Considerations for Chewable Tablets.'' 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. 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 collection of information in investigational new drug applications is approved by OMB under control number 0910–0014; the collection of information (including prescription drug labeling) in new drug applications and abbreviated new drug applications, as well as supplements to these applications, is approved by OMB under control number 0910–0001; the collection of biologics license applications is approved by OMB under control number 0910–0338; and the format and content of prescription drug labeling is approved by OMB under control number 0910–0572.

III. Electronic Access

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

Dated: August 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17967 Filed 8–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5297]

Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; 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 final guidance for industry entitled ''Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations.'' This guidance is intended to assist sponsors of microdose radiopharmaceutical diagnostic drugs on the nonclinical studies recommended to support human clinical trials and marketing applications. This guidance finalizes the draft guidance of the same name issued on September 13, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on August 21, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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; 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 this 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 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 guidance for industry entitled ''Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations.'' This guidance is intended to assist sponsors of microdose radiopharmaceutical diagnostic drugs on the nonclinical studies recommended to support human clinical trials and marketing applications. This guidance incorporates comments received and finalizes the draft guidance of the same name issued on September 13, 2017 (82 FR 43025). The guidance includes a few editorial changes and a new sentence clarifying the definition of the term diagnostic radiopharmaceutical.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonclinical study recommendations 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. 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.

III. Electronic Access

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

Dated: August 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17961 Filed 8–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted a Supplemental Information Request (SIR) to the Office of Management and Budget (OMB) for review and approval. A 60-day Federal Register Notice was published in the **Federal Register** on April 24, 2018. There were seven public comments. Comments submitted during the first public review of this SIR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this SIR should be received no later than September 20, 2018.

ADDRESSES: Submit your comments, including the Information Collection Request (ICR) Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update, OMB No. 0906–XXX, New.

Abstract: HRSA is requesting approval to collect updated statewide needs assessments from Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program awardees. The previous statewide needs assessment that was approved under OMB control number 0915–0333 has been discontinued. Eligible entities that are states, the District of Columbia, and non-profit organizations will submit statewide needs assessment updates in response to a forthcoming SIR. The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, territories, tribal entities, and in certain circumstances nonprofit organizations are eligible to receive funding through MIECHV and have the flexibility, within the parameters of the authorizing statute, to tailor the program to serve the specific needs of their communities.

The statewide needs assessment is a critical and foundational resource that assists awardees in identifying and understanding how to meet the needs of eligible families living in at-risk communities in their states.

After taking into consideration public comments in response to the 60-day Notice published in the **Federal Register** on April 24, 2018 (83 FR 17826), HRSA is proposing final revisions to the SIR guidance for the needs assessment update by making the following changes:

- Inserting references to the statutory requirements for each section of the guidance—specifically the sections of statute that require an assessment of state capacity to provide substance abuse treatment and counseling services.
- Increasing the burden estimate for respondents from 95.57 to 120 in response to comments that the original estimate was too low.

Need and Proposed Use of the Information: Congress, through enactment of the Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended, established the MIECHV Program. Section 50603 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 511(b)(1) of the Social Security Act, and requires that states review and update their statewide needs assessments (which may be separate from, but in coordination with, the Title V statewide