Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Head Start parent survey for plus study	1,350	450	2	0.25	225
Head Start parent supplemental survey for plus study	1,350	450	2	0.08	72
Head Start teacher child report for plus study	150	50	20	0.17	170
Head Start teacher survey for plus study	150	50	2	0.50	50
Head Start program director survey for plus study	50	17	2	0.25	8
Head Start center director survey for plus study	100	33	2	0.25	17
Early care and education administrators plus survey	600	200	2	0.50	200
Early care and education providers plus survey	900	300	2	0.50	300
Total					4,514

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper,

OPRE Reports Clearance Officer.

[FR Doc. 2014–04400 Filed 2–27–14; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1620]

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 March 31, 2014.

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 emailed 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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)—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. 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), we 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 our 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, we revised this information collection in order to facilitate exports of raw, bulk collagen, and gelatin originating from the United States into the EC. We announced OMB approval of the revised information collection in the **Federal Register** of May 10, 2011 (76 FR 27061).

We request 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.

We use the information to maintain lists of firms and processors that have demonstrated current compliance with U.S. requirements. We provide 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.

We request 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.

We use the information to maintain a list of approved firms and processors for raw, bulk collagen, and gelatin. We make the list available on our Web site. We include 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, 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 EC 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 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 us 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 December 26, 2013 (78 FR 78364) 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	Number of responses per respondent	Total annual responses	Average burden 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.

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. We have retained our previous estimates of total annual responses because the number of submissions are few and have remained relatively stable. 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. We estimate that we 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. 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 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. We estimate that we 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. We estimate that we 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: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04348 Filed 2–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0180]

Draft Guidance for Industry on Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting Human Immunodeficiency Virus-1 Resistance Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV–1 Resistance Data.'' The purpose of this guidance is to assist sponsors in submitting human immunodeficiency virus (HIV) clinical virology data that are important for supporting clinical trials of products in development for the treatment of HIV. HIV resistance data submitted in appropriately formatted datasets are critical components in the review of investigational antiviral products for the treatment of HIV. The information in this guidance will facilitate the development of anti-HIV products. This draft guidance revises the guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV Resistance Data'' issued on June 5, 2006.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 29, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa K. Naeger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, rm. 6366, Silver Spring, MD 20993–0002, 301–796–0771.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV–1 Resistance Data.'' The purpose of this guidance is to assist sponsors in submitting HIV clinical virology data that are important for supporting clinical trials of products in development for the treatment of HIV. This guidance revises and replaces the guidance on submitting HIV resistance data published in June 2006. The revised guidance provides the format, recommended definitions, standardization of column headings and variables, and recommended data for submission of HIV resistance datasets.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on submitting HIV clinical virology data. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04425 Filed 2–27–14; 8:45 am]

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