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

review activity, which our current submission format is incapable of doing. Data supplied in ODM format by sponsors during the pilot project will not replace any regulatory requirements for submitting CRFs. We anticipate that a successful pilot will allow CDER and CBER to routinely accept CRFs from studies employing electronic data capture (EDC) in ODM format in marketing applications provided in electronic format.

DATES: Submit written or electronic requests to participate in the pilot project by September 10, 2007. General comments on the pilot project are welcome at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Armando Oliva, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6310, Silver Spring, MD 20993–0002, 301–796–0514.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the opportunity to participate in a pilot project being conducted by CDER and CBER involving the testing of the ODM standard developed by the CDISC, with the goal of replacing the existing portable document format (PDF)-based CRFs derived from clinical trials that use EDC and, therefore, lack paper CRFs. CDISC is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trial data and metadata for medical and biopharmaceutical product development (*http://www.cdisc.org*).

Under existing Federal regulations (21 CFR 314.50), applicants must provide CRFs with a marketing application. Since November 1997, under 21 CFR part 11, we have accepted CRFs in electronic format instead of paper. FDA has issued several guidances that provide recommendations concerning electronic submissions. In the **Federal Register** of October 19, 2005 (70 FR 60842), FDA announced the availability of a guidance entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (*http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/cber/gdlns/esubapp.htm*). In section III.E.3. of that guidance, FDA recommends that applicants submit an individual subject's complete CRF as a single, PDF file. The guidance recommends that if a paper CRF was used in the clinical trial, the submitted CRF should be a scanned image of the paper CRF, including all original entries with modifications, addenda, corrections, comments, annotations, and any extemporaneous additions (i.e., audit trail). The guidance further recommends that if EDC was used in the clinical trial, the applicant should submit a PDF-generated form or other PDF representation of the information (e.g., subject profile).

Based on our experience, PDF-based CRFs from clinical trials that employ EDC are not ideal to support all review activity. Although the PDF-based CRFs for trials that use EDC can provide a record of the observations collected during the trial (i.e., the data) and additional information about what was collected (metadata), they typically do not provide an audit trail. CDER and CBER are interested in adopting a new, standard format that can replace the PDF-based CRF and that can reliably provide all three components of the CRF in an electronic format: Data, metadata, and audit trail.

The ODM is an XML-based standard that facilitates the electronic exchange of clinical trial data, metadata, and audit trail. We are working with CDISC to develop the capabilities within CDER and CBER to review CRFs using ODM. CDISC employed the current production version (Version 1.2) of the ODM on the CDISC Web site, and we performed some initial testing of limited CRF data in ODM. To help in this development, we are launching this pilot project and seeking sponsors willing to provide CRFs in ODM format to test our capabilities to review these files. However, data supplied during the pilot project will not replace any regulatory requirements for submitting CRFs.

The purpose of this pilot project is to obtain additional experience with ODM-based CRFs. We anticipate that a successful pilot will allow CDER and CBER to routinely accept CRFs from studies that employ EDC in ODM format in marketing applications submitted in electronic format.

II. Pilot Project Description

This pilot project is part of an effort to improve the quality of CRFs provided to CDER and CBER in electronic format and to improve the centers' capability to review these files. Eventually, CDER and CBER expect to recommend new technical specifications for the submission of CRFs that are derived from clinical trials that employ EDC and, therefore, lack paper CRFs.

A. Initial Approach

Because only a limited number of sponsors are needed (i.e., approximately five), CDER and CBER will use their discretion in choosing participants, based on participants' previous experience submitting CRFs in accordance with existing guidance. Participants should be willing to provide the same CRFs in two formats: PDF, in accordance with existing guidance, and ODM. If PDF-based CRFs have already been submitted as part of an existing new drug application or biologics license application on file with the agency, then participants need only provide the ODM-based CRFs with the same information. Having the same information available in both PDF and ODM provides the best opportunity to compare the two formats.

B. How to Participate

Written requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any 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.

Dated: March 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4451 Filed 3–12–07; 8:45 am]

BILLING CODE 4160–01–S