DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–223]

Emergency Responder Health Monitoring and Surveillance

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft publication available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft publication for public comment. The document is entitled, "Emergency Responder Health Monitoring and Surveillance."

The draft document and instructions for submitting comments can be found at: *http://www.cdc.gov/niosh/docket/review/docket223/.*

The document proposes a new framework for ensuring responder safety and health by monitoring and conducting surveillance of their health and safety during the entire cycle of emergency response, including the pre-deployment, deployment, and post-deployment phases of a response. The proposed system is referred to as the "Emergency Responder Health Monitoring and Surveillance (ERHMS)" system, which includes a guidance section describing the principles of ensuring optimal responder safety and health, as well as a tools section to help facilitate the execution of these principles during an actual response.

The goals of this proposed system are to ensure that only properly trained and fit responders are deployed to a response, that the health and safety of all responders are appropriately monitored during a response, and that a systematic and comprehensive evaluation be conducted to determine the potential need for long term surveillance of responders' health after their deployment has been completed. This system will help to ensure that hazardous occupational exposures and signs and symptoms observed during an emergency response are utilized to mitigate adverse physical and psychological outcomes and determine whether protective measures are sufficient to prevent or reduce harmful exposures to workers. Data collected during the pre-, during-, and post-deployment phases will also help to identify which responders would benefit from medical referral and possible enrollment in a long-term health surveillance program.

The document, entitled "Emergency Responder Health Monitoring and Surveillance," can be viewed at: *http://www.cdc.gov/niosh/docket/review/docket223/.*

This guidance does not have the force and effect of the law.

Public Comment Period: Comments must be received by April 5, 2011.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, identified by Docket Number NIOSH–223, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.
- *Facsimile:* (513) 533–8285.
- *E-mail: nioshdocket@cdc.gov.*

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226.

A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at *http://www.cdc.gov/niosh/docket,* and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to Docket Number NIOSH–223.

FOR FURTHER INFORMATION CONTACT: Renée Funk, D.V.M., telephone (404) 498–1376, e-mail *rjf8@cdc.gov,* NIOSH, MS–E20, 1600 Clifton Road NE., Atlanta, GA 30333.

Dated: January 28, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011–2527 Filed 2–3–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0603]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fees and Fee Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 7, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0540. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, e-mail: *Juanmanuel.vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug User Fees and Fee Waivers and Reductions—(OMB Control Number 0910–0540)—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (ADUFA) (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from or a reduction of those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled

"Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions." This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. The guidance also describes the types of fees and fee waivers and reductions, the information FDA recommends respondents submit in support of a request for a fee waiver or reduction, how respondents may submit such a request, and FDA's process for reviewing requests.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed—application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of December 2, 2010 (75 FR 75175), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(d)(1)(A) Significant barrier to innovation	22	1	22	2	44
740(d)(1)(B) Fees exceed cost	0	1	0	2	0
740(d)(1)(C) Free choice feeds	2	1	2	2	4
740(d)(1)(D) Minor use or minor species	52	1	52	2	104
740(d)(1)(E) Small business	0	1	0	0	0
Request for reconsideration of a decision	5	1	5	2	10
Request for review—(user fee appeal officer)	2	1	2	2	4
Total					166

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

Based on FDA's database system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the number of submission types received by FDA in fiscal year 2008.

Dated: January 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2441 Filed 2–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0053]

Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Town Hall Discussion with the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this public meeting in the Dallas-Fort Worth, TX area is to engage in a dialogue about issues of importance to FDA's Center for Devices and Radiological Health (CDRH) and to members of the public, including the medical device industry, healthcare professionals, patients, and consumers.

Dates and Time: The public meeting will be held on March 10, 2011, from 8 a.m. to 12 noon CST.

Location: The public meeting will be held at the Irving Convention Center at Las Colinas, 500 West Las Colinas Blvd., Irving, TX 75039. The meeting will not be videotaped or webcast.

Contact: Heather Howell, Food and Drug Administration; Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 4320, Silver Spring, MD 20993, 301–796–5718, *e-mail: heather.howell@fda.hhs.gov.*

Registration and Requests for Oral Presentations: If you wish to attend the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm239730.htm.* Persons without Internet access may call Heather Howell at 301–796–5718 to register for the meeting.

Provide complete contact information for each attendee, including name, title, company or organization, address, e-mail, telephone and fax number. Registration requests must be received by 5 p.m. EST on Friday, February 25, 2011.

If you wish to make an oral presentation during any of the sessions at the meeting (*see* section II of this document, Public Meeting), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. CST.

If you need special accommodations due to a disability, please contact Susan Monahan at 301–796–5661, or by e-mail at *susan.monahan@fda.hhs.gov* at least 7 days in advance of the meeting.

Comments: FDA is holding this public meeting to share information and discuss issues of importance to the public, including the medical device industry, healthcare professionals, patients, and consumers.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets