shared ownership of IP rights with research entities difficult and in some cases impossible. Specifically, a majority of university policies typically reflect a requirement for the university to own any IP created under research projects they conduct, even if the project is funded with outside money. These university policies have made it difficult for the Board to contract with universities for research due to the IP ownership requirements contained in the Order.

As a result, USDA is amending § 1250.542 of the Regulations to incorporate language utilized by research and promotion boards created under the 1996 Act that would provide the Board with flexibility in negotiating over the ownership of IP rights. The research and promotion boards created under the 1996 Act have utilized this language to negotiate ownership rights over IP to effectively expend assessment funds to promote agricultural commodities.

Summary of Comments

AMS published the notice of proposed rulemaking in the **Federal Register** on March 16, 2016 [81 FR 14021]. The comment period ended on May 16, 2016. AMS received one timely comment from a university. The commenter expressed that it is the policy of the university to retain ownership of intellectual property generated through research funded by external parties and encouraged AMS to adopt policies and rules that closely follow the standard approaches articulated in Federal Government grants. However, the egg research and promotion program is not a grant program and is not subject to Federal grants policy. In addition, the Board does not receive Federal funding. All funds are received from egg producers required under the enabling legislation to pay an assessment to the Board to fund programs designed to increase demand for eggs and egg products both domestically and internationally. Accordingly, AMS did not incorporate the Federal grants policy into the final rule.

List of Subjects in 7 CFR Part 1250

Administrative practice and procedure, Advertising, Agricultural research, Eggs and egg products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1250 is amended as follows:

PART 1250—EGG RESEARCH AND PROMOTION

■ 1. The authority citation of 7 CFR part 1250 continues to read as follows:

Authority: 7 U.S.C. 2701–2718; 7 U.S.C. 7401.

■ 2. Revise § 1250.542 to read as follows:

§ 1250.542 Patents, Copyrights, Inventions, Trademarks, Information, Publications, and Product Formulations.

(a) Except as provided in paragraph (b) of this section, any patents, copyrights, inventions, trademarks, information, publications, or product formulations developed through the use of funds collected by the Board under the provisions of this subpart shall be the property of the U.S. Government, as represented by the Board, and shall, along with any rents, royalties, residual payments, or other income from the rental, sales, leasing, franchising, or other uses of such patents, copyrights, inventions, trademarks, information, publications, or product formulations, inure to the benefit of the Board; shall be considered income subject to the same fiscal, budget, and audit controls as other funds of the Board; and may be licensed subject to approval by the Secretary. Upon termination of this subpart, § 1250.358 shall apply to determine disposition of all such property.

(b) Should patents, copyrights, inventions, trademarks, information, publications, or product formulations be developed through the use of funds collected by the Board under this subpart and funds contributed by another organization or person, the ownership and related rights to such patents, copyrights, inventions, trademarks, information, publications, or product formulations shall be determined by an agreement between the Board and the party contributing funds towards the development of such patents, copyrights, inventions, trademarks, information, publications, or product formulations in a manner consistent with paragraph (a) of this section.

Dated: December 8, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–29988 Filed 12–13–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0146]

RIN 0910–AH23

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations on accreditation of third-party certification bodies to conduct food safety audits and to issue certifications to provide for a reimbursement (user fee) program to assess fees for the work FDA performs to establish and administer the third-party certification program under the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3212, Silver Spring, MD 20993–0002, 301–796–7599.

SUPPLEMENTARY INFORMATION:

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I. Background

A. FDA Food Safety Modernization Act and Section 808 of the Federal Food, Drug, and Cosmetics Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities and international collaborations with foreign regulatory counterparts.

FSMA added section 808 to the FD&C Act (21 U.S.C. 384d), which directs FDA to establish a program for accreditation of third-party certification bodies [1] to conduct food safety audits and to certify that eligible foreign entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA food safety requirements. FSMA specifies two uses for the food and facility certifications issued by accredited third-party certification bodies under this program. First, facility certifications will be used by importers that want to establish eligibility for the Voluntary Qualified Importer Program (VQIP) under section 806 of the FD&C Act (21 U.S.C. 384b). VQIP offers participating importers expedited review and entry of food that is part of VQIP. Second, section 801(q) of the FD&C Act (21 U.S.C. 381(q)) gives FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act. The authority to mandate import certification for food, based on risk, is one of the tools we can use to help prevent potentially harmful food from reaching U.S. consumers.

B. Third-Party Certification Regulation

On November 27, 2015, FDA published in the **Federal Register** a final rule, ''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (third-party certification regulation), to implement section 808 of the FD&C Act on accreditation of third-party certification bodies to conduct food safety audits of eligible foreign entities (including registered foreign food facilities) and to issue certifications of foreign food facilities and foods for humans and animals for purposes of sections 801(q) and 806 of the FD&C Act (80 FR 74570). The third-party certification regulation establishes the framework, procedures, and requirements for accreditation bodies and third-party certification bodies for purposes of the program under section 808 of the FD&C Act. It sets requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that accreditation bodies must demonstrate that they have to qualify for recognition. Accreditation bodies also must demonstrate capability to meet the applicable program requirements of the third-party certification regulation that would apply upon recognition. Additionally, the regulation establishes requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that third-party certification bodies must demonstrate that they have to qualify for accreditation. Third-party certification bodies also must demonstrate capability to meet the applicable program requirements of the third-party certification regulation that would apply upon accreditation.

Under FSMA section 307 (21 U.S.C. 384d), accredited third-party certification bodies must perform unannounced facility audits conducted under the third-party certification program, notify FDA upon discovering a condition that could cause or contribute to a serious risk to the public health, and submit to FDA reports of regulatory audits conducted for certification purposes. The regulation includes stringent requirements to prevent conflicts of interest from influencing the decisions of recognized accreditation bodies and accredited third-party certification bodies.

C. Purpose of This Rulemaking

This rulemaking implements section 808(c)(8) of the FD&C Act to establish a reimbursement (user fee) program to assess fees and require reimbursement for the work we perform to establish and administer the third-party certification program. In this document, we amend the third-party certification regulation (21 CFR part 1, subpart M) to provide for the assessment of user fees on accreditation bodies that include application fees for accreditation bodies seeking FDA recognition and annual monitoring fees, once recognized. We also provide for the assessment of user fees that include application fees for only those third-party certification bodies that seek FDA direct accreditation and annual monitoring fees for any third-party certification body participating in FDA's program, whether accredited directly by FDA or by an FDA-recognized accreditation body.

D. The Proposed Rule

FDA published a proposed rule titled ''User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and To Issue Certifications'' on July 24, 2015 (80 FR 43987). The proposed rule on the third-party certification program user fees 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. The comment period closed on October 7, 2015.

E. Public Comments

FDA received comments from accreditation bodies, certification bodies, foreign governments, industry associations, consumer groups, and members of industry. In the remainder of this document, we describe the comments that are within the scope of this rulemaking, respond to them, and explain any revisions we made from the proposed rule.

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 certification bodies conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food

[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 final rule uses the term ''third-party certification body'' rather than the term ''third-party auditor/certification body'' that was used in the proposed rule.

facilities) that meet the applicable food safety requirements. Under this provision, we will recognize accreditation bodies to accredit third-party certification bodies, except for limited circumstances in which we may directly accredit third-party certification bodies to participate in the third-party certification program.

Our authority for this 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 certification bodies and audit agents to reimburse us for the work performed to establish and administer the third-party certification program under section 808. Accordingly, section 808(c)(8) of the FD&C Act authorizes us to assess fees and require reimbursement from accreditation bodies applying for recognition under section 808, third-party certification bodies applying for direct accreditation under section 808, and recognized accreditation bodies and accredited third-party certification bodies participating in the third-party certification program under section 808.

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

III. Comments on Who Is Subject to a User Fee Under This Subpart (§ 1.700)

We proposed in § 1.700 that four main groups would be subject to a user fee under the regulation: (a) Accreditation bodies submitting applications, including renewal applications, for recognition in the third-party certification program; (b) recognized accreditation bodies participating in the third-party certification program; (c) third-party certification bodies submitting applications, including renewal applications, for direct accreditation; and (d) accredited third-party certification bodies participating in the third-party certification program. On our own initiative, and consistent with the third-party certification regulation, in this final rule we are using the term ''third-party certification body'' rather than the term ''third-party auditor/certification body'' that was used in the proposed rule.

Additionally, in the proposed rule we noted that the proposed user fee program would not recover all costs associated with the establishment and administration of the third-party certification program, such as the costs of any work by FDA in reviewing requests for reconsideration and waivers, revoking recognition of accreditation bodies, or withdrawing accreditation of third-party certification bodies, where necessary (80 FR 43987 at 43989). We also identified some of FDA's initial startup costs that would not be fully recouped, such as for some previously incurred costs for training employees and developing the third-party certification program IT portal that will accept applications for recognition and for direct accreditation and submissions from recognized accreditation bodies and accredited third-party certification bodies. We solicited comment on whether the costs for activities other than application processing and monitoring (*i.e.,* unaccounted for costs) should be paid for through user fees and if so, to whom should the fees be charged and how should the fees be calculated.

FDA received no adverse comments specific to our proposal to assess user fees on accreditation bodies submitting applications to FDA for recognition, third-party certification bodies submitting applications to FDA for direct accreditation, and recognized accreditation bodies and accredited third-party certification bodies participating in the program.

(Comment 1) In response to our request for comments on unaccounted for costs, some comments suggest that these costs should be recouped through fees paid by recognized accreditation bodies and accredited third-party certification bodies. Some comments opine that accreditation bodies should be responsible for paying any additional user fees related to maintenance of a database for recognized accreditation bodies and accredited certification bodies for the third-party certification bodies they accredit under the FDA program, as some accreditation bodies already invoice the certification bodies for these services. The comments do not address the feasibility of calculating or collecting such fees.

(Response 1) We decline the suggestion to assess additional fees on recognized accreditation bodies and accredited third-party certification bodies. Section 808(c)(8) of the FD&C Act requires us to establish a user fee program that assesses fees to reimburse FDA for the work in establishing and administering the third-party certification program. The statute further provides that FDA must not generate surplus revenue from the user fee program.

In implementing this provision, FDA is estimating the average costs of work it will perform to establish the program by recognizing accreditation bodies under section 808(b)(1) of the FD&C Act to accredit third-party certification bodies to participate in the third-party certification program (and, in limited circumstances under section 808(b)(1)(A)(ii), to directly accredit third-party certification bodies). Additionally, FDA is estimating the average costs of work it will perform in administering the program through monitoring, under section 808(f) of the FD&C Act, of recognized accreditation bodies and accredited third-party certification bodies, including through onsite audits of eligible entities issued certifications. The user fee program gives us flexibility to adjust estimates of the number of hours various activities will require and the hourly rates for performing the work, which will allow us to ensure that we are not generating a surplus.

We do not think it would be feasible at this time to accurately calculate and collect fees for all additional unaccounted for costs. For example, we do not have information on the number of, if any, waiver requests, revocations, and withdrawals we may get. It would be difficult to project a fee based on this limited information and assess it on accreditation bodies and certification bodies.

Additionally, it would be difficult to fairly distribute a fee for startup costs to future participants. We also do not want to disincentivize early participants from applying by imposing higher fees early on to cover initial program start-up costs related to setting up an IT portal or training employees.

(Comment 2) Some comments agree that both accreditation bodies and certification bodies are the appropriate parties to be assessed fees.

(Response 2) We agree and are finalizing § 1.700 as proposed, with conforming editorial changes as discussed previously.

IV. Comments on What User Fees Are Established Under This Subpart (§ 1.705)

Under the proposed user fee program we would assess user fees for two types of activities: (1) Application review; and (2) performance monitoring.

We proposed in § 1.705(a) that application fees would be assessed on accreditation bodies seeking FDA recognition or renewal of recognition and on third-party certification bodies seeking direct accreditation (and renewal of direct accreditation) by FDA. The application fees would be based on

the estimated average cost of the work FDA performs in reviewing and evaluating each type of application. To calculate the estimated average cost of reviewing applications for recognition and for direct accreditation, we estimated the average number of hours it would take for FDA to conduct the relevant activities and multiplied that by the appropriate fully supported full time equivalent (FTE) hourly rate to derive flat rates for reviews of each of the following types of applications: (1) Initial applications for recognition of accreditation bodies; (2) applications for renewal of recognition; (3) initial applications for direct accreditation of third-party certification bodies; and (4) applications for renewal of direct accreditation.

We requested comment on an alternative approach for calculating application fees by tracking the actual number of hours it takes FDA staff to conduct relevant activities for each applicant, multiply that number by the fully supported FTE hourly rate calculated by the Agency for the applicable fiscal year, and then bill each applicant separately for the actual application costs attributable to it.

