(Response) We acknowledge that accelerated approval products often constitute the only treatment option or one of a limited number of treatment options available to patients. We revised the questionnaire to include information for participants in this study about the treatment landscape for the disease.

(Comment 13) One comment recommends enrolling a diversity of participants across demographic categories and geographic locations. They suggest screening for pretest participants, individuals who have recently participated in prescription drug research, and individuals with prior use of oncology products or accelerated approval products.

(Response) Participants will be internet panel members. We will use soft quotas to ensure recruitment of a low health literacy population as well as a demographically diverse set of participants. Pretest participants will not be allowed to participate in the main study. We added questionnaire items asking participants whether they have been diagnosed with cancer, and if so whether they have ever taken prescription drugs, and specifically accelerated approval products, for cancer.

(Comment 14) One comment noted that participants may pay more attention to information presented in a study, including claims designed to be intentionally misleading, and asked what efforts we will take to avoid response bias.

(Response) The study design does not include intentionally misleading claims. Based on previous research with DTC prescription drug websites, we expect the median time spent on the study stimuli to be under a minute to 2 minutes (Ref. 3). In general, we attempt to minimize response bias by following best practices, such as keeping the survey length short and cognitive-testing and pretesting the questions to make sure they are clearly written.

(Comment 15) One comment requested that the screener and consent form be made available.

(Response) The screener and consent form are available as part of the information collection submission to the OMB.

(Comment 16) One comment noted that the wording of Q4 and Q9 could lead participants toward a specific response.

(Response) These questions are designed to measure whether participants processed the information in the disclosure. Thus, Q4 asks about the unknown outcome information from the disclosure, and Q9 asks about the continuing research information from the disclosure. Because these are not meant to be questions about perceptions, we have changed the wording of Q4 to clarify that we are asking about what the website said, rather than what they might think. We will evaluate these items in cognitive interview and pretesting.

(Comment 17) One comment recommended adding intermediate response values for Q10–Q17 and Q24–Q26.

(Response) We have added intermediate response values for these items, with the exception of Q26, the Perspective Taking Scale, to be consistent with its previous use.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total Hours
Pretest screener	916	1	1	0.08 (5 minutes)	73.28
Study screener	1,507	1	1	0.08 (5 minutes)	120.56
Pretest	385	1	1	0.33 (20 minutes)	127.05
Main Study	633	1	1	0.33 (20 minutes)	208.89
Total					529.78

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references are on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Beaver J.A., L.J. Howie, L. Pelosof, et al., ''A 25-Year Experience of U.S. Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review.'' *JAMA Oncology,* 4(6):849–856, 2018. doi:10.1001/jamaoncol.2017.5618.

2. Sullivan H.W., A.C. O'Donoghue, K.T. David, *et al.,* ''Disclosing Accelerated Approval on Direct-to-Consumer Prescription Drug websites.'' *Pharmacoepidemiology and Drug Safety,* 27:1277–1280, 2018. *https://doi.org/10.1002/pds.4664.*

3. Sullivan H.W., A.C. O'Donoghue, D.J. Rupert, *et al.,* ''Placement and Format of Risk Information on Direct-to-Consumer Prescription Drug Websites.'' *Journal of Health Communication,* 22:171–181, 2017.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09418 Filed 5–7–19; 8:45 am]

BILLING CODE 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; 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 ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' The intent of this guidance is to provide recommendations regarding best practices for utilizing animal

studies for the evaluation of organ preservation devices.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 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–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 guidance document entitled ''Utilizing Animal Studies to Evaluate Organ Preservation Devices'' to the Office of Policy, 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: Carolyn Neuland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G226, Silver Spring, MD 20993–0002, 301–796–6523.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the leapfrog guidance ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' The intent of this guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices, while considering both regulatory least burdensome principles and ethical principles in animal testing. This 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, safe, and effective organ preservation devices to the market faster to increase the availability of organs for transplant for patients awaiting transplants. FDA recognizes that best practices for conducting animal studies to evaluate organ preservation devices are evolving with the rapid advancements in such technologies. This guidance is not intended to be comprehensive or prescriptive.

This 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 guidance represents the Agency's initial thinking, and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to submit a Pre-Submission 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176*).

Early stakeholder feedback was sought to inform the development of this guidance through the Center for Devices and Radiological Health's (CDRH's) notice on the fiscal year 2016 proposed guidance development issued

December 29, 2015 (80 FR 81335). Specific questions were posed to solicit input into the content of the draft guidance and comments were collected through Docket No. FDA–2012–N–1021. FDA also considered comments received on the draft guidance that appeared in the **Federal Register** of September 15, 2017 (82 FR 43390). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

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 ''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 guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH 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.* 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 guidance refers to previously approved collections of information. 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 the following FDA regulations and guidance and the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been approved by OMB as listed in the following table:

21 CFR Part; guidance; or FD&C act section	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09402 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice; correction.

SUMMARY: The Advisory Council on Blood Stem Cell Transplantation (ACBSCT) meeting has been rescheduled due to unforeseen circumstances and will now be held on Tuesday, July 2, 2019, from 10:00 a.m.–4:00 p.m. Eastern Time. The meeting will be held by webinar and conference call. The webinar link, conference call-in number, agenda, and instructions for registration will be posted 15 business days before the meeting on the ACBSCT website at *https://bloodcell.transplant.hrsa.gov/about/advisory_council/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Designated Federal Officer, at the Healthcare Systems Bureau, Division of Transplantation, HRSA, 5600 Fishers Lane, 8W60, Rockville, Maryland 20857; 301–443–6839; or *RWalsh@hrsa.gov.*

New meeting date: Tuesday, July 2, 2019, rather than May 7, 2019, as previously announced.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–09434 Filed 5–7–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Visioning Session

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee program.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards.

Date and Times: Wednesday, July 10, 2019: 9:00 a.m.–5:00 p.m. (EDT), Thursday, July 11, 2019: 8:30 a.m.–5:00 p.m. (EDT).

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 505–A, Washington, DC 20201.

Status: Open. There will be a public comment period during the final 15 minutes of the first day of the meeting.

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,[1] established a regulatory framework to support the exchange of electronic information between covered entities, and directed the Secretary of Health and Human Services (HHS) to publish regulations adopting standards, code sets, and unique identifiers. The administrative simplification provisions of HIPAA pertain to retail pharmacy and medical transactions, such as eligibility, claims, payment, enrollment, and authorizations.

NCVHS advises the HHS Secretary on health data, statistics, privacy, national health information policy, and is mandated to report to Congress on the implementation status of HIPAA. Since mid-2017, the Subcommittee on Standards has been focused on developing a ''predictability roadmap'' through collaboration with industry to identify and evaluate barriers to the efficient and timely update and

[1] Along with Section 1104 (c) of the Patient Protection and Affordable Care Act (ACA) of 2010.