ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total No. of Responses	Hours per Response	Total Hours
1240.63(a)(2)(ii)(A) and (B)	65	1.88	122	4	488

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

Dated: March 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4450 Filed 3–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0130]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling; Trans Fatty Acids in Nutrition Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling; Trans Fatty Acids in Nutrition Labeling'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 12, 2006 (71 FR 60157), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0515. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4454 Filed 3–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0257]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2006 (71 FR 59653), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0597. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4455 Filed 3–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0069]

Animal Drug User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act of 2003 (ADUFA) to seek public comments relative to the program's overall performance and reauthorization as directed by Congress.

Date and Time: The public meeting will be held on April 24, 2007, beginning at 9 a.m.

Location: The public meeting will be held at the Food and Drug Administration, 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. There is parking near the building. Photo identification is required to clear building security.

Contact: Aleta Sindelar, Office of the Director (HFV–3), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9004, FAX 240–276–9020, e-mail: *aleta.sindelar@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Registration is not required to attend the meeting. Requests to make an oral presentation at the meeting must be submitted by April 17, 2007, to the contact person. Your request to make a presentation should include the following information: Name, title, firm name, address, telephone, fax number, and e-mail address. We will try to accommodate all persons who wish to make a presentation. The time allotted for

presentations may depend on the number of persons who wish to speak.

If you require special accommodations due to a disability, please contact Aleta Sindelar at least 7 days in advance of the meeting.

Comments: Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments. Electronic comments may be submitted to the docket at the following site: *http://www.fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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. The docket will remain open for written or electronic comments through May 24, 2007.

SUPPLEMENTARY INFORMATION:

I. Background

ADUFA amended the Federal Food, Drug, and Cosmetic Act (the act) and authorized FDA to collect fees for certain animal drug applications, establishments, products and sponsors in support of the review of animal drugs. These additional resources support FDA's responsibilities under the act to provide greater public health protection by ensuring that animal drug products that are approved to be safe and effective are readily available for both companion animals and animals intended for food consumption.

The FDA animal drug user fee program was authorized in 2003 and implemented in 2004. A significant part of the preparations for the program included determining the fee levels for fiscal year (FY) 2004. ADUFA provides for four fees: (1) A sponsor fee, (2) an establishment fee, (3) a product fee, and (4) an application fee. ADUFA also provides for specific waivers and exemptions from fees. FDA prepared guidance for the industry regarding the fees, billings and submission of fees, as well as waivers and exemptions (*http://www.fda.gov/cvm/adufa.htm*).

The total amounts authorized for collection were: $5 million for FY 2004; $8 million in FY 2005; and $10 million in each FY 2006 through 2008, subject to annual inflation and workload adjustments after 2004. ADUFA provided for four types of fees to be assessed each fiscal year, with each fee type expected to raise 25 percent of the annual amount collected. Thus, in FY 2004, we expected to receive $1.25 million from sponsor fees, establishment fees, product fees, and application fees, for a total of $5 million dollars. The user fees are used to achieve shorter, more predictable review times by increasing the review staff at FDA and building better management systems. As a result, we anticipate substantial savings to the industry in regulatory review and developmental expenses.

FDA's animal drug premarket review program is making continual and substantial improvements in the animal drug review process as a result of user fees. This helps ensure an adequate supply of safe and effective therapeutic and production animal drugs.

II. Agenda

In the language authorizing ADUFA, Congress directed the Secretary of Health and Human Services (the Secretary) to consult with the Committee on Energy and Commerce of the House of Representatives; the Committee on Health, Education, Labor and Pensions of the Senate; appropriate scientific and academic experts; veterinary professionals; representatives of consumer advocacy groups; and the regulated industry in developing recommendations to Congress for the reauthorization of ADUFA and for the goals and plans for meeting the goals associated with the process for review of animal drug applications. As directed by Congress, FDA is holding a public meeting to gather information on what we should consider to include in the reauthorization of ADUFA (*http://www.fda.gov/cvm/adufa.htm*) and hear stakeholder views on this subject.

We are offering the following two general questions for consideration, and we are interested in responses to these questions and any other pertinent information stakeholders would like to share.

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What suggestions or changes would you make relative to the reauthorization of ADUFA?

We have published a number of reports that may help inform the public about the ADUFA program. Key documents such as, ADUFA-related guidance, legislation, performance reports, and financial reports, can be found at *http://www.fda.gov/cvm/adufa.htm*.

III. Meeting Format

In general, the meeting format will include presentations by FDA followed by the open public comment period. Registered speakers for the open public comments will be grouped and invited to speak in the order of their affiliation and time of registration (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry). FDA presentations are planned from 9 a.m. until 10:30 a.m. The open public comment portion of the meeting for registered speakers is planned to begin at 10:30 a.m. An opportunity for public comments from meeting attendees will commence following the registered presentations, if time permits. The docket will remain open for written or electronic comments through May 24, 2007.

IV. Transcripts

Meeting transcripts will be made available on the CVM Website (*http://www.fda.gov/cvm/adufa.htm*) approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: March 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4452 Filed 3–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0064]

Electronic Case Report Form Submission; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) are seeking sponsors interested in participating in a pilot project to test the submission of case report form (CRF) data provided electronically in extensible markup language (XML) based on the Operational Data Model (ODM) developed by the Clinical Data Interchange Standards Consortium (CDISC). This pilot will test the ability of a new data format to support all