(i) Additional Standards (Version 3.0, November 14, 2014);

(ii) Nominations Related Standards (Version 3.0, November 14, 2014);

(iii) Flowing Gas Related Standards (Version 3.0, November 14, 2014);

(iv) Invoicing Related Standards (Version 3.0, November 14, 2014);

(v) Quadrant Electronic Delivery Mechanism Related Standards (Version 3.0, November 14, 2014);

(vi) Capacity Release Related Standards (Version 3.0, November 14, 2014);

(vii) Internet Electronic Transport Related Standards (Version 3.0, November 14, 2014);

(viii) Minor Correction/Clarification, Request No. MC15009, approved April 30, 2015; and

(ix) Minor Correction/Clarification, Request No. MC15012, approved May 29, 2015.

* * * * *

■ 8. Section 284.13 is amended by revising paragraph (c)(2)(vi) to read as follows:

§ 284.13 Reporting requirements for interstate pipelines.

* * * * *

(c) * * *

(2) * * *

(vi) The receipt and delivery points and the zones or segments covered by the contract in which the capacity is held, including the location code for each point zone or segment along with a posting on the pipeline's Web site that identifies active and inactive points, the date the point becomes active or inactive, the location of the point, and an identification of the upstream or downstream entity, if any, at that point;

* * * * *

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

List of Revisions in NAESB's WGQ Version 3.0 Business Practice Standards to Its Prior Business Practice Standards

Version 3.0 makes the following changes to the Version 2.1 Standards:

a. Revises Standards 0.3.28, 1.1.3, 1.3.1, 1.3.2 through 1.3.5, 1.3.7 through 1.3.9, 1.3.11, 1.3.13 through 1.3.15, 1.3.22, 1.3.27, 1.3.33, 1.3.41, 1.3.42, 1.3.51, 1.3.80, 2.3.5, 2.3.9, 2.3.14, 2.3.15, 2.3.21, 2.3.26, 2.3.40, 2.3.46, 2.3.47, 3.3.3, 3.3.7, 3.3.14, 3.3.15, 4.3.2, 4.3.3, 4.3.16, 4.3.23, 4.3.35, 4.3.45, 4.3.46, 4.3.54, 4.3.90, 5.3.2, 5.3.32, 5.3.44, 5.3.45, 5.3.48, 5.3.49, 5.3.53, 5.3.54, 5.3.56; Datasets 0.4.1, 0.4.2, 0.4.4, 1.4.1 through 1.4.7, 2.4.1 through 2.4.11, 2.4.17, 2.4.18, 3.4.1 through 3.4.4, 5.4.14 through 5.4.17, 5.4.20 through 5.4.27; Principles 1.1.15, 1.1.18, 2.1.5; and Definitions 1.2.2, 1.2.4, 2.2.5.

b. Adds Standards 0.2.5, 4.3.105, 5.3.73.

c. Deletes Standards 1.3.52, 2.3.49, 3.3.2, 3.3.20, 4.3.4, 4.3.39, 4.3.65, 5.3.27, 10.3.2; Datasets 2.4.12 through 2.4.16; and Principles 1.1.5, 1.1.7, 1.1.9, 1.1.17, 4.1.31.

Version 2.1 made the following changes to the Version 2.0 Standards:

a. Revises Standards 0.3.18, 0.3.20, 0.3.21, 1.3.27, 1.3.55, 1.3.73, 2.3.32, 4.3.23, 4.3.28, 4.3.35, 4.3.52, 4.3.67, 5.3.2, 5.3.4, 5.3.26, 5.3.38, 5.3.70, 5.3.71, 6.5.2, 7.3.16, 7.3.27; Datasets 0.4.1 through 0.4.3, 1.4.1 through 1.4.7, 2.4.1 through 2.4.7, 2.4.9 through 2.4.11, 2.4.13 through 2.4.18, 3.4.1 through 3.4.4, 5.4.14 through 5.4.17, 5.4.20 through 5.4.22, 5.4.24 through 5.4.26; and Definitions 10.2.8, 10.2.30.

b. Adds Standards 0.3.23 through 0.3.29, 1.3.58, 1.3.73, 1.3.81, 2.3.66, 4.3.103, 4.3.104; and Dataset 0.4.4.

c. Deletes Standards 0.3.19, 1.3.47, 1.3.49, 1.3.50, 1.3.54, 1.3.57, 1.3.59 through 1.3.61, 1.3.63, 2.3.33 through 2.3.35, 3.3.1, 4.3.39, 4.3.51, 4.3.56, 4.3.59, 4.3.73, 4.3.74, 4.3.76.

[FR Doc. 2015–17921 Filed 7–23–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0146]

RIN 0910–AG66

User Fee Program To Provide for Accreditation of Third-Party Auditors/Certification Bodies To Conduct Food Safety Audits and To Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this proposed rule to amend the proposed rule, ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (Accreditation of Third-Party Auditors proposed rule) and to propose to establish a reimbursement (user fee) program to assess fees and require reimbursement for the work performed to establish and administer the system for the Accreditation of Third-Party Auditors under the FDA Food Safety Modernization Act (FSMA).

DATES: Submit either electronic or written comments on the proposed rule by October 7, 2015.

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2011–N–0146 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–3708.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Introduction

President Obama signed FSMA (Pub. L. 111–353) into law on January 4, 2011. FSMA enables us to better protect public health by helping to ensure the safety and security of the U.S. food supply. Among other things, FSMA gives us important new tools to better ensure the safety of imported foods, which constitute approximately 15 percent of the U.S. food supply (including approximately 80 percent of our seafood, 50 percent of our fresh fruit, and 20 percent of our vegetables). One of these tools is a new program authorized by section 307 of FSMA for third-party auditing and certification of eligible foreign entities, including registered foreign food facilities that meet our applicable requirements.

B. Accreditation of Third-Party Auditors Proposed Rule

On July 29, 2013, FDA published for public comment in the **Federal Register** a proposed rule, ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (Accreditation of Third-Party Auditors proposed rule) to establish a program that would provide for accreditation of third-party auditors/certification bodies (CBs) to conduct food safety audits of eligible foreign entities (including registered foreign food facilities), and to issue food and facility certifications (third-party accreditation program) (78 FR 45782, July 29, 2013). Under this program, FDA would recognize accreditation bodies (ABs) to accredit CBs, except for limited circumstances in which we may directly accredit CBs. The Accreditation of Third-Party Auditors proposed rule contains eligibility requirements for ABs to qualify for recognition and requirements that ABs participating in the FDA program must meet, once recognized. It also contains eligibility requirements for CBs to qualify for accreditation and requirements that CBs choosing to participate in the FDA program must meet, once accredited. These proposed requirements would ensure the competence and independence of the ABs and CBs participating in the third-party accreditation program. The Accreditation of Third-Party Auditors proposed rule also provides for the monitoring and oversight of participating ABs and CBs, and procedures for removing a CB or an AB from the program. Finally, the Accreditation of Third-Party Auditors proposed rule proposes requirements relating to auditing and certification of eligible foreign entities under the program and for notifying FDA of conditions in an audited facility that could cause or contribute to a serious risk to the public health. More information on the Accreditation of Third-Party Auditors proposed rule can be found on FDA's Web site at *http://www.fda.gov/FSMA.*

The comment period on that proposed rule closed on January 27, 2014, and FDA is currently working on the final rule, which will respond to the comments submitted. Because that rule has not yet been finalized, this user fee proposed rule is based on the Accreditation of Third-Party Auditors proposed rule. When this user fee proposed rule is finalized, this proposed rule will be finalized to align with the Accreditation of Third-Party Auditors final rule.

