

Dated: May 17, 2012.

Elaine L. Baker,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

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BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Administration for Children and
Families**

**Proposed Information Collection
Activity; Comment Request**

Proposed Projects

Title: FPLS Child Support Services
Portal Registration (FCSSP).

OMB No.: 0970-0370.

Description: The purpose of the
Federal Child Support Services Portal
Registration is to collect information
from an authorized individual

registering to use the FPLS Child
Support Services Portal. This
information collection is necessary to
authenticate the individual's identity
and comply with the statutory
requirement that OCSE establish and
implement safeguards to restrict access
to confidential information in the FPLS
to authorized persons. 42 U.S.C.
653(m)(2).

After identity is authenticated, secure
accounts will be created for authorized
users to view data for their respective
applications.

Respondents: Employers, Financial
Institutions, Insurers, State Agencies,
Local Access and Visitation Providers.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Registration Screens	588	1	0.10	58.8

Estimated Total Annual Burden
Hours: 58.8.

In compliance with the requirements
of Section 506(c)(2)(A) of the Paperwork
Reduction Act of 1995, the
Administration for Children and
Families is soliciting public comment
on the specific aspects of the
information collection described above.
Copies of the proposed collection of
information can be obtained and
comments may be forwarded by writing to
the Administration for Children and
Families, Office of Planning, Research
and Evaluation, 370 L'Enfant
Promenade SW., Washington, DC 20447,
Attn: ACF Reports Clearance Officer.
Email address:
infocollection@acf.hhs.gov. All requests
should be identified by the title of the
information collection.

The Department specifically requests
comments on: (a) Whether the proposed
collection of information is necessary
for the proper performance of the
functions of the agency, including
whether the information shall have
practical utility; (b) the accuracy of the
agency's estimate of the burden of the
proposed collection of information; (c)
the quality, utility, and clarity of the
information to be collected; and (d)
ways to minimize the burden
information to be collected; and (d)
ways to minimize the burden of the
collection of information on
respondents, including through the use
of automated collection techniques or
other forms of information technology.
Consideration will be given to

comments and suggestions submitted
within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012-12601 Filed 5-23-12; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2012-N-1029]

**Agency Information Collection
Activities; Submission for Office of
Management and Budget Review;
Comment Request; General Licensing
Provisions; Section 351(k) Biosimilar
Applications**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing
that a proposed collection of
information has been submitted to the
Office of Management and Budget
(OMB) for review and clearance under
the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the
collection of information by June 25,
2012.

ADDRESSES: To ensure that comments on
the information collection are received,
OMB recommends that written
comments be faxed to the Office of
Information and Regulatory Affairs,
OMB, Attn: FDA Desk Officer, Fax: 202-

395-7285, or emailed to
oira_submission@omb.eop.gov. All
comments should be identified with the
OMB control number 0910-New and
title "General Licensing Provisions;
Section 351(k) Biosimilar
Applications". Also include the FDA
docket number found in brackets in the
heading of this document.

FOR FURTHER INFORMATION CONTACT:
Juanmanuel Vilela, Office of
Information Management, Food and
Drug Administration, 1350 Piccard Dr.,
PI50-400B, Rockville, MD 20850,
301-796-7651,
juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In
compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.

**General Licensing Provisions; Section
351(k) Biosimilar Applications—(OMB
Control Number 0910—New)**

On March 23, 2010, the President
signed into law the Patient Protection
and Affordable Care Act (Affordable
Care Act) (Pub. L. 111-148). The
Affordable Care Act contains a subtitle
called the Biologics Price Competition
and Innovation Act of 2009 (BPCI Act)
which amends the Public Health Service
Act (PHS Act) and establishes an
abbreviated licensure pathway for
biological products shown to be
biosimilar to, or interchangeable with,
an FDA-licensed biological reference
product. (See sections 7001 through
7003 of the Affordable Care Act.)

Section 351(k) of the PHS Act (42
U.S.C. 262(k)), added by the BPCI Act,

sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(k) defines biosimilarity to mean “that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product”. (See section 351(i)(2) of the PHS Act.) A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and clinical studies, unless FDA determines, in its discretion, that certain studies are unnecessary in a 351(k) application. (See section 351(k)(2) of the PHS Act.) To demonstrate interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and that the biosimilar biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biosimilar biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. (See section 351(k)(4) of the PHS Act.) Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider. (See section 351(i)(3) of the PHS Act.) This **Federal Register** information collection document begins the process of requesting public comment and obtaining OMB approval for the information collection regarding the burden on the submission of a 351(k) application not otherwise covered by existing OMB approvals.

In estimating the information collection burden for 351(k) applications, FDA has reviewed the collection of information regarding the general licensing provisions for biologics license applications under section 351(a) of the PHS Act to OMB (approved under OMB control number 0910-0338). For the information collection burden for 351(a) applications, FDA described § 601.2(a) (21 CFR 601.2(a)) as requiring a manufacturer of a biological product to

submit an application on forms prescribed for such purpose with accompanying data and information including certain labeling information to FDA for approval to market a product in interstate commerce. FDA also added in the burden estimate the container and package labeling requirements provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimated hours per response for § 601.2, and §§ 610.60 through 610.65, were 860 hours.

In addition, in submitting a 351(a) application, an applicant completes the Form FDA 356h “Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use.” 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 biological product submissions using FDA Form 356h are included under the applicable requirements approved under OMB control number 0910-0338.

FDA intends for an applicant to submit a 351(k) application following Form FDA 356h, modifying the information submitted to support the information required under section 351(k) of the BPCI Act. To submit an application seeking licensure of a proposed biosimilar product under section 351(k)(2)(A)(i) and (k)(2)(A)(iii), FDA believes that the estimated burden hours would be approximately the same as noted under OMB control number 0910-0338 for a 351(a) application—860 hours. The burden estimates for seeking licensure of a proposed biosimilar product that meets the standards for interchangeability under section 351(k)(2)(B) and (k)(4) would also be 860 hours. Until we gain more experience with biosimilar applications, FDA believes this estimate is appropriate for 351(k) applications because to determine biosimilarity or interchangeability of a proposed 351(k) product, the application and the information submitted is expected to be comparably complex and technically demanding as a proposed 351(a) application. FDA may determine, in its discretion, that an element required under a 351(k) application to be unnecessary to support licensure of a biosimilar or interchangeable product. In those cases, the number of hours per response may be less than the hours estimated.

A summary of the collection of information requirements in the submission of a 351(k) application as described under the BPCI Act follows:

Section 351(k)(2)(A)(i) requires manufactures of 351(k) products to submit an application for FDA review and licensure before marketing a biosimilar product. An application submitted under this section shall include information demonstrating that:

- The biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies (including toxicity) and a clinical study or studies (including immunogenicity and pharmacokinetics or pharmacodynamics). The Secretary of Health and Human Services (the Secretary) may determine that any of these elements is unnecessary.
- The biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product.
- The condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.
- The route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product.
- The facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Section 351(k)(2)(A)(iii) requires the application to include publicly-available information regarding the Secretary’s previous determination that the reference product is safe, pure, and potent. The application may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

Under section 351(k)(2)(B) and (k)(4), a manufacturer may include information demonstrating that the biological product meets the standards for interchangeability either in the application described in this document to show biosimilarity, or in a supplement to such an application. The information submitted to meet the standard for interchangeability must show that: (1) The biological product is biosimilar to the reference product and can be expected to produce the same

clinical result as the reference product in any given patient and (2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

In addition to the collection of information regarding the submission of a 351(k) application for a proposed biosimilar or interchangeable biological product, section 351(l) of the BPCI Act establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHS Act. The burden estimates for the patent provisions under section 351(l)(6)(C) of the BPCI Act are included in table 1 of this document and are based on the estimated number of 351(k) biosimilar respondents. Based on similar reporting requirements, FDA estimates this notification will take 2 hours. A summary of the collection of information requirements under 351(l)(6)(C) follows:

Not later than 30 days after a complaint from the reference product sponsor is served to a 351(k) applicant in an action for patent infringement described under 351(l)(6), section 351(l)(6)(C) requires that the 351(k) applicant provide the Secretary with notice and a copy of such complaint. The Secretary shall publish in the **Federal Register** notice any complaint received under 351(l)(6)(C)(i).

FDA has not received any 351(k) applications to date. Under table 1 of

this document, the estimated number of respondents submitting 351(k) applications is based on the estimated annual number of manufacturers that would submit the required information to FDA and the estimated annual number of 351(k) submissions FDA would receive. In making this estimate, FDA has taken into account, among other things, the expiration dates of patents that relate to potential reference products, and general market interest in biological products that could be candidates for 351(k) applications.

On November 2 and 3, 2010, FDA held a public hearing and established a public docket to obtain input on specific issues and challenges associated with the implementation of the BPCI Act. (See Docket No. FDA-2010-N-0477.) Based in part on this input, FDA announced the availability of three draft guidances describing FDA's current interpretation of certain statutory requirements added by the BPCI Act as well as quality and analytical issues, demonstrating biosimilarity, and implementation policy issues. These draft guidances are: "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009," "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," and "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product." The **Federal Register** documents for these guidances reference this **Federal Register** information collection document regarding the burden on the submission of a 351(k) application not otherwise

covered by existing OMB approvals. In addition, we note that the draft guidance on "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product" recommends that labeling for a product subject to approval under section 351(k) include statements that indicate that: (1) The product is approved as biosimilar to a reference product for stated indication(s) and (2) the product (has or has not) been determined to be interchangeable with the reference product. FDA has determined, under 5 CFR 1320.3(c)(2), that these labeling recommendations are not "collections of information" for the purposes of the PRA because the statements will comprise solely information that FDA will supply to the applicant for the purpose of disclosing it to the public, i.e., FDA's determination upon review of the application submitted under section 351(k), that the product is biosimilar and/or interchangeable to its reference product.

In the **Federal Register** of February 15, 2012 (77 FR 8880), FDA published a 60-day notice requesting comments on the information collection for the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. In the **Federal Register** of February 23, 2012 (77 FR 10752), FDA published a correction to the 60-day notice providing the correct docket number to submit comments. FDA received no comments that pertained to the information collection analysis.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

351(k) Application for Biosimilars (42 U.S.C. 262(k))	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
351(k)(2)(A)(i) and (k)(2)(A)(iii)	2	1	2	860	1720
351(k)(2)(B) and (k)(4)	1	1	1	860	860
351(l)(6)(C)	2	1	2	2	4

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

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0477]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records

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 investigational device exemptions reports and records.

DATES: Submit either electronic or written comments on the collection of information by July 23, 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: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleston@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.

Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 520(g)(6) to the FD&C Act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the FD&C Act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and

development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, i.e., devices that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements. The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available. Section 812.10 permits the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety. Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations.

Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in the original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE.

Upon approval of an IDE application by FDA, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation that affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Section 812.150 requires a sponsor to submit reports to FDA.