Clinical Laboratory Improvement Amendments Waiver Applications—(OMB Control Number 0910–0598)—Extension

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) (Pub. L. 100–578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are ''simple'' and that have an ''insignificant risk of an erroneous result'' may obtain a certificate of waiver (42 U.S.C. 263a(d)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are ''simple'' and have ''an insignificant risk of an erroneous result'' under CLIA (69 FR 22849, April 27, 2004).

On January 30, 2008, FDA published a guidance document entitled ''Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm*). This guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an Agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting.

Based on previous years' experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 112,000 hours. The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
CLIA waiver application	40	1	40	780	31,200	$66,200

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA waiver records	40	1	40	2,800	112,000

Dated: August 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22660 Filed 9–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of the FDA Electronic Submission Gateway (ESG) and the Safety Reporting Portal (the SRP) to collect adverse event reports and other

safety information for FDA-regulated products.

DATES: Submit either electronic or written comments on the collection of information by November 13, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

II. Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803 (OMB Control Number 0910–0645)—Revision

The SRP (formerly referred to as the MedWatch^{Plus} Portal and Rational Questionnaire) and the ESG are the Agency's electronic systems for collecting, submitting, and processing adverse event reports and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). Many of the adverse event reports submitted to FDA are currently filed in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, approved under OMB control numbers 0910–0284 and 0910–0291. This notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, approved under OMB control number 0910–0645.

III. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive three types of adverse event reports electronically via the SRP using rational questionnaires. In this notice, FDA seeks comments on the extension of OMB approval for the existing three rational questionnaires, as well as comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the Center for Tobacco Products (CTP).

A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–085) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines ''reportable food'' as an ''article of food (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. To further the development of the RFR, section 417 of the FD&C Act required FDA to establish an electronic portal by which instances of reportable food (''RFR reports'') must be submitted to FDA by responsible parties and may be submitted by public health officials. A ''responsible party'' is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. The RFR electronic portal was established in 2009 as part of the MedWatch^{Plus} Portal, now the SRP, and approved under OMB control number 0910–0645.

The Congressionally identified purpose of the RFR is to provide ''a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health'' (121 Stat. 965). The RFR reports are designed to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (Pub. L. 111–353)

(the legislation or FSMA). Section 211 of the legislation amended section 417 of the FD&C Act to require FDA to collect additional information in the Agency's RFR reports:

(1) A description of the article of food;

(2) Affected product identification codes, such as Universal Product Code, Stock Keeping Unit, or lot or batch numbers sufficient for the consumer to identify the article of food;

(3) Contact information for the responsible party; and

(4) Any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

Section 211 of FSMA also amended section 417 of the FD&C Act to require FDA to generate one-page notices from RFR reports to post on *www.fda.gov* for grocery stores to display to consumers when a reportable food has been sold. The amendment made by section 211 of FSMA took effect June 4, 2012, 18 months after the date of enactment. To comply with this statutory deadline, FDA initially obtained OMB approval of the additional collection of information requirements under the emergency processing provisions of the PRA under OMB control number 0910–0709. The new data improves the RFR's effectiveness in carrying out its purpose of tracking patterns of adulteration in food and supporting FDA's efforts to target limited inspection resources to protect the public health.

Table 1 of this document, entitled ''New Data Elements for RFR Reports,'' presents the new data elements aded by FDA to RFR Reports on June 4, 2012.

