ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0945–0006, scheduled to expire on March 31, 2014. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before April 23, 2014.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–21138–30D for reference.

Information Collection Request Title: The Civil Rights Information Request Form.

OMB No.: 0945–0006.

Abstract: This request for OMB approval of The Civil Rights Information Request Form is for a 3 year extension. The Civil Rights Information Request Form is designed to collect data from health care providers who have requested certification to participate in the Medicare Part A program. As part of the Medicare certification process, health care facilities must receive a civil rights clearance from the Office for Civil Rights (OCR). OCR uses the information to determine compliance with civil rights statutes and regulations. The civil rights information is requested only when a health care provider applies for Medicare Part A certification; it is *not* necessary on a regular yearly basis. Entities that are affected by the Civil Rights Information Request Form are: Health care providers applying for Medicare certification, and individuals who, as a result of civil rights clearances, should be granted equal access to quality health care, regardless of race, color, national origin, disability, age and sex.

Need and Proposed Use of the Information: To ensure adherence to the statutory requirements, compliance reviews are requested when health care providers, such as hospitals, nursing homes and home health agencies, apply to participate in the Medicare Part A program. When a provider seeks Medicare certification, OCR conducts a compliance review to determine whether the provider will be able to comply with Title VI, Section 504, and the Age Discrimination Act. Such reviews are an effective means of working with health care providers because potential civil rights concerns can be identified prior to receipt of Federal financial assistance. The technical assistance available to recipients on the OCR Web site helps providers take steps to comply with their obligations to refrain from prohibited discrimination.

Likely Respondents: Healthcare providers.

Burden Statement: In conducting a complaint investigation or compliance review of a health care or social service provider, OCR determines whether a compliance review was performed by OCR. In many instances, the procedure decreases the burden on the recipient since the compliance review and corrective actions, as necessary, may reduce or eliminate the need for a formal investigation involving interviews, examination of records, collection and submission of data associated with issues already addressed through a recent compliance review certification process. To further reduce provider burden in completing the compliance review process, OCR has developed several Corporate Agreements with health care corporations. These Agreements are designed to expedite the civil rights compliance review process by implementing a practice whereby all of a corporation's national policies and procedures are reviewed and approved at OCR's headquarters' level. Subsequent to such approval, only local facility-specific information is reviewed by OCR for civil rights compliance during the review process.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
The Civil Rights Information Request Form	2900	1	8	23,200

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–06267 Filed 3–21–14; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–13XA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care—New—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC has entered into a partnership with Walgreen Company

(a.k.a. Walgreens pharmacies, a national retail pharmacy chain) and the University of North Texas Health Science Center to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will be implemented at ten sites and will provide patient-centered HIV care for approximately 1,000 persons.

The patient-centered HIV care model will include the core elements of pharmacist provided Medication Therapy Management (MTM) as well as additional pharmacist services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration between pharmacists and medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence.

The expected outcomes of the model program are increased retention in HIV care, adherence to HIV medication therapy and HIV viral load suppression.

CDC requests OMB approval to collect standardized information from ten project sites over the three year project period. CDC also requests approval to conduct retrospective data collection during the first year of the three-year project period. This retrospective data collection will be used to determine both project sites' and participants' baseline characteristics which are needed to compare outcomes before and after program implementation.

Pharmacy, laboratory, and medical data will be collected through abstraction of participant clients' pharmacy and medical records. These data are needed to monitor retention in care, adherence to therapy, viral load suppression and other health outcomes. Program specific data, such as the number of MTM elements completed per project site and project sites' characteristics, will be collected by project site personnel.

The data collection will allow CDC to conduct continuous program performance monitoring. Program performance monitoring will allow adjustment of the model program, as needed, in order to develop a final implementation model which can be used to establish similar collaborations in a variety of clinical settings. The data collection will also allow comparison of project outcomes within the project cohort.

There is no cost to participants other than their time. The total estimated annualized burden hours are 5,113.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clinic Data Manager	Project clinic characteristics form	10	3	30/60
Pharmacist	Project pharmacy characteristics form	10	3	30/60
Clinic Data Manager	Patient Demographic Information form	10	100	5/60
Clinic Data Manager	Initial patient information form	10	100	1
Clinic Data Manager	Quarterly patient information form	10	400	30/60
Pharmacist	Pharmacy record abstraction form	10	400	30/60

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–06317 Filed 3–21–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0627]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit either written or electronic comments on the collection of information by May 23, 2014.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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,1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical