offering of alternative non-opioid pain management, discussion of safe storage and proper disposal of opioids, screening for overdose risk, and review the history of substance use), discharge planning, family training, rehabilitation services, medical and nursing care, interdisciplinary team goal setting and care planning. We are also soliciting information on publicly available instruments for capturing patients' and family members' experiences with IRF care in a variety of formats (for example, standardized, computer readable format) that can be collected by providers or CAHPS® survey vendors. We are interested in suggested topic areas and publicly available instruments that can measure the quality of care from the patients' and/or family members' perspective in IRFs within acute-care hospitals, critical access hospitals, and free-standing facilities; instruments that can be used to track changes over time; and items that are developed for and/or can be modified to address low case volume. Existing instruments are preferred if they have been tested, have been found to have a high degree of reliability and validity, and for which there is evidence of wide use in one or more patient care settings, including those in rural and frontier communities. Instruments capable of risk adjustment, and/or instruments that minimize duplication of efforts and/or that utilize common quality measures, where available, are preferred. Whenever possible, preference will be given to quality measures identified by the Secretary under section 1139A or 1139B of the Act, or endorsed under section 1890 of the Act.

The following information would be especially helpful in any comments responding to this request for information:

- A brief cover letter summarizing the information requested for submitted instruments and topic areas, respectively, and how the submitted materials could be used to help fulfil the intent of the survey.
- (Optional) Information about the person submitting the materials for the purpose of follow-up questions about the submission, which includes the following:
  - ++ Name.
  - ++ Title.
  - ++ Organization.
  - ++ Mailing address.
  - ++ Telephone number.
  - ++ Email address.
- When submitting topic areas, we encourage including, to the extent available, the following information:
  - ++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
  - ++ Relevant peer-reviewed journal articles or full citations.
- When submitting publicly available instruments or survey questions, we encourage including to the extent available the following information:
  - ++ Name of the instrument.
  - ++ Indication that the instrument is publicly available.
  - ++ Copies of the full instrument in all available languages.
  - ++ Topic areas included in the instrument.
  - ++ Measures that can be derived from data collected using the instrument.
  - ++ Instrument reliability (internal consistency, test-retest, etc.) and validity (content, construct, criterion related).
  - ++ Results of cognitive testing (one-on-one testing with a small number of respondents to ensure that they understand the questionnaire.)
  - ++ Results of field testing.
  - ++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).
  - ++ Relevant peer-reviewed journal articles or full citations.
  - ++ CAHPS® trademark status.
  - ++ NQF endorsement status.
  - ++ Survey administration instructions.
  - ++ Data analysis instructions.
  - ++ Guidelines for reporting survey data.

If you wish to provide comments on this information collection, please submit your comments as specified in the **ADDRESSES** section of this request for information.

Comments must be received on/by January 19, 2016.

III. Collection of Information Requirements

This RFI does not impose any information collection requirements. We believe it is a solicitation of comments from the general public. As stated in the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(h)(4), it is exempt from the requirements of the PRA (44 U.S.C. 3501 *et seq.*).

The data collected via this RFI will be used to develop the IRF PEC Survey. While surveys are generally subject to the requirements of the PRA, we believe the IRF PEC Survey is exempt. Section I. of this RFI explains that we plan to collect this information in support of the NQS and, under sections 1886(j)(7) and 1890A(e) of the Act and develop the IRF PEC Survey into a quality measure that we may consider proposing for adoption in the IRF Quality Reporting Program (QRP). In accordance with section 102 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–110), the PRA shall not apply to the collection of information for the development of quality measures.

Also, as stated earlier in section I. of this RFI, we will develop the CMS IRF PEC Survey in accordance with CAHPS® Survey Design Principles and are developing this survey and plans to submit the resulting instrument to AHRQ for recognition as a CAHPS® survey. Upon receiving recognition as a CAHPS® survey and prior to implementation, CMS will submit the CAHPS recognized IRF PEC Survey through the OMB approval process. At that time, the public will have the opportunity to review, comment, or review and comment on the proposed information collection request prior to its submission to OMB for review and approval.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–29623 Filed 11–19–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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