TABLE 1—NEW DATA ELEMENTS FOR RFR REPORTS

Field text	Mandatory or optional input	Authority if mandatory
Reason this food is reportable (agent)	Mandatory	Section 417(e)(4) of the FD&C Act.
What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?	Mandatory	Section 417(e)(5) of the FD&C Act.
How did you determine which products/lots/batches were affected?	Mandatory	Section 417(e)(4) and (5) of the FD&C Act.
To the best of your knowledge, has all of the reportable food been removed from commerce?	Mandatory	Section 417(e)(6) of the FD&C Act.
What corrective actions have been taken to prevent future occurrences?	Optional.	
Product Commodity Type	Mandatory	Section 417(e)(3) of the FD&C Act.
Manufacturing/Production Date(s)	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Use-by dates, if any, or approximate Shelf Life	Mandatory	Section 417(e)(7) of the FD&C Act.
Was product treated to reduce microorganisms	Mandatory (but conditional)	Section 417(e)(3) and (4) of the FD&C Act.
Microbial Reduction Treatment Details	Mandatory (but conditional)	Section 417(e)(3) and (4) of the FD&C Act (Conditional for microbial hazards only and only after ''yes'' answer to ''was product treated to reduce microorganisms?'')
Is a Bacterial Isolate Available for collection?	Mandatory (but conditional)	Section 417(e)(4) of the FD&C Act (Conditional for microbial hazards only.)
Animal Species Intended for	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Life Stage of Animal Intended for	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Have you notified all immediate previous sources of this reportable food?	Optional	
Have you notified all immediate subsequent recipients of this reportable food?	Mandatory	Section 417(e)(6) of the FD&C Act.

In this request for extension of OMB approval, FDA is combining the burden hours associated with OMB control number 0910–0709 with the burden hours approved under this OMB control number (0910–0645).

B. Reports Concerning Experience With Approved New Animal Drugs

Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b) of FDA's regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

If an applicant must report adverse drug experiences and product/manufacturing defects and chooses to do so using the Agency's paper forms, the applicant is required to use Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs'' (see § 514.80(d)). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects. Collection of information using existing paper forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910–0284. Alternatively, an applicant may choose to report adverse drug experiences and product/manufacturing defects electronically. Collection of this information electronically was approved in 2010 under OMB control number 0910–0645. The electronic submission data elements to report adverse drug experiences and product/manufacturing defects electronically remain unchanged in this request for extension of OMB approval.

C. Pet Food Early Warning System

Section 1002(b) of FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food.

FDA developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, to make it easy for the public to report a safety problem with pet food. The Pet Food Early Warning System is designed to identify adulteration of the pet food supply and outbreaks of illness associated with pet food to enable FDA to quickly identify, track, and remove from commerce such articles of food. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. In 2010, OMB approved the Pet Food Early Warning System component of the SRP under OMB control number 0910–0645, and FDA launched the rational questionnaire by which consumers may electronically report adverse events associated with pet food. The electronic submission data elements to report adverse events associated with pet food remain unchanged in this request for extension of OMB approval.

D. Voluntary Tobacco Product Adverse Event and Product Problem Reports

As noted, this notice seeks comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the FDA Center for Tobacco Products (CTP) to collect voluntary tobacco product adverse event and product problem reports.

FDA has broad legal authority under the FD&C Act to protect the public health. CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The Family Smoking Prevention and Tobacco Control Act of 2009 (Pub. L. 111–31) (Tobacco Control Act) amended the FD&C Act by creating a new section 909 (21 U.S.C. 387i, Records and Reports on Tobacco Products). Section 909(a) of the FD&C Act (21 U.S.C. 387i(a)) authorizes FDA to establish regulations with respect to mandatory adverse event reports associated with the use of a tobacco product. At this time, FDA is proposing to collect voluntary adverse event reports associated with the use of tobacco products from interested parties such as health care providers, researchers, consumers, and other users of tobacco products. Information collected in voluntary adverse event reports will contribute to CTP's ability to be informed of, and assess the real consequences of, tobacco product use. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

CTP currently receives adverse event and product problem reports primarily via paper MedWatch forms, approved under OMB control number 0910–0291. MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products, do not specifically include questions relevant for the analysis of adverse events or product problems related to tobacco products. The proposed voluntary tobacco product adverse event and product problem rational questionnaire will include these specific questions. The questionnaire evolved with input from a National Institutes of Health team of human-factors experts, from other regulatory Agencies, and with extensive input from consumer advocacy groups and the general public. FDA is also working with the FDA Internet team to follow the HHS Internet guidelines for Web design. FDA has and will continue to reach out to professional organizations and community interest groups to collect feedback during the user acceptance testing. The rational questionnaire will provide the user with detailed navigation instructions to include drop-down menus, lists of values, controlled vocabularies, and mouse over help where possible. In addition, CTP will issue guidance for the rational questionnaire. Finally, we note that users who are unable to submit reports using the electronic system will still be able to provide their information by paper form (by mail or fax) or telephone.

