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.

[FR Doc. 2014–02684 Filed 2–7–14; 8:45 am]

BILLING CODE 4184–01–P

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]

BILLING CODE 4154–01–P

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_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, *PRAStaff@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