

email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be deemed registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as registered outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2015 and wish to maintain their status as an outsourcing facility in FY 2016 must register during the annual registration period that lasts from October 1, 2015, to December 31, 2015. Failure to register and complete payment by December 31, 2015, will result in a loss of status as an outsourcing facility on January 1, 2016. Entities should submit their registration information no later than December 10, 2015, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

#### B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Invoices must be paid within 30 days.

#### C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$50,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the

Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only; do not send mail to this address.)

3. If paying with a wire transfer: Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993. The originating financial institution may charge a wire transfer fee. An outsourcing facility should ask its financial institution about the fee and add it to the payment to ensure that the order is fully paid. The tax identification number of FDA is 53-0196965.

Dated: July 28, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-2372]

#### Promoting Semantic Interoperability of Laboratory Data; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Library of Medicine (NLM) of the National Institutes of Health are announcing the following public workshop entitled "FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data." The purpose of this workshop is to receive and discuss input from stakeholders regarding proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records.

**Date and Time:** The public workshop will be held on September 28, 2015, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**Contact Person:** Steven Gitterman, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 5518, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6694, FAX: 301-847-2512, email: [steven.gitterman@fda.hhs.gov](mailto:steven.gitterman@fda.hhs.gov).

**Registration:** Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. September 18, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. (EDT).

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than 4 p.m. on September 14, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. Persons interested in viewing the Webcast must register

online by September 18, 2015, 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 23, 2015. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**Requests for Oral Presentations:** This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which will be addressed in greater detail in a subsequent discussion paper (see **SUPPLEMENTARY INFORMATION**). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by September 2, 2015. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 7, 2015. If selected for presentation, any presentation materials must be emailed to Michael Waters at [michael.waters@fda.hhs.gov](mailto:michael.waters@fda.hhs.gov) no later than September 18, 2015, 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Comments:** FDA, CDC, and NLM are holding this public workshop to receive input from stakeholders and discuss proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including electronic health records. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public

workshop topics. The deadline for submitting comments related to this public workshop is 4 p.m. on October 26, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document at <http://www.regulations.gov> or 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. 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, and will be posted to the docket at <http://www.regulations.gov>.

**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 (see **Comments**). 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 the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop on the posted events list).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

There is broad acknowledgement that interoperability between information providers and information consumers is essential for progress in health care. Semantic interoperability is the building block for permitting meaningful use of medical information across disparate systems; it is essential for supporting patient care, medical research, epidemiology, and numerous other patient health public health goals.

Laboratory tests are a critical aspect of patient care that may influence between 70 to 80 percent of clinical decisions and represent an important target for achieving interoperability. Much of laboratory information is directly generated by medical devices and as such should be readily amenable to standardization that would enable semantic interoperability; however, significant challenges exist both in the adoption of standards by device

manufacturers and implementation by clinical and public health laboratories. FDA, CDC, and NLM are in unique positions to encourage and promote the adoption of standards for laboratory data that can enable semantic interoperability through the public health mandate of the Department of Human and Health Services (HHS), the role of FDA in device regulation, the leadership role of CDC in laboratory science and support, and the pivotal role of NLM in the development, enhancement, and adoption of clinical vocabulary standards.

The primary purpose of this workshop is to discuss and receive input from stakeholders regarding standards for the reporting of laboratory data and means to facilitate adoption by industry and laboratories. Specific models for semantic interoperability of laboratory data will be discussed, including the use of Logical Observation Identifiers Names and Codes (LOINC) for identifying laboratory tests, uniform Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) coding sets for describing results of qualitative test results and Unified Code for Units of Measure (UCUM) reporting of quantitative results. The use of other standards within interoperable laboratory result messages such as Unique Device Identifier (UDI) codes will also be addressed, as well as mechanisms for distributing device coding information such as Structured Product Labeling (SPL) or Electronically Exchanging Directory of Services (eDOS). Specifically, NLM, CDC, and FDA seek input from laboratorians, industry, government, academia, health care practitioners, and other stakeholders on these topics. This discussion is viewed as essential in expediting the adoption of standards to facilitate semantic interoperability of laboratory results.

##### **II. Topics for Discussion at the Public Workshop**

This public workshop will consist of brief presentations providing information to frame the goals of the workshop, and an interactive discussion via several panel sessions. The presentations will focus on proposed interoperability standards and mechanisms to promote adoption and implementation. Following the presentations there will be a moderated discussion where the participants and additional panelists will be asked to provide their individual perspectives.

In advance of the meeting, FDA, CDC, and NLM will place a summary of the issues they believe need to be addressed for promoting semantic interoperability

on file in the public docket (docket number found in brackets in the heading of this document) and will post it at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. The deadline for submitting comments to this document for presentation at the public workshop is September 18, 2015, although comments related to this document can be made until September 28, 2015.

The Agencies will use the input from this workshop and public comments to determine appropriate next steps to advance semantic interoperability of laboratory data.

Dated: July 28, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0007]

#### Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2016

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2016 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2016.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>, or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at [cvmagdufa@fda.hhs.gov](mailto:cvmagdufa@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j-21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j-21(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for fiscal years after FY 2014 may be adjusted for workload. The target revenue amounts for each fee category for FY 2016, after the adjustment for workload, are as follows: For application fees the target revenue amount is \$2,426,000; for product fees the target revenue amount is \$3,639,000; and for sponsor fees the target revenue amount is \$3,639,000.

For FY 2016, the generic new animal drug user fee rates are: \$233,300 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$116,650 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); \$8,705 for each generic new animal drug product; \$83,800 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$62,850 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$41,900 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2016 product and sponsor fees by December 31, 2015. These fees will be due by January 31, 2016. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2015, and will remain in effect through September 30, 2016. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program.

##### II. Revenue Amount for FY 2016

###### A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113-14, specifies that the aggregate revenue amount for FY 2016 for abbreviated application fees is \$1,857,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is \$2,786,000 each (see 21 U.S.C. 379j-21(b)).

###### B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA II for each year for FY 2014 through FY 2018 include an inflation adjustment; therefore, no further inflation adjustment is required.

###### C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2014, AGDUFA provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload. (See 21 U.S.C. 379j-21(c)(2).)

FDA calculated the average number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended on June 30, 2015.

The results of these calculations are presented in the first two columns in table 1. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of 30.6305 percent for FY 2016. This is the workload adjuster for FY 2016.