DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2976]

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 Union

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 May 24, 2017.

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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726.

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. Firms and Processors That Export to the EU OMB Control Number 0910–0320—Extension

The European Union (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 Regulation (EC) No. 854/2004. 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, fax 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 quarterly the lists of firms and processors eligible to export products of animal origin to the EU. Firms and processors placed on lists of eligible exporters are subject to audit by FDA and EU officials. Complete requests for inclusion on the lists of eligible exporters, which is voluntary, must be submitted 12 months to remain on the list of firms and processors eligible to export products of animal origin to the EU. 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.

In the **Federal Register** of October 4, 2016 (81 FR 68424), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment which was not PRA-related, and therefore is not addressed in this supporting statement.

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	.25 (15 minutes)	3
Game Meat and Game Meat Products	5	1	5	.25 (15 minutes)	1
Gelatin	7	1	7	.25 (15 minutes)	2
Collagen	18	1	18	.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 1 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: April 17, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1748]

Guerbet Group; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new drug applications (NDAs) held by Guerbet Group. Guerbet Group notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Withdrawal of approval is effective May 24, 2017.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The applications listed in table 1 in this document are no longer marketed, and Guerbet Group has requested that FDA withdraw approval of the applications pursuant to the process in § 314.150(c) (21 CFR 314.150(c)). The company has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
NDA 018905	Hexabrix (ioxaglate meglumine and ioxaglate sodium) Injection USP, 39.3%/19.6%.	Guerbet Group, 821 Alexander Rd., Suite 204, Princeton, NJ 08540.