became effective: November 17, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 17, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* January 29, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for LUMOXITI (BLA 761104) was initially submitted on January 29, 2018.

3. *The date the application was approved:* September 13, 2018. FDA has verified the applicant's claim that BLA 761104 was approved on September 13, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 159 days, 163 days, and 2 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19214 Filed 8–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0053—Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Coronavirus 2019 Data Report

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 of the Paperwork Reduction Act of 1995, 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 November 2, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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: Coronavirus 2019 Data Report OMB No. 0915-0906–0053—Extension.

Abstract: This information collection request was previously approved by the Office of Management and Budget (OMB) on June 11, 2020, as an emergency clearance (OMB No.: 0906–0053). HRSA is currently undergoing the standard Paperwork Reduction Act process for normal OMB approval.

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/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net 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.

FY 2020 Coronavirus Aid, Relief, and Economic Security Act

On March 27, 2020, the President signed into law the ''Coronavirus Aid, Relief, and Economic Security Act'' (CARES Act). The CARES Act appropriated $90 million to HRSA's RWHAP to prevent, prepare for, and respond to coronavirus disease 2019 (COVID–19). This funding supports 581 RWHAP recipients across the country, including city/county health departments, state health departments, health clinics, community-based organizations, and AIDS Education and Training Centers in their efforts to help prevent or minimize the impact of COVID–19 on RWHAP clients. The award provides RWHAP recipients the flexibility to meet evolving COVID–19 needs in their respective communities, including extending operational hours, increasing staffing hours, purchasing additional equipment, enhancing workforce training and capacity development, and providing critical services to people with HIV during this pandemic, such as home-delivered meals, emergency housing, and transportation.

HRSA identified a new data collection need to support HRSA's requirement to monitor and report quarterly to the Secretary of HHS the COVID–19 activities conducted with the CARES Act funding. The COVID–19 Data Report module will provide monthly reporting on the types of services provided and number of people served for the treatment or prevention of COVID–19 among RWHAP clients (and immediate household members in limited circumstances). This module will be required for all providers (regardless of whether they are recipients or subrecipients) who receive CARES Act RWHAP funding.

Need and Proposed Use of the Information: HRSA proposes that service providers who receive CARES Act RWHAP funding report aggregate information on the number of clients and immediate household members tested for COVID–19, the number of clients newly diagnosed (or presumed

positive) with COVID–19, the cumulative number of clients with COVID–19, the number of clients who received services in each RWHAP service category (identified in Policy Clarification Notice 16–02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds), and the types of services provided using telehealth technology in the COVID–19 Data Report. The information obtained in this module will assist HRSA in understanding how CARES Act RWHAP funding is being used to support RWHAP clients and immediate household members and ensure that HRSA is compliant with federal reporting requirements.

Likely Respondents: All RWHAP providers (regardless of whether they are recipients or subrecipients) who receive CARES Act RWHAP funding.

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
COVID–19 Data Report	2045	12	24,540	2	49,080
	2045		24,540		49,080

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–19247 Filed 8–31–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

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

ACTION: Notice; correction.

SUMMARY: The original **Federal Register** Notice announcing the September 2020 Advisory Commission on Childhood Vaccines (ACCV) meeting indicated that this meeting would be held on September 3–4, 2020. This meeting is not being conducted over 2 days, and instead will only take place only on September 4, 2020.

The ACCV will hold a public meeting on September 4, 2020, at 10:00 a.m. ET. The meeting will be held via Adobe Connect and telephone conference. This will not be an in-person meeting. The public can join the meeting by:

1. (Audio Portion) Calling the conference phone number 888–790–1734 and providing the following information:

Leader Name: Ms. Tamara Overby
Passcode: 4177683

2. (Visual Portion) Connecting to the ACCV Adobe Connect Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/.* Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

Information about the ACCV and the agenda for this public meeting can be obtained by accessing the following website: *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Program Analyst, Division of Injury Compensation Programs (DICP), HRSA, in one of three ways: (1) Send a request to the following address: Annie Herzog, Program Analyst, DICP, HRSA, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857; (2) call (301) 443–6593; or (3) send an email to *ACCV@hrsa.gov.* Meeting times could change. For the latest information regarding the meeting, including start time, please check the ACCV website: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

This meeting will only take place on September 4, 2020, and is not being conducted over 2 days (September 3–4, 2020) as stated in a previous **Federal Register** Notice.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–19257 Filed 8–31–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Exploring the Roles of Biomolecular