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

[60Day–22–0765; Docket No. CDC–2022–0032]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comments on an information collection titled, CDC's Fellowship Management System (FMS). CDC uses the information collected to aid and enhance the selection of fellowship participants and host sites and to track participant information that helps strengthen the current, emerging, and ever-changing public health workforce.

DATES: CDC must receive written comments on or before May 13, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0032 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Data collection for fellowship programs using CDC's Fellowship Management System (OMB Control No. 0920–0765, Exp. 3/31/2023)—Revision—Center for Surveillance, Education, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Scientific Education and Professional Development (DSEPD/CSELS) requests a three-year revision to continue the use of the CDC Fellowship Management System (FMS) to collect data under the approved OMB Control Number (0920–0765). 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, and 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 likely 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 in to use FMS, expanding the benefits of the system to a broader set of CDC programs. Finally, the platform change should also enhance user experience. This Revision does not propose substantive changes to the nature or extent of information collected from respondents, and 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 burden table reflects OMB-approved changes since 2020 and anticipated growth in fellowships from 2022 onward. CDC requests approval for an estimated total of 14,914 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Fellowship applicants	FMS Fellowship Application Information Collection Instrument.	5146	1	87/60	7,462
Reference Letter Writers	FMS Fellowship Application Information Collection Instrument.	6842	1	15/60	1,711
Public Health Agency or Organization Staff.	FMS Host Site Information Collection Instrument.	960	1	75/60	1,200
Public Health Agency or Organization Staff.	FMS Activity Tracking Information Collection Instrument.	555	2	30/60	555
Fellowship Alumni	FMS Alumni Tracking Information Collection Instrument.	6463	1	37/60	3,986
Total					14,914

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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–2021–P–0959]

Determination That MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Technetium Tc-99m Succimer Kit, Injectable, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Michelle Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240 402–0374, *Michelle.Weiner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, is the subject of NDA N017944, held by GE Healthcare, and initially approved on May 18, 1982. MPI DMSA KIDNEY REAGENT is indicated to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders. MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit), Injectable, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps, & McNamara, P.C. submitted a citizen petition dated August 27, 2021 (Docket No. FDA–