Health and Human Services approved for the Committee charter to be renewed. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on October 1, 2010. Renewal of the SACHRP charter provides authorization for the Committee to operate until October 1, 2012.

A copy of the Committee charter is available on the SACHRP Web site at *http://www.hhs.gov/ohrp/sachrp/charter.htm.* A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is *http://fido.gov/facadatabase.*

Dated: November 16, 2010.

Jerry Menikoff,

Director, Office for Human Research Protections, and Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2010–29517 Filed 11–22–10; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charter for the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. App), the U.S. Department of Health and Human Services is hereby announcing renewal of the charter for the Advisory Committee on Blood Safety and Availability (ACBSA).

FOR FURTHER INFORMATION CONTACT: Jerry Holmberg, PhD; Senior Advisor for Blood Policy and Executive Secretary, Advisory Committee on Blood Safety and Availability; Department of Health and Human Services; 1101 Wootton Parkway; Tower Building, Suite 250; Rockville, MD 20852; Telephone: (240) 453–8803; Fax: (240) 453–8456; E-mail address: *acbsa@hhs.gov.*

SUPPLEMENTARY INFORMATION: ACBSA was established in 1996. The Committee provides advice and guidance to the Secretary, through the Assistant Secretary for Health, on a range of blood safety issues that encompass broad public health and societal implications that cannot be resolved through analysis of scientific data alone. The range of issues on which the Committee is tasked to provide advice and guidance includes, but is not limited to: (1) Definition of public health parameters around safety and availability of the blood and blood products; (2) broad public health, ethical, and legal issues related to transfusion and transplantation safety; and (3) implications for safety and availability of various economic factors affecting product cost and supply.

Since the ACBSA was established, renewal of the Committee charter has been carried out at the appropriate intervals as stipulated by FACA. The previous Committee charter was scheduled to expire on October 9, 2010. On October 8, 2010, the Secretary of Health and Human Services approved for the Committee charter to be renewed. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on October 9, 2010. Renewal of the ACBSA charter provides authorization for the Committee to operate until October 9, 2012.

A copy of the Committee charter is available on the ACBSA Web site at *http://www.hhs.gov/ash/bloodsafety/.* A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is *http://fido.gov/facadatabase.*

Dated: November 17, 2010.

Jerry A. Holmberg,

Senior Advisor for Blood Policy, Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 2010–29518 Filed 11–22–10; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0422]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information From United States Firms and 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 December 23, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 United States Firms and Processors That Export to the European Community (OMB Control Number 0910–0320)—Revision

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. The European Commission, the executive branch of the EC, requires countries trading with any of the EC member countries to provide lists of firms and processors approved to export certain animal-derived commodities to the EC. As stated in the notice published in the **Federal Register** of April 4, 1996 (61 FR 15077), FDA established a list of U.S. firms and processors that intended to export shell eggs, dairy products, and game meat and game meat products to the EC.

Although the 1996 **Federal Register** notice did not include on the list firms and processors exporting raw, bulk collagen, and gelatin intended for

human consumption, EC directives require that shipments of raw, bulk collagen, and gelatin products be accompanied by certification stating that the product, derived from ruminant bones, bovine hides, and pigskins, has been produced in compliance with EC Council Directive 2003/863/EC. The directive contains the requirements for sourcing, manufacture, transport, and storage of raw materials and manufacture of finished products. Chapter III, Article 23, of the directive requires lists identifying non-EC firms and processors that meet EC requirements and have the appropriate animal and public health certificates. Therefore, FDA is revising this information collection in order to facilitate exports of raw, bulk collagen, and gelatin originating from the United States into the EC. The description of the data elements to be collected from firms and processors of raw, bulk collagen, and gelatin products follows. The estimated burden hours associated with this information collection remain 37 total hours. FDA requests the following information from each firm or processor seeking to be included on the lists for shell eggs, dairy products, game meat, game meat products, and animal casings:

- Business name and address;
- Name and telephone number of person designated as business contact;
- Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
- Name and address of manufacturing plants for each product; and
- 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.

FDA uses the information to maintain lists of firms and 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 firms and processors that meet U.S. regulatory requirements. Products processed by firms and processors not on the lists are subject to detention and possible refusal at the port.

FDA requests the following information from each firm or processor seeking to be included on the lists for raw, bulk collagen, and gelatin:

- Business name and address;
- Name, telephone number, and email address of contact person;
- List of products presently shipped to the EC and those intended to be shipped within the next 2 years;
- Name and address of the manufacturing and processing plant for each product;
- Names and affiliations of any Federal, State, and local governmental agencies that inspect the plant, government assigned plant identifier, such as plant number and last date of inspection; and
- A copy of the most recent (within 1 year of the date of application) inspection report issued by a State, local or Federal public health regulatory agency and a copy of a recent laboratory analysis as required by the EC of the finished product including: Total aerobic bacteria, coliforms (30 °C), coliforms (44.5 °C), anaerobic sulphite-reducing bacteria (no gas production), *Clostridium perfringens, Staphylococcus aureus, Salmonella,* Arsenic, Lead, Cadmium, Mercury, Chromium, Copper, Zinc, Moisture (105 °C), Ash (550 °C), SO_2, and H_2O_2.

FDA will use the information to maintain a list of approved firms and processors that will be posted on FDA's Web site. FDA intends to place on the list only firms and processors that are not the subject of an unresolved regulatory enforcement action. If a listed firm or processor subsequently becomes the subject of a regulatory enforcement action or an unresolved warning letter, FDA will view such a circumstance as evidence that the firm or processor is no longer in compliance with applicable U.S. laws and regulations. Should this occur, FDA will take steps to remove that firm or processor from the list and send a revised list to the EC authorities, usually within 48 to 72 hours after the relevant FDA action. If a firm or processor has been delisted as a result of a regulatory enforcement action or unresolved warning letter, the firm or processor will have to reapply for inclusion on the list once the regulatory action has been resolved.

FDA intends to update the list of firms and processors eligible to export raw, bulk collagen, and gelatin to the EC quarterly. Firms and processors placed on the approved exporters list are subject to audit by FDA and EC officials. Complete requests for inclusion must be submitted to FDA every 12 months to remain on the list. Inclusion on the list is voluntary. However, raw, bulk collagen, and gelatin products from firms or processors not on the approved exporters list for these products will not receive an export certificate, and these products may be detained at EC ports of entry.

Description of Respondents: The respondents to this collection of information include U.S. producers of shell eggs, dairy products, game meat, game meat products, animal casings, gelatin, and collagen.

In the **Federal Register** of August 18, 2010 (75 FR 51077), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Products	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Shell Eggs	10	1	10	0.25	3
Dairy	120	1	120	0.25	30
Game Meat and Game Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					37

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

FDA bases its estimates of the number of respondents and total annual responses on the submissions that the Agency has received in the past 3 years for each product type. To calculate the estimate for the hours per response values, we assumed that the information requested is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission. We believe that this effort should take no longer than 15 minutes (0.25 hour) per response. FDA estimates that it will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3. FDA estimates that it will receive 1 submission from 120 dairy product producers annually, for a total of 120 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 30 hours. FDA estimates that it will receive one submission from five game meat and game meat product producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive one submission from five animal casings producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive one submission from three gelatin producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. FDA estimates that it will receive one submission from three collagen producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: November 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29483 Filed 11–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for reports of corrections and removal.

DATES: Submit either electronic or written comments on the collection of information by January 24, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910–0359)—Extension

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act (FDAMA) of 1997 (21 U.S.C. 301) (Pub. L. 105–115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.