C. Regulatory Use of Certifications Under FSMA

FDA will use certifications issued by accredited CBs in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk under section 801(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381), and in deciding whether an importer is eligible to participate in the Voluntary Qualified Importer Program (VQIP) under section 806(a) of the FD&C Act (21 U.S.C. 384b(a)) for expedited review and entry of food imports. These and other potential uses of facility and food certifications are discussed in more detail in the **Federal Register** notice announcing the Accreditation of Third-Party Auditors proposed rule (78 FR 45782 at 45785 through 45786). On June 5, 2015, FDA published a notice of availability, ''Draft Guidance for Industry on the Voluntary Qualified Importer Program for Food Importers and Guidelines in Consideration of the Burden of the Voluntary Qualified Importer Program Fee Amounts on Small Business,'' which contains draft criteria and procedures for VQIP participation (80 FR 32136). The VQIP draft guidance can be found on FDA's Web site at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.*

D. Reimbursement (User Fee) Program Under Section 808(c)(8) of the FD&C Act

Section 808(c)(8) of the FD&C Act (21 U.S.C. 384d(c)(8)), established by FSMA, requires FDA to establish by regulation a reimbursement (user fee) program by which we assess fees and require reimbursement for the work we perform to establish and administer the third-party accreditation program under section 808 of the FD&C Act. In this document, we are proposing to establish this user fee program.

II. Legal Authority

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act directs us to establish a new program for accreditation of third-party auditors 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 will recognize ABs to accredit CBs, except for limited circumstances in which we may directly accredit CBs to participate in the third-party accreditation program.

Our authority for this proposed rule is derived in part from section 808(c)(8) of the FD&C Act, which requires us to establish by regulation a reimbursement (user fee) program by which we assess fees and require accredited third-party auditors and audit agents to reimburse us for the work performed to establish and administer the third-party accreditation program under section 808 of the FD&C Act. Accordingly, section 808(c)(8) of the FD&C Act authorizes us to assess fees and require reimbursement from ABs applying for recognition under section 808 of the FD&C Act, CBs applying for direct accreditation under section 808 of the FD&C Act, and recognized ABs and accredited CBs participating in the third-party accreditation program under section 808 of the FD&C Act.

Further, section 701(a) (21 U.S.C. 371(a)) authorizes us to issue regulations for the efficient enforcement of the FD&C Act, including this proposed rule to establish a user fee program for the third-party accreditation program under section 808 of the FD&C Act. Thus, FDA has the authority to issue this proposed rule under sections 808 and 701(a) of the FD&C Act.

III. Description of the Proposed Rule

This proposal includes the following: (1) Who would be subject to a user fee; (2) how user fees would be computed; (3) how FDA would notify the public about annual fee rates; (4) how the user fee would be collected; and (5) what the consequences would be for not paying a user fee.

A. Who would be subject to a user fee?

In determining what user fees to establish, FDA considered the obligations the Agency would have under the Accreditation of Third-Party

Auditors proposed rule and the parties that would be participating in the third-party accreditation program. FDA is likely to perform a significant amount of work reviewing applications for recognition of ABs, even where FDA denies an application (see proposed 21 CFR 1.631). Reviewing renewal applications is also a source of cost to FDA, but that will likely take fewer resources than reviewing original applications for recognition. FDA will also perform a significant amount of work to monitor recognized ABs, which may include onsite assessments of statistically significant numbers of CBs accredited by the recognized AB and onsite audits of eligible entities that such CBs certified (see proposed § 1.633). FDA also will perform a significant amount of work to periodically evaluate the performance of each accredited CB to determine whether it continues to comply with the requirements for participation (see proposed § 1.662).

In certain circumstances, FDA would consider applications from CBs for direct accreditation (see proposed § 1.670). This application review, and any subsequent monitoring and renewal application review, would add to FDA's program costs.

FDA tentatively concludes that there are four main groups to whom costs should be attributed for the purposes of charging fees:

- ABs submitting applications or renewal applications for recognition in the third-party accreditation program;
- Recognized ABs participating in the third-party accreditation program subject to FDA monitoring activities;
- CBs submitting applications or renewal applications for direct accreditation; and
- Accredited CBs (whether accredited by recognized ABs or by FDA through direct accreditation) participating in the third-party accreditation program subject to FDA monitoring activities.

These are the parties identified in proposed § 1.700.

We note that under this proposed rule, FDA's collection of fees through the proposed user fee program would not recover all costs associated with the establishment and administration of the third-party accreditation program under section 808 of the FD&C Act. Other FDA costs include those involving reconsiderations of certain regulatory decisions such as denial of an application for recognition or waiver request (see proposed § 1.691), reviewing waiver requests (see proposed § 1.663), revocation of recognition of ABs or withdrawal of accreditation of CBs (see proposed § 1.634 and § 1.664), and maintaining a Web site listing recognized ABs and accredited CBs (see proposed § 1.690). Additionally, FDA would bear general initial startup costs, mainly due to training new employees and establishing an IT system to support the new third-party accreditation program.

FDA requests comment on whether any of the costs to FDA of the third-party accreditation program that are not accounted for in this proposed rulemaking should be paid for through user fees collected under section 808(c)(8) of the FD&C Act, and if so, to whom should the fees be charged and how should the fees be calculated (*e.g.,* the estimated average cost of processing a waiver request, per hour of FDA's work to determine whether to revoke recognition of an AB or withdraw accreditation of a CB, a flat annual fee to recognized ABs and accredited CBs to cover maintenance of the Web site).

B. What user fees would be established?

Proposed § 1.705 would establish application fees and annual fees. The proposed rule would establish application fees for ABs applying for recognition (proposed § 1.705(a)(1)), recognized ABs submitting renewal applications (proposed § 1.705(a)(2)), CBs applying for direct accreditation (proposed § 1.705(a)(3)), and CBs applying for renewal of direct accreditation (proposed § 1.705(a)(4)). The proposed rule would establish annual fees for recognized ABs (proposed § 1.705(b)(1)), CBs directly accredited by FDA (proposed § 1.705(b)(2)), and CBs accredited by recognized ABs (proposed § 1.705(b)(3)). The application fees would fund our review of the applications. The annual fees would support relevant monitoring activities.

1. Application Fee for ABs Applying for Recognition

Under proposed § 1.705(a)(1), ABs applying for recognition would be subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of ABs. The average cost of the work FDA performs in reviewing and evaluating one application for recognition of an AB would be estimated by: (1) Estimating the number of hours, on average, it would take a full-time federal employee (FTE) to review and evaluate an application for recognition and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

Data collected over a number of years and used consistently in other FDA user fee programs (*e.g.,* under the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act) show that every seven FTEs who perform direct FDA work require three indirect and supporting FTEs. These indirect and supporting FTEs function in budget, facility, human resource, information technology, planning, security, administrative support, legislative liaison, legal counsel, program management, and other essential program areas. On average, two of these indirect and supporting FTEs are located in the Office of Regulatory Affairs (ORA) or the FDA center where the direct work is being conducted, and one of them is located in the Office of the Commissioner.

To calculate an hourly rate of a fully supported FTE (*i.e.,* an hourly rate that takes into account the direct work performed by FTEs and the work performed by indirect and supporting FTEs), FDA would first calculate the average cost of the direct work performed by an FTE per year and multiply that average annual cost of the work performed by an FTE by 1.43 (10 total FTEs divided by 7 direct FTEs). FDA would then divide the fully supported cost of an FTE per year by the average number of supported direct FDA work hours in that year an average FTE is available for work assignment (which excludes, *e.g.,* annual leave, sick leave, and trainings).

For example, in fiscal year (FY) 2013, a recent fiscal year for which data is available, the estimated average cost of an FTE doing Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) related field activities work was $216,543, excluding the cost of inspection travel. Multiplying $216,543 by 1.43 results in an average fully supported cost of $309,657 per FTE, excluding travel costs. Dividing this average fully supported cost of an FTE in FY 2013 by the total number of supported direct work hours available for assignment per FTE (1,600 hours) results in an average fully supported cost of $194 per supported direct work hour in FY 2013, excluding travel costs.

In this example, to estimate the inflation-adjusted average fully supported cost for FY 2015, we use the method set forth in the Prescription Drug User Fee Act provisions of the FD&C Act (21 U.S.C. 379h), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently in setting user fees. FDA previously determined the FY 2014

inflation adjustment factor to be 2.20 percent (78 FR 46980, August 2, 2013), and the inflation adjustment factor for the FY 2015 to be 2.0813 percent (79 FR 44807, August 1, 2014). The inflation adjustment factor for FY 2015 (2.0813 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2014 (2.20 percent), which equals a compounded inflation adjustment factor of 1.043271 (rounded) (1.020813 × 1.0220). After adjusting for inflation, the estimated cost of $192 per supported direct work hour in FY 2013 increases to $202 per supported direct work hour in FY 2015.

For the purposes of providing a sense of the fee we are proposing, in this document we use $202 as the base unit fee in determining the hourly fee rate, prior to including domestic or foreign travel costs as applicable for the activity.

When travel is required, we would have one hourly rate for domestic travel and one hourly rate for foreign travel. To calculate an hourly rate of a fully supported FTE including travel costs, FDA would calculate the additional cost per hour spent on travel (taking into account domestic and foreign travel, as applicable), adjust for inflation, and add this amount to the base unit fee.

For the purposes of providing a sense of the fee we are proposing, in this document we demonstrate calculation of additional costs per hour spent on travel using information from ORA's inspection trips related to FDA's CFSAN and CVM field activities programs. In FY 2013, ORA spent a total of $2,797,656 on 235 foreign inspection trips related to FDA's CFSAN and CVM field activities programs which averaged a total of $11,905 per trip. The average paid hours per trip was 120 hours. Dividing $11,905 per trip by the average paid hours per trip (120 hours) results in a total and an additional cost of $99 per paid hour spent for foreign inspection travel costs in FY 2013. To adjust for inflationary increases in FY 2014 and FY 2015, we multiply $99 by the compounded inflation adjustment factor previously mentioned in this document (1.04327), which results in an adjusted estimated additional cost of $103 per paid hour spent for foreign inspection travel costs in FY 2015. We then add $103 to $202 (base unit fee) to get a total of $305 per paid hour for each direct hour of work requiring foreign inspection travel.

In addition, in FY 2013, ORA spent a total of $4,687,907 on 11,779 domestic regulatory inspection trips related to FDA's CFSAN and CVM activities programs which averaged a total of $398 per inspection. Dividing $398 by the average number of hours per inspection (27.91 hours) results in an additional cost of $14 per hour spent for domestic inspection travel costs in FY 2013. To adjust for inflationary increases in FY 2014 and FY 2015, we multiply $14 by the compounded inflation adjustment factor previously mentioned in this document (1.04327), which results in an adjusted estimated additional cost of $15 per paid hour spent for domestic inspection travel costs in FY 2015. We then add $15 to $202 (base unit fee) to get a total of $217 per paid hour for each direct hour of work requiring domestic inspection travel.

To provide a sense of the fee we are proposing, we calculate an estimated fee using these 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 differ from the Preliminary Regulatory Impact Analysis (PRIA) for the Accreditation of Third-Party Auditors proposed rule (Ref. 1). FDA's thinking may also continue to evolve as we consider the RIA for the Accreditation of Third-Party Auditors final rule. We estimate that it would take, on average, 60 person-hours to review an AB's submitted application, 48 person-hours for an onsite performance evaluation of the applicant AB (including travel and other steps necessary for a fully supported FTE to complete an onsite performance evaluation), and 45 person-hours to prepare a written report documenting the onsite audit.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $202/hour, to estimate the portion of the user fee attributable to those activities: $202/hour × (60 hours + 45 hours) = $21,210. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most ABs are located in foreign countries, so for this estimated fee we use the fully supported FTE hourly rate for work requiring foreign inspection travel, $305/hour, to estimate the portion of the user fee attributable to those activities: $305 × 48 hours (*i.e.,* 2 fully supported FTEs × (2 travel days + 1 day onsite)) = $14,640. The estimated average cost of the work FDA performs in total for reviewing an application for recognition for an AB based on these figures would be $21,210 + $14,640 = $35,850.

We anticipate that the RIA for the Accreditation of Third-Party Auditors final rule, which FDA intends to publish in the fall of 2015, will include updated hourly estimates based on comments received on that rulemaking. In addition, we expect that all of these estimates used to calculate the actual user fees will be informed by FDA's experience with the third-party accreditation program, once that program begins, and the estimates used to calculate the user fees will be updated accordingly. For example, if it takes less time, on average for us to prepare written reports documenting audits, we will use that information to decrease the fee for the following year. As another example, if an AB applying for recognition is located in the United States, domestic travel, not foreign travel will be needed to conduct onsite audits of such applicant ABs. This, too, would lower the average cost to FDA of conducting onsite audits, and, in turn, would contribute to lowering the estimated fee rate.

Note that in the above calculation, we estimate the average number of hours it would take for FDA to conduct relevant activities, and multiply that by the appropriate fully supported FTE hourly rate to generate one flat fee that would be paid by every applicant AB. Alternatively, we could track the number of hours it actually takes FDA staff to conduct relevant activities for each applicant AB, and multiply that number by the fully supported FTE hourly rate calculated by the Agency for the applicable fiscal year. We could then bill each applicant AB separately for the actual application costs attributable to it. Under this approach, we would likely bill after ABs learn whether or not they are accepted into the program.

The proposed approach provides predictability for FDA and for industry, and allows FDA to collect application fees before beginning to perform the work of reviewing the application. However, this alternative approach may create incentives for higher quality applications. Applications that are faster to review, *e.g.,* because they are better prepared, could result in lower fees, while applications that are slower to review, *e.g.,* because they are less organized or necessitate more back-and-forth with the applicant, could result in higher fees. Similarly, applicants that facilitate the onsite audit process and have higher quality operations would likely have shorter onsite audits than other applicants. Still, because FDA would bill applicant ABs after completing application review, applicants whose applications are not accepted may have a lowered incentive to pay the application fee at all. This alternative approach might also raise questions regarding differences in

application review costs that in turn could take additional FDA resources to resolve.

We request comment on the proposed and alternative approaches, particularly whether one approach would create more favorable incentives for quality of the application. For the alternative approach, we also request comment on possible consequences we should impose on ABs for not paying the fee on time. We also request comment on whether we should adopt the alternative approach for a portion of the application review process, *e.g.,* the onsite audit portion, while maintaining a flat fee for other portions, *e.g.,* the paper application review. Such a hybrid approach may be most consistent with how ABs currently charge CBs and provide a balance of predictability and incentives.

2. Application Fee for Recognized ABs Submitting Renewal Applications

Under proposed § 1.705(a)(2), recognized ABs submitting renewal applications would be subject to a renewal application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of ABs. The average cost of the work FDA performs in reviewing and evaluating renewal applications for recognized ABs would be estimated by: (1) Estimating the number of hours it would take an FTE to review and evaluate a renewal application, on average and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

The review and evaluation of renewal applications submitted by recognized ABs, including the onsite assessments, is expected to be less burdensome than the review and evaluation required for initial applications for recognition submitted by ABs. As above, to provide a sense of the fee we are proposing, we calculate an estimated fee here using estimates that represent FDA's current thinking of the number of hours it would take FDA to perform relevant activities and the fully supported FTE hourly rates described above. We estimate that it would take, on average, 40 person-hours to review an AB's renewal application, including review of reports prepared by FDA detailing the FDA performance evaluations, which include FDA's onsite assessments of the AB, review of the AB's annual self-assessment reports submitted to FDA, and review of relevant records maintained by the AB. We estimate that for AB's seeking renewal of recognition, approximately 25 percent of such FDA performance evaluations will be conducted onsite and we expect that it will take 1 fully supported FTE 2 travel days and 2 onsite days to conduct an onsite assessment for a total of 32 hours. Therefore, on average, 8 person-hours (*i.e.,* 25 percent × 1 fully supported FTE × (2 travel days + 2 onsite days)) would be spent on an onsite evaluation of an AB as part of FDA's review of an AB's renewal of recognition application. In addition, 41.25 person-hours would be spent on report preparation. For activities FDA employees are likely to perform at their worksites (*i.e.,* the application review and report preparation), we use the fully supported FTE hourly rate excluding travel, of $202/hour, while for activities FDA employees are likely to need to travel to foreign countries to perform (*i.e.,* the onsite audit), we use the fully supported FTE hourly rate for work requiring inspection travel, of $305/hour. The estimated average cost of the work FDA performs in reviewing and evaluating an application for renewal of recognition for an AB would be $16,413 ($202/hour × (40 hours + 41.25 hours)) plus $2,440 ($305/hour × 8 hours), which is $18,853 total. As previously mentioned, the hourly rate used would be adjusted each year for changes in FDA's costs using an inflation adjustment factor, and we expect the estimates of the number of hours each activity takes will be revised in the RIA of the Accreditation of Third-Party Auditors final rule. More generally, we expect that these estimates will be informed by FDA's experience with the third-party accreditation program, once that program begins.

Similar to the alternative approach we discussed for initial application fees, we are considering billing each applicant for the actual amount of time FDA takes to review and evaluate the particular applicant's renewal application, using the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year. We see the same policy considerations as discussed for the analogous alternative approach for the initial application fees discussed above. We request comment on the proposal and alternative approach for renewal application fees. We also request comment on whether we should adopt the alternative approach for a portion of the renewal application review process, *e.g.,* the onsite audit portion, while maintaining a flat fee for other portions, *e.g.,* the paper application review.

3. Application Fee for CBs Applying for Direct Accreditation

Under proposed § 1.705(a)(3), CBs applying for direct accreditation would be subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation. As with the two proposed application fees for ABs, the average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation of CBs would be estimated by: (1) Estimating the number of hours, on average, it would take an FTE to review and evaluate an application for direct accreditation and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

Again, to provide a sense of the fee we are proposing, we calculate an estimated fee here using estimates that represent FDA's current thinking of the number of hours it would take FDA to perform relevant activities and the fully supported FTE hourly rates described above. For activities FDA employees are likely to perform at their worksites, we use the fully supported FTE hourly rate excluding travel, of $202/hour, while for activities FDA employees are likely to need to travel to foreign countries to perform, we use the fully supported FTE hourly rate for work requiring inspection travel, of $305/hour. We tentatively estimate that it would take, on average, 60 person-hours to review a CB's application for direct accreditation, 48 person-hours to conduct an onsite performance evaluation of the applicant CB, including travel and other steps necessary for a fully supported FTE to complete an onsite performance evaluation, and 45 person-hours to prepare a written report documenting the onsite performance evaluation. Given that FDA employees are likely to conduct application review and report preparation at their worksites, the estimated average cost of the work FDA performs for those activities would be $202/hour × (60 hours + 45 hours) = $21,210. FDA employees will likely travel to foreign countries for the onsite performance evaluations, so the estimated average cost of the work FDA performs for those activities would be $305 × 48 hours (*i.e.,* 2 fully supported FTEs × (2 travel days + 1 day onsite)) = $14,640. Therefore, the estimated average cost of the work FDA performs in reviewing and evaluating an application for direct accreditation for a CB would be $21,210 + $14,640 = $35,850. As previously mentioned, the hourly rate used would be adjusted each year for changes in FDA's costs using an inflation adjustment factor, we expect the estimates of the number of hours each activity takes will be revised in the RIA for the Accreditation of Third-Party

Auditors final rule based on comments to that proposed rulemaking, and we expect our estimates used to calculate actual user fees will be informed by FDA's experience with the third-party accreditation program, once that program begins.

Similar to the alternative approach we discussed for initial application fees for AB recognition, we considered an alternative approach for direct accreditation applications where FDA would bill each applicant for the actual amount of time FDA takes to review and/or evaluate the particular applicant's application, using the fully supported FTE hourly rate calculated by the Agency for the applicable fiscal year. This would likely have the same policy considerations as discussed for the analogous alternative approach discussed in section III.B.1. We request comment on this alternative. We also request comment on whether we should adopt the alternative approach for a portion of the application review process, *e.g.,* the onsite audit portion, while maintaining a flat fee for other portions, *e.g.,* the paper application review.

4. Application Fee for CBs Applying for Renewal of Direct Accreditation

Under proposed § 1.705(a)(4), CBs applying for renewal of direct accreditation would be subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for direct accreditation. The average cost of the work FDA performs in reviewing and evaluating renewal applications for directly accredited CBs would be estimated by: (1) Estimating the number of hours it would take an FTE to review and evaluate a renewal application, on average and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

The review and evaluation of renewal applications submitted by directly accredited CBs, including the onsite assessments, is expected to be less burdensome than the review and evaluation required for initial applications for direct accreditation. As above, to provide a sense of the fee we are proposing, we calculate an estimated fee here using estimates that represent FDA's current thinking of the number of hours it would take FDA to perform relevant activities and the fully supported FTE hourly rates described above. We estimate that it would take, on average, 40 person-hours to review a CB's renewal application, including review of reports prepared by FDA detailing the records review from the FDA performance evaluations, which include FDA's onsite assessments of the CB, review of the CB's annual self-assessment reports submitted to FDA, and review of relevant records maintained by the CB. In addition, we estimate that 32 person-hours (*i.e.,* 1 fully supported FTE × (2 travel days + 2 onsite days)) would be spent on onsite audits and 45 person-hours would be spent on report preparation. For activities FDA employees are likely to perform at their worksites (*i.e.,* the application review and report preparation), we use the fully supported FTE hourly rate excluding travel, of $202/hour, while for activities FDA employees are likely to need to travel to foreign countries to perform (*i.e.,* the onsite audit), we use the fully supported FTE hourly rate for work requiring inspection travel, of $305/hour. The estimated average cost of the work FDA performs in reviewing and evaluating a renewal application for direct accreditation for a CB would be $17,170 ($202/hour × (40 hours + 45 hours)) plus $9,760 ($305/hour × 32 hours), which is $26,930 total.

As previously mentioned, the hourly rate used would be adjusted each year for changes in FDA's costs using an inflation adjustment factor, and we expect the estimates of the number of hours each activity takes will be revised in the RIA for the Accreditation of Third-Party Auditors final rule. More generally, we expect that these estimates will be informed by FDA's experience with the third-party accreditation program, once that program begins.

Similar to the approach we discussed for renewal application fees for AB recognition, we considered an alternative approach to renewal applications for direct accreditation of CBs where FDA would bill each applicant for the actual amount of time FDA takes to review and evaluate the particular applicant's renewal application, using the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year. We see the same policy considerations as discussed for the analogous alternative approach for renewal application fees for ABs discussed above. We request comment on the proposal and alternative approach for these renewal application fees. We also request comment on whether we should adopt the alternative approach for a portion of the renewal application process, *e.g.,* the onsite audit portion, while maintaining a flat fee for other portions, *e.g.,* the paper application review.

5. Annual Fees for Recognized ABs

Proposed § 1.633(a) of the Accreditation of Third-Party Auditors proposed rule states that FDA would periodically evaluate the performance of each recognized AB to determine its compliance with the applicable requirements of that proposed rule. Such evaluation would occur by at least 4 years after the date of recognition for a 5-year term of recognition, or by no later than the mid-term point for recognition granted for less than 5 years. FDA may conduct additional performance evaluations of a recognized AB at any time.

Proposed § 1.705(b)(1) would require recognized ABs to pay an annual fee for the estimated average cost of the work FDA performs to monitor performance of recognized ABs under proposed § 1.633. The average cost of the work FDA performs to monitor performance of a recognized AB would be estimated by: (1) Estimating the number of hours, on average, it would take an FTE to monitor the performance of a recognized AB and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

To calculate the annual fee for each recognized AB, FDA would take the estimated average cost of work FDA performs to monitor performance of a single recognized AB and annualize that over the average term of recognition. For the calculations in this document, we assume an average term of recognition of 5 years. We also assume that FDA would monitor 10 percent of recognized ABs onsite. Terms of recognition may initially be shorter than 5 years during the first few years of the program, but we anticipate that 5 years is likely to be the most common term of recognition as the program continues. We estimate that for one performance evaluation of a recognized AB, it would take, on average (taking into account that not all recognized ABs would be monitored onsite), 24 hours for FDA to conduct records review, 4.8 hours of onsite performance evaluation (*i.e.,* 10 percent × 2 fully supported FTEs × (2 travel days + 1 day onsite)), and 8 hours to prepare a report detailing the records review and onsite performance evaluation. Using the fully supported FTE hourly rates described above, the estimated average cost of the work FDA performs to monitor performance of a single recognized AB would be $6,464 ($202/hour × (24 hours + 8 hours)) plus $1,464 ($305/hour × 4.8 hours), which is $7,928. Annualizing this amount over 5 years would lead to an annual fee of

roughly $1,585 to $1,878, depending on inflation.

The proposed approach is relatively simple and consistent with industry models. However, if a recognized AB leaves the program, either voluntarily or because FDA revokes such AB's recognition, before FDA conducts its monitoring activities, such AB will have paid an annual fee for monitoring that never occurs. If a recognized AB leaves the program after FDA conducts its monitoring activities, but before the term of recognition ends, such AB's annual fees will not fully compensate FDA for monitoring. In addition, if an AB completes its term of recognition in the program but its term of recognition is less than the average term of recognition used to calculate the annual fee, the proposed approach will not fully reimburse FDA for monitoring of that AB.

We request comment on the proposed approach and whether another approach would resolve some of these issues. For example, each AB could pay in full for monitoring in the year that FDA conducts it. FDA could calculate the fee using the same method applied under the proposed approach (*i.e.,* by estimating the number of hours, on average, it would take an FTE to monitor the performance of a recognized AB and multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year). Or, FDA could track the number of hours spent monitoring that particular AB and multiply the fully supported FTE hourly rate by that number of hours. Either way, in general, FDA would receive the money as costs are incurred. However, a large fee for each instance that FDA conducts a performance evaluation that may or may not be charged in any given year may be financially impractical for ABs who would otherwise participate in the program. They may prefer a smaller fee collected annually, rather than a much larger fee due at one time.

Under another alternative, FDA would calculate the annual monitoring fee using the same method applied by the proposed approach, adjusted for inflation, but the fee would be annualized based on the term of recognition for each recognized AB. So if an AB is only recognized for a term of 3 years, the fee would be annualized over 3 years, while an AB that is recognized for a 5-year term would have its fee annualized over 5 years. As a result, an AB with a shorter term of recognition would have a higher annual fee than an AB with a longer term of recognition. Under this alternative, FDA would need to calculate a different annual fee for each possible term length, and FDA would have to ensure that ABs are billed an annual fee consistent with their particular term lengths.

6. Annual Fees for CBs Directly Accredited by FDA

Similarly, proposed § 1.662 of the Accreditation of Third-Party Auditors proposed rule states that FDA would periodically evaluate the performance of each accredited CB to determine whether the accredited CB continues to comply with the requirements and whether there are deficiencies in the performance of the accredited CB that, if not corrected, would warrant withdrawal of its accreditation. FDA would evaluate each directly accredited CB annually. FDA may conduct additional performance evaluations of an accredited CB at any time.

Proposed § 1.705(b)(2) would require directly accredited CBs to pay an annual fee for the estimated average cost of the work FDA performs to monitor directly accredited CBs under proposed § 1.662. The average cost of the work FDA performs to monitor directly accredited CBs would be estimated by: (1) Estimating the number of hours, on average, it would take an FTE to monitor the performance of a directly accredited CB and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year. We estimate that it would take FDA about the same amount of time to conduct records review (24 hours) and to prepare a report detailing the records review and onsite performance evaluation (8 hours) as it would for FDA to perform these activities for a recognized AB. However, we expect to conduct onsite performance evaluations for 100 percent of directly accredited CBs (48 hours per directly accredited CB, including travel and other steps necessary for a fully supported FTE to complete an onsite performance evaluation). In addition, because FDA would be conducting these activities annually for each directly accredited CB, the annual fee for a directly accredited CB would cover the full cost of performance evaluation, approximately $21,104. We request comment on this proposal.

7. Annual Fees for CBs That Are Accredited by a Recognized AB

Proposed § 1.662(a) of the Accreditation of Third-Party Auditors proposed rule states that FDA would evaluate an accredited CB annually evaluated by a recognized accreditation body by not later than 3 years after the date of accreditation for a 4-year term of accreditation, or by no later than the mid-term point for accreditation granted for less than 4 years. FDA may conduct additional performance evaluations of an accredited CB at any time.

Under proposed § 1.705(b)(3), CBs accredited by recognized ABs would be subject to an annual fee for the estimated average cost of the work FDA performs to monitor CBs under proposed § 1.662 that are accredited by a recognized AB. The average cost of the work FDA performs to monitor performance of a CB accredited by a recognized AB would be estimated by: (1) Estimating the number of hours, on average, it would take an FTE to monitor the performance of a CB accredited by a recognized AB and (2) multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year.

To calculate the annual fee for each CB accredited by a recognized AB, FDA would take the estimated average cost of work FDA performs to monitor performance of a single CB accredited by a recognized AB and annualize that over 4 years, assuming that 4 years would be the most common term of accreditation. We estimate that FDA would conduct, on average, the same activities for the same amount of time to monitor CBs accredited by a recognized AB as we would to monitor an AB recognized by FDA, costing approximately $7,928. Annualizing this over 4 years would generate an annual fee of approximately $1,982 to $2,250, depending on inflation.

The proposed provision is analogous to proposed § 1.705(b)(1), which would establish the annual fee for recognized accreditation bodies. As discussed for that provision, the proposed approach is relatively simple and consistent with industry models. But if an accredited CB leaves the program, either voluntarily or because of a decision from its AB or FDA, before FDA conducts its monitoring activities, such CB will have paid an annual fee for monitoring that never occurs. If the CB leaves the program after FDA conducts its monitoring activities, but before the term ends, the CB's annual fees will not fully compensate FDA for monitoring. In addition, if a CB completes its term of accreditation in the program but its term is less than 4 years, the proposed approach will not fully reimburse FDA for monitoring of that CB. We request comment on the proposed approach and any possible alternatives. For example, each CB could pay in full for monitoring in the year that FDA conducts it. FDA could calculate the fee using the same method applied under the proposed approach (*i.e.,* estimating the number of

hours, on average, it would take an FTE to monitor the performance of a CB accredited by a recognized AB and multiplying that estimate by the fully supported FTE hourly rates calculated by the Agency for the applicable fiscal year). Or, FDA could track the number of hours spent monitoring that particular CB and multiply the fully supported FTE hourly rate by that number of hours. Either way, in general, FDA would receive the money as we incur the costs. However, a large fee for each instance that FDA conducts a performance evaluation that may or may not be charged in any given year may be impractical for CBs who would otherwise participate in the program.

Under another alternative, FDA would calculate the annual monitoring fee using the same method applied under the proposed approach, adjusted for inflation, but the fee would be annualized based on the term of accreditation for each CB. So if a CB is only accredited for a term of 2 years, the fee would be annualized over 2 years, while a CB that is accredited for a 4-year term would have its fee annualized over 4 years. As a result, a CB with a shorter term of accreditation would have a higher annual fee than a CB with a longer term of accreditation. FDA would need to calculate a different annual fee for each possible term length, and FDA would have to ensure that CBs are billed an annual fee consistent with their particular term lengths.

8. General Fee Structure and Alternatives

Having an application fee that is separate from the annual monitoring fee would allow FDA to recover costs of work performed to review applications that are ultimately denied because the applicants do not meet the eligibility criteria for the program. In addition, we understand that it is common for ABs to charge an application fee to CBs that apply for accreditation and an annual fee to accredited CBs; our proposed fee structure is consistent with this industry model.

The application fee would likely be significantly higher than the annual monitoring fee, as can be seen by the examples above. We are wary that a high application fee could deter participation in the program. We considered alternative fee structures to address this potential issue. For example, we considered annualizing the cost of application review over the length of the term of recognition (*e.g.,* 5 years) or accreditation (*e.g.,* 4 years), adjusting for inflation. The annualized application fee could be added to the annual fee funding FDA's monitoring costs to generate a single annual fee. Under this alternative, the total fee paid each year by participants in the program would be consistent, adjusting for inflation, over the term of the recognition or accreditation. In an application year, the total fee charged for that year would be lower under this alternative than under the proposed fee structure, but the total fee charged in each subsequent year of the term of recognition or accreditation would be higher than under the proposed fee structure.

We decided against this alternative approach for several reasons. First, if an application is not accepted into the program or an applicant leaves the program before the end of the term of recognition or accreditation, *e.g.,* because FDA revokes an AB's recognition under proposed § 1.634, FDA would not recover the total cost of reviewing the application. Second, while an excessively large application fee could deter participation in a way that would negatively affect program participation, an application fee that is appropriately high, and not annualized over the length of the term of recognition or accreditation, could serve as a barrier for lower quality applicants that may not have sufficient resources to meet the program criteria and carry out the duties of program participants as prescribed in proposed 21 CFR part 1, subpart M.

Third, as described above, the cost to FDA of reviewing a renewal application is expected to be less than the cost to FDA of reviewing an initial application. Therefore, to avoid overcharging ABs and directly accredited CBs in their second or third terms of recognition or direct accreditation, we would need to establish two different annual fees for ABs and two different annual fees for directly accredited CBs; one for those in their first term and one for those who are in a subsequent term, with the latter reduced to account for the lower annualized cost to FDA of reviewing renewal applications. For proper billing, FDA would need to keep track of which term each participant was in as well as the length of the term, adding another layer of complexity. Moreover, FDA would continue to need to establish a separate annual fee that does not include an application surcharge for those CBs that are accredited by ABs. For these reasons, FDA tentatively concludes that the alternative fee structure could potentially reimburse FDA less for work performed and could lead to more lower-quality applications.

We request comment on the proposed fee structure, the alternative discussed here, and any other alternative fee structures that may be simpler or more consistent with industry practice.

C. How will FDA notify the public about the fee schedule?

In general, FDA publishes notices in the **Federal Register** in late summer announcing the fee rates of its user fee programs for the upcoming fiscal year (*e.g.,* Generic Drug User Fee Rates for Fiscal Year 2015 (79 FR 44797, August 1, 2014) and Medical Device User Fee Rates for Fiscal Year 2015 (79 FR 44178, July 30, 2014)). Therefore, under proposed § 1.710, FDA would notify the public of the fee schedule annually prior to the beginning of the fiscal year for which the fees apply. Each new fee schedule would be calculated based on the parameters in this proposed rulemaking, adjusting for improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year and inflation. For example, after experience with the program, FDA is likely to have more accurate estimates of the costs of performing certain activities to carry out the program than it does now. FDA would use these revised estimates to calculate the fee.

