Proximal Anastomotic Assist Devices

Surgeons use proximal AADs in CABG procedures to avoid the need to clamp the aorta when attaching a harvested vessel to it. If a proximal AAD is not used, the surgeon must use a clamp to stop the flow of blood to a segment of the aorta while the harvested vessel is surgically attached. Using a clamp can cause calcified plaque particles to dislodge from the aorta and travel through the blood stream to the brain, risking neurological dysfunction or stroke.

The proper geographic market in which to analyze the effects of the proposed transaction on the market for proximal AADs is the United States. Proximal AADs are medical devices that must be approved by the FDA before being marketed in the United States. As with other medical devices, the clinical testing and regulatory approval process for proximal AADs can be costly and time-consuming, preventing proximal AADs approved outside of the United States but not approved within the United States from serving as a competitive alternative for U.S. consumers.

There are currently three firms in the U.S. market for proximal AADs, making it a highly concentrated market. The evidence indicates that J&J and Guidant's manual proximal AADs are each others' closest competitors. Medtronic also participates in the market with an automatic device that it recently launched in the United States. A fourth firm, St. Jude Medical, removed its automatic device, Symmetry®, from the market last year amidst reports of device failures. J&J's proximal AAD, eNclose®, was developed and is manufactured by Novare; J&J and Novare have a distribution agreement making J&J the sole distributor of eNclose® in the United States.

As with the other medical devices discussed, entry into the market for proximal AADs is difficult, costly, and time-consuming. Additionally, the alleged safety concerns regarding St. Jude's Symmetry device have resulted in greater scrutiny of proximal AADs by the FDA. The increased scrutiny is likely to substantially increase the cost of developing a proximal AAD. In addition, it appears that the publicity surrounding Symmetry's removal from the market has dampened physician enthusiasm for these devices. These developments, along with the declining number of overall U.S. CABG procedures, decrease the likelihood of entry into this market.

The proposed acquisition is likely to cause significant competitive harm in the market for proximal AADs by eliminating competition between J&J and Guidant and reducing the number of competitors in the market from three to two. The evidence has also shown that J&J and Guidant's products are likely each others' closest competitors in the proximal AAD market because they are more similar to each other than to Medtronic's product. The proposed acquisition is therefore likely to enable the combined J&J/Guidant to raise prices for proximal AADs unilaterally.

The proposed acquisition's anticompetitive effects in the market for proximal AADs are remedied by the proposed Consent Agreement's requirement that J&J terminate its distribution agreement with Novare for Novare's proximal AAD, eNclose. It is anticipated that it will take Novare no more than two months to find a new distribution partner for eNclose.

Appointment of an Interim Monitor and a Divestiture Trustee

The proposed Consent Agreement contains a provision that allows the Commission to appoint an interim monitor to oversee J&J's compliance with all of its obligations and performance of its responsibilities pursuant to the Commission's Decision and Order. The interim monitor is required to file periodic reports with the Commission to ensure that the Commission remains informed about the status of the divestitures, about the efforts being made to accomplish the divestitures, and the provision of services and assistance during the transition period for the EVH divestiture.

Finally, the proposed Consent Agreement contains provisions that allow the Commission to appoint a divestiture trustee if any or all of the above remedies are not accomplished within the time frames required by the Consent Agreement. The divestiture trustee may be appointed to accomplish any and all of the remedies required by the proposed Consent Agreement that have not yet been fulfilled upon expiration of the time period allotted for each.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission, with Chairman Majoras and Commissioner Harbour recused.

Donald S. Clark,

Secretary.

[FR Doc. 05–22165 Filed 11–7–05; 8:45 am]

BILLING CODE 6750–01–P

GOVERNMENT ACCOUNTABILITY OFFICE

Advisory Council on Government Auditing Standards; Notice of Meeting

The Advisory Council on Government Auditing Standards will meet Monday, December 5, 2005, from 8:30 a.m. to 5 p.m., in room 7C13 of the Government Accountability Office building, 441 G Street, NW., Washington, DC.

The Advisory Council on Government Auditing Standards will hold a meeting to discuss issues that may impact government auditing standards. The meeting is open to the public. Council discussions and reviews are open to the public. Members of the public will be provided an opportunity to address the Council with a brief (five minute) presentation on Monday afternoon.

Any interested person who plans to attend the meeting as an observer must contact Sharon Chase, Council Assistant, 202–512–9406. A form of picture identification must be presented to the GAO Security Desk on the day of the meeting to obtain access to the GAO Building. For further information, please contact Ms. Chase. Please check the Government Auditing Standards Web page (*http://www.gao.gov/govaud/ybk01.htm*) one week prior to the meeting for a final agenda.

