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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–30809 Filed 12–24–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1620]

Agency Information Collection Activities; Proposed Collection; 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 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, dairy products, game meat, game meat products, animal casings, gelatin, and collagen to the European Community (the EC).

DATES: Submit either electronic or written comments on the collection of information by February 24, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 United States Firms and Processors That Export to the European Community (OMB Control Number 0910–0320)—Extension

The 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 gelatin and raw, bulk collagen intended for human consumption, EC directives require that shipments of gelatin and raw, bulk collagen 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 and 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 gelatin and raw, bulk collagen 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 gelatin and raw, bulk collagen:

- 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), sulfur dioxide, and hydrogen peroxide.

We use the information to maintain a list of approved firms and processors for gelatin and raw, bulk collagen. 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 gelatin and raw, bulk collagen 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, gelatin and raw, bulk collagen 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.

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: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30804 Filed 12–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1615]

Draft Generic Drug User Fee Act Information Technology Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft information technology (IT) plan entitled ''GDUFA Information Technology Plan.'' This plan is intended to provide FDA's approach for enhancing business processes, data quality and consistency, supporting technologies, and IT operations as described in the Generic Drug User Fee Act (GDUFA) Performance Goals and Procedures for Fiscal Years 2013 through 2017. FDA is publishing a draft version of the IT plan for comment to allow industry and other interested stakeholders to provide feedback as FDA moves towards a fully automated standards-based environment that enhances the regulatory review process for human pharmaceuticals.

DATES: Submit either electronic or written comments by February 24, 2014.

ADDRESSES: Submit written requests for single copies of the draft ''GDUFA Information Technology Plan'' 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 plan.

Submit electronic comments on the draft plan 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: Cheryl Ford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6737, *UserFeesProgram-Informatics@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Signed into law on July 9, 2012, GDUFA is designed to speed the delivery of safe and effective generic drugs to the public. GDUFA increases FDA's authorities and responsibilities to address issues such as drug shortages, drug supply chain, safety, security, and drug innovation. As generic drugs account for more than three-quarters of all prescriptions dispensed in the United States, GDUFA authorizes FDA to collect user fees from industry that will provide funding to expand and modernize FDA's generic drug regulatory process.

The draft GDUFA IT plan considers assumptions, available resources, and statutory requirements that conform to the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012. Section 1136 of FDASIA, Electronic Submission of Applications, gives FDA the authority to require a standardized electronic format for the submission of information and data in standardized formats. Section 1136 addresses abbreviated new drug applications under the GDUFA program as well as investigational new drug applications, biologics license applications, and new drug applications under the Prescription Drug User Fee Act program and describes new standards and processes affecting drug and biologics approvals, drug supply chain, and other topics related to human pharmaceuticals. The draft GDUFA IT plan describes key activities for enabling progress toward achieving GDUFA IT goals.

II. 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–31008 Filed 12–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1566]

Draft Guidance for Industry on Naming of Drug Products Containing Salt Drug Substances; 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 ''Naming of Drug Products Containing Salt Drug Substances.'' The United States Pharmacopeial (U.S.P.) Convention has adopted a monograph naming policy that changed the nomenclature for compendial drug products that contain a salt. Under the new policy, drug names and strengths for new compendial drug products will be based on the active moiety. The name and strength of the active ingredient (e.g., salt) will appear elsewhere on the drug product label and labeling. The policy became official on May 1, 2013. This draft guidance describes the U.S.P. policy, discusses the Center for Drug Evaluation and Research's (CDER's) application of the policy, and recommends how CDER and industry can implement the policy.

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 March 26, 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.