In addition, for evaluation of novel excipients with a proposed use in formulations for biological drug products reviewed by CDER/OND, submitters should provide:

- Stability studies of the excipient under storage and potential in-use conditions (*e.g.,* over infusion time). Novel excipients should be evaluated for their potential to prevent denaturation and degradation of proteins during storage.
- For some excipients, studies should address their potential protein-excipient interaction and impact on drug product immunogenicity as well as their potential for masking process related impurities.

Full packages should be submitted through a Type V DMF or other master file no later than 3 months after notification that FDA has selected the proposal. For more information on submitting Type V DMFs, see the FDA draft guidance for industry entitled ''Drug Master Files'' (Ref. 8).

FDA will evaluate the full package and determine whether the excipient is appropriate for the proposed use for use in clinical trials. FDA will issue a letter to the novel excipient submitter announcing its decision.

For each novel excipient evaluated under the second stage of the program, FDA will publish on the Pilot Program web page the initial proposal and the determination letter. Information that cannot be publicly disclosed will be redacted. This web page will also include a content outline identifying information that should be included in an Initial Proposal and other relevant information regarding the pilot.

3. Effect of Determination

A determination that the excipient is appropriate for use in clinical trials means that FDA has determined it is appropriate to use the novel excipient in an IND within the defined use without additional justification. However, the drug sponsor would still need to demonstrate that the excipient is safe in the proposed formulation. The information submitted under the full package would remain in the Type V DMF or other master file, and the master file holder may grant authorization to reference the information in the master file at the holder's discretion. Moreover, we do not anticipate that a novel excipient may be used in an abbreviated new drug application because data and information currently required to support use of a novel excipient may not be submitted in an abbreviated new drug application. After it has been used in approved drug products, the novel excipient would be added to the Inactive Ingredient Database in accordance with Agency practice.

If FDA determines that the excipient is not appropriate for the proposed use, an IND sponsor would be expected to provide additional information to demonstrate that the use of the novel excipient is appropriate within the context of the IND.

II. Paperwork Reduction Act of 1995

The information collection activities associated with the Pilot Program refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this Pilot Program. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 pertaining to the submission of abbreviated new drug applications, new drug applications, and DMFs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 pertaining to the submission of IND content and format; chemistry, control, and manufacturing data; pharmacology and toxicology data; and pharmacokinetics and biological data have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 58 pertaining to good laboratory practice regulations for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338.

III. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, Guidance for Industry, ''Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients,'' May 2005 (available at *https://www.fda.gov/media/72260/download*). For the most recent version of a guidance, check the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*
2. FDA Guidance for Industry, ''S7A Safety Pharmacology Studies for Human Pharmaceuticals,'' July 2001 (available at *https://www.fda.gov/media/72033/download*).
3. FDA, Guidance for Industry, ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals,'' January 2010 (available at *https://www.fda.gov/media/71542/download*).
4. FDA, Guidance for Industry, ''S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals,'' July 1997 (available at *https://www.fda.gov/media/71971/download*).
5. International Council for Harmonization (ICH), Guidance for Industry, ''Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals S5(R3),'' February 2020 (available at *https://database.ich.org/sites/default/files/S5-R3_Step4_Guideline_2020_0218_1.pdf*).
6. FDA, Guidance for Industry, ''The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals,'' March 1996 (available at *https://www.fda.gov/media/71921/download*).
7. FDA, Guidance for Industry, ''S8 Immunotoxicity Studies for Human Pharmaceuticals,'' April 2006 (available at *https://www.fda.gov/media/72047/download*).
8. FDA, Draft Guidance for Industry ''Drug Master Files,'' October 2019 (available at *https://www.fda.gov/media/131861/download*).

Dated: September 1, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19335 Filed 9–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906–0042, Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 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, or any other aspect of the ICR related to the Maternal and Child Health (MCH) Jurisdictional Survey that is to be administered in the U.S. territories and jurisdictions (excluding the District of Columbia) for purposes of collecting information related to the well-being of all mothers, children, and their families.

DATES: Comments on this Information Collection Request must be received no later than November 8, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to 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 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: MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906–0042, Extension.

Abstract: The purpose of the Title V MCH Block Grant is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring state flexibility. Utilizing a three-tiered national performance measure framework, which includes National Outcome Measures, National Performance Measures, and Evidence-Based and Informed Strategy Measures, State Title V programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the state and federal program offices to assess the progress achieved in key MCH priority areas and to document Title V program accomplishments.