Jeanette M. Franzel,

Director, Financial Management and Assurance.

[FR Doc. 05–22205 Filed 11–7–05; 8:45 am]

BILLING CODE 1610–02–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

SOR titled, ''Medicare Prescription Drug Plan Finder (MPDPF) System, HHS/CMS/CBC, System No. 09–70–0564.'' Under the provisions of Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), CMS has provided the participants of eligibility transactions a query and response solution in a single data center using a three-tier architecture. Enterprise Business Services (EBS), the user interface, will have the responsibility of receiving identifying information on Medicare beneficiaries for processing eligibility requests and enrollment assistance with the Medicare Prescription Drug Benefit Program. These inbound messages will be sent to EBS for processing of the eligibility request and for securing the information from the CMS Community Based Organization/Customer Service Representative (CBO/CSR) Data Store, and for sending an available plan option response back via the internet. EBS will capture the identifying information and enrollment selection, and transmit it to the selected Medicare Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MAPD). This initiative will streamline and facilitate drug benefit eligibility determination and the enrollment process.

The primary purpose of this system is to provide a Web accessible inquiry system that will provide a mechanism to support an individual beneficiary's efforts in performing drug benefit eligibility queries and to enroll them into selected plans. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) assist PDPs and MAPDs directly or through the Enterprise Business Services; (3) support constituent requests made to a Congressional representative; and (4) support litigation involving the Agency related to this system. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that the Aroutine use'' portion of the system be published for comment, 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 Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 1, 2005. To ensure that all parties have adequate time in which to comment, the new SOR, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance Data Development, 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 daylight time.

FOR FURTHER INFORMATION CONTACT: Thomas Dudley, Division of Website Project Management, Beneficiary Information Services Group, Center for Beneficiary Choices, CMS, Mail Stop S1–01–26, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850. His telephone number is 410–786–1442, or e-mail at *Thomas.Dudley@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: The public version of the toll will use knowledge based authentication (KBA), to provide the end user access to personalized information about their drug benefit eligibility and enrollment. KBA allows a user to access the system based on what they know without the need for a user id/password. To successfully authenticate, the user will need to provide the following information: Health Insurance Claim Number (HICN), Date of Birth, Last Name, Type of Enrollment, Effective date of enrollment, and Zip Code. This information will then be validated in the CMS Data Center. All data elements must match to successfully authenticate the user. If the authentication fails, the user will be taken directly to the default route and asked to respond to a series of questions in lieu of authentication. They will not be provided with ''retry'' options. If successfully authenticated, Part D and Part C information will be retrieved from the data center and passed to MPDPF.

CMS has planned to provide the participants of eligibility transactions a query and response solution in a single data center using a three-tier architecture. EBS, the user interface, will have the responsibility of receiving identifying information on Medicare beneficiaries for processing eligibility requests and enrollment assistance with the Medicare Prescription Drug Benefit Program. These inbound messages will be sent to EBS for processing of the eligibility request and for securing the information from the CMS CBO/CSR Data Store, and for sending a response back via the internet.

The drug benefit itself is very complex. The user must self-identify him/herself into one of 4 categories in order to get the options applicable in his/her circumstances (full dual subsidy eligible; full subsidy eligible; partial subsidy eligible; no subsidy eligible). CMS knows from prior education and consumer research efforts that it is extremely difficult for persons with Medicare to understand the nuances of these options and to accurately categorize them. This presents a challenge for both the direct beneficiary user and those assisting the beneficiary (CSRs and CBOs). However, CMS data systems contain information that can easily provide the user's categorization and then enable the drug benefit tool to accurately present only those options that are applicable to his/her unique circumstances. This is the primary driver for the development of the eligibility query.

A secondary, but also essential, driver is to provide an efficient means for users to explore their drug benefit choices. We need to ensure that we provide tools that can encourage the maximum number of Medicare beneficiaries to use self-service options given the volume of inquiries we are projecting and the extraordinary costs for servicing those calls. To meet the varying needs of different end-users, two different versions of the MPDPF will be developed: one tool will be used for the Public (including CBOs, and beneficiaries) and the other tool will be dedicated to CSR staffing the call centers that service 1–800–Medicare.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for the System

Authority for this system is given under the provisions of Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173). This new prescription drug benefit program was enacted into law on December 8, 2003, amended Title XVIII of the Social Security Act (the Act), and codified at Title 42 Code of Federal Regulations (CFR) Parts 403, 411, 417 and 423 by establishing a new Medicare ''Part D'' Prescription Drug Benefit program. Part D of Title XVIII of the Act, as amended by the MMA, and its implementing regulations at 42 CFR Parts 403, 411, 417 and 423.

