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 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>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current State and Local Government Employees</td>
<td>1,400</td>
<td>1</td>
<td>1,400</td>
<td>1</td>
<td>1,400</td>
</tr>
</tbody>
</table>

† 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.

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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 from sale 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 from sale 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.

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.


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,