

Prevention, and the Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Grant Reviewer Recruitment and Recordkeeping.

Title: Case Plan Requirement, Title IV-E of the Social Security Act.

OMB No.: 0970-0428.

Respondents: State and Tribe title IV-B and title IV-E agencies.

Description: Under section 471(a)(16) of title IV-E of the Social Security Act (the Act), to be eligible for payments, states and tribes must have an approved title IV-E plan that provides for the development of a case plan for each child for whom the State or Tribe receives foster care maintenance payments and that provides a case review system that meets the requirements in section 475(5) and 475(6) of the Act.

The case review system assures that each child has a case plan designed to achieve placement in a safe setting that is the least restrictive (most family-like) setting available and in close proximity

to the child’s parental home, consistent with the best interest and special needs of the child. Through these requirements, States and Tribes also comply, in part, with title IV-B section 422(b) of the Act, which assures certain protections for children in foster care.

The case plan is a written document that provides a narrative description of the child-specific program of care. Federal regulations at 45 CFR 1356.21(g) and section 475(1) of the Act delineate the specific information that should be addressed in the case plan. The Administration for Children and Families (ACF) does not specify a recordkeeping format for the case plan nor does ACF require submission of the document to the Federal government. Case plan information is recorded in a format developed and maintained by the State or Tribal child welfare agency.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Plan	544,098	1	4.80	2,626,436

Estimated Total Annual Burden Hours: 2,626,436.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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 may be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. 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 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-2017-D-5297]

Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations.” This draft guidance is intended to assist developers of microdose radiopharmaceutical diagnostic drugs on the nonclinical studies recommended to support human clinical trials and marketing authorization. The draft guidance discusses how to refine nonclinical

study recommendations for this class of drug given its unique characteristics. This draft guidance is intended to provide recommendations for a pathway to full drug development (marketing authorization) for microdose radiopharmaceutical diagnostic drugs.

DATES: Submit either electronic or written comments on the draft guidance by November 13, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that