B. Collection and Maintenance of Data in the System

Information collected for this system will include but is not limited to, individuals who voluntarily access and who successfully validate information required by the Web-based Application Systems maintained by CMS. Information collected for this system will include, but is not limited to, last name, gender, HICN, telephone number, geographic location, type of enrollment (Medicare Part A or Part B), and effective date of enrollment in Part A and Part B.

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

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

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 MPDPF information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of MPDPF. CMS has the following policies and procedures concerning disclosures of information that will be 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 that the data is being collected, *e.g.*, to provide a Web accessible inquiry system that will provide a mechanism to support an individual beneficiary's efforts in performing drug benefit eligibility queries and to enroll them into selected plans.

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 of disclosure of the record;

b. Remove or destroy at the earliest time all patient-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 Agency contractors, or consultants who have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need to have 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 CMS functions relating to purposes for this system.

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

2. To Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through the Enterprise Business Services, a CMS intermediary for the administration of Title XVIII of the Act.

PDPs and MAPDs require MPDPF information in order to establish the validity of evidence or to verify the accuracy of information presented by the individual, as it concerns the individual's entitlement to Part D benefits under the Medicare Prescription Drug Benefit Program.

3. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

Individuals sometimes request the help of a Member of Congress in resolving some issue relating to a matter before CMS. The Member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

4. To 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. 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. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which CMS collects the information.

B. Additional Provisions Affecting Routine Use Disclosures. This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, Subparts A and E, 65 FR 82462 (12–28–00)). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small

that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

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 include 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; 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 the disclosure of information relating to individuals.

Dated: October 27, 2005.

Charlene Frizzera,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

09–70–0564

SYSTEM NAME:

''Medicare Prescription Drug Plan Finder (MPDPF) System, HHS/CMS/CBC''

SECURITY CLASSIFICATION:

Level 3 Privacy Act Sensitive

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850, and at various contractor locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Information collected for this system will include but is not limited to, individuals who voluntarily access and who successfully validate information required by the Web-based Application Systems maintained by CMS.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information collected for this system will include, but is not limited to, last name, gender, Health Insurance Claim Number (HICN), telephone number, geographic location, type of enrollment (Medicare Part A or Part B), and effective date of enrollment in Part A and Part B.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system is given under the provisions of Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173). This new prescription drug benefit program was enacted into law on December 8, 2003, amended Title XVIII of the Social Security Act (the Act), and codified at Title 42 Code of Federal Regulations (CFR) parts 403, 411, 417 and 423 by establishing a new Medicare ''Part D'' Prescription Drug Benefit program. Part D of Title XVIII of the Act, as amended by the MMA, and its implementing regulations at 42 CFR Parts 403, 411, 417 and 423.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system is to provide a Web accessible inquiry system that will provide a mechanism to support an individual beneficiary's efforts in performing drug benefit eligibility queries and to enroll them into selected plans. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) assist PDPs and MAPDs directly or through the Enterprise Business Services; (3) support constituent requests made to a Congressional representative; and (4) support litigation involving the Agency related to this system.

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

2. To Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through the Enterprise Business Services, a CMS intermediary for the administration of Title XVIII of the Act.

3. To a Member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

4. To 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.

B. Additional Provisions Affecting Routine Use Disclosures. This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, Subparts A and E , 65 Fed. Reg. 82462 (12–28–00)). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

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

STORAGE:

Computer diskette and on magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by the individual identifiable information of the beneficiary.

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 include 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; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained in a secure storage area with identifiers. Disposal occurs 6 years and 3 months from the time the individual accesses the MPDPF.

SYSTEM MANAGER AND ADDRESS:

Director, Beneficiary Information Services Group, Center for Beneficiary Choices, CMS, Mail Stop S1–01–26, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

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 should contact the system 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:

Sources of information contained in this records system include data collected from the initial voluntary inquiry made by or on behalf of the individual and validated through the Medicare Beneficiary Database.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–22192 Filed 11–7–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 013'' (Recognition List Number: 013), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of ''Modifications to the List of Recognized Standards, Recognition List Number: 013'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section VI of this document for electronic access to the searchable