

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible

for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-75	60	1	60	3,600

Estimated Total Annual Burden Hours: 3,600.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Community Living

Proposed Information Collection Activity; Comment Request; State Developmental Disabilities Council 5-Year State Plan

AGENCY: Administration for Community Living, Administration on Intellectual and Developmental Disabilities, HHS.
ACTION: Notice.

SUMMARY: A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) by any amendments. The State Plan will be used (2) by the Council as a planning document; (3) by the citizenry of the State as a mechanism for commenting on the plans of the Council; (4) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (e.g., during site visits), and as a support for management decision making.

DATES: Submit written comments on the collection of information by April 11, 2014.

ADDRESSES: Submit written comments on the collection of information by email to: Valerie.Bond@aoa.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Valerie Bond, Administration on

Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4302, Washington, DC 20201, 202-690-5841.

SUPPLEMENTARY INFORMATION: In compliance with the requirements of Section 506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living 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: Valerie Bond, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program, One Massachusetts Avenue NW., Room 4302, Washington, DC 20201.

The Department specifically requests comments on: (a) Whether the proposed Collection of information is necessary for the proper performance of the function 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; (d) ways to minimize the burden information to be collected; and (e) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection technique comments and or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Respondents: 56 State Developmental Disabilities Councils.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan	56	1	367	20,552

Estimated Total Annual Burden
Hours: 20,552.

Dated: February 4, 2014.

Kathy Greenlee,

*Administrator and Assistant Secretary for
Aging.*

[FR Doc. 2014-02839 Filed 2-7-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1394]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

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 March 12,
2014.

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_](mailto:oira_submission@omb.eop.gov)
submission@omb.eop.gov. All
comments should be identified with the
OMB control number 0910-0470. Also
include the FDA docket number found
in brackets in the heading of this
document.

FOR FURTHER INFORMATION CONTACT: FDA
PRA Staff, Office of Operations, Food
and Drug Administration, 1350 Piccard
Dr., PI50-400B, Rockville, MD 20850,
PRASStaff@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.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910-0470)—Extension

The “Guidance for Industry on
Special Protocol Assessment” describes
Agency procedures to evaluate issues
related to the adequacy (e.g., design,

conduct, analysis) of certain proposed
studies. The guidance describes
procedures for sponsors to request
special protocol assessment and for the
Agency to act on such requests. The
guidance provides information on how
the Agency interprets and applies
provisions of the Food and Drug
Administration Modernization Act of
1997 and the specific Prescription Drug
User Fee Act of 1992 (PDUFA) goals for
special protocol assessment associated
with the development and review of
PDUFA products. The guidance
describes the following two collections
of information: (1) The submission of a
notice of intent to request special
protocol assessment of a carcinogenicity
protocol, and (2) the submission of a
request for special protocol assessment.

Notification for a Carcinogenicity Protocol

As described in the guidance, a
sponsor interested in Agency
assessment of a carcinogenicity protocol
should notify the appropriate division
in FDA’s Center for Drug Evaluation and
Research (CDER) or the Center for
Biologics Evaluation and Research
(CBER) of an intent to request special
protocol assessment at least 30 days
prior to submitting the request. With
such notification, the sponsor should
submit relevant background information
so that the Agency may review reference
material related to carcinogenicity
protocol design prior to receiving the
carcinogenicity protocol.

Request for Special Protocol Assessment

The guidance asks that a request for
special protocol assessment be
submitted as an amendment to the
investigational new drug application
(IND) for the underlying product and
that it be submitted to the Agency in
triplicate with Form FDA 1571 attached.
The guidance also suggests that the
sponsor submit the cover letter to a
request for special protocol assessment
via fax to the appropriate division in
CDER or CBER. Agency regulations (21
CFR 312.23(d)) state that information
provided to the Agency as part of an
IND is to be submitted in triplicate and
with the appropriate cover form, Form
FDA 1571. An IND is submitted to FDA
under existing regulations in part 312
(21 CFR part 312), which specifies the
information that manufacturers must
submit so that FDA may properly
evaluate the safety and effectiveness of
investigational drugs and biological
products. The information collection
requirements resulting from the
preparation and submission of an IND
under part 312 have been estimated by
FDA and the reporting and

recordkeeping burden has been
approved by OMB under OMB control
number 0910-0014.

FDA suggests that the cover letter to
the request for special protocol
assessment be submitted via fax to the
appropriate division in CDER or CBER
to enable Agency staff to prepare for the
arrival of the protocol for assessment.
The Agency recommends that a request
for special protocol assessment be
submitted as an amendment to an IND
for two reasons: (1) To ensure that each
request is kept in the administrative file
with the entire IND and (2) to ensure
that pertinent information about the
request is entered into the appropriate
tracking databases. Use of the
information in the Agency’s tracking
databases enables the appropriate
Agency official to monitor progress on
the evaluation of the protocol and to
ensure that appropriate steps will be
taken in a timely manner.

The guidance recommends that the
following information should be
submitted to the appropriate Center
with each request for special protocol
assessment so that the Center may
quickly and efficiently respond to the
request:

- Questions to the Agency concerning
specific issues regarding the protocol;
and
- All data, assumptions, and
information needed to permit an
adequate evaluation of the protocol,
including: (1) The role of the study in
the overall development of the drug; (2)
information supporting the proposed
trial, including power calculations, the
choice of study endpoints, and other
critical design features; (3) regulatory
outcomes that could be supported by
the results of the study; (4) final labeling
that could be supported by the results
of the study; and (5) for a stability
protocol, product characterization and
relevant manufacturing data.

Description of Respondents: A
sponsor, applicant, or manufacturer of a
drug or biologic product regulated by
the Agency under the Federal Food,
Drug, and Cosmetic Act or section 351
of the Public Health Service Act (42
U.S.C. 262) who requests special
protocol assessment.

Burden Estimate: Table 1 of this
document provides an estimate of the
annual reporting burden for
notifications for a carcinogenicity
protocol and requests for a special
protocol assessment.

*Notification for a Carcinogenicity
Protocol.* Based on the number of
notifications for carcinogenicity
protocols and the number of
carcinogenicity protocols currently
submitted to CDER and CBER, CDER