-for-Service (FFS) programs. Information maintained in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor, consultant or CMS grantee; (2) assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent; (3) facilitate research on the quality and effectiveness of care provided, as well as epidemiological projects; (4) support litigation involving the Agency; and (5) combat fraud, waste, and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or grantees that have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need access to the records in order to assist CMS.

2. To assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent pursuant to agreements with CMS to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

4. To assist the Department of Justice (DOJ), court or adjudicatory body when:

a. The Agency or any component thereof, or

b. Any employee of the Agency in his or her official capacity, or

c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To support a CMS contractor that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

6. To support another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in a program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

All records are accessible by individual name or identification number.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986;

the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained for a period of six years and three months. All claims-related records are encompassed by the document preservation order and will be retained until notification is received by DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Ombudsman Casework and Trends Management, Medicare Ombudsman Group, Office of External Affairs, CMS, 7500 Security Boulevard, Mail Stop S1–11–21, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual health care provider should write to the system manager who will require the system name, National Provider Identifier, address, date of birth, and gender, and for verification purposes, the subject individual health care provider's name (woman's maiden name, if applicable), and Social Security number (SSN). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual health care provider should contact the systems manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The data contained in this system of records are obtained from the individuals who communicate or correspond with CMS.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E8–3678 Filed 2–26–08; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Pediatric Advisory Committee and Request for Nominations for a Nonvoting Industry Representative on the Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on its Pediatric Advisory Committee notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy on June 30, 2008, effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by March 28, 2008, for vacancies listed in this notice. Concurrently, nomination material for prospective candidates should be sent to FDA by March 28, 2008.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Carlos Peña (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, or by e-mail: *Carlos.Peña@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The agency requests nominations for a nonvoting industry representative on the Pediatric Advisory Committee.

I. Function

The committee advises and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 355a, and 355c); (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes as specified in section 3 of the Best Pharmaceuticals for Children Act (Public Law 107–109); (5) pediatric labeling changes as specified in section 5 of the Best Pharmaceuticals for Children Act; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur as specified in section 17 of the Best Pharmaceuticals for Children Act; (7) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products; (8) research involving children as subjects as specified in 21 CFR 50.54; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The committee also advises and makes recommendations to the Secretary of Health and Human Services (the Secretary) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

II. Selection Procedure

Any pediatric products industry, association, or organization interested in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select an industry representative, within 60 days after the receipt of the FDA letter, and the industry