in a DB2 relational database management environment (DASD data storage media).

RETRIEVABILITY:

Information is most frequently retrieved by HICN, provider number (facility, physician, IDs), service dates, and beneficiary state code.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against 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; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 20 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Quality Measurement and Health Assessment Group, Office of Clinical Standards and Quality, CMS, Room C1–23–14, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name, and the retrieval selection criteria (e.g., HICN, Provider number, etc.).

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:

Medicare Beneficiary Database (09–70–0536), National Claims History File (09–70–0558), and private physicians, private providers, laboratories, other providers and suppliers who are participating in health care transparency projects sponsored by the Agency.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–17907 Filed 9–11–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0230]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 12, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0320. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information From U.S. Processors That Export to the European Community—(OMB Control Number 0910–0320)—Extension

The European Community (EC) is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member states. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to

detention and possible refusal at the port. FDA requests the following information from each processor seeking to be included on the lists:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product; and
5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection.

In the **Federal Register** of June 21, 2007 (72 FR 34256), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	.25	3
Dairy	120	1	120	.25	30
Game Meat and Meat Products	5	1	5	.25	1
Animal Casings	5	1	5	.25	1
Gelatin	3	1	3	.25	1
Collagen	3	1	3	.25	1
Total					37

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on the responses received over the past 3 years. We estimate that the annual reporting burden would be approximately 37 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. No record retention is required. In previous years, FDA estimated that the agency's communication with trade associations and states resulted in a reporting burden of 520 hours. FDA no longer receives information from trade associations and states under this program. Accordingly, the proposed annual burden for this information collection has been reduced by 520 hours. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: September 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18033 Filed 9–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 14, 2007 (72 FR 45435). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portions of the meeting. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cathy A. Miller, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Cathy.Miller1@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2007, FDA announced that a meeting of the Cardiovascular and Renal Drugs Advisory Committee would be held on October 16 and 17, 2007.

On page 45435, in the second column, the *Date and Time* portion of the document is amended to read as follows:

Date and Time: The meeting will be held on October 16, 2007, from 8 a.m. to 5 p.m.

On page 45435, in the third column, the *Agenda* portion of the document is amended to read as follows:

Agenda: On October 16, 2007, the committee will discuss regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic from Shire Development, Genzyme Corp., and Fresenius Medical Care.

Dated: September 5, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–18031 Filed 9–11–07; 8:45 am]

BILLING CODE 4160–01–S