We requested comment on whether the proposed or alternative approach would create more favorable incentives for quality of the application. For the alternative approach, we specifically requested comment on possible consequences we should impose for not paying the application fee on time, since with this approach we would likely not be able to bill the applicant until after it learns whether it is accepted into the program. We also requested 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).

Under proposed § 1.705(b), recognized accreditation bodies would be 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. Under § 1.633(a), FDA will periodically evaluate the performance of each recognized accreditation body 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 a term of recognition of less than 5 years. We would 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 for the applicable fiscal year. To calculate the annual fee for each recognized accreditation body, FDA would take the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualize that over the average term of recognition (*e.g.,* 5 years).

The proposed user fee program also would assess fees for the estimated average cost for the work FDA will perform in monitoring the performance of third-party certification bodies accredited by FDA-recognized accreditation bodies, and third-party certification bodies directly accredited by FDA. We estimated the average number of hours it would take for FDA to conduct relevant monitoring activities for each, including a representative sample of onsite audits, and multiplied that by the appropriate fully supported FTE hourly rate. We further proposed that these monitoring fees would be annualized over the length of the term of accreditation (*e.g.,* 4 years).

In developing the proposed rule, we also considered annualizing the cost of application review over the length of the term of recognition (*e.g.,* 5 years) or direct accreditation (*e.g.,* 4 years), adjusting for inflation, and adding this to the annual fee funding FDA's monitoring activities. We tentatively concluded in the proposed rule that this alternative fee structure could potentially reimburse FDA less for work performed and could also lead to more lower-quality applications. We requested comment on the proposed annual fee structure, the alternative annual fee structure described in the proposed rule, and any other alternative fee structures that may be simpler or more consistent with industry practice.

(Comment 3) Some comments propose a different approach whereby FDA would establish one application fee for accreditation bodies which encompasses all of the anticipated costs (and specify what those costs are for each part of the assessment process) and then provide for reimbursements upon completion of the process for costs that were not incurred. The comment suggests that this would create incentives for an accreditation body to have a well-documented and implemented accreditation process and to cooperate fully to facilitate the assessment by FDA. Some comments request that we simplify the user fee program, but do not provide suggestions as to what changes would simplify the program.

(Response 3) We decline to accept the alternative approach, for a couple of reasons: First, we expect that the costs for reviewing applications for recognition will not vary significantly among the accreditation bodies, because we expect most, if not all, of the accreditation bodies that seek recognition under the third-party certification program will use documentation of their conformance with International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) 17011:2004, Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2004) (Ref. 1) to support their applications. This will allow FDA to use a common approach in reviewing accreditation body applications and, as a result, will help keep the costs of application review fairly steady and predictable across applications, making the alternative approach unnecessary.

Second, in authorizing FDA to assess fees and recover the costs associated with establishing and administering the third-party certification program, section 808(c)(8) of the FD&C Act helps to ensure that FDA has a stable funding base for the program. The alternative approach would limit our ability to develop and execute program plans or to sustain program services and operations at predictable levels. Third, the alternative approach would be administratively burdensome and would generate new administrative costs associated with providing a series of reimbursements at various steps in the processing of a single application. The net result would be to drive up program costs, which would increase user fee rates.

With respect to the comments requesting that we simplify the user fee program, we decline to adopt a different approach absent any feasible suggestions as to what changes would simplify the program. Further, the approach we have established in this final rule limits the types of fees that are assessed to just application fees and annual fees. Our approach is designed to be simple. It is similar to the fee structure used by several accreditation bodies, who charge third-party certification bodies initial fees and annual fees (Ref. 2).

(Comment 4) Some comments recommend that the recognized accreditation bodies and accredited third-party certification bodies pay for monitoring as it is conducted. The comments note that for a recognized accreditation body this would assume that the level of monitoring would be related to its performance, the number of third-party certification bodies it accredited, and their performance. The comments further assert that the level of

monitoring FDA performs for an accredited third-party certification body would be based on its performance, the number of clients that the accredited third-party certification body has certified, and their performance.

(Response 4) We disagree. As explained in Response 3, the user fee program is designed to provide FDA a stable funding base for operating the program. The proposed approach of paying for monitoring as it is conducted would not offer stability and predictability for FDA or for recognized accreditation bodies and accredited certification bodies. In addition, we note that the number of certification bodies the accreditation body has accredited under the program is only one of several factors we may consider in developing our plans for monitoring a recognized accreditation body. Under § 1.633(b) we may elect to observe a representative sample of certification bodies the recognized accreditation body accredited when conducting an assessment of its accreditation body. The size of the representative sample may depend on a number of factors including the scope of accreditation of the certification bodies accredited by the accreditation body, how many years the accreditation body has been in the program, how many prior assessments of the accreditation body we have performed, and the length of time since any prior assessments, in addition to the number of third-party certification bodies it has accredited. Similarly, when monitoring an accredited third-party certification body under § 1.662 we may elect to observe regulatory audits the accredited third-party certification body performs, and we will base our decision regarding how many onsite observations to conduct based on a number of factors such as how many years the certification body has been in the program, how many prior assessments we have performed and the length of time since the last assessment, in addition to the number of eligible entities the certification body certifies. Further, we do not anticipate that the cost of monitoring will vary greatly among accreditation bodies or among certification bodies. We note that the third-party certification regulations allow recognized accreditation bodies and accredited third-party certification bodies to use documentation of their conformance with applicable ISO/IEC standards, which we expect will allow FDA greater consistency and efficiency in conducting monitoring activities.

(Comment 5) Some comments recommend that FDA establish application and monitoring fees that relate to costs for the services by FDA and that these be paid in the years the services are provided, rather than annualized fees.

(Response 5) We decline the recommendation to change the fee structure from an estimated average cost to a pay-as-you go system. As explained in Response 3, the estimated average cost approach to the fee assessments provides prospective applicants, participants, and FDA predictability that allows for proper planning and budgeting. The monitoring fee is structured to annualize the payments for the total cost of monitoring recognized accreditation bodies and accredited third-party certification bodies, which provides predictability that helps accreditation bodies, third-party certification bodies, and FDA in planning and budgeting. Additionally, the recommended approach would be administratively burdensome and would generate new administrative costs associated with billing for various monitoring activities across the duration of each accreditation body's recognition and each third-party certification body's accreditation. The net result would be to drive up program costs, which would increase user fee rates. Further, we do not think that system suggested in the comment would be particularly beneficial to participants, since we do not anticipate that there will be much variability in the cost of monitoring services. We note that the user fee program is flexible. The fee rates are adjusted annually, as appropriate, so estimates regarding the cost of monitoring will be refined regularly.

V. Comments on How Will FDA Notify the Public About the Fee Schedule (§ 1.710)

We proposed to notify the public of the fee schedule annually prior to the beginning of the fiscal year for which the fees apply. We further proposed that each new fee schedule would be calculated based on the parameters in the proposed rulemaking and adjusted for improvements in the cost to FDA of performing relevant work for the upcoming year and inflation. At our own initiative, we revised proposed § 1.710 to create an exception to the requirement to provide notice prior to the start of the fiscal year for which the fees apply, in order to provide notice of the FSMA Third-Party Certification Program User Fee Rate for FY 2017, which is published elsewhere in this issue of the **Federal Register**. The notice for fiscal year (FY) 2017 sets the application fee rate for accreditation bodies applying for recognition. The rate will be effective on January 13, 2017, and will allow accreditation bodies to apply to participate in the third-party certification program prior to the start of FY 2018.

(Comment 6) Several comments address user fee costs. Some raise general concerns that user fees may serve as a disincentive to program participation by accreditation bodies and third-party certification bodies, especially during the initial phase of the program. One such comment characterized the estimated user fee amounts as ''somewhat high.'' Other comments noted the proposed fees were reasonably aligned with the third-party certification body fees assessed under the Global Food Safety Initiative (GFSI). (By way of background, a group of international retailers established GFSI in 2000 with the goal of reducing the need for duplicative third-party audits by benchmarking private food safety schemes against a harmonized set of criteria for food safety and management systems.)

(Response 6) With respect to the comments suggesting that user fees may serve as a disincentive to program participation by accreditation bodies and third-party certification bodies, we note that the FD&C Act requires us to establish by regulation a 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. With respect to comments suggesting that the estimated user fee rates in the proposed rule may be too high, we disagree. We have designed the proposed user fee program to be flexible—that is, we expect that the estimates of the number of FTE hours used to calculate the actual user fees for accreditation bodies and third-party certification bodies will be informed by FDA's experience with the program each year (80 FR 43987 at 43990). Once the program begins we will update the estimates used to calculate the annual user fees as appropriate on a yearly basis. For example, if we determine it takes less time, on average, for us to prepare written reports documenting our onsite assessments of recognized accreditation bodies, we will use that information to decrease the fee for the following year.

(Comment 7) Some comments contend that the third-party certification program user fees and the indirect costs of complying with the third-party certification regulation will be passed down to food firms, negatively impacting the number of foreign food facilities that will become certified under the program and resulting in

further proliferation of the multitude of audit schemes.

(Response 7) The comments did not provide any data to support assertions regarding the indirect impacts of the proposed rule on dynamics of markets for third-party audits of foreign food facilities and private audit standards. Absent data or other information to support changes to the proposal, we are not modifying § 1.710 in anticipation of possible market forces on third-party audits and private audit schemes.

(Comment 8) Some comments discourage FDA from annually reviewing its fees for at least one 5-year cycle because fluctuations in the fees could significantly disadvantage accreditation bodies or third-party certification bodies that enter the program early.

(Response 8) We disagree with the suggestion to review fees less frequently than annually. Section 808(c)(8) of the FD&C Act provides that FDA shall not generate a surplus from the user fee program. By annually reviewing (and, if appropriate, adjusting) the fee rates, we can help ensure that we do not generate a surplus.

VI. Comments on When a User Fee Required by This Subpart Must Be Submitted (§ 1.715)

We proposed to require accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation to submit their application fees concurrently with submitting an application, including a renewal application. We also proposed that recognized accreditation bodies and accredited third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

(Comment 9) Some comments support having initial and renewal application fees paid upon application. The comments also assert that FDA should not review any applications until payment has been received.

(Response 9) We agree and are maintaining these requirements in the final rule.

VII. Comments on Whether User Fees Under This Subpart Are Refundable (§ 1.720)

Under proposed § 1.720, user fees would not be refundable. We requested comment on whether we should consider refund requests under this program, and if so, under what circumstances.

At our own initiative, we are revising § 1.720 to clarify that we will not refund any fees accompanying completed applications or annual user fees. However, user fees submitted with applications will not be considered to have been accepted until the application is complete and ready for FDA review. Applications for recognition and direct accreditation will not be substantively reviewed by FDA until a completed submission with all of the required elements is received in accordance with §§ 1.631(a) and 1.671(a).

(Comment 10) Some comments recommend that FDA charge a flat fee for the application fees, but provide for refunds of portions of the initial application and renewal application fees if we do not incur all the anticipated costs during review of the application. This would ensure that FDA has adequate funding to cover costs up front without overburdening accreditation bodies or third-party certification bodies financially if we don't end up using all the costs.

(Response 10) We disagree with providing a refund as described by the comment. As noted in Response 3, we anticipate that costs for reviewing applications for recognition will not vary significantly among the accreditation bodies. In addition, it would be administratively burdensome to track and process refunds at various stages of the application process for each applicant and would potentially drive up the costs of the program.

VIII. Comments on the Consequences of Not Paying a User Fee Under This Subpart on Time (§ 1.725)

In proposed § 1.725(a), we proposed that applications would not be considered complete until FDA receives the application fee. In proposed § 1.725(b), we proposed that a recognized accreditation body that fails to submit its annual user fee within 30 days of the due date would have its recognition suspended. We proposed that FDA would notify the accreditation body electronically that its recognition is suspended and would notify the public of the suspension on the Web site that lists the recognized accreditation bodies. We requested comment on our tentative conclusion that there is no reason for the process of notifying the accreditation body and the public of suspension to differ from the process of notifying the accreditation body and the public of revocation in these respects. We also requested comment on whether FDA should notify a certification body if the recognition of its accreditation body has been suspended.

We further proposed that while an accreditation body's recognition is suspended, it will not be able to accredit additional third-party certification bodies. However, we proposed that any certification bodies accredited by such accreditation body prior to the suspension would be unaffected by the suspension, as would any food or facility certification issued by such certification body. We also proposed that if payment is not received within 90 days of the payment due date, FDA would revoke the accreditation body's recognition and provide notice of such revocation in accordance with the procedures in § 1.634. Accordingly, we proposed to amend § 1.634(a)(4) by adding 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 a basis for revoking an accreditation body's recognition.

In proposed § 1.725(c), we proposed that an accredited third-party certification body that fails to submit its annual user fee within 30 days of the due date would have its accreditation suspended. We proposed that FDA would electronically notify the certification body that its accreditation is suspended and would notify the public of the suspension on the Web site that lists the recognized accreditation bodies and accredited third-party certification bodies. While a certification body's accreditation is suspended, it would not be allowed to issue food or facility certifications as part of FDA's third-party certification program. However, we proposed that food or facility certifications issued by a certification body prior to the suspension of its accreditation would remain in effect. We proposed that if payment is not received within 90 days of the payment due date, FDA would withdraw the third-party certification body's accreditation under § 1.664(a), and provide notice of such withdrawal in accordance with the procedures in § 1.664. Accordingly, we proposed to amend § 1.664(a) by adding 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 a basis for withdrawal of accreditation. We requested comment on whether the consequences of a third-party certification body failing to pay a user fee by the due date are appropriate.

(Comment 11) Some comments agree with FDA's proposal to suspend an accreditation body's recognition or a third-party certification body's accreditation if it fails to submit its annual user fee within 30 days of the payment due date and to revoke the accreditation body's recognition or withdraw a certification body's accreditation if it fails to submit its annual user fee within 90 days of the payment due date.

(Response 11) We agree and are retaining these provisions in the final rule.

(Comment 12) One comment recommends that notice of the suspension or revocation on FDA's Web site differentiate between suspension and revocation for financial reasons and suspension or revocation for failure to conform to requirements.

(Response 12) We agree with respect to notice of revocation or withdrawal. In accordance with §§ 1.634(f) and 1.664(h), FDA will provide the basis for revocation of recognition and for withdrawal of accreditation on its Web site, as applicable. With respect to suspension of recognition or accreditation by FDA, failure to pay the user fee would be the only reason for FDA suspension.

(Comment 13) One comment recommends that FDA should notify a third-party certification body if its accreditation body's recognition has been suspended and that FDA should notify an accreditation body if a third-party certification body accredited by that accreditation body is suspended.

(Response 13) At this time FDA has determined that, unlike notice of withdrawal of accreditation and notice of revocation of recognition, notice of suspension is not essential to the operation of an accredited certification body or a recognized accreditation body. For example, accredited certification bodies would remain accredited even if their accreditation body had their recognition suspended. Further, we note that FDA's electronic portal for the third-party certification program currently does not have the capability to provide notice of suspension. We will consider the feasibility of adding this capability as resources allow.

IX. Comments on Possible Exemptions

We did not propose a small business exemption or reduction in the proposed rule because no statutory requirement to establish or consider an exemption or reduction in user fees exists in section 808 of the FD&C Act. However, we requested comment on whether we should account for small businesses in other ways, including whether an exemption or fee reduction would be appropriate. We requested that comments in favor of 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.

(Comment 14) Some comments recommend that there be no exemption or reduced fee for small businesses or entities because the costs to FDA for performing the work activities are not lower for small businesses or entities. Other comments recommend that the user fees for public-sector and private-sector accreditation bodies or third-party certification bodies be the same because the costs to FDA are not lower for one group compared to the other. Some comments recommend that the program offer reduced fees or exemptions for small businesses to be consistent with the principles embedded in FSMA. Other comments request a reduction in fees or an exemption for public-sector accreditation bodies or third-party certification bodies.

(Response 14) We agree that there be no exemptions or reduced fees for small businesses or entities or for public-sector entities. Section 808(c)(8) of the FD&C Act makes no distinction between public and private bodies for purposes of the user fee program, and, as noted previously, contains no requirement to establish or consider an exemption or reduction in user fees. As explained in Responses 3 and 4, we agree that the cost to FDA for performing the application review and monitoring will not vary greatly across entities participating in the third-party certification program, regardless of the entity's size or public versus private status. Moreover, creating exemptions or fee reductions would hinder FDA's ability to create a stable funding base for the third-party certification program.

