"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

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

SUPPLEMENTARY INFORMATION:

I. Background

In 2010, CDRH held three Town Hall meetings in Minneapolis, MN; Boston, MA; and Los Angeles, CA to provide the public with a new venue to discuss issues of interest with the Center. Any member of the public was invited to provide comments to or ask questions of CDRH participants. Due to the positive feedback we received for holding these meetings we plan to continue this activity in 2011 in three different locations.

II. Public Meeting

The objective of this public meeting is to engage in a dialogue about issues that are of importance to the public.

The public meeting will open with an introduction of CDRH Senior Staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will describe CDRH's Strategic Priorities for 2011. Members of the public will then be given the opportunity to present comments to CDRH Senior Staff followed by a Question and Answer session during which any member of the public may ask questions of the CDRH Senior Staff on any topic of interest.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: February 1, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–2490 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–0002]

Industry Exchange Workshop on Food and Drug Administration Drug and Device Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Southwest Regional Office, in co-sponsorship with the Association of Food and Drug Officials (AFDO), the Mid-Continental Association of Food and Drug Officials (MCAFDO), and the FDA Medical Device Industry Coalition, is announcing a public workshop entitled "The Future of Medical Products Regulation: Ensuring Safety and Integrity in a Global Market". This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

Date and Time: The public workshop will be held on June 20 and 21, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Marriott Dallas/Plano at Legacy Town Center, Plano, Texas, 7120 Dallas Pkwy., Plano, Texas 75024, 972–473–6444, or toll-free 888–236–2427.

Attendees are responsible for their own accommodations. To make reservations at the Marriott Dallas/Plano at Legacy Town Center, at the reduced conference rate, contact the Marriott Dallas/Plano at Legacy Town Center before May 20, 2011, citing meeting code "AFDO Conference".

Contact: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, Texas 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *David.Arvelo@fda.hhs.gov.*

Registration: You are encouraged to register by May 24, 2011. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

COST OF REGISTRATION

Government (AFDO/Mid-Continental AFDO Member)	$425.00
Government (Non-Member):	525.00
Non-Government (AFDO/MCAFDO Member)	425.00
Non-Government (Non-Member)	525.00
To be added to registration fee for public workshop registration postmarked after May 24, 2011	100.00

If you need special accommodations due to a disability, please contact David Arvelo (*see Contact*) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to "AFDO". Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at