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

Claudette Grant,

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

[FR Doc. 2017–19444 Filed 9–12–17; 8:45 am]

BILLING CODE 4160–18–P

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.

[FR Doc. 2017–19367 Filed 9–12–17; 8:45 am]

BILLING CODE 4184–25–P

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

identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–5297 for ''Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Adebayo Laniyonu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5400, Silver Spring, MD 20993–0002, 301–796–1392.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonclinical studies recommended for microdose radiopharmaceutical diagnostic drugs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collection of information for radioactive drug research committees in 21 CFR 361.1 has been approved under OMB control number 0910–0053. The collection of information for the regulations on in vivo radiopharmaceuticals used for diagnosis and monitoring in 21 CFR 315.4, 315.5, and 315.6 has been approved under OMB control number 0910–0409.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–19435 Filed 9–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Government owned intellectual property covering HIV-1 reverse transcriptase inhibitors available for licensing and commercialization.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of