

Dated: May 17, 2012.

Elaine L. Baker,

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

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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.

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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
oir_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,