to use an online data entry system for the program and participant survey data. In response to the 60-day **Federal Register** notice related to this proposed data collection and published on June 27, 2014, four sets of relevant comments were received. Most of the comments were minor suggestions for improving the ease of use and acceptability of the data collection tools. The originally proposed data collection tools, the comments with responses and a revised set of data collection tools may be found on the ACL/AoA Web site at: *http://www.aoa.gov/AoARoot/AoA_Programs/Tools_Resources/collection_tools.aspx*. ACL/AoA estimates the burden of this collection of information as 224 hours for project staff, 820 hours for local agency and database entry staff, and 2,000 hours for individuals. Total burden is 3,044 hours per year.

Dated: September 12, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–22184 Filed 9–16–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcement of the Intent To Award a Single-Source Cooperative Agreement to the Gerontology Institute, University of Massachusetts Boston

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source cooperative agreement in the amount of $75,000 to the Gerontology Institute, University of Massachusetts Boston (UMass Boston) to support and stimulate the expansion of work already underway by UMass Boston in providing pension counseling services to residents of the State of Illinois.

DATES: The award will be issued for a project period to run concurrently with the existing grantee's budget period.

FOR FURTHER INFORMATION CONTACT: Valerie Soroka, Office of Elder Rights, Administration on Aging, Administration for Community Living, 1 Massachusetts Avenue NW., Washington, DC 20001. Telephone: 202–357–3531; Email: *valerie.soroka@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: The ACL's Pension Counseling & Information Program consists of six regional pension counseling projects, covering 29 states. The state of Illinois, with 64 million workers and a pension participation rate of 42%, is one of the largest states without an ACL-funded pension counseling project. The Pension Action Center at UMass Boston, which conducts ACL's New England Pension Assistance Project, is currently providing pension counseling services to residents of Illinois with funding from the Retirement Research Foundation. Additional funds are needed to leverage the foundation's funding, in order to ensure that the current provision of services to Illinois residents will be continued. This supplementary funding would be provided for the approved period.

This program is authorized under Title II of the Older Americans Act (OAA) (42 U.S.C. 3032), as amended by the Older Americans Act Amendments of 2006, Public Law 109–365.

(Catalog of Federal Domestic Assistance 93.048)

Dated: September 11, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–22185 Filed 9–16–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0730]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Threshold of Regulation for Substances Used in Food-Contact Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On October 30, 2013, the Agency submitted a proposed collection of information entitled, ''Threshold of Regulation for Substances Used in Food-Contact Articles'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0298. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22123 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0062]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Exception From General Requirements for Informed Consent'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

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: On July 23, 2014, the Agency submitted a proposed collection of information entitled ''Medical Devices; Exception From General Requirements for Informed Consent'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0586. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22089 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0627]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval To Market a New Drug

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 October 17, 2014.

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 0910–0001. 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.

Application for FDA Approval to Market a New Drug—(OMB Control Number 0910–0001)—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Under the FD&C Act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination whether the product is safe and effective for use.

This approval request is for all information collection requirements imposed on applicants by the regulations under part 314 (21 CFR part 314) who apply for approval of a new drug application (NDA) or abbreviated new drug application (ANDA) in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; statistical; and pediatric use sections.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application. (The burden hours for § 314.50(h) are already approved by OMB under OMB control number 0910–0513 and are not included in the burden estimates in Table 1 of this document.)

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug, drug product, or method of use.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that the application contain a financial certification or disclosure statement or both.

Section 314.50(l) requires that an archival, review, and field copy of the application be submitted, including the content of labeling and all labeling and labels.

Section 314.52 requires that any notice of certification of invalidity or non-infringement of a patent to each patent owner and the NDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend its application at the time notice is provided to include a statement certifying that the required notice has been provided. A 505(b)(2) applicant also is required to amend its application to document receipt of the required notice.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the FD&C Act. (The information collection burden estimate for 505(b)(2) applications is included in table 1 of this document under the estimates for § 314.50 (a), (b), (c), (d), (e), (f), (g), (i), (j), (k) and (l)).

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (The burden hours for § 314.80(c)(1) and (c)(2) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (The burden hours for