

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)—New—National Center for Environmental Health (NCEH) and Agency for Toxic Substances and Disease Registry (ATSDR)/Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The overarching goal of the Healthy Homes and Lead Poisoning Surveillance

System (HHLPSS) is to establish Healthy Homes Surveillance Systems at the state and national levels. Currently, 40 state and local Childhood Lead Poisoning Prevention Programs (CLPPP) report information (e.g., presence of lead paint, age of housing, and type of housing) to CDC via the National Blood Lead Surveillance System (NBLSS) (OMB No. 0920–0337, exp. 1/31/2012). The addition of a new panel of housing questions would help to provide a more comprehensive picture of housing stock in the United States and potentially modifiable risk factors.

The objectives for developing this system are two-fold. First, the program would like to use surveillance data to estimate the extent of housing-related injuries and asthma. This is important because it will allow the program to systematically track the management and follow-up of those residents with these health outcomes.

The next objective for the development of this system is to

examine potential housing-related risk factors. Childhood lead poisoning is just one of many adverse health conditions that are related to common housing deficiencies. Multiple hazards in housing, e.g., mold, vermin, radon and the lack of safety devices, continue to adversely affect the health of residents. It is in the interest of public health to expand from a single focus on lead poisoning prevention to a coordinated, comprehensive, and systematic approach to eliminating multiple housing-related health hazards.

HHLPSS builds upon previous efforts by the NBLSS. While the earlier NBLSS was focused on homes of children less than six years old, the new HHLPSS, upon approval, will replace the NBLSS and will enable flexibility to evaluate all homes, regardless of the presence of children < age 6 years.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden hours
State and Local Health Departments for Child Surveillance	40	4	4	640
Total	640

Carol Walker,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
[FR Doc. 2010–12538 Filed 5–24–10; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Miner Safety and Health Training—Western United States, Request for Application (RFA) OH10–001, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the aforementioned meeting:

Time and Date: 8:30 a.m.–5 p.m., June 15, 2010 (Closed).
Place: Hyatt Regency Pittsburgh International Airport, 1111 Airport Boulevard, Pittsburgh, Pennsylvania 15231.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Miner Safety and Health Training Program—Western United States, RFA OH10–001.”

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: S. Price Connor, PhD, Scientific Review Officer, Office of Extramural Programs, CDC, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, Georgia 30333, Telephone (404) 498–2511.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 18, 2010.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.
[FR Doc. 2010–12564 Filed 5–24–10; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0260]

Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of availability and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled

“Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2).” The draft guidance provides information to the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA). Further, the draft guidance addresses inquiries that the agency has received through its Reportable Food Registry help desk and/or by other means since the implementation of the Reportable Food Registry on September 8, 2009, and provides information on the new Safety Reporting Portal. The agency is also seeking comments from industry on the Reportable Food Registry requirements, and specifically on the issue of “transfer” as discussed in the current Edition 1, and draft Edition 2 guidance.

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 comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by July 26, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Defense, Communication and Emergency Response (HFS-005), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). This law amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry. Section 417 of the act requires

the Secretary of Health and Human Services (the Secretary) to establish within FDA a Reportable Food Registry. The congressionally-identified purpose of the Reportable Food Registry is to provide a “reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health” (Pubic Law 110-085, section 1005(a)(4)). The Secretary has delegated to the Commissioner of Food and Drugs the responsibility for administering the act, including section 417. To further the development of the Reportable Food Registry, section 417 of the act requires FDA to establish an electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. After receipt of reports through the electronic portal, FDA is required to review and assess the information submitted for purposes of identifying reportable food, submitting entries to the Reportable Food Registry, issuing an alert or notification as FDA deems necessary, and exercising other existing food safety authorities under the act to protect the public health. The requirements under the Reportable Food Registry became effective on September 8, 2009.

In the **Federal Register** of June 11, 2009, FDA announced the availability of a draft guidance entitled “Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007” and gave interested parties an opportunity to submit comments by July 27, 2009 (74 FR 27803). The agency reviewed and evaluated these comments and issued a final guidance on September 9, 2009 (74 FR 46434). This draft guidance is the second edition of that guidance entitled “Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)” and responds to inquiries that the agency has received through its Reportable Food Registry help desk and/or by other means since the implementation of the Reportable Food Registry on September 8, 2009, and informs industry about the new Safety Reporting Portal. The Safety Reporting Portal is a joint FDA-National Institutes of Health (NIH) system that facilitates the process of reporting several categories of safety information to the FDA and the NIH. As of May 24, 2010, the Reportable Food electronic portal will be a part of the Safety Reporting Portal.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on the topics discussed. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control numbers 0910-0643 and 0910-0645. This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR 7.46 has been approved under OMB control number 0910-0249.

III. Request for Comments

In addition, although the industry is encouraged to submit comments regarding any of the requirements under the Reportable Food Registry, the agency is seeking comments specifically with regard to the meaning of the word “transfer” as it appears in section 417(d)(2)(B) of the act. The meaning of the word “transfer” in this context was discussed in Edition 1 of the guidance at Question and Answer numbers 27 and 28, and in the draft Edition 2 guidance at Question and Answer numbers E.4 and E.5.

Section 417(d)(2) of the act provides an exemption from the requirement that a responsible party submit a reportable food report. In order for the exemption to apply, the adulteration must have originated with the responsible party, the responsible party must have detected the adulteration “prior to any transfer to another person” of the article of food, and the responsible party must have corrected the adulteration or destroyed the food. However, Congress did not provide a definition for the term “transfer” as it is used in section 417(d)(2)(B) of the act. In Edition 1 of the guidance at Question and Answer numbers 27 and 28, and in the draft Edition 2 guidance at Question and Answer numbers E.4 and E.5, FDA said that a transfer to another person occurs when the responsible person releases the food to another person. In this document, FDA is asking for comment on whether this interpretation of the term “transfer” is appropriate, and if not,

what other interpretations of the term "transfer" as it is used in section 417(d)(B)(2) of the act would be more appropriate. Specifically, we are requesting comment on whether the interpretation of the term "transfer" should be dependent upon possession of the food, whether the interpretation should be dependent on ownership of the food, or whether there are other interpretations we should consider, such as a combination of possession and/or ownership.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>.

Dated: May 19, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-12456 Filed 5-24-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0241]

Draft Guidance for Industry on Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #188 entitled "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine." The purpose of this draft guidance is to assist sponsors or non-applicants with filling out form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product

Defect Report," as required by FDA regulations.

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 written or electronic comments on the draft guidance by August 9, 2010.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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

FOR FURTHER INFORMATION CONTACT: Lynn Post, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9191, email: Lynn.Post@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #188 entitled "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine." The purpose of this draft guidance is to assist sponsors or non-applicants with filling out Form FDA 1932, in both paper and electronic format. Section 512(l) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360b(l)) and § 514.80(b) (21 CFR 514.80(b)) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less

apparent effects may take years to manifest. An applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report."

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in section 512(l) of the act and § 514.80 have been approved under OMB Control No. 0910-0645.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

Dated: May 19, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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