By legislation (Sections 505(a) and 506(a) of Title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH Health agency. In establishing state reporting requirements, HRSA's Maternal and Child Health Bureau considers the availability of national data from other federal agencies. Data for the national performance and outcome measures are pre-populated for states in the Title V Information System. National data sources identified for the National Performance Measures and National Outcome Measures in the MCH Block Grant program seldom include data from the Title V jurisdictions, with the exception of the District of Columbia. The eight remaining jurisdictions (*i.e.,* American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico and U.S. Virgin Islands) have limited access to significant data and MCH indicators, with limited capacity for collecting these data.

Sponsored by HRSA's Maternal and Child Health Bureau, the MCH Jurisdictional Survey is designed to produce data on the physical and emotional health of mothers and children under 18 years of age in the following eight jurisdictions—American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and Virgin Islands. More specifically, the MCH Jurisdictional Survey collects information on factors related to the well-being of children, including health status, visits to health care providers, health care costs, and health insurance coverage. In addition, the MCH Jurisdictional Survey collects information on factors related to the well-being of mothers, including health risk behaviors, health conditions, and preventive health practices. This data collection enables the jurisdictions to meet federal performance reporting requirements and to demonstrate the impact of Title V funding relative to MCH outcomes for the U.S. jurisdictions in reporting on their unique MCH priority needs.

The MCH Jurisdictional Survey was designed based on information-gathering activities with Title V leadership and program staff in the jurisdictions, experts at the Centers for Disease Control and Prevention and other organizations with relevant data collection experience. Survey items are based on the National Survey of Children's Health; the Behavioral Risk Factor Surveillance System; the Youth Behavior Surveillance System; and selected other federal studies. The Survey is designed as a core questionnaire to be administered across all jurisdictions with a supplemental set of survey questions customized to the needs of each jurisdiction.

Need and Proposed Use of the Information: Data from the MCH Jurisdictional Survey is used to measure progress on national performance and outcome measures under the Title V MCH Block Grant Program. This survey instrument is critical to collect information on factors related to the well-being of all mothers, children, and their families in the jurisdictional Title V programs, which address their unique MCH needs.

Likely Respondents: The respondent universe is women age 18 or older who live in one of the eight targeted U.S. jurisdictions (Puerto Rico, U.S. Virgin Islands, Guam, Northern Mariana Islands, American Samoa, Palau, Marshall Islands, or Federated States of Micronesia) and who are mothers or guardians of at least one child aged 0–17 years living in the same household.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. Included is 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

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Burden hours per form	Total burden hours
Adult Parents—Puerto Rico ..	Screener	2,480	1	2,480	0.03	74.40	299.40
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.07	17.50	
Adult Parents—U.S. Virgin Islands.	Screener	2,153	1	2,153	0.03	64.59	289.59
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.07	17.50	
Adult Parents—Guam	Screener	684	1	684	0.03	20.52	245.52
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.07	17.50	
Adult Parents—American Samoa.	Screener	426	1	426	0.03	12.78	232.78
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.05	12.50	
Adult Parents—Federated States of Micronesia.	Screener	339	1	339	0.03	10.17	230.17
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.05	12.50	
Adult Parents—Marshall Islands.	Screener	284	1	284	0.03	8.52	236.02
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.08	20.00	
Adult Parents—Northern Mariana Islands.	Screener	470	1	470	0.03	14.10	241.60
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.08	20.00	
Adult Parents—Palau	Screener	467	1	467	0.03	14.01	226.51
	Core	250	1	250	0.83	207.50	
	Jurisdiction Module	250	1	250	0.02	5.00	
Total		7,303		7,303			2,001.59

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. 2021–19447 Filed 9–7–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Evaluation of Office of Acquisitions System (OASYS) and FFRDC Contract Administration System (FCAS) Vendor Portals National Cancer Institute (NCI); Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on August 31, 2021. That Notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Marla Jacobson, 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–5267 or email your request, including your address to: *marla.jacobson@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 31, 2021, in FR Doc. 2021–18767, on page 48747, as found within the **SUPPLEMENTARY INFORMATION** section, within the Estimated Annualized Burden Hours table for the Total Annual Burden Hours for the form name column Survey—FCAS total currently reads ''1'' and is corrected to read: ''0'', the form name column Registration—FCAS total currently reads ''1'' and is corrected to read: ''0''. These corrections revise the Total Annual Burden Hours total currently reads ''232'' and is corrected to read: ''230''.

Dated: September 1, 2021.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2021–19281 Filed 9–7–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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