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whether LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were withdrawn from sale for reasons of safety or effectiveness.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that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were not withdrawn for reasons of safety or effectiveness.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that LIPTRUZET (ezetimibe and atorvastatin) tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, were withdrawn for reasons of safety or effectiveness.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,

comments, and other materials relating to the contemplated exclusive license should be directed to: The Patrick McCue, Ph.D., Senior Licensing and Patenting Manager, Technology Advancement Office, The National Institutes of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Telephone: (301) 451–5560; Email: *patrick.mccue@nih.gov.* A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: These technologies, and the corresponding patent applications, are directed to cyclopentane-peptide nucleic acids (PNA) and their use in qualitative and quantitative detection of nucleic acids. The technologies overcome a stability problem and sensitivity to outside contamination that is inherent to PCR-based detection systems, wherein the PNA probes bind to DNA with greater stability and selectivity compared to a complementary DNA sequence.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the Technology Advancement Office, NIDDK, receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 17, 2015.

Anna Z. Amar,

Acting Deputy Director, Technology Advancement Office, NIDDK.

[FR Doc. 2015–29650 Filed 11–19–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Extension, Without Change, of an Existing Information Collection; Comment Request

ACTION: 30-Day notice of Information Collection for review; Form No. I–515A; Notice to Student or Exchange Visitor; OMB Control No. 1653–0037.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** on August 19, 2015, Vol. 80 No. 20396 allowing for a 60 day comment period. No comments were received on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, without change, of a currently approved information collection.

(2) *Title of the Form/Collection:* Notice to Student or Exchange Visitor.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* (No. Form I–515A); U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. When an academic student (F–1), vocational student (M–1), exchange visitor (J–1), or dependent (F–2, M–2 or J–2) is admitted to the United States as a nonimmigrant alien under section 101(a)(15) of the Immigration and Nationality Act (Act), he or she is required to have certain documentation. If the student or exchange visitor or dependent is missing documentation, he or she is provided with the Form I–515A, Notice to Student or Exchange Visitor. The Form I–515A provides a list of the documentation the student or exchange visitor or dependent will need to provide to the Department of Homeland Security (DHS), Student and Exchange Visitor Program (SEVP) office within 30 days of admission.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 10,701 responses at 10 minutes (0.1667 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,776. annual burden hours.

Dated: November 16, 2015.

Scott Elmore,

Program Manager, Forms Management Office, Office of the Chief Information Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2015–29582 Filed 11–19–15; 8:45 am]

BILLING CODE 9111–28–P