health outcomes in studies for heart failure treatment technologies should be of interest to CMS. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 27, 2017. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting should include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association <$10,000 or major association >$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), fax number, and email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at *http://www.dhs.gov/real-id-enforcement-brief.* We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

V. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: January 10, 2017.

Kate Goodrich,

Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–01043 Filed 1–18–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0394]

Regulation of Intentionally Altered Genomic DNA in Animals; Draft 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 draft guidance for industry (GFI) #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals.'' This draft guidance revises GFI #187 entitled ''Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs'' (current GFI #187). Current GFI #187 clarifies FDA's requirements

and recommendations for producers and developers of genetically engineered (GE) animals and their products. It describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply with respect to GE animals. This draft revision of current GFI #187 expands the scope of the guidance to include animals intentionally altered through use of genome editing techniques. The draft revised GFI #187 now applies to ''those animals whose genomes have been intentionally altered using modern molecular technologies.'' The Agency is seeking comment on the draft revised GFI #187, including the nomenclature that best describes these animals and on any existing empirical evidence indicating that certain types of genome editing may pose minimal risk.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), 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 draft guidance by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2008–D–0394 for ''Regulation of Intentionally Altered Genomic DNA in Animals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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.

FOR FURTHER INFORMATION CONTACT: Laura R. Epstein, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–796–8558, *laura.epstein*@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability, for public comment, of draft revised GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals.'' This draft guidance revises current GFI #187 entitled ''Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs'' to expand the scope of the guidance to address animals intentionally altered through use of genome editing techniques. FDA is also requesting comment on nomenclature and on whether certain types of genome editing may pose minimal risk. Before finalizing the draft revised guidance, the agency intends to modify its regulatory approach if it receives evidence demonstrating low risk.

In the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (the *Strategy;* released by the White House Office of Science and Technology Policy on September 16, 2016),[1] FDA noted its intent to clarify its policy on the regulation of products derived from genome editing techniques, including, as appropriate, identifying and/or updating relevant existing guidance documents. FDA also stated, as an example, its intent to update GFI #187, ''Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs,'' to clarify how developers of animals produced using emerging technologies (*e.g.,* genome editing) may meet applicable statutory and regulatory requirements. FDA is issuing this draft revised guidance for public comment consistent with this commitment in the *Strategy* document. Under the Coordinated Framework for the

[1] *https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.*

Regulation of Biotechnology, we intend to work cooperatively with other relevant agencies that may also be considering their policies or approaches related to genome editing applications within their jurisdictions. As we finalize the draft revised guidance, we will be consistent with the principles for the regulation of biotechnology products articulated in the 2017 Update to the Coordinated Framework (*https://www.whitehouse.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf*) and the goals and objectives of the July 2015 EOP memorandum (*https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf*).

A. Key Draft Revisions

Draft revised GFI #187 is intended to clarify that, unless otherwise excluded,[2] the altered genomic DNA in an animal (referred to in this document as ''animals with intentionally altered genomic DNA'') that is intended to affect the structure or function of the body of the animal or, in some cases, to diagnose, cure, mitigate, treat, or prevent disease in the animal, meets the drug definition in section 201(g) of the FD&C Act. For the purposes of draft revised GFI #187, ''altered genomic DNA'' refers to the portion of an animal's genome that has been intentionally altered. Such intentional alterations may be made, for example, through the use of ''nucleases'' or ''genome editing technologies,'' including engineered nuclease/nucleotide complexes such as zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs), and the clustered regularly interspersed short palindromic repeats (CRISPR) associated systems.

Similar to current GFI #187, draft revised GFI #187 is intended to clarify FDA's requirements and recommendations for producers and developers of animals with intentionally altered genomic DNA. Current GFI #187 and draft revised GFI #187 describe how the new animal drug provisions of the FD&C Act apply with respect to the intentionally altered genomic DNA of such animals.

Animals may have intentional genomic alterations that are heritable or non-heritable (*e.g.,* those alterations intended to be used as gene therapy). Although much of draft revised GFI #187 is relevant to non-heritable intentional genomic alterations, and FDA intends to regulate non-heritable intentional genomic alterations in much the same way as described in this draft revised guidance, this draft revised guidance primarily addresses animals whose genomes have been intentionally altered for heritable purposes.

B. Additional Issues for Consideration and Comment

FDA requests comment on draft revised GFI #187. In particular, we request comments on two major categories of questions.

1. In the first, we seek the public's input on how to refer to these animals. In the past, FDA has used the term ''genetically engineered'' to refer to animals containing recombinant DNA constructs intended to alter the structure or function of the body of the animal. For this draft revised guidance, we have used the phrase ''animals whose genomes have been altered intentionally.'' Other terms that could be used include ''genome edited animals,'' ''intentionally altered animals,'' or expanding the term ''genetically engineered'' to include the deliberate modification of the characteristics of an organism by manipulating its genetic material. The public is encouraged to suggest other phrases that are accurate and inclusive.

2. The second set of questions for which we seek public input is on whether there is any existing empirical evidence demonstrating that certain types of genome editing may pose minimal risk, with particular emphasis on the following:

a. Are there categories of animals whose genomes have been intentionally altered for which specific empirical evidence indicates that there are no significant target animal, user safety, food safety, or environmental risks? If so, what is that evidence?

b. Are there categories of animals whose genomes have been intentionally altered for which empirical evidence exists to demonstrate that genome editing is durable on a genotypic and phenotypic level and would continue to be durable over the lifetime of a particular product? If so, what is that evidence?

c. Is there empirical evidence to demonstrate that there are degrees of introduced changes (*e.g.,* insertions or deletions of any size or single nucleotide substitutions) that are likely to pose less risk than other changes? If so, what is that evidence?

d. Is there empirical evidence that indicates that the degree of taxonomic relationship between the introduced gene and the recipient animal influences the health of that recipient animal or the extent to which the trait is expressed? If so, what is that evidence?

We noted in current GFI #187 that we might issue a separate guidance on the regulation of GE animals bearing non-heritable alterations. Draft revised GFI #187 removes references to this and other guidance documents that we intend to develop in the future. This was not done to indicate that we no longer intend to issue such guidance documents. In light of changing priorities over time, we may issue other guidance documents before developing those identified in current GFI #187, and therefore decided we should not indicate in the text of the revised guidance any additional guidance documents that we may develop in the future.

Current GFI #187 states, ''FDA is discussing with other agencies the best approach for oversight of GE insects. Future guidance may be developed to address them.'' Draft revised GFI #187 eliminates this language. As indicated in the *Strategy,* FDA, EPA, and USDA intend to ''continue to examine their regulatory structures with the goal of clarifying how the U.S. Federal Government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products.'' FDA is continuing to work with EPA and USDA, and will address this issue through action(s) separate from this draft revision to current GFI #187. Elsewhere in this issue of the **Federal Register**, we have published a notice announcing the availability of a draft guidance for industry on regulation of mosquito-related products.

II. Significance of Guidance

This level 1 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 Regulation of Intentionally Altered Genomic DNA in Animals. 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.

[2] In Draft Guidance for Industry #236, ''Regulation of Mosquito-Related Products,'' FDA has proposed to clarify that the phrase ''articles (other than food) intended to affect the structure or any function of the body of man or other animals'' does not include articles intended to prevent, destroy, repel, or mitigate mosquitoes for population control purposes. Instead, such products are pesticides regulated by the Environmental Protection Agency (EPA) (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf).*

III. Paperwork Reduction Act of 1995

This draft 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 have been approved under OMB Control Nos. 0910–0032, 0910–0045, 0910–0117, and 0910–0284.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00839 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Psychopharmacologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Psychopharmacologic Drugs Advisory Committee scheduled for February 16, 2017, is cancelled. This meeting was announced in the **Federal Register** of December 27, 2016 (81 FR 95147). The meeting is no longer needed.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: January 11, 2017.

Janice M. Soreth,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2017–01170 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4389]

Genome Editing in New Plant Varieties Used for Foods; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We invite comment on specific questions contained in this document related to foods derived from such genome edited plant varieties. FDA is taking this action to help inform our thinking about foods derived from new plant varieties produced using genome editing techniques.

DATES: Submit either electronic or written comments by April 19, 2017.

ADDRESSES: You may submit comments 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–4389 for ''Genome Editing in New Plant Varieties Used For Foods; Request for Comments.'' 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 Division of Dockets Management 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.'' We will review this copy, including the claimed confidential information, in our 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments