completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: 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., 14th Floor, Silver Spring, MD 20993–0002. If needed, FDA's tax identification number is 53–0196965.

*C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2018, or To Register a New Establishment for FY 2018*

Go to the Center for Devices and Radiological Health's Web site at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm* and click the ''Access Electronic Registration'' link on the left side of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the ''Access Electronic Registration'' link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2017. Manufacturers of licensed biologics should register in the BER system at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/default.htm.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (*Note:* This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the BER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

*D. Enter Your DFUF Order PIN and PCN*

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: August 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–18378 Filed 8–28–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–4119]**

## Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2018

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2018 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

**FOR FURTHER INFORMATION CONTACT:** Donald Prater, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3234, Silver Spring, MD 20993, 301–348–3007.

**DATES:** This fee is effective October 1, 2017.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and To Issue Certifications to Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2018 third-party certification program user fee rate announced in this notice is effective on October 1, 2017, and will remain in effect through September 30, 2018.

### II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2018

In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

*A. Estimating the Full Cost per Direct Work Hour in FY 2018*

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees,

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.

divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2018 cost. The FY 2018 FDA-wide average cost for payroll (salaries and benefits) is $154,638; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $89,224; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,922 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2018 average fully supported cost to $267,783 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third party certification user fees for FY 2018 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2018 average fully supported cost of $267,783 per FTE by the average number of supported direct FDA work hours in FY 2016—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2016

| | |
|---|---|
| Total Number of Hours in a Paid Staff Year | 2,080 |
| Less: | |
| 10 paid holidays | −80 |
| 20 days of annual leave | −160 |
| 10 days of sick leave | −80 |
| 12.5 days of training | −100 |
| 26.5 days of general administration | −184 |
| 26.5 days of travel | −212 |
| 2 hours of meetings per week | −104 |
| Net Supported Direct FDA Work Hours Available for Assignments | =1,160 |

Dividing the average fully supported FTE cost in FY 2018 ($267,783) by the total number of supported direct work hours available for assignment in FY 2016 (1,160) results in an average fully supported cost of $231 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2018.

*B. Adjusting FY 2016 Travel Costs for Inflation To Estimate FY 2018 Travel Costs*

To adjust the hourly rate for FY 2018, FDA must estimate the cost of inflation in each year for FY 2017 and FY 2018. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1)), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2017 inflation rate to be 1.5468 percent; this rate was published in the FY2017 PDUFA user fee rates notice in the **Federal Register**. Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.5468 percent for FY 2017 and 1.6868 percent for FY 2018 and FDA intends to use this inflation rate to make inflation adjustments for FY 2018 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2018 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2017 and 2018, therefore, is 1.032597 (or 3.2597 percent) (1 plus 1.5468 percent times 1 plus 1.6868 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $231 already takes into account inflation as the calculation above is based on FY 2018 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2018 prior to including travel costs as applicable for the activity. For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2016, the Office of Regulatory Affairs spent a total of $2,166,592 on 344.31 foreign inspection trips related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of $6,293 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,293 per trip by 120 hours per trip results in a total and an additional cost of $52 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2016. To adjust $52 for inflationary increases in FY 2017 and FY 2018, FDA must multiply it by the same inflation factor mentioned previously in this document (1.032597 or 3.2597 percent), which results in an estimated cost of $54 (rounded to the nearest dollar) per paid hour in addition to $231 for a total of $285 per paid hour ($231 plus $54) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2018 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2018

| Fee category | Fee rates for FY 2018 |
|---|---|
| Hourly rate without travel | $231 |
| Hourly rate if travel is required | 285 |

## III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual fees. In FY18, the only fees that will be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, and the annual fee for certification bodies accredited by a recognized accreditation body. Table 3 provides an overview of the fees for FY 2018.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2018

| Fee category | Fee rates for FY 2018 |
|---|---|
| Initial Application Fee for Accreditation Body Seeking Recognition | $37,935 |
| Annual Fee for Recognized Accreditation Body | 1,752 |
| Annual Fee for Accredited Certification Body | 2,190 |

*A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act*

Section 1.705(a)(1) (21 CFR 1.705(a)(1)) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it

would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 60 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 45 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $231/hour, to calculate the portion of the user fee attributable to those activities: $231/hour × (60 hours + 45 hours) = $24,255. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $285/hour, to calculate the portion of the user fee attributable to those activities: $285/hour × 48 hours (*i.e.,* 2 fully supported FTEs × (2 travel days + 1 day onsite)) = $13,680. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $24,255 + $13,680 = $37,935. Therefore the application fee for accreditation bodies applying for recognition in FY 2018 will be $37,935.

*B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act*

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 24 hours for FDA to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 4.8 hours of onsite performance evaluation (*i.e.,* 10 percent × 2 fully supported FTEs × (2 travel days + 2 day onsite)). Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single recognized accreditation body would be $7,392 ($231/hour × (24 hours + 8 hours)) plus $1,368 ($285/hour × 4.8 hours), which is $8,760. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $1,752 for FY 2018.

*C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act*

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time we assume an average term of accreditation of 4 years. This fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that FDA would conduct, on average, the same activities, for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single accredited certification body would be $7,392 ($231/hour × (24 hours + 8 hours)) plus $1,368 ($285/hour × 4.8 hours), which is $8,760. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,190 for FY 2018.

## IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2018

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications, certification bodies applying for direct accreditation, and certification bodies applying for renewal of direct accreditation. Section 1.705(b) establishes annual fees for recognized accreditation bodies, certification bodies directly accredited by FDA, and certification bodies accredited by recognized accreditation bodies.

Although we will not be collecting all of these other fees in FY 2018, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2018 based on the fully supported FTE hourly rates for FY 2018 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

| Fee category | Estimated fee rates for FY 2018 |
|---|---|
| Renewal application fee for recognized accreditation body | $21,049 |
| Initial application fee for certification body seeking direct-accreditation from FDA | 37,935 |
| Renewal application fee for directly-accredited certification body | 28,755 |
| Annual fee for certification body directly-accredited by FDA | 21,072 |

## V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the invoice date. Detailed payment information will be included with the invoice when it is issued.

## VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in § 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual

fee within 90 days of the due date, we will withdraw its accreditation.

Dated: August 23, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–18222 Filed 8–28–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Office of the Director, National Institutes of Health: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Advisory Committee to the Director, National Institutes of Health.

*Date:* September 14, 2017.

*Time:* 2:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *Woodgs@od.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 24, 2017.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017–18339 Filed 8–28–17; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

*Name of Committee:* National Cancer Institute Council of Research Advocates.

*Date:* September 25, 2017.

*Time:* 9:00 a.m. to 4:30 p.m.

*Agenda:* Welcome and Chairman's Remarks, NCI Updates and Legislative Update.

*Place:* National Institutes of Health, 40 Convent Drive, Building 40, Conference Rooms 1201/1203, Bethesda, MD 20892.

*Contact Person:* Amy Williams, NCI Office of Advocacy Relations National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 240–781–3406 *williaam@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: NCRA: *http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 24, 2017.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017–18343 Filed 8–28–17; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0690]**

### Cooperative Research and Development Agreement: Environmentally Friendly Buoy Mooring System

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of intent; request for comments.

**SUMMARY:** The Coast Guard is announcing its intent to enter into a Cooperative Research and Development Agreement (CRADA) with American Underwater Contractors, Inc. (AUC) to develop, demonstrate, evaluate and document the use of environmentally friendly buoy mooring systems (line and anchor) attached to a navigational buoy to determine the feasibility and practicality of the Coast Guard using both helix (screw) anchors and elastic mooring lines in environmentally sensitive areas. While the Coast Guard is currently considering partnering with AUC, we are soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants, who have the interest and capability to bring similar contributions to this type of research, to consider submitting proposals for consideration in similar CRADAs.

**DATES:** Comments must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before September 27, 2017.

Synopses of proposals regarding future CRADAs must reach the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) on or before September 27, 2017.

**ADDRESSES:** Submit comments online at *http://www.regulations.gov* following Web site instructions.