coordination and collaboration with two new required narratives and associated drop-down menu data.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Leveraged Funding—eliminated Section B and folded data into Section A to simplify.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Instruction Manual—deleted redundant text and updated AT Taxonomy.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

(A) A web-based system that collects data from states.

(B) A performance measurement survey that states collect from individuals

(C) A customer satisfaction survey that states collect from individuals.

(A) Fifty-six grantees report to ACL using the *web-based data collection system.* A workgroup of grantees estimated that the average amount of time required to complete all responses to the data collection instrument is 80 hours annually. The estimated response burden includes time to review the instructions, gather existing data, and complete and review the data entries. These estimates are based on the experience of staff who implement these programs at the state level. In addition, we project that clean-up and clarification of data elements will require no change in data burden estimates.

(B) The fifty-six grantees ask consumers to complete surveys that provide information on their performance related to the state's *measurable goals.* Historical data from states indicates that the average state will ask for this information from 3,242 consumers at 1 minute per consumer to complete the question survey, for a total of 54 hours annually.

(C) The fifty-six grantees also ask consumers to complete *customer satisfaction surveys.* Historical data from states indicated that the average state asks for this information from 3,242 consumers at 1 minute per consumer, for a total of 54 hours annually.

	Number of responses	Hours per response	Annual burden per grantee	Total annual burden hours
Work-Based System	56	1.428	80	4,480
Performance Measurement	3,242	0.01666	54	3.024
Customer Satisfaction	3,242	0.01666	54	3,024
Subtotal	.....	.....	188	10,528
Program Support	56	4	208	11,648
Record Keeping Burden	56	0.14286	8	448
Subtotal	.....	.....	216	12,096
Total	.....	.....	404	22,624

Dated: December 29, 2020.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2020–29150 Filed 1–4–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2105]

Mouse Embryo Assay for Assisted Reproduction Technology Devices; 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 a final guidance entitled ''Mouse Embryo Assay for Assisted Reproduction Technology Devices.'' This guidance document provides recommendations on conducting the mouse embryo assay to support premarket submissions and lot release of assisted reproduction technology devices.

DATES: The announcement of the guidance is published in the **Federal Register** on January 5, 2021.

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–2019–D–2105 for ''Mouse Embryo Assay for Assisted Reproduction Technology Devices.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Mouse Embryo Assay for Assisted Reproduction Technology Devices'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Pei-Hsuan (Chris) Hung, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2647, Silver Spring, MD 20993–0002, 240–402–5928.

SUPPLEMENTARY INFORMATION:

I. Background

The majority of assisted reproduction technology (ART) devices directly or indirectly contact gametes and/or embryos during use. The mouse embryo assay (MEA) is used to assess the potential for embryotoxicity of devices that contact gametes and/or embryos. Several classification regulations under part 884 (21 CFR part 884) include special controls that require MEA testing or information. MEA may also be used by sponsors to support premarket submissions for other devices that are intended to contact gametes and/or embryos during their use. However, there are no voluntary consensus standards that describe how to conduct the MEA. This guidance provides recommendations for conducting the MEA to support premarket submissions and lot release for ART devices that are intended to contact gametes and/or embryos and to comply with the special controls for those devices classified under part 884 that require MEA testing or information.

A notice of availability of the draft guidance appeared in the **Federal Register** of June 13, 2019 (84 FR 27637). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor technical edits and clarifications. Specifically, the final guidance includes revisions to recommend that liquid-based test articles should be prepared per the instructions for use; clarify FDA's recommended exposure time for test articles depending on their clinical use duration; include additional specificity on the number of embryos that should be used; discuss how accelerated aging can also be used to develop test articles at the end of the proposed shelf-life; and when procedural modifications or options should be justified in the test report. In addition, FDA made editorial changes to the guidance for clarity.

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 ''Mouse Embryo Assay for Assisted Reproduction Technology Devices.'' 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.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Mouse Embryo Assay for Assisted Reproduction Technology Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16015 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: December 28, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29081 Filed 1–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2199]

Investigational New Drug Submissions for Individualized Antisense Oligonucleotide Drug Products: Administrative and Procedural Recommendations; Draft Guidance for Sponsor-Investigators; 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 ''IND Submissions for Individualized Antisense Oligonucleotide Drug Products: Administrative and Procedural Recommendations.'' FDA is publishing this draft guidance to help sponsor-investigators (hereafter referred to as sponsors) developing individualized antisense oligonucleotide (ASO) drug products for a severely debilitating or life-threatening genetic disease. Most often, individuals with such diseases will not have adequate alternative therapy available for treating their disease. This draft guidance is intended to help sponsors of such development programs, who may be relatively unfamiliar with FDA regulations, processes, and practices, with the administrative and procedural aspects of interacting with FDA, including seeking feedback from FDA on their development programs and making regulatory submissions related to these development programs.

DATES: Submit either electronic or written comments on the draft guidance by March 8, 2021 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 Submission

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–2020–D–2199 for ''IND Submissions for Individualized Antisense Oligonucleotide Drug Products: Administrative and Procedural Recommendations.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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.