FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1670, Silver Spring, MD 20993, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the FD&C Act is appropriate for the submission of a marketing application to FDA. This guidance highlights criteria for submitting applications under the abbreviated approval pathways described in section 505(j) and 505(b)(2) of the FD&C Act (21 U.S.C. 355(j) and 21 U.S.C. 355(b)(2), respectively), identifies considerations to help potential applicants determine whether an application would be more appropriately submitted under section 505(j) or pursuant to section 505(b)(2) of the FD&C Act, and provides direction to potential applicants on requesting assistance from FDA in making this determination.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) added section 505(b)(2) and 505(j) of the FD&C Act, which describe abbreviated approval pathways for drug products regulated by the Agency under the FD&C Act. The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to ''make available more low cost generic drugs by establishing a generic drug approval procedure'' with new incentives for drug development in the form of exclusivities and patent term extensions. With the passage of the Hatch-Waxman Amendments, the FD&C Act describes different routes for obtaining approval of two broad categories of drug applications: New drug applications (NDAs) and abbreviated new drug applications (ANDAs).

This guidance focuses on those applications that can be submitted as ANDAs under section 505(j) of the FD&C Act, petitioned ANDAs under section 505(j)(2)(C) of the FD&C Act, or NDAs pursuant to section 505(b)(2) of the FD&C Act. This guidance does not discuss stand-alone NDAs.

In the **Federal Register** of October 13, 2017 (82 FR 47749), FDA announced the availability of the draft guidance of the same title dated October 2017. FDA received four comments on the draft guidance and those comments were considered as the guidance was finalized. We note that we received comments requesting clarification on the process for obtaining therapeutic equivalence evaluations. We will address therapeutic equivalence in a forthcoming guidance document (see ''Guidance Agenda: New and Draft Guidances CDER Plans to Publish During Calendar Year 2019''). The final guidance contains minor clarifications to the draft guidance. The guidance announced in this notice finalizes the draft guidance dated October 2017.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.94 have been approved under OMB control number 0910–0001. The collection of information for controlled correspondence and pre-ANDA meeting requests has been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09662 Filed 5–9–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Chart Abstraction of Ryan White HIV/AIDS Program Recipient Data, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 9, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA

Information Collection Clearance Officer, at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Chart Abstraction of Ryan White HIV/AIDS Program Data, OMB No. 0906–xxxx–New.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

HRSA is required to assess the quality of care provided by RWHAP grant recipients. HHS guidelines (*e.g.,* Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV; Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents; and Sexually Transmitted Diseases Treatment Guidelines, 2015) and U.S. Preventative Services Task Force (USPSTF) guidelines serve as the basis for assessing the quality of care within the RWHAP. The purpose of the *Chart Abstraction of RWHAP Data* study is to assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. The study will collect data from RWHAP service providers via a provider screening phone interview, a provider pre-site visit interview, and medical records data abstraction. The data will reflect the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, sexually transmitted infections (STIs), and opioid use disorder provided through the RWHAP and allow HRSA to assess the extent to which care provided with funding through the RWHAP meets the HHS and USPSTF guidelines.

Need and Proposed Use of the Information: National RWHAP client-level data is collected through the RWHAP Client Level Data Reporting System. The RWHAP Client Level Data Reporting System dataset (OMB control number 0915–0323) is HRSA's primary source of annual, client-level data collected from its nearly 2,000 funded grant recipients/service providers and the data have been used to assess the numbers and types of clients receiving services and limited HIV outcomes. However, the RWHAP Client Level Data Reporting System dataset does not include relevant data in order to fully assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. This proposed new ICR will provide the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, STIs, and opioid use disorder data and allow HRSA to assess the extent to which care provided with funding through the RWHAP meets the HHS and USPSTF guidelines.

Likely Respondents: HRSA RWHAP Part A, Part B, Part C, and Part D service providers funded to deliver outpatient ambulatory health services to eligible clients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Provider Site screening interview	100	1	100	.5	50
Provider Pre-Site Visit Interview	50	1	50	1	50
Medical Record Data Abstraction	50	1	50	2	100
Total	200		200		200

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–09666 Filed 5–9–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2019 Schedule

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: 2019 public meeting dates of the Health Information Technology Advisory Committee.

SUMMARY: The Health Information Technology Advisory Committee