X. Economic Analysis of Impacts

We have examined the impacts of the final 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 us 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). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule demonstrates how user fees will be calculated and assessed for different activities FDA conducts under FDA's third-party accreditation program. This rule does not require action by entities affected by the Third-Party Certification regulation; it merely provides additional information so that affected entities can make an informed decision on whether to participate in FDA's third-party certification program. FDA analyzed the costs and benefits of FDA's third-party certification program including imposition of user fees resulting from participating in the third-party certification program in the regulatory impact analysis of the Third-Party Certification final rule. Therefore because this rule does not require actions by affected entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

The full analysis of the economic impacts of the Third-Party Certification regulation is available at *https://www.regulations.gov* under the docket number (FDA–2011–N–0146) for this final rule (Ref. 3) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XI. Paperwork Reduction Act of 1995

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

XII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the proposed rule ''User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and To Issue Certifications'' published on July 24, 2015 (80 FR 43987). We stated that we had determined, 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'' such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that

would affect our previous determination.

XIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 conclude that the 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.

XIV. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fisher Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. International Organization for Standardization/International Electrotechnical Commission, ISO/IEC ''17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies,'' Copies are available from the International Organization for Standardization, 1, rue de Varembe, Case postale 56, CH–1211 Geneve 20, Switzerland, or on the Internet at *http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=29332* or may be examined at the Division of Dockets Management (see **ADDRESSES**) (Reference Docket No. FDA–2011–N–0146 and/or RIN 0910–AG66).

2. 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 (Pub. L. 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,* November 2013.

3. FDA, ''Final Regulatory Impact Analysis: Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications,'' *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM471886.pdf,* November 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, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

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

§ 1.634 When will FDA revoke recognition?

(a) * * *

(4) * * *

(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 would FDA withdraw accreditation?

(a) * * *

(4) If payment of the third-party 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 an undesignated center heading and §§ 1.700 through 1.725 to read as follows:

Requirements for User Fees Under This Subpart

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 certification program;

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

(c) Third-party certification bodies submitting applications or renewal applications for direct accreditation; and

(d) Accredited third-party certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party certification 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) Third-party 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 third-party 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) Third-party 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 third-party certification bodies under § 1.662.

(3) Third-party 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 third-party 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. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. 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 third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party 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?

User fees accompanying completed applications and annual fees 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 third-party certification bodies. The accreditation of third-party certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications issued by such third-party 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 third-party 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 third-party 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 third-party certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While a third-party certification body's accreditation is suspended, the third-party certification body will not be able to issue food or facility certifications. A food or facility certification issued by a third-party 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 third-party certification body's accreditation under § 1.664(a)(4), and provide notice of such withdrawal in accordance with § 1.664.

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30033 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–342]

RIN 1117–AB33

Establishment of a New Drug Code for Marihuana Extract

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is creating a new Administration Controlled Substances Code Number for ''Marihuana Extract.'' This code number will allow DEA and DEA-registered entities to track quantities of this material separately from quantities of marihuana. This, in turn, will aid in complying with relevant treaty provisions.

Under international drug control treaties administered by the United Nations, some differences exist between the regulatory controls pertaining to marihuana extract versus those for marihuana and tetrahydrocannabinols. The DEA has previously established separate code numbers for marihuana and for tetrahydrocannabinols, but not for marihuana extract. To better track these materials and comply with treaty provisions, DEA is creating a separate code number for marihuana extract with the following definition: ''Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.'' Extracts of marihuana will continue to be treated as Schedule I controlled substances.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

As provided in 21 CFR 1308.03, each controlled substance or basic class thereof is assigned a four digit Administration Controlled Substance Code Number (''Code number'' or ''drug code'') that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, the DEA uses these code numbers in establishing aggregate production quotas for basic classes of controlled substances listed in Schedules I and II as required by 21 U.S.C. 826.

Consistent with the Controlled Substances Act (CSA), the schedules contained in DEA regulations include marihuana (drug code 7360) in Schedule I. 21 CFR 1308.11(d)(23). This listing includes (unless specifically excepted or unless listed in another schedule) any material, compound, mixture, or preparation, which contains any quantity of the substance, or which contains any of its salts, isomers, and salts of isomers that are possible within the specific chemical designation. Because the definition of marihuana in 21 U.S.C. 802(16) includes both derivatives and preparations of marihuana, the DEA until now has used drug code 7360 for extracts of marihuana. This final rule finalizes a