request by October 17, 2016. Space is limited; therefore, FDA will select and notify manufacturers by October 24, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain views from patients on prosthetic limb devices so that these perspectives may be considered in the total product life cycle of prosthetic limb medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this patient workshop is November 30, 2016.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: September 26, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–23924 Filed 10–3–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–2976]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Firms and Processors That Export to the European Union

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 reporting requirements in implementing the lists of United States (U.S.) firms/processors exporting shell eggs, game meat and game meat products, gelatin, and collagen to the European Union (the EU).

**DATES:** Submit either electronic or written comments on the collection of information by December 5, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2016–N–2976 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Firms and Processors That Export to the European Union.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown

St., North Bethesda, MD 20852, *PRAStaff@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.

**Information From U.S. Firms and Processors That Export to the EU (OMB Control Number 0910–0320)—Extension**

The EU is a group of 28 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. For certain food products, including those listed in this document, EU 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. Regulation (EC) No 854/2004 of the European Parliament and of the European Council states that products of animal origin may only be imported from establishments that appear on a list of establishments for which the competent authority of the exporting country has guaranteed compliance with applicable regulatory requirements and that shipments of these products must be accompanied by documents that certify the products' compliance with applicable regulatory standards. Section 801(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)) authorizes FDA to provide the certification described in this document. As stated in the notice published in the **Federal Register** of April 4, 1996 (61 FR 15077), we established a list of U.S. firms and processors eligible to export shell eggs, dairy products, and game meat and game meat products to the EU. In response to changing EU requirements, we revised this information collection and lists of eligible exporters in order to facilitate U.S. exports of gelatin and collagen to the EU. In 2001, we revised this collection to include firms and processors intending to export gelatin products to the EU (66 FR 12802, February 28, 2001) and in 2010, we revised the collection again to include firms and processors intending to export collagen products to the EU (75 FR 51077, August 18, 2010).

We request the following information from each firm or processor seeking to be included on the lists of eligible exporters for shell eggs, and game meat and game meat products (dairy products will be covered under OMB control number 0910–0509):

- Business name and address;
- Name and telephone number of person designated as business contact;
- Lists of products presently being shipped to the EU 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.

We request the following information from each firm or processor seeking to be included on the list of eligible exporters for gelatin and collagen products:

- Food Facility Registration Number and Pin Number (if applicable);
- Business name and address;
- Name, telephone number, facsimile number, and email address of main business contact person;
- List of products presently shipped to the EU and those intended to be shipped within the next 2 years;
- Name and address of the manufacturing and processing plant for each product (manufacturer type for primary producer);
- 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 EU of the finished product including: Total aerobic bacteria, coliforms (30 degrees C), coliforms (44.5 degrees C), anaerobic sulphite-reducing bacteria (no gas production), *Clostridium perfringens, Staphylococcus aureus, Salmonella,* arsenic, lead, cadmium, mercury, chromium, copper, zinc, moisture (105 degrees C), ash (550 degrees C), sulfur dioxide, and hydrogen peroxide.

We use the information to maintain lists of firms and processors that have demonstrated current compliance with U.S. requirements. We make the lists available on our Web site. We include on the lists only firms and processors that are not the subject of an unresolved regulatory enforcement action or unresolved warning letter. If a listed firm or processor subsequently becomes the subject of a regulatory enforcement action or an unresolved warning letter, we 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, we will take steps to remove that firm or processor from the list and send a revised list to the EU authorities, usually within 48 to 72 hours after the relevant regulatory enforcement 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.

We update the lists of firms and processors eligible to export products of animal origin to the EU quarterly. Firms and processors placed on lists of eligible exporters are subject to audit by FDA and EU officials. Complete requests for inclusion must be submitted to us every 12 months to remain on these lists. Inclusion on the lists is voluntary. However, products of animal origin from firms or processors not on lists of eligible exporters for these products are not eligible for export certificates for these products, and these products may be detained at EU ports of entry.

*Description of Respondents:* The respondents to this collection of information include U.S. producers of

shell eggs, game meat and game meat products, gelatin, and collagen.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Products | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Shell Eggs | 10 | 1 | 10 | 0.25 (15 minutes) | 3 |
| Game Meat and Game Meat Products | 5 | 1 | 5 | 0.25 (15 minutes) | 1 |
| Gelatin | 7 | 1 | 7 | 0.25 (15 minutes) | 2 |
| Collagen | 18 | 1 | 18 | 0.25 (15 minutes) | 5 |
| Total | | | | | 11 |

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

We base our estimates of the number of respondents and total annual responses on the submissions that we have 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. We estimate that we 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 hours. This collection has previously covered information collected to maintain lists of eligible exporters of dairy products; dairy products will be covered under OMB control number 0910–0509, so the estimated burden has been removed from this collection. We estimate that we 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. We estimate that we will receive one submission from seven gelatin producers annually, for a total of seven annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.75 hours, rounded to 2 hours. We estimate that we will receive one submission from 18 collagen producers annually, for a total of 18 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 4.5 hours, rounded to 5 hours. The estimated burden for collagen producers includes animal casings, which have been listed separately in previous notices. Therefore, the proposed annual burden for this information collection is 11 hours.

Dated: September 28, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–23930 Filed 10–3–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2013–N–0115; FDA–2013–N–0717]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

| Title of collection | OMB control No. | Date approval expires |
|---|---|---|
| Manufactured Food Regulatory Program Standards | 0910–0601 | 9/30/2019 |
| Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign | 0910–0753 | 9/30/2019 |

Dated: September 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–23898 Filed 10–3–16; 8:45 am]

**BILLING CODE 4164–01–P**