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 December 21, 2015.

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 0910–0726. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Improving Food Safety and Defense Capacity at the State and Local Level: Review of State and Local Capacities OMB Control Number 0910–0726—Extension

The Food Safety Modernization Act (FSMA) (Pub. L. 111–353) states that a review must be conducted to assess the State and local capacities to show needs for enhancement in the areas or staffing levels, laboratory capacities, and information technology systems. This mandate referenced in FSMA section 110 stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). This review was completed in 2013 through this information collection request.

This collection provided a baseline measurement of the nation's current food safety and food defense capabilities; FDA wants to renew this information collection to gather more data. By renewing this collection, FDA will be able to analyze the gaps and trends at the State and local levels, allowing FDA and its partners to develop ways to create a national integrated food safety system.

FDA will conduct the survey electronically, allowing FDA to conduct streamlined analysis while creating a low-burden, user-friendly environment for respondents to complete the survey. Once the results have been tabulated, FDA and its partners can assess the current progress towards an integrated food safety system.

In the **Federal Register** of August 31, 2015 (80 FR 46025), 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]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Current State and Local Government Employees	1,400	1	1,400	1	1,400

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

Dated: November 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29663 Filed 11–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–3404]

Determination That LIPTRUZET (Ezetimibe and Atorvastatin) Tablets, 10 Milligrams/10 Milligrams, 10 Milligrams/20 Milligrams, 10 Milligrams/40 Milligrams, and 10 Milligrams/80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 milligrams (mg)/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ezetimibe and atorvastatin tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn

from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, are the subject of NDA 20–0153, held by Merck Sharp & Dohme Corp., and initially approved on May 3, 2013. LIPTRUZET is indicated for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL–C), apolipoprotein B (Apo B), triglycerides (TG), and non-high-density lipoprotein cholesterol (non-HDL–C), and to increase high-density lipoprotein cholesterol (HDL–C) in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia. LIPTRUZET is also indicated for the reduction of elevated total-C and LDL–C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (*e.g.,* LDL apheresis) or if such treatments are unavailable.

In a letter dated June 1, 2015, Merck Sharpe & Dohme Corp. notified FDA that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Lupin Pharmaceuticals, Inc. submitted a citizen petition dated September 21, 2015 (Docket No. FDA–2015–P–3404), under 21 CFR 10.30, requesting that the Agency determine whether LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29639 Filed 11–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of In Vitro Diagnostics for the Detection of Diseases or Pathogenic Agents

AGENCY: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), at the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Omega Diagnostics Group PLC (''Omega''), a company incorporated under the laws of the United Kingdom, having an office in Alva, Scotland, an exclusive patent license to practice the following inventions embodied in the following patent applications: US Provisional Patent Application No.60/846,354, entitled, ''(S,S)-trans-1,2-cyclopentane Diamine-modified and Gamma-lysine-modified Peptide Nucleic Acids as Probes for Nucleic Acid Detection: Synthesis and Applications,'' filed 22 Sep 2006 [HHS Ref No. E–308–2006/0–US–01]; US Provisional Patent Application No. 60/896,667, entitled, ''Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate,'' filed 23 Mar 2007 [HHS Ref No. E–308–2006/1–US–01]; International Application PCT/US2007/020466, entitled, ''Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate,'' filed 21 Sep 2007 [HHS Ref No. E–308–2006/2–PCT–01]; US Patent Application No. 12/441,925, filed 21 Sep 2007, [HHS Ref No. E–308–2006/2–US–02]; US Patent Application No. 12/409,159, entitled, ''Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens,'' filed 23 Mar 2009 [HHS Ref No. E–308–2006/3–US–01]; US Patent No. 9,156,778, entitled, ''Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens,'' issued 13 Oct 2015 [HHS Ref No. E–308–2006/3–US–02]; US Provisional Patent Application No. 61/684,354, entitled, Cyclopentane-peptide Nucleic Acids for Qualitative and Quantitative Detection of Nucleic Acids,'' filed 17 Aug 2012 [HHS Ref No. E–260–2012/0–US–01]; International Application PCT/US2013/055252, filed 16 Aug 2013 [HHS Ref No. E–260–2012/0–PCT–02]; European Patent Application No. 13753962.3, filed 11 Feb 2015, [HHS Ref No E–260–2012/0–EP–03]; Korea Patent Application No. 10–2015–7006286, filed 11 Mar 2015, [HHS Ref No E–260–2012/0–KR–04]; and US Patent Application No. 14/421,732, filed 13 Feb 2015, [HHS Ref No E–260–2012/0–US–05].

The patent rights in these inventions have been assigned to the United States of America. Omega is seeking a worldwide territory for this license. The field of use may be limited to use of the Patent Rights for the development and sale of trans-cyclopentane-modified peptide nucleic acids (PNA) in a diagnostic system incorporating an enzyme-linked immunosorbent assay or Omega's proprietary VISITECT® technology for the detection of diseases or pathogenic agents including viruses and microorganisms.

DATES: Only written comments or applications for a license (or both) which are received by the Technology Advancement Office, NIDDK, on or before December 7, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries,