DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

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Final Regulatory Impact Analysis

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I. Regulatory Impact Analysis

FDA has 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 (Public Law 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 final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the Third-Party program will be used primarily on voluntary basis where private enterprises determine that the benefits of participating in our program outweighs their associated user fee and compliance costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that

would meet or exceed this amount. Annualized cost of the Third-Party final rule is estimated to range from approximately $2.8-$11.6 million, depending on the scenario.

A. Need for Regulation

This RIA analyzes the impact of the final rule entitled Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Third-Party final rule). We are amending our regulations to provide for accreditation of third party certification bodies (CBs) to conduct food safety audits of foreign food entities, including foreign food facilities, and to issue food and facility certifications, pursuant to section 307 of FSMA (section 808 of the FD&C Act). Use of accredited third-party CBs and food and facility certifications will help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. FDA expects that these regulations for a third-party accreditation program will increase efficiency by reducing the number of redundant food safety audits. (Ref. 1) In addition, we believe that food producers who comply with the Third-Party final rule in order to participate in FDA's Voluntary Qualified Importer Program (VQIP) will help enable FDA to use its limited resources for import oversight more efficiently. We believe that a trusted program for foreign food safety audits and certifications—with clear requirements, standards, and procedures and operated under government oversight—will be appealing to accreditation bodies (ABs), CBs, and foreign food entities. Widespread participation and broad acceptance of audits and certifications will help increase efficiency and reduce costs by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act.

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. The undersupply of credible information about the safe food

practices of foreign firms stems from the same market failures that gave rise to our role in safeguarding food safety in the United States. However, we do not have the resources to monitor and ensure the safety of foods produced overseas at the same level that we do domestically. FSMA directs us to establish a system for accreditation of third-party CBs to conduct food safety audits and to issue certifications to foreign food facilities. We are creating a program to implement the FSMA requirement. When implemented, the Third-Party final rule will allow us to supplement our oversight of foreign food entities with a complementary system of food safety audits by CBs accredited by recognized ABs and, in limited circumstances, through our direct accreditation of CBs.

A third-party certification system is intended to provide customers with relatively inexpensive assurance that suppliers are maintaining high standards of safety in their goods. A pervasive problem in markets is the presence of "asymmetric information," where sellers know more about the safety of their products than buyers. The problem arises for two reasons. First, the value of the product to an individual buyer is less (usually far less) than the cost to that buyer of directly observing the actions that determine the safety of the food products. Second, because the value of the products increase with the increased safety assurances of the good, the sellers cannot credibly communicate that fact to the buyer – the buyer will correctly believe that the seller will claim high safety independent of the actual level of assurance.

By contracting the reporting of safety with a third-party food safety auditor, one that is paid a fixed fee independent of the outcome of the audit, the seller can theoretically overcome both problems. A certification of compliance by a third-party food safety auditor can be distributed widely to all customers, reducing information-based inefficiencies that already exist in private markets through the elimination of the incentives for multiple verification activities

per supplier, and potentially reducing the burden of some of the activities required by private purchasers.

For domestic food producers we are much better able to ensure the safety of food, through our inspection programs and our ability to directly enforce our food safety requirements, than we are for foreign food producers. For example, carrying out the same level of inspectional activities for foreign producers is far more costly. In this context, the use of competent and reliable third-party certification bodies allows for cost-effective and credible verification of food safety compliance by foreign food entities.

Finally, the creation of a rigorous and credible program for accredited third-party certification for imported foods will help us address some of the practical issues that make it more difficult for us to efficiently and effectively monitor the compliance of foreign food entities. Under these requirements, foreign producers who opt to be audited under our program will be assessed for compliance with our food safety requirements.

B. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

Previously, FDA proposed a combined preliminary regulatory impact analysis (PRIA) for the FSVP and the Third-Party proposed rules. FDA has decided to present the final rules for FSVP and Third-Party separately because FSVP does not require third party auditors to be accredited under this program. As a consequence some comments with regard to the Third-Party proposed rule may no longer be relevant. For example, in the Third-Party final rule, we do not assume that FSVP foreign suppliers will choose to participate in FDA's Third-Party accreditation program once it is implemented. Secondly, estimated costs of the Third-Party final rule are approximately $2.8-$11.6 million per year (annualized at 7% over 10 years) which is well below the threshold for conducting a formal regulatory analysis.

Under section 3(f) of Executive Order 12866, an economically "significant regulatory action" is a rule that has an annual effect of $100 million or more.

(Comment 1) The benefits of the Third-Party proposed rule are not quantified.

(Response 1) We have determined that the benefits of the Third-Party final rule justify the costs of the rule.

(Comment 2) The PRIA fails to consider alternative solutions.

(Response 2) As this is not an economically significant rule, we did not formally assess various regulatory alternatives. However, for the purpose of informing affected parties of potentially different cost structure, we have provided results of analyses of different scenarios from the proposed program below.

(Comment 3) Exporters have to bear the burden of additional costs of audits and certificates under FDA's Third-Party rule.

(Response 3) There are two types of foreign food exporters that are required to comply with the Third-Party rule. The first group includes entities that want to export food to the U.S. and are designated under §801(q) of the FD&C Act based on the risk of the food, including known safety risks associated with the food; the country, territory or origin of the food; or the food safety programs, systems or standards of the country, territory or origin of the food; a finding by the Secretary, supported by scientific risk-based evidence, regarding the adequacy of the food safety programs, systems, and standards of the country, territory, or region of origin of the food, coupled with other factors; and certain information submitted to the Secretary. Currently, the Secretary has not made such designation but reserves the right to make that determination in the future. Section 801(q) of the FD&C Act is one tool FDA can use to prevent potentially harmful food, especially foods and origins of food with known

risks, from reaching U.S. customers. We believe that the benefits of preventing entry of certain foods with known risks into the U.S. outweigh additional audit costs incurred by the supplier of the food.

The second group includes entities that choose to participate in FDA's Voluntary Qualified Importer Program (VQIP) under §806 of the FD&C Act. Entities that voluntarily choose to comply with the Third-Party rule to qualify for VQIP must necessarily deem that private gains of joining the program exceeds the additional cost that they incur.

(Comment 4) Will FDA offer auditor training to countries so that they are able to meet the requirements of the Third-Party rule?

(Response 4) It is the responsibility of certification bodies that operate in different countries to ensure appropriate training of their auditors to conduct food safety audits.

(Comment 5) The food industry is under "audit fatigue." Costs of audits incurred by large food production operations are high and FDA's proposed rule will add to the number of audits food producers conduct and consequently increases their operation cost.

(Response 5) We believe that food safety audits and certificates conducted under the Third-Party program may actually lead to reduction of the total number and cost of audits conducted by food producers. A study on food safety audits conducted in compliance with the Global Food Safety Initiative (GFSI) concluded that adoption of audits that are widely recognized by different accreditation bodies result in reduction of the total number of audits performed by food producers. We expect that the food safety audit performed as described in the Third-Party rule will be viewed as more reliable and adopted by multiple accreditation bodies recognized by FDA; therefore, we believe that it will reduce the multiplicity of audits that food producers face as evidenced in the results of the GFSI study.

(Comment 6) Auditing must be economically feasible; therefore, an actual economic assessment should be completed to reflect true program costs.

(Response 6) In the Regulatory Impact Analysis (RIA) of the Third-Party final rule, we have updated the estimates of costs that a food producer incurs for a typical food safety audit. In addition, we have estimated the compliance costs and user fee costs that accreditation bodies and certification bodies are expected to incur in addition to the current cost of food safety audits. We believe that our revised estimates in the RIA of the Third-Party final rule reflect the true program costs. In the RIA, we have assumed that the accreditation and certification bodies pass down their compliance and user fee costs to the foreign suppliers that are audited under our program. A foreign supplier must determine whether complying with the Third-Party final rule is economically feasible based on the costs of audits of certification bodies accredited under our program.

(Comment 7) Third-Party proposed rule states that potentially all accreditation bodies and their associated certification bodies would participate in FDA's Third-Party program. This claim is implausible because FDA has not shown that it can produce a meaningful incentive in the form of expediting the admission of imports.

(Response 7) When the Third-Party proposed rule was published, FDA had not yet published the VQIP draft guidance. In the VQIP draft guidance, FDA outlines the benefits (incentives) that importers and their associated foreign suppliers receive when accepted in VQIP. Our estimate of the number of accreditation bodies, certification bodies, and foreign suppliers is primarily to illustrate how costs of food safety audits may change once the Third-Party program is implemented. All affected parties including accreditation bodies, certification bodies, and potential eligible entities under §801(q) and §806 of the FD&C Act

are informed by benefits described in the VQIP draft guidance and cost estimates and requirements included in the Third-Party final rule to determine whether it is beneficial for them to participate in FDA's Third-Party program. Furthermore, in the RIA of the Third-Party final rule, we describe three alternative scenarios where there are fewer eligible entities than when it was presented in the proposed rule. As a consequence, fewer accreditation bodies apply for, and receive recognition from the FDA, and fewer certification bodies apply for, and receive direct accreditation from the FDA. These costs are also illustrative and subject to change once the program is implemented. Future changes in cost estimates mainly depends on updates in fees, actual demand by foreign suppliers for food safety audits by certification bodies accredited under our program, and other factors.

(Comment 8) The PRIA suggests that the Third-Party rule does not disqualify existing certification bodies to conduct audits under our program and that accreditation bodies and certification bodies vary in quality and capability to implement FDA's requirements.

(Response 8) FDA recognizes that currently, the quality of food safety audits by certification bodies (whether accredited or not) vary. Through the Third-Party rule, FDA aims at standardizing food safety audits conducted by certification bodies that are ultimately accredited under our program. In the Third-Party final rule, FDA describes requirements for accreditation bodies and certification bodies who choose to participate in our program. We describe different scenarios in the RIA of the Third-Party final rule to illustrate potential burden to accreditation bodies, certification bodies, and foreign suppliers that comply with the standardized requirements set forth in the Third-Party rule.

(Comment 9) The PRIA is flawed by numerous unfounded assumptions regarding key cost elements which potentially results in significant underestimation of the cost impact of the proposed rule.

(Response 9) The comment does not specify the flaws in assumptions used in estimating the costs of the Third-Party rule. For the RIA of the Third-Party final rule, we have revised the cost estimates in a number of ways that have resulted in modification of costs per foreign supplier. Major modifications of assumptions which affect the costs of the Third-Party program include the following:

1. We have increased the cost of current food safety audits from an average of $3,600 to $7,500.

2. We have modified the cost of number of activities conducted by FDA in managing the Third-Party program.

3. We have imposed, in part, FDA's cost of managing the Third-Party program on accreditation bodies and certification bodies through user fees. We assume that accreditation bodies and certification bodies pass the user fee costs along with their compliance costs to the foreign suppliers that are audited under our program.

4. We do not assume that a portion of FSVP importers and their associated foreign suppliers will participate in the Third-Party program to satisfy certain verification requirements of FDA's FSVP rule. Therefore, we excluded approximately 47,500 eligible entities from our estimates.

5. We consider three scenarios in which initially 200 importers and their associated foreign suppliers would participate in FDA's Voluntary Qualified Importer Program. In each scenario, we consider different participation rate for each year in a 10-year period. Therefore,

we have estimated the costs of scenarios where approximately 1,200 to 6,000 eligible entities have importers who participate in VQIP each year and are audited and certified under our Third-Party program.

Changes in our assumptions of cost elements of the proposed rule results in increase of the cost of food safety audits by $227 to $694 depending on the considered scenario ($204 in PRIA) for foreign suppliers that are currently audited by accredited certification bodies. We expect that cost of food safety audits will be increased by $2,102 to $2,569 ($1,104 in PRIA) for foreign suppliers that are currently audited by unaccredited certification bodies. Total cost to industry is estimated at approximately $2.8-$11.6 million (approximately $57 million in PRIA).

(Comment 10) The PRIA does not address economies or diseconomies of scale due to various assumptions that lead to change in industrial organization of food safety audit industry.

(Response 10) Circular A-4, guidance document to the Executive Order 12866, requires more rigorous approaches (e.g., quantification of benefits, sensitivity analysis) to rules that are deemed to be economically significant. Using the most current (2013) Implicit Price Deflator for the Gross Domestic Product, the current threshold for economically significant rules, after adjustment for inflation, is $141 million. Since the Third-Party final rule is not an economically significant rule, we are not required to conduct sensitivity analysis on cost of food safety audits based on scale of economies. Cost estimates provided in the RIA of the Third-Party analysis are for illustrative purposes and subject to change including changes in annual FSMA reinspection fees, and particularly on actual demand of foreign suppliers for audits by certification bodies accredited under our program. Moreover,

cost estimates presented in the PRIA provide the least costly scenario. If less than 69 accreditation bodies are recognized by the FDA, certification bodies that would like to participate under our program and not accredited by any FDA-recognized accreditation body must pay royalty, assessment and accreditation fees to a FDA-recognized body in addition to the user fee and compliance costs that they incur (also see Section E.).

(Comment 11) For non-English-speaking countries, translation of all records into English would significantly increase compliance costs. How flexible are the English language requirements for the purpose of compliance with the Third-Party rule?

(Response 11)In the final rule, we have added flexibility to allow certain records to be maintained in a language other than English, so long as an English translation of the records is provided to FDA within a reasonable time if FDA requests such translation.

C. Principal Changes to the PRIA of the 2013 Proposed Rule

Affected Entities

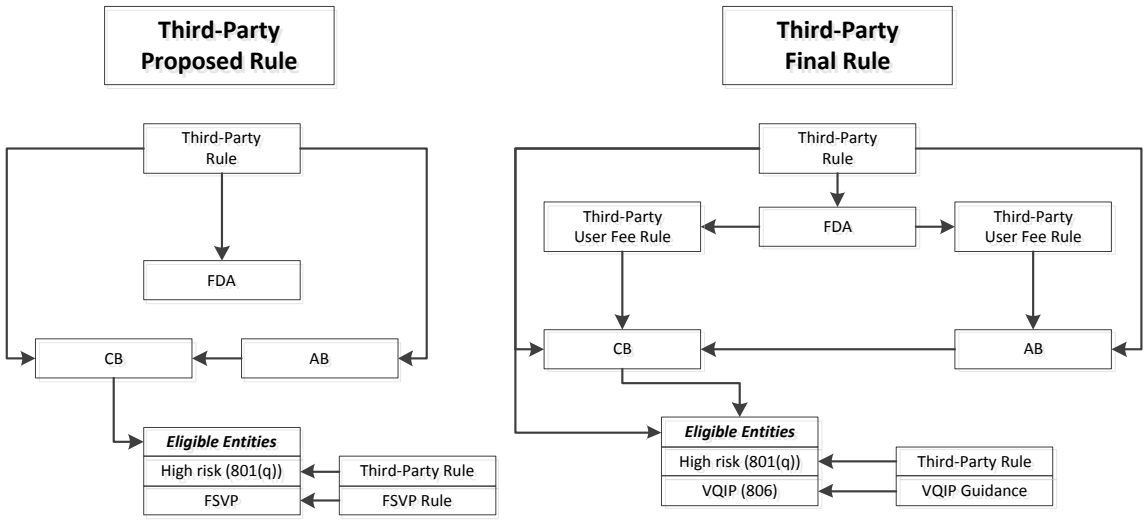
Following the publication of the Third-Party proposed rule, pursuant to section 806 of FD&C Act, FDA published the Voluntary Qualified Import Program (VQIP) draft guidance document (Ref. 2). The VQIP draft guidance document describes the eligibility criteria for, and benefits of, participation in VQIP. Foreign food importers who benefit from the VQIP are required to acquire third-party audits of their suppliers as described in the Third-Party final rule. In this RIA, we estimate effect of participation of eligible entities in the VQIP program on FDA's Third-Party accreditation program.

In the Third-Party proposed rule, we assumed that certain importers—to satisfy verification requirement under the FSVP proposed rule—would voluntarily use CBs who are participating under FDA's proposed Third-Party program. However, in the RIA, we only estimate those eligible

entities that get food safety audits to satisfy the requirements of sections 801(q) and 806 of the FD&C Act. In the final rule, we clarify that importers who acquire an audit of a foreign supplier for VQIP may use that audit in meeting certain verification requirements of FSVP. We also clarify that an importer could voluntarily use a CB who is accredited under FDA's Third-Party program to perform audits for FSVP purposes, but audits performed for the sole purpose of FSVP would not be regulatory or consultative audits under this rule. Audits conducted solely for the purposes of FSVP would not be subject to this rule's requirements pertaining to audits. Considering that in addition to the 801(q) and 806 eligible entities, some foreign suppliers may voluntarily participate in FDA's Third-Party program for other purposes, this RIA provides lower bound estimate of the burden of the Third-Party accreditation program. Figure 1 illustrates the interdependence of the Third-Party final rule, Third-Party User Fee proposed rule, and the VQIP draft guidance document. In contrast to the Third-Party proposed rule, in this analysis, we estimate the burden of FDA's activities in managing the Third-Party program through user fees imposed on ABs and CBs as described in the Third-Party User Fee proposed rule.

Costs

Figure 1: Modifications to the Third-Party Proposed Rule—Regulatory Actions and Burden of Affected Entities*



* The arrows in the above diagram indicate requirements imposed on ABs, CBs, and eligible entities upon their recognition, accreditation or status determination by the FDA.

Costs: FDA

In the RIA of the Third-Party final rule, we use FDA FSMA reinspection rates for FY2015 (Ref. 3) for the work that FDA personnel conducts to manage the Third-Party program: $202 per hour for a fully-supported employee, $217 per hour if domestic travel is required, and $305 per hour if foreign travel is required. In addition, FDA has revised estimates of amount of hours it takes for FDA personnel to review applications for recognition by ABs, and periodic monitoring of ABs and CBs. Table 1 presents the changes in average estimated time it takes for FDA personnel to conduct each of the activities listed. Estimated total FDA personnel hours to review initial application for recognition from ABs and for direct accreditation by CBs has changed from 414 hours to 153 hours. On average, the number of hours to review an application for renewal of recognition by ABs has decreased from 176.5 hours to 89.25 hours while renewal of application for direct accreditation has decreased from 286 hours to 117 hours.

FDA has also revised its estimates for monitoring activities of ABs and CBs. On average, the amount of time it takes FDA personnel to evaluate performance of a recognized AB or a CB accredited under the third-party program is decreased from 154.6 hours to 36.8 hours (see Table 1); while on average, monitoring of directly-accredited CBs, on average, has decreased from 241 hours to 80 hours (see Table 1). Since we published the proposed rule, we have moved forward considerably in our implementation plan. The changes in the estimation of FDA burden reflect our current thinking, based on a more detailed understanding of how we envision administering the Third-Party program.

Table 1: Change in Number of Hours to Review to Conduct Application Review and Monitoring Activities (per AB/CB) by FDA Personnel

§1.631 Initial AB Recognition (One-time)

§1.671 Initial CB Direct Accreditation (One-time)			
FDA Activity	**PRIA**	**Final RIA**	**% Change**
Application records review	168	60	- 64%
Onsite assessment	96	48	- 50%
Report preparation	150	45	- 70%
Total	**414**	**153**	**- 63%**
§1.631 Renewal of AB Recognition (Every 5 years)*			
FDA Activity	**PRIA**	**Final RIA**	**% Change**
Initial Records Review	40	40	0%
Onsite assessment	24	8	- 67%
Report preparation	112.5	41.25	- 63%
Total	**176.5**	**89.25**	**- 49%**
§1.671 Renewal of CB Direct Accreditation (Every 4 years)*			
FDA Activity	**PRIA**	**Final RIA**	**% Change**
Initial Records Review	40	40	0%
Onsite assessment	96	32	- 67%
Report preparation	150	45	- 70%
Total	**286**	**117**	**- 59%**
§1.633 FDA monitoring of recognized ABs (Every 4 years) **§1.662(a) FDA monitoring of CBs accredited under the third-party program (Every 3 years)**			
FDA Activity	**PRIA**	**Final RIA**	**% Change**
Initial Records Review	40	24	- 40%
Onsite assessment	9.6	4.8	- 50%
Monitoring report preparation	105	8	- 92%
Total	**154.6**	**36.8**	**- 76%**
§1.662(b) FDA monitoring of directly-accredited CBs (Annual)			
FDA Activity	**PRIA**	**Final RIA**	**% Change**
Initial Records Review	40	24	- 40%
Onsite assessment	96	48	- 50%
Monitoring report preparation	105	8	- 92%
Total	**241**	**80**	**- 67%**

* For the purpose of this analysis we are assuming that all ABs are recognized for the maximum duration of 5 years and that all CBs are accredited for the maximum duration of 4 years.

Costs: Affected Entities

We revised our estimates on the cost of food safety audits and certification by CBs currently accredited under other programs. In the PRIA of the Third-Party proposed rule, we used

an average cost of $1,200 per day, and 3 days for a typical food safety audit. Hence, we estimated that a food safety audit and certification, on average, costs around $3,600. Our revised estimate is in agreement with costs of food safety audits cited in other FSMA regulations. We increased the cost per audit and included travel and incidental costs associated with audits for our final rule analysis. We have increased the audit costs from $3,600 per audit estimated in the PRIA of the Third-Party proposed rule to a range of $5,000 and $7,500 per audit, depending on facility size. We also have included travel and incidental costs of $1,000 for the final rule.

For purposes of this analysis we assume one audit per supplier annually based on the fact that the food industry is moving toward the practice of recognizing an audit done under certain rigors, such as a GFSI-approved audit, and that the results of such an audit can be used to satisfy multiple customers. (Ref. 4) This effort by industry is an attempt to reduce the number of audits that a supplying facility would be subjected to on an annual basis.

An audit of a facility would usually take a day or more depending on the type of audit that is done; some audits can last four days or more. (Ref. 5) The costs of an audit would depend on the auditor and the type of facility being audited. Daily rates for audits range from about $500 to $2,000 per day; a 5 day audit could cost a facility $7,500 to $10,000. (Ref.5) British Retail Consortium (BRC)-sponsored audits take on average about 2.5 days and cost about $3750 including reporting time and auditor fees, but not including travel expenses (Ref. 6). GMA-SAFE offers two auditing programs, the GMA-SAFE Express audit (a 2-day audit which requires that the auditor be in the facility for at least 16 hours) or the GMA-SAFE full audit (which usually runs about 3 to 4 days and requires that the auditor be in the facility for at least 32 hours). (Ref. 7) Supplier assessments conducted under the GMA-SAFE requirements are billed at an hourly rate of $160/hr (based on the average cost of assessments performed in 2008). In addition to the auditing

fee, the facility bidding on an audit would also be responsible for the auditor's travel and incidental expenses. On average, a GMA-SAFE express audit costs about $3,500 and a full audit costs around $5,000, plus travel and incidental expenses (Ref. 6). Making use of this auditing cost information, for purposes of this analysis we estimate that audits of facilities with less than 20 employees would cost $1,500-$3,750 (average $2,625); audits of a small facility with 20 to 99 employees would cost about $3,750; audits of facilities with 100 to 499 employees would cost about $3,750-$5,000 (average $4,375); and audits of facilities with more than 500 employees would cost $5,000. We estimate the travel expenses for the auditor to be $250-$1000 (average $625). We use number of employees as a rough measure for the complexity of the operation, although we recognize that other factors might influence audit costs.

D. Rule Coverage

Affected Entities

The coverage of the Third-Party final rule includes eligible entities seeking audits, certification, and/or recertification by CBs accredited under the third-party program, ABs voluntarily seeking recognition, renewal of recognition, and/or to maintain recognition under the Third-Party final rule, and CBs voluntarily seeking accreditation, renewal of accreditation, and/or to maintain accreditation under of the Third-Party final rule (including those accredited by recognized ABs and those directly accredited by us to conduct food safety audits).

Eligible entities

An eligible entity means a foreign entity in the food import supply chain that chooses to be subject to a food safety audit under the Third-Party final rule conducted by an accredited third-party certification body. Based on OASIS data, we estimate that there are 200,692 foreign food exporters that offer their food for import into the U.S. These foreign food exporters include

129,757 food production facilities and 70,935 farms. In addition, according to FDA's ORA database, there are 27,992 importers which offer food for import by 156,175 foreign food exporters into U.S., or approximately 5.6 foreign food exporter per importer.

A small proportion of these foreign food exporters may offer food subject to mandatory certification requirements under §801(q) of the FD&C Act (§ 801(q) entities). In that case, the foreign food exporters must either comply with the Third-Party final rule in order to obtain certification from a CB accredited under the third-party program to gain admission of their food products subject to mandatory certification into the U.S., or lose access to U.S. markets. Where we have designated a foreign government to issue certifications for purposes of section 801(q) of the FD&C Act, the certification alternatively may be secured from a designated government. We expect that, only in limited circumstances, we would designate a foreign food exporter as a §801(q) entity. Though difficult to predict, in our cost estimates, we assume that 75 foreign food exporters will be designated as a §801(q) entity in a given year, and that they all will choose to comply with the Third-Party final rule in order to gain access to the U.S. market (see Table 3).

In addition to the §801(q) entities, some food exporters will seek certificates to participate in VQIP under §806 of the FD&C Act.

Some foreign food exporters currently receive third-party food safety audits from CBs currently accredited under other programs or CBs not accredited under any program to satisfy requirements set forth under other government or private programs, prior to implementation of our program. Since VQIP is a voluntary program, eligible entities that choose to participate in it must deem that the private gains of participating in VQIP outweighs the potentially costlier audits conducted by auditors accredited under the Third-Party program.

We consider three different scenarios for the participation rate of VQIP importers and their associated eligible entities in a 10-year period: 1) constant number of VQIP importers in every year, 2) increasing participation over time, peaking at 20% of all importers of perishable products by the fifth year, with stagnant growth in subsequent years, 3) increasing participation over time, peaking at 40% of all importers of perishable products by the tenth year of the program.

The VQIP draft guidance document proposes to cap the acceptance of applications by importers for the VQIP at 200 for the initial year of the program. Under Scenario 1, we consider 200 importers participating in each of first 10 years of the VQIP (see Table 2). Average number of foreign suppliers per importer is approximately 5.58; therefore, under Scenario 1, we expect that 200 importers and approximately 1,116 eligible entities (200 importers x 5.58 eligible entities per importer) will be participating in the VQIP every year for a 10 year period (see Tables 2 and 3).

According to FDA's ORADSS database, the number of importers of perishable products is approximately 2,759. These importers would have an incentive to participate in VQIP in order to expedite entry of their perishable food products into the U.S., so we assume for the purpose of this analysis that importers of those products are the ones that would have an incentive to voluntarily participate in VQIP. Under Scenario 2, we consider 200 importers participating in the initial year of the VQIP and increasing steadily until the fifth year of the program until 552 importers (20% x 2,759 importers of perishable products) are participating in the program. For years 6 through 10, we consider 3% increase in participation of new importers in the VQIP (see Table 2). Multiplying the number of importers by the number of eligible entities per importers (5.58), we expect that the number of eligible entities

participating in VQIP, under Scenario 2, increase from 1,116 to 3,527 in a 10-year period (see Table 3).

Under Scenario 3, we consider number of importers increase from 200 in the initial year of VQIP to 1,104 importers (40% x 2,759 importers of perishable products) in the 10th year of the program. Tables 2 and 3 include the number of importers and their associated eligible entities for scenario 3.

Table 2 - Potential number of importers participating in the VQIP program in its initial 10 years

Scenario	Year									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
1	200	200	200	200	200	200	200	200	200	200
2	200	288	376	464	552	562	579	596	614	632
3	200	300	400	500	600	700	800	900	1,000	1,104

Table 3 - Potential number of eligible entities participating in the VQIP program in its initial 10 years

Scenario	Year									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
1	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116	1,116
2	1,116	1,607	2,098	2,589	3,080	3,136	3,231	3,326	3,426	3,527
3	1,116	1,674	2,232	2,790	3,348	3,906	4,464	5,022	5,580	6,160

Currently some foreign food exporters receive their audits from CBs not accredited under any program. A study by the Research Triangle Institute (RTI) (Ref. 7) estimates that 26,007 foreign food exporters, or about 13% of all foreign food exporters, currently receive third-party food safety audits by CBs currently accredited under other programs (see Appendix A). The remaining 174,685 (200,692 – 26,007) foreign food exporters either currently receive their audits from CBs not accredited under any program or currently do not obtain third-party food safety audits. For the purpose of this analysis we need to estimate the number of eligible entities already using CBs currently accredited under other programs and that will choose to use CBs

accredited under the third-party program; they likely will have lower costs of compliance with the Third-Party final rule than eligible entities that either currently receive audits from CBs not accredited under any program or currently do not obtain third party food safety audits.

For purposes of this analysis we assume that the number of eligible entities that will have foods subject to §801(q) of the FD&C Act is 75 in a given year. Furthermore we assume that the proportion of the §801(q) eligible entities receiving food safety audits and certification from CBs currently accredited under other programs is the same as the proportion of all foreign food exporters who are currently obtaining food safety audits/certificates from CBs currently accredited under other programs. In other words, we estimate the number of eligible entities currently receiving food safety audits/certificates from CBs currently accredited under other programs at 10 (13% x 75 eligible entities) and we assume that the remaining 65 eligible entities obtain third party food safety audits/certificates from CBs not accredited under any program (see Table 4).

In addition, we project that 13% of eligible entities participating under the proposed VQIP program, or 145 eligible entities (13% x 1,116 eligible entities) in Scenario 1 are currently audited by CBs accredited under other programs. The remaining 971 eligible entities are currently obtaining their onsite audits from CBs not accredited under any program . Similarly, under Scenario 2 (and Scenario 3), we estimate that, on average, 13% of the 3,729 eligible entities (8,349 in Scenario 3) are currently audited and certified by CBs currently accredited under other programs and the remaining eligible entities are audited and certified by CBs not accredited under any program. Tables 4 include estimates of foreign food exporters, § 801(q) entities, FSVP-compliant foreign suppliers and accreditation status of their certifiers.

Based on the above calculations of different participation scenarios, on average, we estimate that potentially 1,191 to 6,235 eligible entities will seek third-party food safety audits and certifications under our program in a given year. We assume that these eligible entities will meet the criteria for certification under § 801(q). Table 4 includes total number of eligible entities under different scenarios considered.

Table 4: Foreign Food Exporters, Eligible Entities Certified by Certification Bodies (CBs) Under the Third- Party Final Rule in a 10 year-period

Certified by	Foreign Food Exporters	Eligible Entities			
		§801(q) of FD&C Act	§806 of FD&C Act		
			Scenario 1	Scenario 2	Scenario 3
CBs currently accredited under other programs	26,007	10	145	459	801
CBs not accredited under any program or No Audits	174,685	65	971	3,068	5,359
Total	200,692	75	1,116	3,527	6,160
Total Eligible Entities (801(q) and 806)			**1,191**	**3,602**	**6,235**

Accreditation Bodies and Certification Bodies

Based on data we reviewed, there are currently 71 ABs operating globally that accredit third-party auditors/CBs for food safety. (Ref. 8) Two of the 71 ABs are represented by two countries that currently do not have trade relations with the U.S. (see Appendix D).[1]

Using the results of a survey of a sample of ABs (Ref. 8), we estimate that there are 568 CBs currently accredited under other programs specializing in food safety audits. Therefore, on average, we estimate that each of these CBs currently accredited under other programs certifies approximately 46 foreign food facilities per year (see Table C1, Appendix C).

[1] In addition, we expect 1 CB to potentially apply for direct accreditation.

We expect that the estimated 1,191-6,235 eligible entities (see Table 4), under the three different scenarios, that currently obtain food safety audits/certificates from CBs not accredited under any program will seek audits under our program. Therefore, we expect that demand for food safety audits will increase for currently accredited CBs that become accredited under our program. We anticipate that that this demand will affect the industrial organization aspect of accredited third-party audit market in two ways: 1) it will lead to increased number of clients for currently CBs currently accredited under other programs who will become accredited under our program, and/or potentially 2) CBs that are not currently accredited will be induced to become accredited under our program. As the demand for third-party audits by CBs currently accredited under other programs grows, these CBs have an incentive to expand and take on more clients. If for the purposes of this analysis we assume that current CBs' client-base may increase by 25% once they are accredited under our program.

FDA has authority to directly accredit third-party CBs only in limited circumstances. In those circumstances, CBs may meet the criteria to become directly accredited by FDA. In this analysis, we assume that circumstances will allow FDA to make the determination necessary to invoke direct accreditation authority and that one CB will satisfy the criteria for direct accreditation. For the purpose of this analysis, we estimate costs of a scenario where one CB becomes directly accredited under our third-party accreditation program. Table 5 includes number of ABs and CBs that would potentially be affected by the Third-Party final rule under the three considered scenarios.

Table 5: Expected Number of Accreditation Bodies and Certification Bodies Recognized or Accredited under the Third-Party Final Rule

Status of ABs/CBs	Number of ABs/CBs		
	Scenario 1	Scenario 2	Scenario 3
ABs seeking recognition under the Third-Party final rule	11	17	25

CBs currently accredited under other programs choosing to comply with the Third-Party final rule	91	140	207
CBs eligible for direct accreditation by FDA	1	1	1
Number of CBs seeking accreditation or direct accreditation	**92**	**141**	**208**

E. Regulatory Options Considered

Option 1: The first option would be no action. This alternative is not feasible as FDA is required to implement a Third-Party accreditation program required under FSMA, so that eligible entities under §801(q) of the FD&C Act would be able to continue to offer their food for import into the U.S. and so that entities can participate in VQIP under §806 of the FD&C Act.

Option 2: The second option described in this document is the rule once finalized. Option 2 includes three different scenarios for the participation rate of VQIP importers and their associated eligible entities in a 10-year period. In Scenario 1, an estimated 1,191 eligible entities would choose to obtain audits and certificates by CBs accredited under FDA's proposed Third-Party accreditation program. Under this scenario, we estimate that 11 ABs become recognized by the FDA to participate in our program. As a consequence, an estimated 91 CBs accredited by these recognized ABs would also comply with the Third-Party final rule. In addition, we assume under this scenario, one CB would apply and obtain direct accreditation from the FDA. Therefore, under Scenario 1, there are 11 ABs and 92 CBs accredited under the third-party program. FDA's costs of managing the Third-Party program including application review and monitoring are passed down to the participating ABs and CBs through user fees. In turn, we assume that the participating ABs and CBs would pass down their user fee and compliance costs to the eligible entities. Under Scenario 1, we estimate that additional cost to an eligible entity that is currently being audited and certified by a CB currently accredited under other programs is approximately $694 per year. Additional cost to an eligible entity that is currently being audited

and certified by a CB not accredited under any program is approximately $2,569. Total costs of the program for the 1,191 eligible entities are estimated at approximately $2.8 million per year (annualized at 7% over a 10-year period).

Under Scenario 2 of Option 2, we consider 200 importers participating in the initial year of the VQIP and increasing steadily until the fifth year of the program until 552 importers (20% x 2,759 importers of perishable products) are participating in the program. Additional cost to an eligible entity that is currently being audited and certified by a CB currently accredited under other programs is approximately $322 per year. Additional cost to an eligible entity that is currently being audited and certified by an CB not accredited under any program is approximately $2,197. Due to the increase in participation of eligible entities (3,602 at year 10), total costs of the program, under this scenario, are estimated at approximately $7.0 million per year (annualized at 7% over a 10-year period).

In Scenario 3, as in previous scenarios, we consider 200 importers participating in the initial year of the VQIP. However, we estimate effect of steady increase of participation in the VQIP program until 1,104 importers (40% of the 2,759 current importers of perishable products) are reached by the 10th year of the program. Additional cost to an eligible entity that is currently being audited and certified by a CB currently accredited under other programs is approximately $227 per year. Additional cost to an eligible entity that is currently being audited and certified by a CB not accredited under any program is approximately $2,102. Total costs of the program, under Scenario 3, are estimated at approximately $11.6 million per year (annualized at 7% over a 10-year period).

F. Benefits of the Third-Party Final Rule

The Third-Party final rule does not impose any direct requirements on any ABs or CBs unless they elect to become part of our program. Instead, the Third-Party final rule will, we expect, create a demand for audits and certification by CBs accredited by recognized ABs participating voluntarily in our program. It is expected that ABs and CBs will comply at a rate that satisfies the demand for audits from third-party CBs accredited under our program. The costs that ABs and CBs incur in complying with the regulation are necessarily less than the private benefits they accrue by becoming recognized or accredited, respectively. Through the Third-Party accreditation program more effective regulatory oversight is achieved. FDA will recoup resources in managing its Third-Party accreditation program through user fees that FDA intends to impose on participating ABs and CBs. Likewise, additional costs accrued by eligible entities that voluntarily choose to meet on-site audit requirements using CBs currently accredited under other programs are outweighed by the private benefits they gain. Eligible entities who choose audits and certifications by CBs accredited under our program include those who choose to participate in FDA's proposed VQIP program (under §806 of the FD&C Act), or those who choose to expand the market of potential buyers for their products. Mandatory compliance with the Third-Party rule include entities subject to §801(q) determinations under the FD&C Act. Currently, there are no entities designated as subject to §801(q) by the Secretary; although, the designation may be made in the future based on risks of certain foods or origins of foods as they become known to the Agency.

G. Costs of the Rule

Costs of the Third-Party final rule include compliance costs of ABs and CBs who choose to participate in our Third-Party program, and user fees imposed by FDA on ABs and CBs for application review and monitoring of program participants. FDA user fees are estimated in Appendix

A. Compliance costs for ABs and CBs are estimated in Appendix B. We list the undiscounted and annualized costs for 10-year period for each of the cost burdens to a potential AB or CB participant of the Third-Party program in Table 6. On average, total undiscounted costs for a 10-year period for an AB is approximately $102,535, or an annual payment of about $13,880 for a 10-year period at 7% discount rate. For directly-accredited CBs, total undiscounted costs are approximately $269,525 while the annualized rate at 7% for a 10-year period is approximately $31,691 (see Table 6). The difference in cost is primarily based on the annual monitoring of directly-accredited CBs as opposed to monitoring of ABs every 4 years.

The undiscounted compliance costs of CBs accredited under the Third-Party rule are approximately $44,394 and their 10-year annualized cost at 7% is approximately $6,165 (see Table 6).

Table 6: Summary User Fee, Compliance, Undiscounted and Annualized Costs of the Third-Party Program—per AB, CB

Status of ABs/CBs	No. of Units	Unit Cost	10-Year Outlay		
			Undiscounted Cost	Annualized Cost	
				3%	7%
ABs					
Initial recognition (user fee)	1	$35,850	$35,850	$4,203	$5,104
Renewal recognition (user fee)	1	$18,853	$18,853	$1,906	$1,914
Monitoring (user fee)	2	$7,928	$15,856	$1,584	$1,578
Compliance	1	$31,976	$31,976	$4,516	$5,284
TOTAL			**$102,535**	**$12,209**	**$13,880**
Directly-Accredited CBs					
Initial direct accreditation (user fee)	1	$35,850	$35,850	$4,203	$5,104
Renewal direct accreditation (user fee)	2	$26,930	$53,860	$5,297	$5,157
Monitoring (user fee)	7	$21,104	$147,728	$15,112	$15,535
Compliance	1	$32,087	$32,087	$5,190	$5,895
TOTAL			**$269,525**	**$29,802**	**$31,691**
CBs accredited under Third-Party program					
Monitoring (user fee)	3	$7,928	$23,784	$2,411	$2,448
Compliance	1	$2010,	$20,610	$3,189	$3,717
TOTAL			**$44,394**	**$5,600**	**$6,165**

Mandatory Compliance: Eligible Entities with Food Subject to §801(q) of the FD&C Act

A regulatory audit of an eligible entity is conducted to determine whether the entity is in compliance with the food safety provisions of the FD&C Act and FDA regulations, and the results of which are used to determine eligibility for certification under §801(q) or §806 of the FD&C Act. Section 1.681 of the Third-Party final rule requires that eligible entities seeking to maintain certification under subpart M apply for recertification on an annual basis (or sooner, if required by the CB accredited under the third-party program). As a baseline, we assume that all eligible entities currently being audited are audited on at least an annual basis to comply with other regulations or private market verification requirements. We believe the cost of certification primarily depends on the size and nature of operation of the facility and on whether the CB is accredited or not. Current costs of certification and recertification by CBs accredited under other programs, at an average-size facility, are estimated at approximately $7,500 (see Section 3, above).

We currently do not have information on the cost for eligible entities that are currently being audited by CBs not accredited under any program. We assume that a food processing facility or farm would—unless its customers required certification from an accredited CB—typically be audited by an CB not accredited under any program because it is cheaper to do so (e.g., the CB would not pass along the costs associated with accreditation and implementation of measures to satisfy AB requirements). We assume that charges of certification and recertification services by CBs not accredited under any program are 25% less or $1,875 (25% x $7,500) than those charged by CBs currently accredited under other programs. Therefore, we believe that it would take an additional $1,875 per year for an eligible entity to switch their food safety audits by an CB not accredited under any program to a CB currently accredited under

other programs (without accounting for additional costs associated with accreditation under our program).

In addition, compliance and user costs ABs and CBs recognized and accredited under the Third-Party final rule would amount to approximately $694 for eligible entities currently being audited by a CB currently accredited under other programs under Scenario 1,$322 per eligible entity under Scenario 2, and $227 per eligible entity under Scenario 3 (see Appendices A and B). Under these assumptions, the total cost for an eligible entity to switch from an CB not accredited under any program to one accredited under the Third-Party final rule is $2,569 ($1,875 + $694) under Scenario 1, and $2,197 and $2,102 for Scenarios 2 and 3, respectively. We use information from Table 1 and Table B10 of Appendix B to calculate an annual Third Party cost for all eligible entities at approximately $2.8-$11.6 million (see Table 7).

H. Summary of Benefits and Costs

Costs of the Third-Party final rule include compliance costs of accreditation bodies and certification bodies who choose to participate in our Third-Party program, and user fees imposed by FDA on accreditation bodies and certification bodies for application review and monitoring of program participants.

Table 7: Summary User Fee, Compliance, Undiscounted and Annualized Costs of the Third-Party Program

Eligible Entity	Audited By		Total
	CBs currently accredited under other programs	CBs not accredited under any program	
SCENARIO 1			
Number of §801(q) Entities	10	65	75
TP Compliance Cost	$694	$2,569	
§801(q) Compliance Cost	**$6,940**	**$166,985**	**$173,925**
Number of §806 Entities	145	971	1,116
TP Compliance Cost	$694	$2,569	
§806 Compliance Cost	**$100,630**	**$2,494,499**	**$2,595,129**

Total TP Compliance Cost - Scenario 1			**$2,769,054**
SCENARIO 2			
Number of §801(q) Entities	10	65	75
TP Compliance Cost	$322	$2,197	
§801(q) Compliance Cost	**$3,220**	**$142,805**	**$146,025**
Number of §806 Entities	459	3,068	3,527
TP Compliance Cost	$322	$2,197	
§806 Compliance Cost	**$147,798**	**$6,740,396**	**$6,888,194**
Total TP Compliance Cost - Scenario 2			**$7,034,219**
SCENARIO 3			
Number of §801(q) Entities	10	65	75
TP Compliance Cost	$227	$2,102	
§801(q) Compliance Cost	**$2,270**	**$136,630**	**$138,900**
Number of §806 Entities	801	5,359	6,160
TP Compliance Cost	$227	$2,102	
§806 Compliance Cost	**$181,827**	**$11,264,618**	**$11,446,445**
Total TP Compliance Cost - Scenario 3			**$11,585,345**

The costs that accreditation bodies and certification bodies incur in complying with the regulation are necessarily less than the private benefits they accrue by becoming recognized or accredited, respectively. Through the Third-Party accreditation program more effective regulatory oversight is achieved. FDA will recoup resources in managing its Third-Party accreditation program through user fees that FDA intends to impose on participating accreditation bodies and third-party certification bodies.

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9. Economic Analysis of Third-Party Food Safety Certification of Imported Food, June, 2012. RTI for FDA under Contract HHSF22320710273G, Task Order 13.

Appendix A: FDA User Fee Costs

Our costs can be categorized into application review, which includes both initial application and renewal application activities, and monitoring activities. These estimated costs are detailed below. Other costs to FDA could include reviewing waiver requests; reconsidering denials of applications for recognitions or denials of waiver requests; revoking recognition of ABs and withdrawing accreditation of CBs; and initial start-up costs, including training new employees and establishing an IT system to support the new program. Because of the nature of these activities, at this time, FDA does not anticipate collecting user fees to pay for these other costs them.

Initial Applications for Recognition of ABs and Direct Accreditation of CBs

Sections 1.631 and 1.671 of the Third-Party final rule require us to review ABs' applications for recognition and, in the limited circumstances in which direct accreditation of CBs is an option, CBs' applications for direct accreditation. In addition to review of such applications for completeness, we will review their submissions against the requirements of the Third-Party regulation and will conduct a performance evaluation (onsite assessment). Our IT system will initially automatically determine if an application is complete.

Under § 1.705(a)(1) of the Third-Party User Fee proposed rule, 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. FDA employees are likely to review applications and prepare reports from their worksites. 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.

The total estimated costs for initial recognition of ABs and initial direct accreditation of CBs include costs for review of submissions, onsite assessment, onsite assessment report preparation, and related costs. To estimate costs related to various activities conducted by FDA employees under the Third-Party program we look to 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 (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFA)). Data shows 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 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 first calculates 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 then divides 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 CFSAN and 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 rate to be 2.20 percent (78 FR 46980, Aug. 2, 2013), and the inflation rate for the FY 2015 to be 2.0813 percent (79 FR 44807, Aug. 1, 2014). 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.

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, FDA determines 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 calculates the additional cost per hour spent on travel (taking into account domestic and foreign travel, as applicable), adjusts for inflation, and adds this amount to the base unit fee.

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 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 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. (Ref. A1)

Initial records review. We currently anticipate that initial records review of an AB's submission, on average, will comprise of 60 person-hours by a FDA full-time employees at $202 per hour. Unit cost for initial records review of an AB's application is estimated at $12,120 (60 hours x $202/hour). Table A1 includes the unit cost of initial records review of an AB's submission during our application review process. We expect to incur similar unit costs for

initial records review of a CB's application for direct accreditation, in the limited circumstances under which we will accept applications for direct accreditation.

Onsite assessment and report. When considering whether to grant an initial application for recognition, we expect to conduct an onsite assessment of the applicant AB.[2] We estimate that, on average, the onsite assessment would take each FDA employee approximately 8 hours onsite, and 16 hours for a roundtrip travel time to a foreign destination. We anticipate that two full-time FDA employees will participate in the initial onsite assessment. On average, unit cost for our labor cost for the initial field audit of an AB is estimated at $14,640 (2 persons x 24 hours/person x $305/hour). Subsequent to a onsite assessment, our personnel who participate in the audit will take approximately 45 person-hours to prepare a written report documenting the onsite assessment. Unit cost for preparation of the written report following the onsite assessment of an AB is estimated at $9,090 (45 person-hours x $202/person-hour). Table A1 includes the unit cost of the initial onsite assessment, and report preparation following the audit of an AB during the application review process.

Total costs. Adding these costs together yields an average total cost of review and evaluation of an initial application for recognition of an AB or an application for direct accreditation of a CB of $35,850 ($12,120 + $14,640 + $9,090) (see Table A1). Undiscounted and annualized costs for our review and evaluation of initial applications for recognition of 69 ABs (§1.631), and direct accreditation of one CB (§1.671) are included in Table A2.

Note that these calculations illustrate how user fees for applications—for ABs applying for recognition or CBs applying for direct accreditation—can be constructed. We expect that all of the

[2] If more evaluations are conducted in-house at FDA, the costs in this section are overestimated.

estimates used to calculate the actual user fees for the Third-Party accreditation program will be informed by FDA's experience with the program, once it 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 ABs applying for recognition are located in the United States, domestic travel, not foreign travel will be needed to conduct onsite assessments 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.

Subsequent Application Reviews (Renewals)

Sections 1.630 and 1.632 of the Third-Party final rule describe the duration of recognition (not to exceed 5 years) and requirements for renewal of recognition by recognized ABs. Sections 1.670 and 1.672 of the Third-Party final rule describe the duration of accreditation (not to exceed 4 years) and requirements of the renewal of direct accreditation of a CB. For the purpose of this analysis, all ABs are recognized for the maximum duration of 5 years and all CBs are accredited for the maximum duration of 4 years. The review and evaluation of renewal applications by recognized ABs and directly-accredited CBs is expected to be less burdensome than the review and evaluation required for initial applications for recognition and direct accreditation, respectively.

The total estimated costs for reviews of renewal applications include estimations of costs for application records review, evaluation (i.e., in-house records reviews or onsite assessments), report preparation, and related costs. As explained above, we use $202/hour and $305/hour to estimate the costs for activities conducted by FDA personnel for ABs and CBs.

Renewal application records review. We expect that review of records for a renewal application from a recognized AB or a directly-accredited CB would take no more than a work week by a full- time FDA employee at $202 per hour. Therefore, the unit cost for renewal application review of a recognized AB or a directly-accredited CB, under §1.631 or §1.671 of the Third- Party final rule, is estimated at $8,080 (5 days x 8 hours/day x $202/hour).

Evaluations and reports. For ABs' renewal application for recognition, it is expected that 25% of such renewals will include an onsite assessment. We expect that it will take 16 hours for FDA personnel to travel to the AB location and 16 hours (2 days) to conduct onsite assessment for a total of 32 hours. Therefore, on average, only 8 hours of FDA personnel (32 hours x 25%) is spent on a field audit of an AB facility as part of its renewal of recognition application process. On average, the cost of an onsite assessment for an AB as part of its renewal of recognition application is estimated at $2,440 (8 hours x $305/hour).

Report preparation for onsite assessments for renewal applications would be similar to the initial onsite assessments (i.e., 45 hours for each of the FDA teams) while the report preparation for in-house records review is expected to utilize 40 hours of time by employees for the AB evaluation. The weighted average, of report preparation for the onsite assessments and in-house records review, results in 41.25 hours ((45 hours x 25%) + (40 hours x 75%)). The unit cost for report preparation of onsite assessments required as part of renewal of recognition application by recognized ABs is estimated at $8,333 (41.25 hours x $202/hour). Total cost for full-time FDA employees to review and evaluate the renewal of recognition application for a recognized AB is estimated at $18,853 ($8,080 + $2,440 + $8,333) (see Table A1).

For directly-accredited CBs, we expect to conduct all of the performance evaluations through onsite assessments. As in performance evaluations of initial application reviews, the

unit cost for application records review is $8,080. Onsite assessment for renewal applications of a directly-accredited CB is estimated at $9,760 (1 person x 32 hours x $305/hour) (see Table A1). Report preparation costs are same as those conducted during the initial onsite assessment or $9,090 (45 hours x $202/hour). Total cost for full-time FDA employees to review the renewal of direct accreditation application of a directly-accredited CB is estimated at $26,930 ($8,080 + $9,760 + $9,090) (see Table A1).

We annualize these costs over a 10-year period at discount rates of 3% and 7% to gain an average cost per year in that period. Estimated annualized costs for our initial and renewal application reviews of the three scenarios described above are approximately between $86,000 and $146,000 when annualized at 7% discount rate over a 10-year period (see Table A2-A4).

Table A1 - Unit Costs (User Fees) of Application Review and Evaluation– FDA

Final Rule Section/Description	Number of Hours	Estimated Hourly Cost	Unit Cost/ User Fees	Frequency
§1.631 Initial AB Recognition				**One-time**
§1.671 Initial CB Direct Accreditation				**One-time**
Application records review	60	$202	$12,120	
Onsite assessment	48	$305	$14,640	
Report preparation	45	$202	$9,090	
Total	**153**		**$35,850**	
§1.631 Renewal of AB Recognition [1]				**Every 5 years[3]**
Application records review	40	$202	$8,080	
Onsite assessment	8	$305	$2,440	
Report preparation	41.25	$202	$8,333	
Total	**89.25**		**$18,853**	
§1.671 Renewal of CB Direct Accreditation [2]				**Every 4 years[3]**
Application records review	40	$202	$8,080	
Onsite assessment	32	$305	$9,760	
Report preparation	45	$202	$9,090	
Total	**117**		**$26,930**	

1. As part of renewal of AB recognition application, we expect to conduct 25% of the evaluations through onsite assessments.
2. As part of renewal of CB direct accreditation application, we will conduct 100% of the evaluations through onsite assessments.
3. For the purpose of this analysis we are assuming that all ABs are recognized for the maximum duration of 5 years and that all CBs are accredited for the maximum duration of 4 years.

Table A2: Scenario 1, 10-Year undiscounted and annualized costs for AB and directly-accredited CB Participants—FDA application review and evaluation process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.631 Initial AB Recognition	1	$35,850	11	$394,350
§1.671 Initial CB Direct Accreditation	1	$35,850	1	$35,850
§1.631 Renewal of AB Recognition	1	$18,853	11	$207,383
§1.671 Renewal of CB Direct Accreditation	2	$26,930	1	$53,860
Total Undiscounted				**$691,443**
Total Annualized Cost (3%)				**$76,701**
Total Annualized Cost (7%)				**$87,460**

Table A3: Scenario 2, 10-Year undiscounted and annualized costs for AB and directly-accredited Participants—FDA application review and evaluation process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.631 Initial AB Recognition	1	$35,850	17	$609,450
§1.671 Initial CB Direct Accreditation	1	$35,850	1	$35,850
§1.631 Renewal of AB Recognition	1	$18,853	15	$282,795
§1.671 Renewal of CB Direct Accreditation	2	$26,930	1	$53,860
Total Undiscounted				**$981,955**
Total Annualized Cost (3%)				**$106,247**
Total Annualized Cost (7%)				**$117,604**

Table A4: Scenario 3, 10-Year undiscounted and annualized costs for AB and directly-accredited CB Participants—FDA application review and evaluation process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.631 Initial AB Recognition	1	$35,850	25	$896,250
§1.671 Initial CB Direct Accreditation	1	$35,850	1	$35,850
§1.631 Renewal of AB Recognition	1	$18,853	15	$320,501
§1.671 Renewal of CB Direct Accreditation	2	$26,930	1	$53,860
Total Undiscounted				**$1,306,461**
Total Annualized Cost (3%)				**$138,016**
Total Annualized Cost (7%)				**$148,265**

Monitoring of Recognized ABs and Directly-Accredited CBs

Section 1.633 of the Third-Party final rule requires us to evaluate the performance of each recognized AB at least by the fourth year of a five year term and by the midway point of a

term of less than five years. It is expected that monitoring activities would be an abbreviated form of the evaluations conducted during the application review process of the ABs.

The total estimated costs for monitoring activities of ABs and directly-accredited CBs include costs for records review, performance evaluation, performance evaluation report preparation, and related costs. We have used $202/hour and $305/hour to estimate the costs of activities conducted by FDA personnel at FDA facilities and foreign locations, respectively.

We assume that 10% of monitoring activities for recognized ABs will be conducted onsite while the remaining monitoring activities will be conducted in-house through review of records and assessment of other information, including reports and notifications submitted by recognized ABs.

We expect that review of records as part of monitoring activities of a recognized AB or a directly-accredited CB would take 3 days by a full- time FDA employee at $202 per hour. Therefore, the unit cost for records review of a directly-accredited CB, as part of §1.671 of the Third- Party final rule, is estimated at $4,848 (3 days x 8 hours/day x $202/hour) (see Table A5).

Unit costs for our onsite assessment activities are equivalent to those performed during initial onsite assessments. We expect that onsite evaluations will be needed for monitoring of 10% of recognized ABs and CBs accredited by FDA-recognized ABs. Therefore, on average, estimated time for periodic onsite monitoring for recognized ABs and CBs currently accredited under the third-party program is 4.8 hours (48 hours x 10%) (see Table A5). Estimated cost for onsite monitoring activities for recognized ABs and CBs currently accredited under the third-party program is $1,464 (4.8 hours x $305/hour). We plan to conduct onsite monitoring activities for each directly-accredited CBs every year. Therefore, estimated cost for onsite

monitoring activities for directly-accredited CBs is $14,640 (48 hours x $305/hour).Estimated time for report preparation for on-site monitoring of a recognized AB, CB currently accredited under the third-party program, or directly-accredited CB is 8 hours. Estimated cost for report preparation for periodic monitoring activity is $1,616 (8 hours x $202/hour). Unit cost of monitoring activities of a recognized AB or an accredited CB is estimated at $7,928 ($4,848 + $1,464 + $1,616). Unit cost for monitoring activity of a directly-accredited CB is estimated at $21,104 ($4,848 + $14,640 + $1,616). (see Table A5).

Section 1.662(a) of the Third-Party final rule requires us to evaluate the performance of each CB currently accredited under the third-party program at least once every three years after the date of accreditation. In addition, it requires us to evaluate annually the performance of the subset of CBs that we directly accredit. These costs are similar to costs of monitoring activities for the recognized ABs and are included in Table A5. Estimated annualized costs for our monitoring for the three scenarios described above are approximately between $256,000 and $321,000 when annualized at 7% discount rate over a 10-year period (see Tables A6-A8).

Table A5: Unit Costs (User Fees) of Monitoring Activities – FDA

Third Party Final Rule Section	Number of Hours	Est. Hourly Cost	Unit Cost	Frequency
§1.633 FDA monitoring of recognized ABs[1]				**Every 4 years**
§1.662(a) FDA monitoring of CBs accredited under the third-party program[1]				**Every 3 years**
Records review	24	$202	$4,848	
Onsite performance evaluation	4.8	$305	$1,464	
Monitoring report preparation	8	$202	$1,616	
Total	**36.8**		**$7,928**	
§1.662(a) FDA monitoring of directly-accredited CBs[2]				**Annual**
Records review	24	$202	$4,848	
Onsite performance evaluation	48	$305	$14,640	
Monitoring report preparation	8	$202	$1,616	
Total	**80**		**$21,104**	

1. We expect to conduct 10% of the monitoring activities of recognized ABs and CBs accredited under the third-party program through onsite assessments.
2. We expect to conduct 100% of the monitoring activities of directly-accredited CBs through onsite assessments.

Table A6: Scenario 1, 10-Year undiscounted and annualized costs for entire AB and CB Participants—FDA Monitoring process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.633 FDA monitoring of recognized ABs	1	$7,928	22	$174,416
§1.662(a) FDA monitoring of CBs accredited under	1	$7,928	273	$2,164,344
§1.662(a) FDA monitoring of directly-accredited CBs	7	$21,104	1	$147,728
Total Undiscounted Cost – 10-Years				**$2,486,488**
Total Annualized Cost (3%)– 10-Years				**$251,979**
Total Annualized Cost (7%)– 10-Years				**$255,634**

Table A7: Scenario 2, 10-Year undiscounted and annualized costs for entire AB and CB Participants—FDA Monitoring process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.633 FDA monitoring of recognized ABs	1	$7,928	27	$214,056
§1.662(a) FDA monitoring of CBs accredited under	1	$7,928	313	$2,481,464
§1.662(a) FDA monitoring of directly-accredited CBs	7	$21,104	1	$147,728
Total Undiscounted Cost – 10-Years				**$2,843,248**
Total Annualized Cost (3%)– 10-Years				**$287,235**
Total Annualized Cost (7%)– 10-Years				**$290,182**

Table A8: Scenario 3, 10-Year undiscounted and annualized costs for entire AB and CB Participants—FDA Monitoring process

Third-Party Final Rule Section	Number of Units	User Fee	Number of ABs/CBs	Undiscounted Cost—10 years
§1.633 FDA monitoring of recognized ABs	1	$7,928	32	$253,696
§1.662(a) FDA monitoring of CBs accredited under	1	$7,928	352	$2,790,656
§1.662(a) FDA monitoring of directly-accredited CBs	7	$21,104	1	$147,728
Total Undiscounted Cost – 10-Years				**$3,192,080**
Total Annualized Cost (3%)– 10-Years				**$321,546**
Total Annualized Cost (7%)– 10-Years				**$323,598**

Appendix B: Compliance Costs of ABs and CBs

We estimate costs of ABs and CBs that would potentially comply with the Third-Party final rule. We assume that the ABs and CBs participating under our Third-Party program would pass down their compliance costs, as well as user fee costs described in Appendix A, to the eligible entities that they audit. In this appendix, we estimate the share of the ABs' compliance and user fee costs on the CBs that they accredit, and share of the CBs' compliance and user fee costs to each eligible entity.

Accreditation Bodies

Application for Recognition

An AB may apply for recognition from FDA in accordance with §1.630 of the Third-Party final rule. We estimate the costs of the three scenarios considered in this analysis where a total of 11 to 25 ABs will apply for recognition from the FDA. We expect that it will take 80 person-hours to compile all the relevant information and complete the application for recognition from the FDA. Furthermore, we proxy the private sector average hourly wage rate of person(s) who will be completing the application with the equivalent of a public sector GS-14, Step 1 employee at $83 per hour (includes 100% overhead cost)(Ref. B1). Therefore, we estimate that it will cost approximately $6,640 (80 hours x $83/hour) for an AB to apply for recognition from the FDA. Unit cost of application for recognition by ABs is included in Table B1.

Section 1.632 of the Third-Party final rule stipulates the term of recognition for an AB not to exceed 5 years. For the purpose of this analysis, all ABs are recognized for the maximum duration of 5 years. Section 1.630 of the Third-Party final rule outlines the requirements of abbreviated application for renewal of recognition by a recognized AB. We expect that applications for renewal of recognition will take significantly less time to prepare.

We use 50% of amount of effort to prepare and submit an application for renewal of recognition to the FDA. Hence, we believe that it would cost approximately $3,320 to complete an application for renewal of recognition every 5 years for recognized ABs. Unit cost of application for renewal of recognition by ABs is included in Table B1.

Some application review activities by the FDA will require the presence of FDA personnel in the facilities of ABs that apply for recognition (§1.631), or in the facilities of recognized ABs as part of renewal of recognition applications (§1.631). During these FDA activities, or onsite assessments, it is expected that the subject AB would assign someone to serve as a liaison with the FDA during the entire time that the FDA team is onsite. We estimate that during the initial onsite assessment at an AB facility, two FDA personnel will spend approximately 8 hours each onsite (the remaining 32 hours is for travel time) at the AB headquarters. For onsite assessments during renewal of recognition of ABs, we expect that one FDA personnel will spend approximately 4 hours onsite at the AB headquarters. We also expect that the person employed by the AB that is assigned to the FDA team would have a management position and as a proxy for the firm's private labor costs we proxy that person's salary as equivalent to a public GS-13, Step 5 pay level ($79/hour including 100% overhead costs; FY2015). It is expected that there will be an AB representative present at the AB headquarters for a total of 8 hours. Therefore, the cost of AB staff labor to assist during a FDA onsite assessment for the initial AB application is estimated at $632 (8 hours x $79/hour). Cost of AB staff labor to assist during FDA's subsequent onsite assessments for renewal of application is estimated at $316 (4 hours x $79/hour). Unit cost of AB labor cost to assist the FDA team during onsite assessments as part of §1.631 of the Third-Party final rule is included in Table B1.

Monitoring

Current business practices of ABs include monitoring the performance of each of their accredited CBs on annual basis (similar to §1.621 of the Third-Party final rule) and internal audits similar to the self-assessments in §1.622 of the Third-Party final rule.

Section 1.633 of the Third-Party final rule requires that the FDA monitor recognized ABs through performance evaluations at least once every 4 years. We expect that approximately10% of onsite assessments conducted as part of §1.633 of the Third-Party final rule will be conducted onsite. As discussed in Appendix A, two FDA personnel participate in FDA's onsite assessment for amount of 8 hours during the onsite assessment of the application review process of an AB. Therefore, on average, it would cost an AB approximately $632 (8 hours x $79/hour) to provide staff labor to act as a liaison for the FDA team during their monitoring activities (see Table B1).

Recordkeeping

The Third-Party final rule requires, in §1.615, that each AB seeking recognition from FDA demonstrate that it has implemented written procedures to maintain records related to its accreditation program and activities demonstrating its authority, qualifications, conflict of interest measures, internal quality assurance program, performance, and corrective actions. Section 1.625 of the Third-Party final rule requires each AB, once recognized, to maintain records that include requests for accreditation, challenges to accreditation decisions, monitoring of CBs that it has accredited, the AB's self-assessments and corrective actions, and regulatory audit reports.

Currently, the AB industry maintains written records of its accreditation program, qualifications, annual self-assessment, annual monitoring of its accredited CBs, and corrective actions. ABs also have provisions in place to ensure that that financial conflict of interest does not occur between themselves and the CBs that they accredit, and between accredited CBs and

entities that they audit. However, we believe that a recognized AB incurs new recordkeeping burden by making its records available for inspection by the FDA.

We expect that it will take approximately 2 hours each year for a recognized AB to maintain its records to accommodate inspection by the FDA. The average hourly wage rate of person(s) who will be completing the application is expected to be equivalent to that of a GS-14, Step 1 employee at $83 per hour (includes 100% overhead cost). Therefore, we estimate that it will cost approximately $166 per year (2 hours/year x $83/hour) for an AB to maintain its records in accordance with §1.615 and §1.625 of the Third-Party final rule. Unit cost of improving recordkeeping procedures for ABs is included in Table B1.

Section 1.624(d) of the Third-Party final rule requires ABs to maintain on its website an up-to-date list of its CBs accredited under the third-party program, the duration and scope of the accreditation, and the date on which the CB paid any fee or reimbursement associated with such accreditation. If the accreditation of a certification body is suspended, withdrawn, or reduced in scope, the website must also include the date of suspension, withdrawal, or reduction in scope and maintain that information for the duration of accreditation or until the suspension is lifted, the certification body is reaccredited, or the scope of accreditation is reinstated, whichever comes first. Currently, some but not all ABs disclose the names of their CBs they accredit and scope of the CBs' accreditation on their website. Therefore, we believe that some recognized ABs will incur a new recordkeeping burden by making information required by proposed §1.624(d) publicly available on their websites.

We assume that ABs applying for recognition already have websites with varying levels of sophistication. According to IT experts, wage rate of a fully-supported web developer and/or web content specialist (including benefits and overhead costs) is approximately $120 per hour.

Work conducted by a web developer to modify an AB's webpage to conform to §1.624(d) is expected to require 160 hours of labor by a fully-supported web developer. Therefore, we expect that each recognized AB would initially spend approximately $19,200 ($120/hour x 160 hours) to update its webpage to conform with this section of the Third-Party final rule. In addition, we estimate that each AB would spend 8 hours annually, following the initial year, to update information as required by §1.624(d) of the Third-Party final rule. We expect the average hourly wage rate of IT person(s) who will be updating information on the AB's webpage to be equivalent to that of a GS-13, Step 5 employee at $79 per hour (includes 100% overhead cost).

Annual unit cost for an AB to update its webpage to conform to disclosure of information per §1.624(d) of the Third-Party final rule is estimated at $632 ($79/hour x 8 hours). One-time and annual unit costs for publicly disclosing information required per §1.624(d) of the Third-Party final rule are included in Table B1.

Reporting

Sections 1.621 and 1.623(a) of the Third-Party final rule require that recognized ABs annually conduct comprehensive assessments of the performance of CBs they have accredited and submit the assessments to the FDA within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically send the assessment of each its accredited CBs to the FDA. Following the implementation of the Third-Party final rule, we expect, on average, each recognized AB would accredit 8.23 CBs (568 existing CBs currently accredited under other programs ÷ 69 ABs). Therefore, submission of performance assessments of 8.23 CBs would take approximately 2.06 hours/AB (0.25 hours/CB x 8.23 CBs/AB). We use hourly wage of an Executive Secretary to estimate each AB's cost of submission of performance assessment of its accredited CBs to the FDA. The Bureau of Labor Statistics (BLS) reports the

median hourly wage rate for an Executive Secretary (Occupational Code 43-6011) as $28.30 (Ref. B2). The hourly wage rate plus 100% overhead cost for such positions are calculated as $57. Therefore, we estimate that it would cost each AB approximately $117 every year (2.06 hours/AB x $57/hour) to report findings of its review of operations of its accredited CBs to the FDA (see Table B1).

Sections 1.622 and 1.623(b) of the Third-Party final rule require that recognized ABs annually conduct a self-assessment and submit the assessments to the FDA within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically send a copy of its self-assessment to the FDA. Unit cost of submission of a self-assessment by an Executive Secretary to the FDA is estimated at $14 (0.25 hour/AB x $57/hour) (see Table B1).

Contract Modification

We expect that upon the implementation of the rule, recognized ABs would modify the contracts they use with CBs accredited under their programs in order to reflect requirements that are set forth in the Third-Party final rule. Minor modifications or addenda to contracts with standard language provided by provisions in the Third-Party final rule would consist of no more than one hour by an AB executive and one hour by a legal counsel. BLS data indicates that a General and Operations Manager (Occupation code 11-1021) in a company earns approximately $144 per hour ($71.79/hour plus 100% overhead) (Ref. B3), and lawyers in management of companies and enterprises (Occupation code 23-1011) earn approximately $163 per hour ($81.68/hour plus 100% overhead) (Ref. B4). Unit costs for contract modification by ABs are included in Table B1.

Table B1: Unit Costs (Compliance Costs) of Participation under the Third-Party Final Rule – per AB

Final Rule Section/Description	Number of Hours/Units	Wage Rate/ Cost	Unit Cost	Frequency
Application for Recognition				
§1.630 Application for recognition	80	$83	$6,640	One-time
§1.630 Application for renewal of recognition	40	$83	$3,320	Every 5 years*
§1.631 Support for FDA team during initial onsite AB recognition onsite assessment	8	$79	$632	One-time
Total	**128**		**$10,592**	
Monitoring				
§1.631 Support for FDA team during renewal of onsite AB recognition onsite assessment	4	$79	$316	Every 5 years*
§1.633 Support for FDA team during onsite monitoring activities of ABs	8	$79	$632	Every 4 years
Total	**12**		**$948**	
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	2	$83	$166	Annual
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	160	$120	$19,200	One-time
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	8	$79	$632	Annual
Total	**170**		**$19,998**	
Reporting				
§1.623(a) Submission of review of CB performance	2.06	$57	$117	Annual
§1.623(b) Submission of self-assessment	0.25	$57	$14	Annual
Total	**2.31**		**$131**	
Contract Modification				
Contract modification between ABs and accredited CBs	1	$144	$144	One-time
Contract modification between ABs and accredited CBs (legal counsel)	1	$163	$163	One-time
Total	**2**		**$307**	

* For the purpose of this analysis we are assuming that all ABs are recognized for the maximum duration of 5 years.

Cost Summary – ABs

Total annualized cost for the ABs, in the three considered scenarios, to conform to the Third-Party final rule for a 10- year period at 7% discount rate is estimated at approximately between $34,261 and $54,218 (see Tables B2-B4).

Table B2: Scenario 1, Undiscounted and Annualized Costs for Participation under the Third-PartyFinal Rule – ABs

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost[1]
Application for Recognition				

§1.630 Application for recognition	1	$6,640	11	$73,040
§1.631 Performance evaluation conducted by FDA during	1	$3,320	11	$36,520
§1.630 Application for renewal of recognition	1	$632	11	$6,952
Total				**$116,512**
Monitoring				
§1.631Performance evaluation conducted by FDA during	1	$316	11	$3,476
§1.633 Support for FDA team during onsite monitoring	2	$632	11	$13,904
Total				**$17,380**
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	10	$166	11	$18,260
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	1	$19,200	11	$211,200
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	9	$632	11	$62,568
Total				**$292,028**
Reporting				
§1.623(a) Submission of review of CB performance	10	$117	11	$12,870
§1.623(b) Submission of self-assessment	10	$14	11	$1,540
Total				**$14,410**
Contract Modification				
Contract modification between ABs and CBs they accredit	8.23	$144	11	$13,036
Contract modification between ABs and CBs they accredit (legal counsel)	8.23	$163	11	$14,756
Total				**$27,793**
Total Undiscounted Cost – 10-Years				**$468,123**
Total Annualized Cost (3%)[4] – 10-Years				**$50,031**
Total Annualized Cost (7%)[4] – 10-Years				**$58,119**

1. Undiscounted cost comprises of summing nominal costs over a 10-year period.
2. Onsite performance evaluation during renewal of application activities is conducted at 25% of facilities.
3. Onsite monitoring activities is conducted at 10% of facilities.
4. Estimated for 10-year period at 7% discount rate

$A = \frac{PV}{\left[(1+i)^{n-1}\left(i*(1+i)^{n}\right)\right]}$, where PV = Present Value, n = 10, and i = 0.07 or 0.03

Table B3: Scenario 2, Undiscounted and Annualized Costs for Participation under the Third-Party Final Rule – ABs

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost
Application for Recognition				
§1.630 Application for recognition	1	$6,640	17	$112,880
§1.631 Performance evaluation conducted by FDA during	1	$3,320	15	$49,800
§1.630 Application for renewal of recognition	1	$632	17	$10,744
Total				**$173,424**
Monitoring				
§1.631Performance evaluation conducted by FDA during	1	$316	15	$4,740
§1.633 Support for FDA team during onsite monitoring	2	$632	26	$16,432

Total				**$21,172**
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	1	$166	116	$19,256
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party	1	$19,200	17	$326,400
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party	1	$632	116	$73,312
Total				**$418,968**
Reporting				
§1.623(a) Submission of review of CB performance	1	$117	68	$7,992
§1.623(b) Submission of self-assessment	1	$14	402	$5,623
Total				**$13,615**
Contract Modification				
Contract modification between ABs and CBs they accredit	8.23	$144	17	$20,147
Contract modification between ABs and CBs they accredit (legal counsel)	8.23	$163	17	$22,805
Total				**$42,952**
Total Undiscounted Cost – 10-Years				**$670,131**
Total Annualized Cost (3%)[4] – 10-Years				**$69,278**
Total Annualized Cost (7%)[4] – 10-Years				**$77,876**

Table B4: Scenario 3, Undiscounted and Annualized Costs for Participation under the Third-Party Final Rule – ABs

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost
Application for Recognition				
§1.630 Application for recognition	1	$6,640	25	$166,000
§1.631 Performance evaluation conducted by FDA during	1	$3,320	17	$56,440
§1.630 Application for renewal of recognition	1	$632	25	$15,800
Total				**$238,240**
Monitoring				
§1.631Performance evaluation conducted by FDA during	1	$316	17	$5,372
§1.633 Support for FDA team during onsite monitoring	2	$632	26	$16,432
Total i f AB				**$21,804**
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	1	$166	124	$20,584
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	1	$19,200	25	$480,000
§1.624(d) Public list of certification bodies, scope of accreditation of CBs accredited under the third-party program, and fee payments	1	$632	124	$78,368
Total				**$578,952**
Reporting				
§1.623(a) Submission of review of CB performance	1	$117	60	$7,068
§1.623(b) Submission of self-assessment	1	$14	505	$7,068
Total				**$14,136**
Contract Modification				

Contract modification between ABs and CBs they accredit	8.23	$144	25	$29,628
Contract modification between ABs and CBs they accredit (legal counsel)	8.23	$163	25	$33,537
Total				**$63,165**
Total Undiscounted Cost – 10-Years				**$916,297**
Total Annualized Cost (3%)[4] – 10-Years				**$91,813**
Total Annualized Cost (7%)[4] – 10-Years				**$99,823**

Accredited Certification Bodies

Application for Direct Accreditation from FDA

Section 1.670(a-b) of the Third-Party final rule allows for CBs to directly apply for accreditation from the FDA under limited circumstances. We estimate that a CB completing and submitting an application for direct accreditation from FDA will expend the same amount of effort as an AB that applies for recognition from the FDA. Hence, we expect that it will take 80 person-hours to compile all the relevant information and complete the application for direct accreditation from the FDA. Therefore, we estimate that it will cost approximately $6,640 (80 hours x $83/hour) for a CB to apply for direct accreditation from the FDA. Unit cost of application for direct accreditation by CBs is included in Table B5.

Section 1.672 of the Third-Party final rule stipulates the term of accreditation for a directly-accredited CB not to exceed 4 years. For the purpose of this analysis, all CBs are accredited for the maximum duration of 4 years. Section 1.670 of the Third-Party final rule outlines the requirements of abbreviated application for renewal of accreditation by directly-accredited CBs. As with the application process for renewal of recognition by ABs, we expect that application for renewal of direct accreditation by CBs to take significantly less effort than the initial application. We use 50% of amount of effort to prepare and submit an application for renewal of direct accreditation to the FDA. Hence, it would cost approximately $3,320 to

complete an application for renewal of direct accreditation every 4 years. Unit cost of application for renewal of direct accreditation by CBs is included in Table B4.

Application review activities by the FDA includes presence of FDA personnel in the facilities of CBs that apply for direct accreditation (§1.671) or that seek renewal of direct accreditation applications (§1.671). During these FDA activities, or onsite assessment, it is expected that the subject CB would assign someone to serve as a liaison with the FDA during the entire time that the FDA team is onsite. As we discussed in Appendix A, we estimate that during the initial onsite assessments, the FDA team spends approximately 8 hours onsite at the CB headquarters. During the onsite assessments conducted as part of the renewal of direct accreditation of CBs, we estimate that one FDA personnel spend approximately 4 hours onsite at the CB facility. We also expect that the person employed by the CB that is assigned to the FDA team would have a management position and a salary equivalent to a GS-13, Step 5 pay level ($79/hour including 100% overhead costs). It is expected that there will be a CB representative present at the CB headquarters for 8 hours for the initial onsite assessment and 4 hours for subsequent onsite assessments for application renewal. Therefore, the cost of CB staff labor to assist during FDA's initial onsite assessment is estimated at $632 (8 hours x $79/hour), and $316 (4 hours x $79/hour) for subsequent onsite assessments for application renewal. Unit cost of CB labor cost to assist FDA team during onsite assessments as part of §1.671 of the Third-Party final rule is included in Table B5.

Monitoring

Current business practices of CBs include internal audits similar to the annual self-assessments required to be prepared under §1.655 of the Third-Party final rule. We note that an

accredited third-party certification body may be required for cause or after denial of renewal, revocation, or relinquishment of recognition of their accreditation body to prepare a report of its self-assessment. However because it is not possible to determine how frequently these reports will need to be prepared, it is not possible to determine how much this will cost. Therefore the compliance costs here represent a lower bound estimate.

Section 1.662(a) of the Third-Party final rule requires that the FDA monitor CBs accredited by recognized ABs through performance evaluations by at least the 3rd year during a 4 year term of accreditation. We expect that approximately 10% of performance evaluations conducted as part of §1.662(a) of the Third-Party final rule will be conducted onsite. As in the AB's monitoring discussed above, it would cost a CB approximately $63 (10% x 8 hours x $79/hour) to provide staff labor to act as a liaison for the FDA team during their monitoring activities. Finally, section 1.662(a) of the Third-Party final rule stipulates that the FDA monitor directly-accredited CBs on an annual basis. FDA will monitor all directly-accredited CB; therefore it would cost a directly-accredited CB approximately $632 (8 hours x $79/hour) to provide support for FDA personnel during monitoring activities. Unit costs of §1.662(a) of the Third-Party final rule are included in Table B5.

As discussed in Appendix A, we expect that approximately10% of onsite assessments conducted as part of monitoring activities of CBs accredited by recognized ABs will be conducted onsite. Two FDA personnel participate in onsite assessment the CB facility for amount of 8 hours during the onsite assessment of the application review process of a CB accredited under the third-party program. Therefore, on average, it would cost a CB accredited under the third-party program approximately $63 (10% x 8 hours x $79/hour) to provide staff labor to act as a liaison for the FDA team during its annual monitoring activities (see Table B1).

Staff burden of directly-accredited CBs to support FDA during the annual monitoring activities is estimated 8 hours. Therefore, it would cost a directly-accredited CB approximately $632 (8 hours x $79/hour) (see Table B5).

Recordkeeping

Section 1.658 of the Third-Party final rule outlines recordkeeping requirements for CBs accredited under the third-party program. Based on descriptions by industry experts, we believe current recordkeeping practices by CBs currently accredited under other programs, for the most part, follow recordkeeping requirements set forth by the Third-Party final rule. (Ref 4, 5, 6) We expect that it will take approximately 2 hour each year for an CB currently accredited under other programs to modify its recordkeeping practices to match the requirements of the Third-Party final rule. The average hourly wage rate of person(s) who will be completing the application is expected to be equivalent to that of a GS-14, Step 1 employee at $83 per hour (includes 100% overhead cost). Therefore, we estimate that it will cost approximately $166 per year for a CB currently accredited under other programs to organize records pertaining to §1.658 of the Third-Party final rule. Unit cost of recordkeeping requirements of CBs currently accredited under other programs included in Table B5.

Section 1.657(d) of the Third-Party final rule requires CBs accredited under the third-party program to maintain on its website an up-to-date list of the eligible entities for which it has issued certifications, duration of scope of certification for each eligible entity, and the date on which an the eligible entity paid any fee with regard to the certification. Currently, it is not customary for CBs accredited under other programs to publish information required per §1.657(d) of the Third-Party final rule on their websites. Therefore, we believe that public disclosure of information required per §1.657(d) is a new burden to the CBs.

We use the same cost estimate of $19,200 used in recordkeeping section of ABs, above, for initial cost of updating a CB's webpage to include the information required in §1.624(c) of the Third-Party final rule. In addition, we estimate that each CB would spend 8 hours annually to update information as required by §1.657(d) of the Third-Party final rule. We expect the average hourly wage rate of IT person(s) who will be updating information on the CB's webpage to be equivalent to that of a GS-13, Step 5 employee at $79 per hour (includes 100% overhead cost). Therefore, the annual unit cost for a CB to update its webpage to conform to disclosure of information per §1.657(d) of the Third-Party final rule is estimated at $632 ($79/hour x 8 hours). One-time and annual unit costs for publicly disclosing information required per §1.657(d) of the Third-Party final rule are included in Table B5.

Reporting

Section 1.656(a) of the Third-Party final rule requires that a CB accredited under the third-party program must submit reports of the regulatory audits it conducts to FDA and to the AB that granted its accreditation within 45 days after completing such audit. In the analysis, we estimate that between 91 and 207 CBs currently accredited under other programs and one directly-accredited CBs that would potentially comply with the Third-Party final rule (see Table 5). Furthermore, we estimate that each CB accredited under the third-party program will conduct annual regulatory audits and certification for approximately 48 and 58 eligible entities. We expect that it would take a CB accredited under the third-party program no more than 15 minutes to electronically submit a copy of a regulatory audit report to the FDA. We use hourly wage rate of an administrative assistant, $57 (includes 100% overhead), to calculate the unit cost of submission regulatory audits of eligible entities by a CB accredited under the third-party program to FDA and its accrediting AB in a given year. Therefore, the annual unit cost for a CB

to submit a copy of a regulatory audit report to FDA or its AB is estimated at $14 (0.25 hours x $57/hour) (see Table B5).

Section 1.656(b) of the Third-Party final rule requires that a CB accredited under the third-party program must submit a copy of its annual self-assessment to its AB, or in the case of direct accreditation to the FDA, within 45 days of the anniversary date of its accreditation. We expect that it would take a CB accredited under the third-party program no more than 15 minutes to electronically submit a copy of its self-assessment to its AB or, in the case of direct accreditation, to the FDA. Therefore, we estimate that the annual submission of self-assessment by CBs accredited under the third-party program at approximately $14 (0.25 hours x $57/hour (see Table B5). We note that an accredited third-party certification body may be required for cause or after denial of renewal, revocation, or relinquishment of recognition of their accreditation body to submit a report of its self-assessment to FDA. However because it is not possible to determine how frequently these reports will need to be submitted, it is not possible to determine how much this will cost. Therefore the compliance costs here represent a lower bound estimate.

Section 1.656(c) of the Third-Party final rule requires that a CB accredited under the third-party program report to the FDA any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. Currently, we do not have any information on frequency of reporting serious public health risks by an accredited CB to its AB. We believe that these occurrences are rare and may occur once every 4 years. It is expected that a CB accredited under the third-party program would take no more than 1 hour to prepare such record (notification). Therefore, we estimate that, on average, it would cost a CB accredited under the third-party program approximately $79 (1 hour x

$79/hour) to document a condition that could cause or contribute to a serious risk to public health. In addition, it would take an administrative assistant no more than 15 minutes to electronically send the report documenting the serious risk to public health to the FDA. Unit cost for documenting and reporting serious risks to the public health discovered during a regulatory or consultative audit of an eligible entity by a CB accredited under the third-party program to the FDA is included in Table B5.

Following reporting of a condition that could cause or contribute a serious risk to the public health to the FDA, a CB accredited under the third-party program is required under §1.656(e) of the Third- Party final rule to immediately notify the eligible entity and its accrediting AB of any conditions identified during the audit which triggered the reporting requirement per §1.656(c) of the Third-Party final rule. We are not aware of any formal process currently used by CBs to communicate conditions that could cause or contribute to a serious risk to the public health to their clients; hence, this provision is considered as a new burden for CBs currently accredited under other programs. It is expected that following reporting of by a CB accredited under the third-party program to the FDA per §1.656(c) of the Third-Party final rule, it would take the accredited CB no more than 15 minutes to transmit the same report to the eligible entity where the condition was observed and to its AB (if other than FDA). The unit cost of reporting a condition that could cause or contribute to a serious risk to the public health by a CB accredited under the third-party program to an eligible entity is included in Table B5.

Contract Modification

We expect that upon the implementation of the rule, CBs accredited under the third-party program would modify the contracts they use with their clients in order to reflect requirements that are set forth in the rule. Minor modifications or addenda to contracts with standard language

provided by provisions in the Third-Party final rule would consist of no more than one hour by an AB executive and one hour by a legal counsel. BLS data indicates that an executive in management, scientific, and technical consulting services earns approximately $144 per hour (includes 100% overhead), and lawyers in management of companies and enterprises earn approximately $163 per hour (includes 100% overhead). Unit costs for contract modification by CBs are included in Table B5.

Table B5: Unit Costs (Compliance Costs) of Participation under the Third-Party Final Rule – per CB Accredited under the Third-Party Program

Third-Party Final Rule Section	Number of Hours/Units	Wage Rate/ Cost	Unit Cost	Frequency
Application for Direct Accreditation				
§1.670(a-b) Application for direct Accreditation	80	$83	$6,640	One-time
§1.670 Application for renewal of direct Accreditation	40	$83	$3,320	Every 4 years*
§1.671) Support for FDA team during initial onsite CB direct accreditation performance evaluation	8	$79	$632	One-time
§1.671 Support for FDA team during renewal of onsite CB direct accreditation performance evaluation	4	$79	$316	Every 4 years*
Total			**$10,938**	
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	0.8	$79	$63	Every 3 years
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	8	$79	$632	Annual
Total			**$695**	
Recordkeeping				
§1.658 Organizing records in accordance with the Third Party rule	2	$83	$166	Annual
§1.657(d) Public list of certification bodies, and other info (initial)	160	$120	$19,200	One-time
§1.657(d) Public list of certification bodies, and other info (annual)	8	$79	$632	Annual
Total			**$19,998**	
Reporting				
§1.656(a) Submission of regulatory audit reports to FDA and to the ABs	.25	$57	$14	Annual
§1.656(b) Submission of self-assessment	0.25	$57	$14	Annual
§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (preparation of report)	1	$79	$79	Every 4 years

§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (submission of report)	0.25	$57	$14	Every 4 years
§1.656(e) Submission of a report to eligible entity documenting a condition that would cause or contribute to a serious risk to the public health	0.25	$57	$14	Every 4 years
Total			**$135**	
Contract Modification				
Contract modification between CBs and eligible entities	1	$144	$144	One-time
Contract modification between CBs and eligible entities (legal counsel)	1	$163	$163	One-time
Total			**$307**	

* For the purpose of this analysis we are assuming that all CBs are accredited for the maximum duration of 4 years.

Cost Summary –CBs Accredited under the Third-Party Program

Total annualized cost for the three considered scenarios for a 10-year period at 7% discount rate is estimated at approximately $425,281 and $844,107 (see Tables B6-B8).

Table B6: Scenario 1, Undiscounted and Annualized Costs under the Third-Party Final Rule –CBs Accredited under the Third-Party Program

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost[1]
Application for Recognition				
§1.670(a-b) Application for direct accreditation	1	$6,640	1	$6,640
§1.670 Application for renewal of direct accreditation	2	$3,320	1	$6,640
§1.671) Support for FDA team during initial onsite CB	1	$632	1	$632
§1.671 Support for FDA team during renewal of onsite CB	2	$316	1	$632
Total				**$14,544**
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	1	$63	273	$17,199
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	7	$632	1	$4,424
Total				**$21,623**
Recordkeeping				
§1.658 Organizing records in accordance with the Third Party rule	1	$166	920	$152,720
§1.657(d) Public list of certification bodies, and other info (initial)	1	$19,200	92	$1,766,400
§1.657(d) Public list of certification bodies, and other info (annual)	1	$632	920	$581,440
Total				**$2,500,560**

Reporting				
§1.656(a) Submission of regulatory audit reports to FDA	1	$57	2,978	$169,718
§1.656(b) Submission of self-assessment	1	$14	920	$12,880
§1.656(c) Reporting to the FDA of a condition that could	1	$79	230	$18,170
§1.656(c) Reporting to the FDA of a condition that could	1	$14	230	$3,220
§1.656(e) Submission of a report to eligible entity	1	$14	230	$3,220
Total				**$207,208**
Contract Modification				
Contract modification between CBs and eligible entities	1	$144	1,191	$171,504
Contract modification between CBs and eligible entities	1	$163	1,191	$194,133
Total				**$365,637**
Total Undiscounted Cost – 10-Years				**$3,109,572**
Total Annualized Cost (7%)[4] – 10-Years				**$350,666**
Total Annualized Cost (3%)[4] – 10-Years				**$425,281**

1. Undiscounted cost comprises of summing nominal costs over a 10-year period.
2. Onsite performance evaluation during renewal of application activities is conducted at 25% of facilities (69 ABs).
3. Onsite monitoring activities is conducted at 10% of facilities (69 ABs).
4. Estimated for 10-year period at 7% discount rate

$A = \frac{PV}{\left[(1+i)^{n-1}\left(i*(1+i)^{n}\right)\right]}$, where PV = Present Value, n = 10, and i = 0.07 or 0.03

Table B7: Scenario 2, Undiscounted and Annualized Costs under the Third-Party Final Rule –CBs Accredited under the Third-Party Program

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost
Application for Recognition				
§1.670(a-b) Application for direct accreditation	1	$6,640	1	$6,640
§1.670 Application for renewal of direct accreditation	2	$3,320	1	$6,640
§1.671) Support for FDA team during initial onsite CB	1	$632	1	$632
§1.671 Support for FDA team during renewal of onsite CB	2	$316	1	$632
Total				**$14,544**
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	1	$63	313	$19,719
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	7	$632	1	$4,424
Total				**$24,143**
Recordkeeping				
§1.658 Organizing records in accordance with the Third Party rule	1	$166	969	$160,854
§1.657(d) Public list of certification bodies, and other info (initial)	1	$19,200	141	$2,707,200
§1.657(d) Public list of certification bodies, and other info (annual)	1	$632	969	$612,408
Total				**$3,480,462**
Reporting				
§1.656(a) Submission of regulatory audit reports to FDA	1	$57	6,972	$397,376
§1.656(b) Submission of self-assessment	1	$14	1,212	$16,968

