previously approved data collection instruments and for two additional data collection instruments.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Description: The STREAMS evaluation includes two components, an impact study and a process study. The evaluation will examine HMRE programs for youth in high school, adult couples, and adult individuals.

1. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study uses an experimental design. Eligible program applicants are randomly assigned to either a program group that is offered program services or a control group that is not. STREAMS collects baseline information from eligible program applicants prior to random assignment and administers a follow-up survey to participants 12 months after random assignment.

2. Process study. The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS conducts semi-structured interviews with program staff and selected community stakeholders, conducts focus groups with program participants, administers a survey to program staff, and collects data on adherence to program curricula through an add on to an existing program MIS (nFORM, OMB no. 0970–0460).

This data collection request is for an extension of previously approved data collection instruments for the impact study and for two additional data collection instruments associated with the impact study. The two additional instruments will allow for longer-term follow-up in two of the five evaluation sites. (1) The second follow-up survey for youth will be administered approximately 24 to 36 months after random assignment to study participants in the STREAMS site serving youth. (2) The second follow-up survey for adults will be administered approximately 30 months after random assignment to study participants in one of the STREAMS evaluation sites serving adults.

Respondents: Study participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Previously Approved Burden that Remains					
Introductory script, grantee staff	8	8	25	0.08	16
Introductory script, program applicants	600	200	1	0.08	16
Add-on to nFORM to conduct random assignment	8	8	25	0.08	16
Follow-up survey for youth	690	230	1	0.5	115
Baseline survey for adults	600	200	1	0.5	100
Follow-up survey for adults	2,300	767	1	0.75	575
Current Request for Approval					
Second follow-up survey for youth	1,500	500	1	0.5	250
Second follow-up survey for adults	800	267	1	0.75	200

Estimated Total Annual Burden Hours: 1,288.

Authority: 42 U.S.C. 603; Sec. 811 (b) Healthy Marriage Promotion and Promoting Responsible Fatherhood Grants of the Claims Resolution Act of 2010, Pub. L. 111–291, 124 Stat. 3064.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–02693 Filed 2–15–19; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6154]

Evaluation of Devices Used With Regenerative Medicine Advanced Therapies; 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 entitled ''Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry.'' The guidance document provides manufacturers, applicants, and sponsors engaged in the development of regenerative medicine therapies, with our current thinking regarding evaluation of devices used in the recovery, isolation or delivery of regenerative advanced therapies, which FDA generally refers to as ''regenerative medicine advanced therapies'' or ''RMATs.'' Specifically, the guidance addresses how FDA intends to simplify and streamline its application of regulatory requirements for combination device and cell or tissue products; what, if any, intended uses or specific attributes would result in a device used

with a regenerative therapy product to be classified as a class III device; the factors to consider in determining whether a device may be labeled for use with a specific RMAT or class of RMATs; when a device may be limited to a specific intended use with only one particular type of cell; and application of the least burdensome approach to demonstrate how a device may be used with more than one cell type. The issuance of this guidance fulfills the statutory requirement set forth in a certain section of the 21st Century Cures Act (Cures Act). The guidance announced in this notice finalizes the draft guidance of the same title dated November 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on February 19, 2019.

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–6154 for ''Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry.'' 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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry.'' The guidance provides manufacturers, applicants and sponsors engaged in the development of regenerative medicine therapies, with our current thinking regarding evaluation of devices used in the recovery, isolation or delivery of regenerative advanced therapies, which FDA generally refers to as ''RMATs.'' Specifically, the guidance addresses how FDA intends to simplify and streamline its application of regulatory requirements for combination device and cell or tissue products; what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device; the factors to consider in determining whether a device may be labeled for use with a specific RMAT or class of RMATs; when a device may be limited to a specific intended use with only one particular type of cell; and application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

The issuance of the final guidance fulfills the statutory requirement set forth in section 3034(b) of the Cures Act (Pub. L. 114–255) and sets forth information about a wide range of concepts related to the regulation of devices used in the recovery, isolation, and delivery of RMATs. As our experience with these products grows, we may consider issuing guidance on more specific topics related to these

devices to provide additional recommendations to stakeholders.

In the **Federal Register** of November 17, 2017 (82 FR 54349), FDA announced the availability of the draft guidance of the same title dated November 2017. FDA considered comments received on the draft guidance. FDA revised the guidance as appropriate in response to the comments and made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2017.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a document entitled ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry.''

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 ''Evaluation of Devices Used with Regenerative Medicine Advanced Therapies.'' 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 found in FDA regulations. These collections of information 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 part 807 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control numbers 0910–0231 and 0910–0332; the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543; and the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

III. Electronic Access

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

Dated: February 13, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02692 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4711]

Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' The FDA Reauthorization Act of 2017 (FDARA) mandated that FDA issue draft guidance specifying how FDA provides nonbinding feedback to the owner, operator, or agent in charge of a device establishment after an inspection of such establishment within 45 days of FDA's receipt of a request for such feedback if the request meets certain statutory criteria. This draft guidance describes FDA's proposed approach for providing nonbinding feedback, including the procedures for requesting nonbinding feedback and FDA's review of requests for nonbinding feedback. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the collection of information by April 22, 2019.

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–2018–D–4711 for ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' 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