3. Updated background section that includes a brief history of the development program and the status of product development and clinical data to date, if applicable.

4. Proposed agenda, including estimated times needed for discussion of each agenda item.

5. List of questions for discussion with a brief summary of each question that explains the need or context for the question.

6. Updated programs/shells for simulations, if applicable.

7. Summary of new information that is available to support discussions.

E. Meeting Summaries

A meeting summary will be sent to the sponsor within 60 days of each meeting.

F. Disclosure

To promote innovation and to provide better clarity on the acceptance of different types of trial designs, trial designs developed through the pilot program may be presented by FDA (*e.g.,* in a guidance or public workshop) as case studies, including while the drug studied in the trial has not yet been approved by FDA. Accordingly, before FDA grants the initial meeting under this pilot program, FDA and the sponsor must agree on the information that FDA may include in these public case studies. The specific information to be disclosed will depend on the content of each application, but FDA intends to focus on information that is beneficial to advancing the use of CIDs, and those elements relevant to the understanding of the CID and its potential use in a clinical trial intended to support regulatory approval. Generally, the Agency does not anticipate that the case studies will need to include information such as molecular structure, the sponsor's name, product name, subject-level data, recruitment strategies, adverse events, or a complete description of study eligibility criteria. FDA does anticipate that the following information will generally need to be disclosed to facilitate discussion of the proposed CID: Study endpoints to the degree necessary to describe the design (*e.g.,* overall survival in the context of a time to event analysis), target population, sample size and power determination, null and alternative hypotheses, key operating characteristics, assumed rates for dichotomous outcomes or mean and variance for continuous outcomes, simulation objectives, simulation scenarios, assumptions (*e.g.,* dropout rate, rate of enrollment), modeling characteristics, critical study design characteristics including any adaptive elements (*e.g.,* decision criteria to add/drop a dose, etc.), and, if a Bayesian approach, how Bayesian methods are being used for design and/or analysis purposes.

It is important that sponsors wishing to participate in the pilot program identify aspects of the design and analysis that they consider non-disclosable and provide a rationale for withholding the information. Participation in the pilot program, including any agreement on information disclosure, will be voluntary and at the discretion of the sponsor. Sponsors that do not wish to make such disclosures may seek regulatory input through other existing channels.

IV. Paperwork Reduction Act of 1995

This notice refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information resulting from formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0429. The collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014.

Dated: August 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18801 Filed 8–29–18; 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 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2019 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 (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

DATES: This fee is effective October 1, 2018.

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.

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 2019 third-party certification program user fee rate announced in this notice is effective on October 1, 2018, and will remain in effect through September 30, 2019.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2019

In each year, the costs of salary (or personnel compensation) and benefits

[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.

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 2019

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, 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 2019 cost. The FY 2019 FDA-wide average cost for payroll (salaries and benefits) is $157,731; non-payroll—including equipment, supplies, information technology, general and administrative overhead—is $91,008; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,400 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2019 average fully supported cost to $273,139 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 2019 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2019 average fully supported cost of $273,139 per FTE by the average number of supported direct FDA work hours in FY 2017—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 2017

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 2019 ($273,139) by the total number of supported direct work hours available for assignment in FY 2017 (1,160) results in an average fully supported cost of $235 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2019.

B. Adjusting FY 2017 Travel Costs for Inflation To Estimate FY 2019 Travel Costs

To adjust the hourly rate for FY 2019, FDA must estimate the cost of inflation in each year for FY 2018 and FY 2019. 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 2018 inflation rate to be 1.6868 percent; this rate was published in the FY 2018 PDUFA user fee rates notice in the **Federal Register** (82 FR 43244, September 14, 2017). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.6868 percent for FY 2018 and 1.7708 percent for FY 2019, and FDA intends to use this inflation rate to make inflation adjustments for FY 2019 for several of its user fee programs; the derivation of this rate is published in the **Federal Register** in the FY 2019 notice for the PDUFA user fee rates (83 FR 37504 at 37505, August 1, 2018). The compounded inflation rate for FYs 2018 and 2019, therefore, is 1.034875 (or 3.4875 percent) (1 plus 1.6868 percent times 1 plus 1.7708 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $235 already takes into account inflation as the calculation above is based on FY 2019 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2019 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 2017, the Office of Regulatory Affairs spent a total of $2,566,050 on 480 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 $5,346 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $5,346 per trip by 120 hours per trip results in a total and an additional cost of $45 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2017. To adjust $45 for inflationary increases in FY 2018 and FY 2019, FDA must multiply it by the same inflation factor mentioned previously in this document (1.034875 or 3.4875 percent), which results in an estimated cost of $47 (rounded to the nearest dollar) per paid hour in addition to $235 for a total of $282 per paid hour ($235 plus $47) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2019 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Hourly rate without travel	$235
Hourly rate if travel is required	282

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 FY 2019, the only fees that could 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, the annual fee for certification bodies accredited by a recognized accreditation body, and the initial application fee for a certification body seeking direct accreditation from FDA. Table 3 provides an overview of the fees for FY 2019.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Initial Application Fee for Accreditation Body Seeking Recognition	$38,211
Annual Fee for Recognized Accreditation Body	1,775
Annual Fee for Accredited Certification Body	2,219
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	38,211

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, $235/hour, to calculate the portion of the user fee attributable to those activities: $235/hour × (60 hours + 45 hours) = $24,675. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $282/hour, to calculate the portion of the user fee attributable to those activities: $282/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $13,536. 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 $24,675 + $13,536 = $38,211. Therefore, the application fee for accreditation bodies applying for recognition in FY 2019 will be $38,211.

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 × two fully supported FTEs × ((2 travel days × 8 hours)) + (1 day onsite × 8 hours))). 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 $7,520 ($235/hour × (24 hours + 8 hours)) plus $1,354 ($282/hour × 4.8 hours), which is $8,874. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $1,775 for FY 2019.

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 $7,520 ($235/hour × (24 hours + 8 hours)) plus $1,354 ($282/hour × 4.8 hours), which is $8,874. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,219 for FY 2019.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for direct accreditation of certification 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 a certification 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, $235/hour, to calculate the portion of the user fee attributable to those activities: $235/hour × (60 hours + 45 hours) = $24,675. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $282/hour, to calculate the portion of the user fee attributable to those activities: $282/

hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $13,536. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $24,675 + $13,536 = $38,211. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2019 will be $38,211.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2019

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

Although we will not be collecting these other fees in FY 2019, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2019 based on the fully supported FTE hourly rates for FY 2019 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 2019
Renewal application fee for recognized accreditation body ...	$21,350
Renewal application fee for directly accredited certification body	28,999
Annual fee for certification body directly accredited by FDA	21,056

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 21 CFR 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 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18802 Filed 8–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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

The meetings 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: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB Team-based R25 Review (2019/01).

Date: September 24, 2018.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail@nih.gov.*

Dated: August 23, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–18769 Filed 8–29–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is by webcast only and is open to the public. Registration is requested for oral comment and is required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/165*.

DATES:

Meeting: October 9, 2018; 1:00—4:00 p.m. (EDT).

Written Public Comment Submissions: Deadline is October 1, 2018.

Oral Comments: Deadline is October 1, 2018.

Registration to view the webcast: Deadline October 9, 2018.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Webpage: The preliminary agenda, registration, and other meeting materials are at *http://ntp.niehs.nih.gov/go/165*.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3209, Fax: 301–451–5759, Email: *wolfe@niehs.nih.gov*. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.