§1.656(c) Reporting to the FDA of a condition that could	1	$79	303	$23,937
§1.656(c) Reporting to the FDA of a condition that could	1	$14	303	$4,242
§1.656(e) Submission of a report to eligible entity	1	$14	291	$4,071
Total				**$446,593**
Contract Modification				
Contract modification between CBs and eligible entities	1	$144	3,602	$518,688
Contract modification between CBs and eligible entities	1	$163	3,062	$587,126
Total				**$1,105,814**
Total Undiscounted Cost – 10-Years				**$5,071,556**
Total Annualized Cost (7%) – 10-Years				**$555,461**
Total Annualized Cost (3%) – 10-Years				**$673,954**

Table B8: Scenario 3, Undiscounted and Annualized Costs under the Third-Party Final Rule –CBs Accredited under the Third-Party Program

Third-Party Final Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost
Application for Recognition				
§1.670(a-b) Application for direct accreditation	1	$6,640	1	$6,640
§1.670 Application for renewal of direct accreditation	2	$3,320	1	$6,640
§1.671) Support for FDA team during initial onsite CB	1	$632	1	$632
§1.671 Support for FDA team during renewal of onsite CB	2	$316	1	$632
Total				**$14,544**
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	1	$63	348	$21,924
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	7	$632	1	$4,424
Total				**$26,348**
Recordkeeping				
§1.658 Organizing records in accordance with the Third Party rule	1	$166	1,036	$171,976
§1.657(d) Public list of certification bodies, and other info (initial)	1	$19,200	208	$3,993,600
§1.657(d) Public list of certification bodies, and other info (annual)	1	$632	1,036	$654,752
Total				**$4,820,328**
Reporting				
§1.656(a) Submission of regulatory audit reports to FDA	1	$57	6,972	$397,376
§1.656(b) Submission of self-assessment	1	$14	1,592	$22,288
§1.656(c) Reporting to the FDA of a condition that could	1	$79	398	$31,442
§1.656(c) Reporting to the FDA of a condition that could	1	$14	398	$5,572
§1.656(e) Submission of a report to eligible entity documenting a condition that would cause or contribute to a	1	$14	369	$5,166
Total				**$461,844**
Contract Modification				
Contract modification between CBs and eligible entities	1	$144	3,602	$518,688
Contract modification between CBs and eligible entities (legal counsel)	1	$163	3,062	$587,126

Total				**$1,105,814**
Total Undiscounted Cost – 10-Years				**$6,428,878**
Total Annualized Cost (7%) – 10-Years				**$695,605**
Total Annualized Cost (3%) – 10-Years				**$844,107**

Cost of Conformance to the Third-Party Final Rule

Undiscounted and annualized compliance and user fee costs of ABs, directly-accredited CBs, and CBs accredited by recognized ABs are summarized in Table B9. In Table 1, we indicated that we expect that 10 § 801(q) entities and between 459 and 2,001 § 806 entities (under different scenarios) are currently being audited and certified by CBs currently accredited under other programs, and the between 3,068 and 13,394 eligible entities are currently being audited by CBs not accredited under any program. We assume that the ABs and CBs participating in the Third-Party program pass down 100% of their compliance and user fee costs to the eligible entities. Accreditation costs for CBs not accredited under any program who choose to become accredited are passed down to eligible entities that are currently being audited by CBs not accredited under any program. In summary, if all ABs' and CBs' compliance costs and user fees are passed down to the eligible entities, additional cost that an eligible entity pays for annual audits and certifications increases between approximately $227 and $694 (see Table B9).

Table B9: AB and CB Pass-Through Costs to Eligible Entities

Description	**Scenarios**		
	1	**2**	**3**
Annualized Cost (7%, 10-year)			
ABs compliance	$58,119	$77,876	$99,823
ABs and directly-accredited CBs user fees	$343,094	$407,786	$471,863
CBs compliance	$425,281	$673,954	$844,107
Number of eligible entities	1,191	3,602	6,235
Pass-through costs to Eligible Entities[1]	**$694**	**$322**	**$227**

1. Pass-through costs are calculated by dividing annualized costs by number of eligible entities for each scenario.

References:

B1: U.S. Office of Personnel and Management, 2015 General Schedule, Retrieved from: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/GS_h.pdf. May 2015.
B2: U.S. Bureau of Labor Statistics, Executive Secretary, Occupational Code: 43-6011, Retrieved from: http://www.bls.gov/oes/current/oes436011.htm#(1), May 2015.
B3: U.S. Bureau of Labor Statistics, Lawyer, Occupational Code: 11-1021, Retrieved from: http://www.bls.gov/oes/current/naics4_551100.htm#11-0000, May 2015.
B4: U.S. Bureau of Labor Statistics, Lawyer, Occupational Code: 23-1011, Retrieved from: http://www.bls.gov/oes/current/naics4_551100.htm#23-0000, May 2015.

Appendix C: Proportion of foreign food exporters certified by accredited CBs under existing programs

RTI (Ref. C1) conducted a search on the number of foreign facilities that are currently being audited for food safety by CBs accredited under existing programs. Currently, most ABs and CBs accredited under other programs do not publicly disclose the number of facilities that they certify for food safety. China National Accreditation Service (CNAS), Japan Accreditation Board (JAB), and National Standards Authority of Ireland (NSAI) which is a CB accredited by the United Kingdom Accreditation Service (UKAS) are a few entities that disclose the facilities that are certified under their auspices.

RTI identified 71 ABs (see Table C2; Appendix C) which include 38 government ABs, 24 private ABs, and 9 ABs with unknown affiliation. We separate CNAS, the Chinese government AB, from the data of the other government ABs since it is proportionally much larger than other ABs. According to RTI, CNAS accredited 30 CBs. On average, each of CNAS' CBs certifies 161 facilities. Therefore, number of food producing facilities certified by CBs accredited by CNAS is estimated at 4,830 (161 facilities/CB x 30 CBs) (see Table B1).

Based on a sample, RTI estimates that, on average, other 37 government ABs have 7.9 auditor/CBs, and each CB that is accredited by a government AB certifies an average of 44 facilities for food safety. Total number of foreign food facilities certified by government ABs other than CNAS is approximately 12,861 (37 ABs x 7.9 CBs/AB x 44 facilities/CB).

RTI also estimates that 24 private ABs, on average have 8.75 CBs and each of their accredited CBs certifies an average of 33 foreign facilities. Total number of

foreign food exporters certified by CBs accredited by private ABs is estimated at 6,930 (24 ABs x 8.75 CBs/AB x 33 facilities/CB).

RTI reports that there are, on average, 4 CBs for each of the remaining 9 ABs. We assume that a CB that is accredited by an AB whose affiliation RTI identified as unknown to be the average of facilities certified by private and government ABs, or 38.5 ((44 + 33)/2). Hence, the total number of foreign food facilities certified by CBs accredited by ABs, whose affiliation was unidentified by RTI, is estimated at 1,386 (9 ABs x 4 CBs/AB x 38.5 facilities/CB).

In total, we estimate that there are 71 ABs, 568 CBs accredited under other programs, and 26,007 foreign facilities that are being audited for food safety by CBs accredited under other programs. Considering that there are an estimated 200,697 foreign food exporters (processors and farms), approximately 13% of foreign food exporters (26,007 / 200,697) that offer their food for import to the U.S. are audited by CBs accredited under other programs. In addition, there are approximately 46 foreign food exporters per CB accredited under other programs.

Table C1. Number of ABs, CBs Accredited under Existing Programs, and Foreign Food Exporters Certified by CBs Accredited under Existing Programs

AB	# of ABs	# of CBs	# of CBs per AB	# of foreign food per CB	# of foreign food exporters	Weighted food exporters per CB
CNAS	1	3	3	161	4,830	8
Other Government ABs	3	29	7.	44	12,861	23
Private ABs	2	21	8.7	33	6,930	12
Other ABs	9	3	4	38.5	1,386	2
Total	**7**	**56**			**26,007**	**46**

References:

C1: Economic Analysis of Third-Party Food Safety Certification of Imported Food, June, 2012. RTI for FDA under Contract HHSF22320710273G, Task Order 13.

Appendix D: Number of Accreditation Bodies

The Third-Party final rule has implications for accreditation bodies (ABs) that accredit CBs who conduct conformity assessment activities (audits)[14] to determine whether products and systems conform to the specifications of a relevant standard. We have identified five major AB organizations that currently accredit CBs for conformity assessment operating globally: International Accreditation Forum (IAF), and the regional InterAmerican Accreditation Cooperation (IAAC), Pacific Accreditation Cooperation (PAC), European co- operation for Accreditation (EA), and Southern African Development Community Accreditation (SADCA). Some ABs belong to multiple AB groups. Overall, within the five major AB groups described above, there are 103 ABs from which 71 have food safety audits as a part of the scope of their operations. Sixty-nine (69) of the identified ABs operate outside the U.S. while 2 ABs operate within the U.S. Most countries have only one AB with the exception of the U.S. (2), and Republic of Korea (2). One AB, JAS-ANZ, represents two countries: Australia and New Zealand.

Data on value of U.S. imports, in U.S. dollars, for FDA-regulated food for FY 2011 were obtained through U.S. International Trade Commission website (http://dataweb.usitc.gov/scripts/user_set.asp). Table D1 includes food imports and their respective NAIC code classifications that were used to obtain trade value of imports by country into the U.S.

[14] "Conformity assessment" is the term used in the standards community to describe the type of activity (i.e., food safety audit) that will be conducted by CBs accredited under the Third-Party final rule.

Table D1 – FDA-Regulated Food, and NAIC Classification of Imports to the U.S.

NAIC Code	Food Classification
1111	Oilseed and Grain Farming
1112	Vegetable and Melon Farming
1113	Fruit and Tree Nut Farming
1114	Greenhouse, Nursery, and Floriculture Production
11193	Sugarcane Farming
11194	Hay Farming
11199	All Other Crop Farming
1125	Animal Aquaculture
3111	Animal Food Manufacturing
3112	Grain and Oilseed Milling
3113	Sugar and Confectionery Product Manufacturing
3114	Fruit and Vegetable Preserving and Specialty Food Manufacturing
3115	Dairy Product Manufacturing
3117	Seafood Product Preparation and Packaging
3118	Bakeries and Tortilla Manufacturing
3119	Other Food Manufacturing
3121	Beverage Manufacturing

Table D2 includes a list of the 69 foreign ABs and 2 U.S.-based ABs, the country in which they are based, and the value of food trade in dollars into the U.S. in FY 2011. Excluding the two ABs representing Cuba and Iran, countries which currently are subject to U.S. trade sanctions, there are potentially 69 ABs that would apply for recognition from the FDA. We believe that the implementation of the Third-Party final rule would increase demand for food safety audits by third party CBs accredited by ABs recognized under our program.

Table D2 – Global List of ABs with the Scope of Food Safety Audits

AB	Country	Volume[1]	AB	Country	Volume[1]
SCC	Canada	15,976	NA	Norway	197
EMA	Mexico	15,476	SANAS	South Africa	196
COFRAC	France	3,683	STC-IS	Russia	120
CNAS	China	3,659	LATAK	Latvia	117
ACCREDIA	Italy	3,522	IPAC	Portugal	110
CGCRE	Brazil	3,381	SAC	Singapore	108
INN	Chile	2,812	HKAS	Hong Kong	89
ONAC	Colombia	2,460	TUNAC	Tunisia	84
NABCB	India	2,294	PNAC	Pakistan	81
NSC	Thailand	2,272	EGAC	Egypt	77
RvA	Netherlands	2,122	FINAS	Finland	73
Standards Malaysia	Malaysia	2,066	ONA	Paraguay	67
UKAS	U.K.	1,828	SLAB	Sri Lanka	67
JAS-ANZ	Australia	1,002	OUA	Uruguay	43
	New Zealand	821	CAI	Czech Republic	41
KAN	Indonesia	1,524	MAURITAS	Mauritius	31
PAO	Philippine	1,517	ISAC	Iceland	23
DAkkS	Germany	1,505	CAS	Croatia	16
ECA	Costa Rica	1,415	LA	Lithuania	16
INDECOPI	Peru	1,326	NAAU	Ukraine	14
OAA	Argentina	1,282	NAT	Hungary	14
BA	Vietnam	1,264	DA	Albania	8
ENAC	Spain	1,252	RENAR	Romania	7
OAE	Ecuador	1,164	JAS	Jordan	6
INAB	Ireland	801	CAECP	Moldova	6
SAS	Switzerland	751	SA	Slovenia	4
JAB	Japan	542	IARM	Macedonia	4
BELAC	Belgium	535	GAC	Georgia	4
BMWFJ	Austria	525	SNAS	Slovakia	3
SWEDAC	Sweden	511	NCA	Kazakhstan	0.2
KAB	South Korea	384	OLAS	Luxembourg	0.07
KAS	South Korea		IAS	Iran	0.02
TURKAK	Turkey	371	ONARC	Cuba	0
TAF	Taiwan	283	ANAB	U.S.	N/A
PCA	Poland	276	ANSI	U.S.	N/A
DANAK	Denmark	237			
ESYD	Greece	216			

1. In millions U.S. dollars; ITC Data.