comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Aggregate Reports for Tuberculosis Program Evaluation (OMB Control No. 0920–0457, Exp. 12/31/2022)—Extension—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Division of Tuberculosis Elimination (CDC/NCHHSTP/DTBE) requests an Extension of the Aggregate Reports for Tuberculosis Program Evaluation information collection, previously approved under OMB Control No. 0920–0457. This request is for a three-year period.

The requested Extension allows awardees to address the change in the national strategies for TB control and prevention emphasizing treatment of individuals with latent TB infection (LTBI) and at high risks of progression to TB disease. This data collection will help programs to assess high-risk populations served and to evaluate the adaptation and effectiveness of new diagnostic tests and drug regimens in treating LTBI.

DTBE is the lead agency for tuberculosis elimination in the United States. To ensure the elimination of tuberculosis in the United States, CDC monitors indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases, and in other persons likely to be infected, and providing therapy for latent tuberculosis infection. In 2000, CDC implemented two program evaluation reports for annual submission: (1) Aggregate report of follow-up and treatment for contacts to tuberculosis cases, and (2) Aggregate report of targeted testing and treatment for latent tuberculosis infection. The respondents for these reports are the 67 state and local tuberculosis control programs receiving federal cooperative agreement funding through DTBE. These reports emphasize treatment outcomes, high-priority target populations vulnerable to tuberculosis, and electronic report entry and submission to CDC through the National Tuberculosis Indicators Project (NTIP), a secure web-based system for program evaluation data. No other federal agency collects this type of national tuberculosis data. The Aggregate report of follow-up for contacts of tuberculosis and Aggregate report of targeted testing and treatment for latent tuberculosis infection are the only data source about latent tuberculosis infection for monitoring national progress toward tuberculosis elimination with these activities. CDC provides ongoing assistance in the preparation and utilization of these reports at the local and state levels of public health jurisdiction. CDC also provides respondents with technical support for NTIP access.

CDC requests OMB approval for an estimated 268 annual burden hours. Participation by respondents is voluntary, and there is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Department Awardee (State, Local, City, or other jurisdiction).	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (3a).	67	1	2
	Targeted Testing and Treatment for Latent Tuberculosis Infection (3b).	67	1	2

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0765]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request ''Fellowship Management System (FMS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 14, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Fellowship Management System (FMS) (OMB Control No. 0920–0765, Exp. 3/31/2023)—Revision—Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Division of Scientific Education and Professional Development (DSEPD), in the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), requests OMB approval to continue use of the CDC Fellowship Management System (FMS) (OMB Control No. 0920–0765), with changes. The mission of DSEPD is to improve health outcomes through a competent, sustainable, and empowered public health workforce. Professionals in public health, epidemiology, medicine, economics, information science, veterinary medicine, nursing, public policy, and other related professionals seek opportunities, through CDC fellowships, to broaden their knowledge, and skills to improve the science and practice of public health. CDC fellows are assigned to state, tribal, local, and territorial public health agencies; federal government agencies, including CDC and Department of Health and Human Services' (HHS) operational divisions, such as Centers for Medicare & Medicaid Services; and to nongovernmental organizations, including academic institutions, tribal organizations, and private public health organizations.

CDC uses FMS to collect, process, and manage data from nonfederal applicants seeking training or public health support services through CDC fellowships. FMS is used to electronically submit fellowship applications, submit fellowship host site proposals, track completion of fellowship activities, and maintain fellowship alumni directories online. FMS is a flexible and robust electronic information system standardized and tailored for each CDC fellowship, collecting only the minimum amount of information needed. The system is critical to streamlining data management for CDC and reducing burden for respondents. FMS is key to CDC's ability to protect the public's health by supporting training opportunities that strengthen the public health workforce.

The proposed revision has two purposes: (1) increase the number of likely respondents, and (2) change the software platform on which FMS operates. The increase in the estimated number of respondents is a result of increased funding that will allow DSEPD to expand many of the fellowships managed through FMS. The change in software platform will provide CDC with an even more efficient, effective, and secure electronic mechanism for collecting, processing, and monitoring fellowship information. The proposed software platform is the Microsoft® Power Platform® (Microsoft Corporation, Cary, Washington). Integration of the suite of Microsoft tools for data management, analysis, and visualization will allow CDC to access fellowship data in real time; moreover, data cleaning and manipulation do not need to be done outside the system, which will increase the security of these data. These increased functionalities will facilitate the enhanced use of administrative data collections for program improvement and evidence building activities across CDC and other federal agencies. The update to the software platform will also make it easier for additional fellowships to opt to use FMS, expanding the benefits of the system to a broader set of CDC programs. Finally, the platform change also should enhance user experience. This revision does not propose substantive changes to the nature or extent of information collected from respondents.

OMB approval is requested for three years. The revision will allow all respondents—fellowship applicants, public health agencies hosting fellowship participants, and fellowship alumni—the continued use of FMS for submission of electronic data with increased efficiency and reduced burdens.

The annualized burden table reflects OMB-approved changes since 2020 and anticipated growth in fellowships from 2022 onward. There is no cost to respondents other than their time. The total estimated annualized burden hours are 13,186.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Fellowship Applicants	FMS Application Module	5,146	1	87/60
Reference Letter Writers	FMS Application Module	6,842	1	15/60
Subset of FMS Fellowship Applicants	FMS Application Module (13.6)	220	1	30/60
Public Health Agency or Organization Staff	FMS Host Site Module	960	1	75/60
Public Health Agency or Organization Staff	FMS Activity Tracking Module	555	2	30/60
Fellowship alumni	FMS Alumni Directory	3,484	1	37/60

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1349]

Mikart, LLC, et al.; Withdrawal of Approval of 31 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 31 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 11, 2022.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040846	Hydrocodone Bitartrate and Acetaminophen Tablets, 325 milligrams (mg); 2.5 mg.	Mikart, LLC, 1750 Chattahoochee Ave. NW, Atlanta, GA 30318.
ANDA 040851	Benzonatate Capsules, 100 mg, 150 mg, and 200 mg	Do.
ANDA 072903	Ibuprofen Tablets, 200 mg	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623.
ANDA 073519	Tolmetin Sodium Capsules, Equivalent to (EQ) 400 mg base	Do.
ANDA 074267	Guanabenz Acetate Tablets, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074498	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074840	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 074844	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 075212	Ranitidine Hydrochloride (HCl) Tablets, EQ 75 mg base	Do.
ANDA 076030	Flecainide Acetate Tablets, 50 mg, 100 mg, and 150 mg	Do.
ANDA 076086	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg	Do.
ANDA 077426	Ranitidine HCl Tablets, EQ 150 mg base and EQ 300 mg base	Do.
ANDA 077641	Zonisamide Capsules, 25 mg, 50 mg, and 100 mg	Do.
ANDA 077979	Alprazolam Extended Release Tablets, 0.5 mg, 1 mg, 2 mg, and 3 mg.	Do.
ANDA 085269	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 085740	Meclizine HCl Tablets, 25 mg	Do.
ANDA 087296	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088164	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088641	Glucamide Tablets, 250 mg	Do.
ANDA 088732	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 088768	Chlorpropamide Tablets, 100 mg	Do.
ANDA 088826	Chlorpropamide Tablets, 250 mg	Do.
ANDA 090572	Cetirizine HCl, Syrup 5 mg/5 milliliters (mL)	Tris Pharma, Inc., 2031 U.S. Hwy. 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 090906	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg, and 1 gram (gm)	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd., Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 201944	Potassium Chloride Extended Release Capsules, 8 milliequivalent (mEq) and 10 mEq.	Tris Pharma, Inc.
ANDA 202095	Levetiracetam Extended Release Tablets, 500 mg and 750 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 202246	Levonorgestrel Tablets, 1.5 mg	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 203298	Calcium Acetate Capsules, 667 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 204180	Amiloride HCl Tablets, 5 mg	USpharma Windlas, LLC, 115 Blue Jay Dr., Suite 101, Liberty, MO 64068.
ANDA 205442	Linezolid Injection, 600 mg/300 mL (2 mg/mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 205790	Prasugrel Tablets, EQ 5 mg base and EQ 10 mg base	USpharma Windlas, LLC.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 11, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.

Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and