D. When must the user fee be submitted?

Under proposed § 1.715(a), ABs applying for recognition and CBs applying for direct accreditation would be required to submit a fee concurrently with submitting their applications or renewal applications. FDA would not review an application until the fee has been submitted (see proposed § 1.725(a)). This approach would require applicants to pay the user fee in a timely manner and would maximize the extent to which work FDA performs to review applications is user fee funded.

Under proposed § 1.715(b), ABs and CBs subject to an annual fee must submit payment within 30 days of receiving billing for the fee. We understand 30 days to be a generally accepted norm in financial transactions and consistent with FDA's practice for its other user fee programs. We request comment on these proposed timeframes.

E. Are user fees refundable?

Under proposed § 1.720, user fees submitted under this subpart would not be refundable. We tentatively conclude that this is the simplest approach and is most likely to encourage higher quality applications and to encourage ABs and CBs to make thoughtful decisions about whether to remain in the program for subsequent years. In addition, we are wary of creating additional costs to administer the program—which would then need to be paid for either through

raising user fees or through appropriated funds—as a result of disagreements between FDA and industry about whether a particular refund would be granted. However, we note that FDA may refund other user fees in a few very limited specific circumstances (see, *e.g.,* User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications; Guidance for Industry and FDA Staff).

We request comment on whether we should consider refund requests under this program and, if so, under what circumstances.

F. What are the consequences of not paying a user fee on time?

Under proposed § 1.725(a), applications would not be considered complete until FDA receives the application fee. In practice, this means that FDA would not review an application until it is informed by the receiving bank that the application fee payment is received. This is consistent with FDA's practices for its other user fee programs with application fees. In addition, this approach would require applicants to pay the user fee in a timely manner and would maximize the extent to which work FDA performs to review applications is user fee funded.

As of the date of this publication, the two receiving banks that FDA uses for user fee payment are the Federal Reserve Bank of New York, for wire transfer, and U.S. Bank, for check payment. For FDA's user fee programs currently in place, these banks generally notify FDA within 24 hours of the receipt of fee payments. We expect the same for the user fee proposed here. FDA intends to publish payment instructions with the addresses for sending payments (by mail, courier, or wire) at the time that the fee payment schedules are published, before the start of the fiscal year. Again, this is consistent with FDA's practice for its other user fee programs.

Under proposed § 1.725(b), a recognized AB that fails to submit its annual user fee within 30 days of the due date would have its recognition suspended. FDA would notify the AB that its recognition is suspended electronically, in English. FDA would notify the public of the suspension on the Web site that lists the recognized ABs (described in previously proposed § 1.690 of the Accreditation of Third-Party Auditors proposed rule). During the period that an AB's recognition is suspended, the AB would not be permitted to accredit additional CBs for participation in FDA's program. However, any CB accredited by such AB prior to the suspension would be unaffected by the suspension, as would any food or facility certification issued by such CB.

Unlike the grounds for revocation listed in proposed § 1.634 of the Accreditation of Third-Party Auditors proposed rule, failure to pay a user fee within 30 days does not necessarily indicate that the AB no longer meets the substantive standards of the program. We tentatively conclude that there should be some significant consequence to the AB for not paying the user fee in a timely manner, but the consequence should be easily reversible once the fee is paid. Therefore, we decided to propose a middle ground, suspension, during which an AB suffers some consequences for not paying the fee, but those consequences are not as significant as the consequences of revocation.

Our proposal to notify the AB electronically in English of suspension is consistent with the provision in proposed § 1.634(c)(1) that FDA would notify the AB electronically in English of revocation. Our proposal to notify the public of the suspension on our Web site is consistent with the provision in proposed § 1.634(f) of the Accreditation of Third-Party Auditors proposed rule that FDA would provide notice on its Web site of the revocation of recognition of an AB. We tentatively conclude that there is no reason for the process of notifying the AB and the public of suspension to differ from the process of notifying the AB and the public of revocation in these respects. We request comment on these tentative conclusions. We also request comment on whether FDA should notify a CB if the recognition of its AB has been suspended.

At some point, an AB that does not pay its annual fee should not be allowed to continue to participate in the program. Therefore, under proposed § 1.725(b)(3), if payment is not received within 90 days of the payment due date, FDA would revoke the AB's recognition under proposed § 1.634(a)(4), and provide notice of such revocation in accordance with the procedures in proposed § 1.634. We are proposing to amend proposed § 1.634(a)(4) by adding a new proposed § 1.634(a)(4)(iii), which would explicitly include failure to pay the annual user fee within 90 days of the payment due date, as specified in § 1.725(b)(3), as a basis for revoking an AB's recognition. We request comment on whether 90 days is an appropriate timeframe and whether all of the consequences of revocation (see proposed § 1.634(d) and (e)) should apply here. Please note that we are no longer soliciting comment on the consequences of revocation generally proposed in § 1.634; we are only requesting comment on the appropriate consequences in the narrow circumstance of failure to pay a user fee.

Under proposed § 1.725(c), an accredited CB that fails to submit its annual user fee within 30 days of the due date would have its accreditation suspended. FDA would notify the CB that its accreditation is suspended electronically, in English. FDA would notify a recognized AB as well, electronically and in English, if the accreditation of one of its CBs is suspended. FDA would notify the public of the suspension on the Web site that lists the recognized ABs and accredited CBs (described in proposed § 1.690). While a CB's accreditation is suspended, it would not be allowed to issue food or facility certifications as part of FDA's third-party accreditation program. However, food or facility certifications issued by a CB prior to the suspension of the CB's accreditation would remain in effect. If payment is not received within 90 days of the payment due date, FDA would withdraw the CB's accreditation under proposed § 1.664(a), and provide notice of such withdrawal in accordance with the procedures in proposed § 1.664. We propose this process to be analogous to the process for suspending recognition of a recognized AB that is delinquent on its fee payment. We are also proposing to amend proposed § 1.664(a) of the Accreditation of Third-Party Auditors proposed rule to add a new proposed § 1.664(a)(4), which would explicitly include failure to pay the annual user fee within 90 days of the payment due date, as specified in § 1.725(c)(3), as a basis for withdrawing a CB's accreditation. We request comment on whether the consequences of a CB failing to pay a user fee by the due date are appropriate. Please note that we are no longer soliciting comment on the consequences of withdrawal of accreditation generally proposed in § 1.664(a); we are only requesting comment on the appropriate consequences in the narrow circumstance of failure to pay a user fee.

G. Possible Exemptions

Under the proposed rule, there would be no exemption or reduced fee for small businesses or entities. Under other (non-food) FDA user fee programs, some exemptions or reductions for small businesses are specified by the authorizing legislation (Refs. 2 and 3). For the user fees proposed here, no such statutory exemption, reduction, or requirement for consideration exists in

section 808 of the FD&C Act. While we are not proposing a small business exemption or reduction here, we believe that some of the proposed approaches and alternative approaches we discussed above could be more amenable to small businesses than others. For example, an annualized fee may be more affordable for a small business than a larger lump sum payment. We seek comment on whether we should account for small businesses in other ways, including whether an exemption or fee reduction would be appropriate. We request that comments that state that FDA should provide an exemption or fee reduction for small businesses state who should be eligible for an exemption or fee reduction; if recommending a fee reduction, how much of a reduction should be granted; and why.

Under the proposed rule, FDA would charge user fees to government entities that are applying to and participating in the program as either an AB or a CB. FDA is requesting comment on the impact of charging a user fee to foreign governments applying to and participating in the program, and whether, for trade or other reasons, we should consider a different approach.

IV. Preliminary Regulatory Impact Analysis

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule demonstrates how user fees will be calculated for different activities FDA conducts under FDA's third-party accreditation program. The proposed rule does not require action by entities affected by the forthcoming Accreditation of Third-Party Auditors final rule; it merely provides additional information so that affected entities can make an informed decision on whether to participate in FDA's third-party accreditation program. FDA plans to analyze the costs and benefits of FDA's third-party accreditation program including imposition of user fees resulting from participating in the third-party accreditation program in the regulatory impact analysis of the Accreditation of Third-Party Auditors final rule. Hence, for the purpose of this rule, the Agency proposes to certify that the resulting final rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

D. Need for This Regulation

The need for the proposed regulation is under the authority of section 808(c)(8) of the FD&C Act, established by FSMA, which requires FDA to establish by regulation a reimbursement (user fee) program by which we assess fees and require reimbursement for the work we perform to establish and administer the third-party accreditation program under section 808 of the FD&C Act.

V. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required (Ref. 4).

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.*

IX. References

The following references have been placed on display in FDA's Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. FDA, ''Preliminary Regulatory Impact Analysis for the proposed rules on Foreign Supplier Verification Programs (Docket No. FDA–2011–N–0143) and Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Docket No. FDA–2011–N–0146) under Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520),'' (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM363286.pdf*), 2013. Accessed and printed on June 23, 2015.
2. FDA, ''FY 2015 Medical Device User Fee Small Business Qualification and

Certification: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments,'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM314389.pdf*), August 1, 2014. Accessed and printed on June 23, 2015.
3. FDA, ''Guidance for Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products,'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079298.pdf*), September 2011. Accessed and printed on June 23, 2015.
4. FDA, ''Memorandum: Proposed Rule: User Fees for FDA's Third Party Accreditation Program for Food and Feed,'' March 3, 2015.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1, as proposed to be amended on July 29, 2013 (78 FR 45782), be further amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350k, 352, 355, 360b, 362, 371, 374, 381, 382, 384a, 384b, 384d, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. In § 1.634, add paragraph (a)(4)(iii) to read as follows:

§ 1.634 When will FDA revoke recognition?

* * * * *

(iii) Failure to pay the annual user fee within 90 days of the payment due date, as specified in § 1.725(b)(3).

* * * * *

■ 3. In § 1.664, add paragraph (a)(4) to read as follows:

§ 1.664 When can FDA withdraw accreditation?

* * * * *

■ (4) If payment of the auditor/certification body's annual fee is not received within 90 days of the payment due date, as specified in § 1.725(c)(3).

* * * * *

■ 4. In subpart M, add §§ 1.700 through 1.725 to read as follows:

Sec.

§ 1.700 Who is subject to a user fee under this subpart?

(a) Accreditation bodies submitting applications or renewal applications for recognition in the third-party accreditation program;

(b) Recognized accreditation bodies participating in the third-party accreditation program;

(c) Auditors/certification bodies submitting applications or renewal applications for direct accreditation; and

(d) Accredited auditors/certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party accreditation program.

§ 1.705 What user fees are established under this subpart?

(a) The following application fees:

(1) Accreditation bodies applying for recognition are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

(2) Recognized accreditation bodies submitting renewal applications are subject to a renewal application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

(3) Auditors/certification bodies applying for direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation.

(4) Accredited auditors/certification bodies applying for renewal of direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for direct accreditation.

(b) The following annual fees:

(1) Recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor performance of recognized accreditation bodies under § 1.633.

(2) Auditors/certification bodies directly accredited by FDA are subject to an annual fee for the estimated average cost of the work FDA performs to monitor directly accredited auditors/certification bodies under § 1.662.

(3) Auditors/certification bodies accredited by recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor auditors/certification bodies that are accredited by a recognized accreditation body under § 1.662.

§ 1.710 How will FDA notify the public about the fee schedule?

FDA will notify the public of the fee schedule annually prior to the beginning of the fiscal year for which the fees apply. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

§ 1.715 When must a user fee required by this subpart be submitted?

(a) Accreditation bodies applying for recognition and auditors/certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and auditors/certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

§ 1.720 Are user fees under this subpart refundable?

No. User fees submitted under this subpart are not refundable.

§ 1.725 What are the consequences of not paying a user fee under this subpart on time?

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of § 1.631(a) until the date that FDA receives the application fee. An application for direct accreditation or for renewal of direct accreditation will not be considered complete for the purposes of § 1.671(a) until FDA receives the application fee.

(b) A recognized accreditation body that fails to submit its annual user fee within 30 days of the due date will have its recognition suspended.

(1) FDA will notify the accreditation body electronically that its recognition is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While an accreditation body's recognition is suspended, the accreditation body will not be able to accredit additional auditors/certification bodies. The accreditation of auditors/certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications

issued by such auditors/certification bodies, would remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will revoke the accreditation body's recognition under § 1.634(a)(4)(iii), and provide notice of such revocation in accordance with § 1.634.

(c) An accredited auditor/certification body that fails to submit its annual fee within 30 days of the due date will have its accreditation suspended.

(1) FDA will notify the auditor/certification body that its accreditation is suspended, electronically and in English. FDA will notify a recognized accreditation body, electronically and in English, if the accreditation of one if its auditors/certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While an auditor/certification body's accreditation is suspended, the auditor/certification body will not be able to issue food or facility certifications. A food or facility certification issued by an auditor/certification body prior to the suspension of the auditor/certification body accreditation will remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will withdraw the auditor/certification body's accreditation under § 1.664(a)(4), and provide notice of such withdrawal in accordance with § 1.664.

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18141 Filed 7–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2015–0320]

RIN 1625–AA00

Safety Zone; Titan SPAR, Mississippi Canyon 941, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a safety zone around the Titan SPAR system, located in Mississippi Canyon Block 941 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility will significantly reduce the threat of allisions, collisions, security breaches, oil spills, releases of natural gas, and thereby protect the safety of life, property, and the environment.

DATES: Comments and related material must be received by the Coast Guard on or before August 24, 2015.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0320 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Rusty Wright, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2138, *rusty.h.wright@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
SPAR A large diameter, vertical cylinder supporting a deck
USCG United States Coast Guard

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number [USCG–2015–0320] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2015–0320) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of