

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 BURDEN¹

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

¹There 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.
 [FR Doc. 2017-08181 Filed 4-21-17; 8:45 am]
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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.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020316	Oxilan-300 and Oxilan-350 (ioxilan) Injection, 62% and 73%	Do.

Therefore, under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 24, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 18, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915-0386—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection

projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than June 23, 2017.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915-0386—Revision

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)), as Public Law 114-53. The Delta Program supports projects that demonstrate evidence-based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity to improve health status in rural communities throughout the Delta Region. Key features of projects are adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

Need and Proposed Use of the Information: For this program, performance measures include: (a) Access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. These performance measures enable HRSA's Federal Office of Rural Health Policy to aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103-62). The proposed revisions to the performance measures include reducing the number of reported measures and showing annual progress compared to baseline data submitted in the grant applications. Examples of the measures that will be removed include the number of people reached through indirect services and the number of quality improvement clinical guidelines/benchmarks adopted.

Likely Respondents: The respondents are the recipients of the Delta States Rural Development Network Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

As a result of the reduction in performance measures, annualized burden is decreasing from 72 hours to 32 hours. The total annual burden hours estimated for this ICR are summarized in the table below.