The rational questionnaire will capture tobacco-specific adverse event and product problem information from voluntary reporting entities such as health care providers, researchers, consumers, and other users of tobacco products. To carry out its responsibilities, FDA needs to be informed when an adverse event, product problem, or error with use is suspected or identified. When FDA receives tobacco-specific adverse event and product problem information, it will use the information to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

IV. Information Collection Burden Estimate

Description of respondents: The respondents to this collection of information include all persons submitting mandatory or voluntary adverse event reports electronically to FDA via the ESG or the SRP.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Adverse Event Report via the SRP (Other than RFR Reports).	3800	1,513	1	1,513	0.6 (36 minutes)	908
Mandatory Adverse Event Report via the SRP (Other than RFR Reports).	3800	636	1	636	1.0	636
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission).	3800	1,491,228	1	1,491,228	0.6 (36 minutes)	894,737

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Mandatory and Voluntary RFR Reports via the SRP.	3800	1,413	1	1,413	0.6 (36 minutes)	848
Total						897,129

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Agency's estimate of the number of respondents and the total annual responses in table 2, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Follow-up reports, if any, are not counted as new reports. Based on its experience with adverse event reporting, FDA estimates that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1.0 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

Voluntary adverse event reports submitted via the SRP (other than RFR Reports) include reports associated with pet food (the Pet Food Early Warning System) and the new tobacco product adverse event and product problem reports. CVM received 845 pet food adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CVM estimates that it will receive, on average, 1,413 pet food reports annually over the next 3 years. CTP estimates that it will receive approximately 100 voluntary tobacco product adverse event and product problem reports annually, after implementation of electronic reporting. CTP received 27 reports in 2010, 30 reports in 2011, and 22 reports in the first half of 2012, and estimates that for the full 12 months of 2012 it will receive over 40 reports. Based on this experience and an expectation that reporting will increase once electronic reporting is launched, CTP estimates that it will receive, on average, 100 voluntary adverse event and product problem reports annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 1,513 voluntary adverse event reports submitted via the SRP, with a burden of 907.8 hours, rounded to 908 hours, as reported in table 2, row 1 (1,413 + 100 = 1,513).

Mandatory adverse event reports submitted via the SRP (other than RFR Reports) include reports of adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. CVM received 144 such adverse event reports in 2010, 537 reports in 2011, and 212 reports in the first 4 months of 2012, and estimates that for the full 12 months of 2012 it will receive 636 reports. Based on this experience, CVM estimates that it will receive, on average, 636 reports of adverse drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 636 mandatory adverse event reports submitted via the SRP, with a burden of 636 hours, as reported in table 2, row 2.

Adverse event reports submitted via the ESG include reports of adverse experiences related to drugs, biological products, and medical devices, as well as, adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. FDA received 586,229 such adverse event reports in 2010; 850,161 reports in 2011; and 497,076 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,491,228 reports. Based on this experience, FDA estimates that it will receive, on average, 1,491,228 adverse event reports submitted via the ESG, with a burden of 894,736.8 hours, rounded to 894,737 hours, as reported in table 2, row 3.

FDA estimates that over the next 3 years it will receive annually 1,413 mandatory and voluntary RFR Reports submitted via the SRP, as reported in table 2, row 4. CFSAN received 845 such adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CFSAN estimates that it will receive, on average, 1,413 mandatory and voluntary RFR Reports submitted via the SRP annually over the next 3 years, with a burden of 847.8 hours, rounded to 848 hours, as reported in table 2, row 4.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291.

While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: August 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22659 Filed 9–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369 (formerly Docket 2007D–0168)]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance