

burden per response for the needs assessment survey is 20 minutes.

The results of the needs assessment will inform the development of the Work@Health training curriculum and delivery methods. CDC anticipates that training will be offered in four models (formats): (1) A “Hands-on” instructor-led workshop model (T1), (2) a self-paced “Online” model (T2), (3) a combination or “Blended” model (T3), and (4) a “Train-the-Trainer” model (T4) designed to prepare qualified individuals to train employers through the Hands-on, Online, or Blended models.

Employers who are interested in participating in Work@Health training will be asked to complete a Pilot Employer Application Form. To be eligible for the T1–T3 pilot trainings, employers must have a minimum of 30 employees, a valid business license, and

have been in business for at least one year. In addition, they must offer health insurance to their employees and have minimal workplace health program knowledge and experience. To be eligible for the T4 training model, applicants may be employers, health departments, business coalitions, trade associations, or other organizations. Participants in the T4 training must have previous knowledge, training and experience with workplace health programs, and an interest in becoming facilitators for the Work@Health program.

CDC anticipates the receipt of approximately 400 applications. CDC will use the application information to select 72 respondents for Phase 1 pilot training and evaluation activities (18 respondents per model). Three-fourths of these individuals will represent small and mid-size employers. Upon

completion of the pilot training, each participant will be asked to complete a 15–20 minute evaluation survey. The customized survey questions will allow CDC to assess respondent satisfaction with the procedures, methods, content and strategies employed in each workplace health training model. The information collected in the pilot training evaluation surveys will inform future modifications and improvements to the training based on employers’ experiences, needs, and recommendations. Only the evaluation survey for the Online model pilot will be the administered electronically, all others will be paper/pencil surveys.

Participation is voluntary and there are no costs to participants other than their time. A separate information collection request will be submitted to obtain OMB approval for Phase 2 information collection.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Employers Employers Participating in the Work@Health Pilot Training Program.	Training Needs Assessment Survey	200	1	20/60	67
	Pilot Employer Application Form	400	1	5/60	33
	Hands-On Pilot Training Evaluation Survey.	18	1	15/60	5
	Hands-On Pilot Training Evaluation Survey.	18	1	15/60	5
	Blended Model Pilot Training Evaluation Survey.	18	1	20/60	6
	Pilot Training Train-the-Trainer Evaluation Survey.	18	1	15/60	5
Total					121

Ron A. Otten,

Director, 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–2013–N–0519]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How To Submit Information in Electronic Format to Center for Veterinary Medicine Using the Food and Drug Administration’s Electronic Submission Gateway

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 the existing reporting requests in CVM Guidance #108, “How to Register with the CVM Electronic Submission System to Submit Information in Electronic Format using the FDA Electronic Submissions Gateway.”

DATES: Submit either electronic or written comments on the collection of information by July 15, 2013.

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:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,
Jonnalynn.capezzuto@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.

Guidance for Industry #108 on How To Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway—21 CFR 11.2 (OMB Control Number 0910-0454)—Extension

CVM accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled "Guidance for Industry 108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any information by email. The likely respondents are sponsors for new animal drug applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Part and form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
\$ 11.2; Form FDA 3538	65	2.4	156	0.08 (5 minutes)	13 (Rounded from 12.5)

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

Dated: May 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0520]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Extension

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 extending OMB approval on the existing recordkeeping requirements for this information collection, regarding animal proteins prohibited in ruminant feed.

DATES: Submit either electronic or written comments on the collection of information by July 15, 2013.

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:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,
Jonnalynn.capezzuto@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 extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this