ways to help women have healthy babies.

The behavioral, clinical, and surveillance projects implemented by NCBDDD are the foundation upon which recommendations and guidelines are revised and updated. Formative research is the mechanism by which evidence is obtained for priority diseases in these three (3) health condition groups and by which recommendations and guidelines are revised and updated.

NCBDDD conducts formative research for developing new messages, materials, and strategies that respond to the changing epidemiology of these priority health conditions. A generic clearance mechanism would increase productivity of CDC programs and improve the quality of public health interventions and health communication programs.

Targeted audience members or representatives provide the information for developing clear and influential health messages, materials, and strategies that promote health and well-being. An integrated research effort is needed to fill in gaps of knowledge, awareness, screening, and prevention behaviors and could simultaneously work to reduce stigma surrounding these topics within special populations, explore cultural issues, and increase the demand for, and uptake of screening by health care providers.

Overall, these formative research activities are intended to provide information that will increase the success of the surveillance or research project through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public.

It is estimated that approximately 8—10 individual projects will be processed each year using this mechanism. Data collection activities from a variety of groups are anticipated. Primary respondents will be Latina Spanish-dominant women of childbearing age (ages 18–45, both childless adult women and parents of young children) and individuals who identify as a member of a specified racial/ethnic/cultural minority community and thus considered hard to reach. Members of the educational, research, and public health community may also be targeted for their subject matter expertise.

This request is submitted to obtain Office of Management and Budget (OMB) clearance for three years. The estimates of annualized burden hours are based on past experience with recruitment and the administration of similar surveys and focus groups. It is estimated that 26,800 respondents will have to be screened annually to recruit the appropriate number of respondents for this data collection activity. Depending on the individual information collection request, information might be collected using the following modes: focus groups, in-person interviews (face-to-face or via telephone, paper-and-pencil questionnaires, or electronically. Electronic modes include handheld devices, computer-assisted self-interviews, computer-assisted personal interviews, web-based surveys, or other point-of-service collection devices.

Specific information will be provided with each individual project submission. The estimated annualized burden hours for this data collection activity are 16,550. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
General public and health care providers	Screener	26,800	1	10/60
General public and health care providers	Consent Forms	10,000	1	5/60
General public and health care providers	Moderator's Guide	10,000	1	1
General public and health care providers	Surveys	5,000	1	15/60

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–13899 Filed 6–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

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 collection of information relating to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Forms FDA 356h and 2567.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under § 601.12(f)(4) in table 1 of this document.

Sections 601.12(b)(1), (b)(3), (c)(1), (c)(3), (c)(5), (d)(1), and (d)(3) require applicants to follow specific procedures to submit information to FDA of any changes, in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report certain labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under § 601.14, the content of labeling required in 21 CFR 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under §§ 601.2(a) (BLAs) and 601.12(f)(1), (f)(2), and (f)(3) (labeling supplements and annual reports) in table 1 of this document.

Section 601.45 requires applicants of biological products for serious or life-threatening illnesses to submit to the Agency for consideration, during the pre-approval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in 21 CFR Parts 640, 660, and 680 that relate to information to be submitted in a license application or supplement for certain blood or allergenic products as follows: §§ 640.6; 640.17; 640.21(c); 640.22(c); 640.25(c); 640.56(c); 640.64(c); 640.74(a) and (b)(2); 660.51(a)(4); and 680.1(b)(2)(iii) and (d).

In table 1 of this document, the burden associated with the information collection requirements in the applicable regulations is included in the

burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one subsection of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products including: § 640.74(b)(3) and (4) for Source Plasma Liquid; § 640.84(a) and (c) for Albumin; § 640.94(a) for Plasma Protein Fraction; § 660.2(c) for Antibody to Hepatitis B Surface Antigen; § 660.28(a), (b), and (c) for Blood Grouping Reagent; § 660.35(a), (c through g), and (i through m) for Reagent Red Blood Cells; § 660.45 for Hepatitis B Surface Antigen; and § 660.55(a) and (b) for Anti-Human Globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.65 or 21 CFR 809.10. Therefore, the burden estimates for these regulations are included in the estimate under §§ 610.60 through 610.65 in table 1 of this document. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485.

Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requires that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve the questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Under § 601.25(b), FDA estimates no further burden for this regulation, and therefore this regulation is not included in table 1 of this document. Under § 601.26(f), FDA estimates no burden for this regulation since there are no products designated to require further study and none are predicted in the future. However, FDA is using an estimate of 1 for calculation purposes. Based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may deem it necessary for further study. As a result, any changes to product labeling would be reported under the appropriate subsection of § 601.12.

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a) until after licensing the product for use in adults. Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a) with adequate justification. The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70 rather then under this section.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.70(b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (Form FDA 2252 approved under OMB control number 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Sections 601.91 through 601.94 concern biological products for which human efficacy studies are not ethical or feasible. Section 601.91(b)(2) requires, in certain circumstances, such postmarking restrictions as are needed to ensure the safe use of the biological product. Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patients or potential patients for biological products approved under part 601, subpart H, when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under subpart H are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under subpart H to submit to the Agency for consideration during preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under §§ 601.91(b)(2) and 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR Part 600 (OMB control number 0910–0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308). The burden estimate for § 601.91(b)(3) is included in the estimate under §§ 610.60 through 610.65.

Section 610.9(a) requires the applicant to present certain information, in the form of a license application or supplement to the application, for a modification of any particular test method or manufacturing process or the conditions which it is conducted under the biologics regulations. The burden estimate for § 610.9(a) is included in the estimate under §§ 601.2(a) and 601.12(b) and (c) in table 1 of this document.

Section 610.11(g)(2) provides that a manufacturer of certain biological products may request an exemption from the general safety test (GST) requirements contained in subpart H. Under § 610.11(g)(2), FDA requires only those manufacturers of biological products requesting an exemption from the GST to submit additional information as part of a license application or supplement to an approved license application. Therefore,

the burden estimate for § 610.11(g)(2) is included in the estimate under §§ 601.2(a) and 601.12(b) in table 1 of this document.

Under § 610.15(d), the Director of CBER or the Director of CDER may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Manufacturers seeking approval of an exception or alternative must submit a request in writing with a brief statement describing the basis for the request and the supporting data.

Section 640.120 requires licensed establishments to submit a request for an exception or alternative to any requirement in the biologics regulations regarding blood, blood components, or blood products. A request for an exception or alternative must be submitted in accordance with § 601.12; therefore, the burden estimate for § 640.120 is included in the estimate under § 601.12(b) in table 1 of this document.

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials. Section 680.1(b)(3)(iv) requires manufacturers to notify FDA when certain diseases are detected in source materials.

Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) (21 CFR 606.110(b)) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(d), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1 of this document.

In July 1997, FDA revised Form FDA 356h ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. As such, the form, now entitled ''Application to Market a New or Abbreviated New Drug or Biologic for Human Use'' helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for nonbiological product submissions to CDER using Form FDA 356h are approved under OMB control number 0910–0001 (an estimated 3,200 submissions × 24 hours = 76,800 hours).

Form FDA 2567 ''Transmittal of Labels and Circulars'' may be used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August of 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted, clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services), and helps ensure that the submission is complete. Form FDA 2253 is approved under OMB control number 0910–0001.

Under tables 1 and 2 of this document, the numbers of respondents are based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received in fiscal year 2012. Based on information obtained from FDA's database systems, there are an estimated 323 licensed biologics manufacturers. The total annual responses are based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under section 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the estimated annual number of suspensions of a biologic license.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. Based on information obtained from FDA's database system, there were an estimated 10,758 submissions of advertising and promotional labeling.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study × 3 studies) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately two to four studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under § 610.15(d), FDA has received no submissions since the implementation of the final rule in April 2011. Therefore, FDA is estimating one respondent and one annual request to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials under § 610.15(d).

There were a total of 2,664 amendments to an unapproved application or supplement and resubmissions submitted using Form FDA 356h.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
601.2(a),[2] 610.60 through 610.65[3]	2567/356h	25	1.8	45	860	38,700
601.5(a)	NA	8	1	8	*0.33	2.64
601.6(a)	NA	1	1	1	*0.33	0.33
601.12(a)(5)	NA	791	16.51	13,057	1	13,057
601.12(b)(1)/(b)(3)/(e)[4]	[2]356h	174	4.01	698	80	55,840
601.12(c)(1)/(c)(3)[5]	[2]356h	117	4.60	538	50	26,900
601.12(c)(5)	[2]356h	18	1.61	29	50	1,450
601.12(d)(1)/(d)(3)[6]/(f)(3)[8]	[2]356h	241	3.08	742	24	17,808
601.12(f)(1)[7]	2567	67	2.48	166	40	6,640
601.12(f)(2)[7]	2567	72	1.78	128	20	2,560
601.12(f)(4)/601.45[9]	2567/2253	102	103.71	10,578	10	105,780
601.26(f)	NA	1	1	1	1	1
601.27(b)	NA	4	1	4	24	96
601.27(c)	NA	6	1	6	8	48
601.70(b) and (d)/601.28	2252	56	1.91	107	24	2,568
610.15(d)	NA	1	1	1	1	1
680.1(c)	NA	9	1	9	2	18
680.1(b)(3)(iv)	NA	1	1	1	2	2
Amendments/Resubmissions	356h	207	12.87	2,664	20	53,280
Total						324,752

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.9(a), 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 601.93(b)(3), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a), (b), and (c), 660.35(a), (c through g), and (i through m), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.
[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
* 20 minutes.

Under table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Annual disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
601.6(a)	1	20	20	*0.33	6.6

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

Dated: June 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13896 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0653]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

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