

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–14–0765]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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. Written comments should be received within 60 days of this notice.

Proposed Project

Fellowship Management System (OMB No. 0920–0765, expires 02/28/2015)—Revision—Division of Scientific Education and Professional Development (DSEPD), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

DSEPD requests an additional three years to continue CDC's use of the Fellowship Management System (FMS) for its electronic application, host site, and directory processes that allow individuals to apply to fellowships online, allow public health agencies to submit fellowship assignment proposals online, and track applicant and alumni information. An extension will allow applicants, public health agencies, and alumni continued use of FMS for submission of electronic data.

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, skills, and experience 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.

FMS provides an efficient and effective electronic mechanism for collecting and processing fellowship application data and fellowship host site assignment proposals; selecting qualified candidates; matching selected fellowship host site assignments with applicants; maintaining a current alumni database; generating reports; and documenting the impact of fellowships on alumni careers. FMS optimizes CDC's ability to provide continuous fellowship service delivery that builds and sustains public health capacity and helps to save lives and protect people from health threats. This proposed extension allows CDC to continue to use standardized electronic tools for streamlined collection of fellowship applications and fellowship assignment proposals, in the process collecting alumni information that will be used to document the impact of public health fellowships on career paths and on the science and practice of public health.

This information collection request was established to support making contextual non-substantive changes to application and host site questions and directions to accurately reflect evolving fellowship eligibility requirements, provide clarification of existing questions, and accommodate changing needs of host organizations. Non-substantive changes of this nature will be requested with this extension to include, e.g., supporting the submission of electronic transcripts and letters of recommendation in lieu of postal delivery; refining selected questions to align with current fellowship eligibility requirements; and clarifying instructions in response to user feedback. DSEPD/CSELS will be eliminating the data collection for two fellowships that are being discontinued (the Public Health Prevention Specialist Program and the CDC Experience Applied Epidemiology Fellowship). No change in burden to individual respondents will result from these non-substantive changes.

The annual burden table has been updated to reflect the number of respondents from nonfederal fellowship applicants, public health agencies, and fellowship alumni. There is no cost to respondents 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)	Total burden hours
Public health agency or organization	Fellowship Management System Host Site.	394	1	85/60	558
Fellowship applicants	Fellowship Management System Application.	1,961	1	40/60	1,307
Fellowship alumni*	Fellowship Management System Directory.	1,382	1	15/60	346
Total	2,211

* Some alumni are deceased or cannot be located. Response burden assumes response from an individual responding alumnus, on average, every three years (which is a likely overestimate of frequency).

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs.

DATES: Submit electronic or written comments on the collection of information by November 24, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive—21 CFR 558; OMB Control Number 0910-0363—Extension

With the passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving state pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) was tailored to the unique circumstances relating to the distribution of medicated feeds. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible.

On December 12, 2013, FDA published a proposed rule in the **Federal Register** (78 FR 75515) intended to improve the efficiency of FDA's VFD program. The provisions included in the proposed rule were based on stakeholder input received in response to solicitations for public comment, including an advance notice of proposed rulemaking on March 29, 2010 (75 FR 15387), and draft text of proposed amendments to the current VFD regulations on April 13, 2012 (77 FR 22247).

While FDA intends to finalize the VFD rulemaking in 2015, the current