

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

information collection request supporting the program expires on December 31, 2014. At this time, the

burden for this information collection remains unchanged.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25 (15 minutes)	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	0.25 (15 minutes)	75
558.6(d)(1)(iv)	20	1	20	0.25 (15 minutes)	5
558.6(d)(2)	1,000	5	5,000	0.25 (15 minutes)	1,250
514.1(b)(9)	1	1	1	3.00	3
Total					95,083

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2 —ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	0.0167 (1 minute)	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	0.0167 (1 minute)	6,263
Total					25,051

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of time required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: September 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1344]

Policy Clarification for Fluoroscopic Equipment Requirements; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Policy Clarification for Fluoroscopic Equipment Requirements.” This draft guidance describes FDA’s intent to clarify the application of certain aspects of the performance standard requirements for fluoroscopic equipment when manufacturers comply with certain

International Electrotechnical Commission (IEC) standards. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 24, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Policy Clarification for Fluoroscopic Equipment Requirements” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify

comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Donald Miller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4646, Silver Spring, MD 20993–0002, 301–796–3299.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document, “Policy Clarification for Fluoroscopic Equipment Requirements” was developed to describe FDA’s intent to clarify the application of certain aspects of the performance standard requirements in 21 CFR 1020.32 for fluoroscopic equipment when the manufacturer has complied with certain IEC standards. FDA believes that a declaration of conformity with the applicable IEC standard and the applicable measure(s) set forth in this guidance as part of the 510(k) submission for their device will sufficiently address the concerns intended to be addressed by certain parts of the requirements of § 1020.32, such that the public health is adequately protected.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will