



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-4886]

Utilizing Animal Studies to Evaluate Organ Preservation Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Utilizing Animal Studies to Evaluate Organ Preservation Devices.” The intent of this draft guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-4886 for “Utilizing Animal Studies to Evaluate Organ Preservation 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.

- 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)). 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 draft guidance document entitled “Utilizing Animal Studies to Evaluate Organ Preservation Devices” to the Office of the Center Director, 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: Elizabeth Kunkoski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1504, Silver Spring, MD 20993-0002, 301-796-6439.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft leapfrog guidance for industry and FDA staff entitled “Utilizing Animal Studies to Evaluate Organ Preservation Devices.” The intent of this draft guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices, with careful considerations of regulatory least burdensome principles, as well as, ethical principles in animal testing. This draft guidance provides clarity on premarket recommendations to develop animal transplant models for organ preservation technologies, which will streamline initiation of clinical studies. Optimizing animal and clinical study designs for premarket submissions will allow us to bring novel organ preservation devices to the market faster to increase the availability of organs for transplant for

patients awaiting transplants. Early stakeholder feedback was sought to inform the development of this draft guidance through CDRH's notice on the fiscal year 2016 proposed guidance development issued December 29, 2015 (80 FR 81335), available at <https://www.federalregister.gov/documents/2015/12/29/2015-32726/medical-device-user-fee-and-modernization-act-notice-to-public-of-web-site-location-of-fiscal-year#h-14>. Specific questions were posed to solicit input into the context of the guidance and comments were collected through Docket No. FDA-2012-N-1021.

This draft guidance is a leapfrog guidance; leapfrog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development. This leapfrog draft guidance represents the Agency's initial thinking, and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with CDRH through the Pre-Submission process to obtain more detailed feedback regarding their organ preservation device. For more information on Pre-Submissions, please see "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" at (<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>).

II. Significance of Guidance

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 "Utilizing Animal Studies to Evaluate Organ Preservation 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.

This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Utilizing Animal Studies to Evaluate Organ Preservation 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 1500083 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance document refers to previously approved collections of information found in FDA regulations and guidances. 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 58 regarding good laboratory practices have been approved under OMB control number 0910-0119. The collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910-0485. The collections of information in 21 CFR part 807, subpart E regarding premarket notification have been approved under OMB control number 0910-0120. The collections of information in 21 CFR part 812 regarding investigational device exemptions

have been approved under OMB control number 0910-0078. The collections of information in 21 CFR part 814, subparts A through E regarding premarket approval have been approved under OMB control number 0910-0231. The collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332. The collections of information in 21 CFR part 820 regarding the Quality System regulation have been approved under OMB control number 0910-0073. The collections of information in the guidance document entitled “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910-0756.

Dated: September 6, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-19613 Filed: 9/14/2017 8:45 am; Publication Date: 9/15/2017]