of tobacco use, conduct tobacco-related research, evaluate tobacco control programs, examine tobacco-use-related health disparities, and use this data to help determine policies and services that need to be provided. A unique feature is the ability to link other social and economic Census Bureau and Bureau of Labor Statistics data and other sponsor-supported supplement data to the TUS–CPS data. Much of this data can also be linked to cancer and other cause-specific mortality data through the National Longitudinal Mortality Study (co-sponsored by three NIH agencies, the National Center for Health Statistics/Centers for Disease Control and Prevention (CDC), and the Census Bureau). This survey has in the past and the 2010–2011 survey will provide in the future invaluable information to measure progress toward tobacco control as part of the NCI's Cancer Trend Progress Report, and the Department of Health and Human Services' Healthy People 2010 and 2020 Goals. This data will also provide a basis for the National Human Genome Research Institute's PhenX Alcohol, Tobacco, and Other Substances Toolkit, provide long-term trend data for CDC and other State and local public health staff, and support the research of extramural scientists. The 2010–2011 TUS–CPS is also relevant to several NCI tobacco control initiatives. The main 2010–2011 survey will allow State and sub-State-specific estimates to be made as do all the previous surveys. The May 2011 Follow-Up questionnaire will consist of an abbreviated version of the main 2010–2011 questionnaire. Data will be collected in May 2010, August 2010, January 2011, and May 2011 from approximately 315,000 respondents (270,000 unique respondents, 45,000 of these in the May 2011 Follow-Up). The 2010–2011 TUS–CPS, complemented by the Follow-Up questionnaire, will be useful for researchers interested in measuring the impact on tobacco cessation of new FDA regulation (the Family Smoking Prevention and Tobacco Control Act) as it is implemented, and will complement Federal tobacco research and policy efforts. *Frequency of Response:* One-time study for the main 2010–2011 survey; One-time study for the May 2011 Follow-Up. *Affected Public:* Individuals or households. *Type of Respondents:* Persons 18 years of age or older. The annualized cost to respondents is estimated at $285,000. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report. The annual reporting burden is presented in the table below.

TABLE—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent per survey period	Number of respondents (annualized)	Responses per respondent	Average time per response (minutes/hour)	Annual burden hours
May 2010: Individuals	30,000	1	9/60 (0.15)	4,500
August 2010: Individuals	30,000	1	9/60 (0.15)	4,500
January 2011: Individuals	30,000	1	9/60 (0.15)	4,500
May 2011 Follow-Up: Individuals	15,000	1	6/60 (0.10)	1,500
Totals	105,000			15,000

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Anne Hartman, M.S., M.A., Health Statistician, National Cancer Institute, 6130 Executive Blvd—MSC 7344, Executive Plaza North, Suite 4005, Bethesda, Maryland 20892–7344, or call non-toll free (301) 496–4970, or FAX your request to (301) 435–3710, or e-mail your request, including your address, to *ah42t@nih.gov* or *hartmana@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 15, 2010.

Kristine Miller,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–1425 Filed 1–25–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0019]

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 written or electronic comments on the collection of information by March 29, 2010.

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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 (the PHS 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 (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the 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 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 additional 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.

Section 601.12(b)(1), (b)(3), (c)(1), (c)(3), (c)(5), (d)(1), and (d)(3) requires 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 parts 640, 660, and 680 (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 these regulations is included in the burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one paragraph 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: § 640.70(a) for Source Plasma; § 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 § 809.10 (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 No. 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 PRA burden for this regulation, and therefore this regulation is not included in table 1 of this document. Under section 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 one 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 paragraph 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 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 No. 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Sections 601.91 through 601.94 concerns biological products for which human efficacy studies are not ethical or feasible. 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 § 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under part 600 (21 CFR part 600) (OMB Control No. 0910–0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB Control No. 0910–0308).

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.

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) (21 CFR 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. The checklist 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. 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 FDA Form 356h are approved under OMB Control No. 0910–0001.

Form FDA 2567 "Transmittal of Labels and Circulars" is 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. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by CBER. 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 No. 0910–0001.

Under table 1 of this document, the number of respondents is 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 2008. Based on information obtained from FDA's database systems, there are an estimated 301 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. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. 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 in this document 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 § 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 4,452 submissions of advertising and promotional labeling. FDA estimates that approximately 15 percent of those submissions were received with Form FDA 2567 and 85 percent were received with Form 2253.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study x 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 §§ 601.91 through 601.94, FDA expects to receive very few applications for these products; however, for calculation purposes, FDA is estimating the annual submission of one application. Under §§ 601.93(b)(3) and 601.94, FDA estimates 240 hours for a manufacturer of a new biological product to develop patient labeling, and to submit the appropriate information and promotional labeling to FDA. The majority of the burden for developing the patient labeling is included under the reporting requirements for § 601.94, therefore minimal burden is calculated for providing the guide to patients under § 601.91(b)(3).

There were a total of 5,338 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.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2(a)[2] and 610.60 through 610.65[3]	2567/356h	23	2	46	860	39,560
601.5(a)	N/A	11	3	33	20 minutes	11
601.6(a)	N/A	1	21	21	20 minutes	7
601.12(a)(5)	N/A	802	9	7,218	1	7,218
601.12(b)(1), (b)(3), and (e)[4]	356h[2]	166	5	830	80	66,400
601.12(c)(1) and (c)(3)[5]	356h[2]	141	5	705	50	35,250
601.12(c)(5)	356h[2]	42	5	210	50	10,500
601.12(d)(1), (d)(3), and (f)(3)[7]	356h[2]	246	3	738	23	16,974
601.12(f)(1)[6]	2567	112	2	224	40	8,960
601.12(f)(2)[6]	2567	53	3	159	20	3,180
601.12(f)(4) and 601.45	2567/2253	42	106	4,452	10	44,520
601.26(f)	N/A	1	1	1	1	1
601.27(b)	N/A	6	1	6	24	144
601.27(c)	N/A	10	1	10	8	80
601.70(b), (d), and 601.28	2252	39	2	78	24	1,872
601.91(b)(3) and 601.94	N/A	1	1	1	240	240
680.1(c)	N/A	9	1	9	2	18
680.1(b)(3)(iv)	N/A	1	1	1	2	2
Amendments/Re-submissions	356h	314	17	5,338	20	106,760
Total						341,697

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

[2] The reporting requirements under §§ 610.9(a), 601.14, 601.27(a), 601.33, 601.34, 601.35, 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 §§ 640.70(a), 640.74(b)(3) and (b)(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 §§ 610.9(a), 600.15(b), 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 §§ 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 § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).

[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(3).

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 RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

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

Dated: January 20, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1439 Filed 1–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices-Foreign Letters of Approval

AGENCY: Food and Drug Administration.

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 reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit written or electronic comments on the collection of information by March 29, 2010.

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: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@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.

Export of Medical Devices-Foreign Letters of Approval (OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

The respondents to this collection of information are companies that seek to export medical devices.

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