needs of Hurricane Fiona older adult survivors living in Puerto Rico and expand the reach and effectiveness of this project by:

- Expanding the grantee's project to restore operations impacted by Hurricane Fiona to additional multipurpose senior centers, including installing solar panels, generators, and cisterns, as well as replenishing the supply of emergency meals for older adults;
- Advancing the capacity of the broader aging services network to deliver services to older adults and their caregivers who were impacted by Hurricane Fiona by continuing to identify and address the most critical needs; and
- Increasing outreach, evaluation, technical assistance, and sub-grantee monitoring and financial oversight activities.

The supplement will accomplish the goals of the program using the following approaches:

- *Partnerships* are essential for delivering programs and services vital to help older adults remain in their communities. PROOE's partnership with the aging network, including multipurpose senior centers, is critical to allow services and programs to be provided in communities at the local level, especially in recovery from disasters.
- *Community-based resources, such as multipurpose senior centers,* provide congregate meals, home delivered meals, evidence-based disease prevention and health promotion services, outreach, information and referral services, socialization as well as many other supports for older adults in their local communities. In Puerto Rico, these centers often provide an access point for healthcare, including offering nursing care to and housing medications that need refrigeration for community-dwelling older adults.
- *Stewardship* is key to any project. The supplement will enable PROOE to increase stewardship over the sub-grant process to manage expanded work and enhance program oversight, monitoring, evaluation, and additional activities proportional to the increased funding and expectations resulting from this supplement.

Program Name: Puerto Rico Disaster Assistance Grant.

Recipient: Puerto Rico Ombudsman Office for the Elderly (PROOE).

Period of Performance: The supplement award will be issued to extend the project period to May 1, 2023, through September 30, 2025.

Total Award Amount: $ 9,779,231.

Award Type: Cooperative Agreement Supplement.

Basis for Award: The Puerto Rico Ombudsman Office for the Elderly (PROOE), the State Unit on Aging (SUA), is currently funded to carry out the objectives of the project entitled Puerto Rico Disaster Assistance Grant for the period of May 1, 2023, through September 30, 2024. Since project implementation began in 2023, the grantee has accomplished a great deal. This supplement will enable the grantee to carry their work even further, serving more older adult survivors of Hurricane Fiona by expanding their project to additional senior centers in local communities. The additional funding will not be used to begin new projects or activities. The PROOE is uniquely positioned to complete the work called for under this project. PROOE is the designated SUA and administers the Older American Act programs and services to support older adults living in the community as well as their caregivers. PROOE's partners include the Territory's network of senior centers and local communities, many of which are in rural areas. Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the older adults being served by this project could be negatively impacted by a disruption, thus posing the risk of re-traumatization and further negative impacts on health and wellbeing in their recovery from Hurricane Fiona. If this supplement is not provided, the project would be less able to address the significant unmet health and social support needs of additional older adult survivors and their caregivers. Similarly, the project would be unable to expand its current reach. Finally, providing this supplement to PROOE will allow for the greater realization of Congress' intent in the Older Americans Act which includes targeting older individuals with greatest economic need (including low- income minority individuals and older individuals residing in rural areas) and older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas) to receive services under this Act, as well as targeting of services to older adult individuals at risk for institutional placement to permit such individuals to remain in home and community-based settings.

Statutory Authority: 42 U.S.C. 3030; Pub. L. 117–328, 136 Stat. 4459.

Dated: April 29, 2024.

Allison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–09542 Filed 5–1–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0394]

Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' This guidance is intended to clarify FDA's requirements and recommendations with respect to heritable intentional genomic alterations (IGAs) in animals. The guidance is being issued as one of two companion documents. This guidance, entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals. This means that for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get approval before marketing their product. For other types of IGAs in animals that do go through the approval process, the companion draft guidance document, GFI #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the approval process applies to heritable IGAs in animals.

DATES: The announcement of the guidance is published in the **Federal Register** on May 2, 2024.

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–2008–D–0394 for ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine (HFV–108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2017 (82 FR 6561), FDA published the notice of availability for a draft GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' giving interested persons until April 19, 2017, to comment on the draft guidance. On April 13, 2017, we published a notice announcing the extension of the comment period to June 19, 2017 (82 FR 17844). FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. As noted, this guidance is intended to clarify our risk-based regulatory approach for developers of heritable IGAs in animals.

The guidance is being issued as one of two companion documents. GFI #187A, ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based approach to the oversight of IGAs in animals. This means that, for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get FDA approval before marketing their product. These are IGAs in animals and animal products for which FDA finds that we understand the product's risks for the specified intended use, any identified risks are appropriately mitigated, and we have no further questions for which we would need to see additional data to address. The guidance explains that FDA's approach is risk-based and ranges from:

• Category 1 products for which we do not expect developers to consult with us prior to marketing an animal containing an IGA where the risk is best understood and mitigated; to

• Category 2 products for which we may not expect developers to submit an application for approval of the IGA if, after looking at data submitted about that product's risk, we find that we understand the product's risks for the specified intended use, any identified risks are appropriately mitigated, and we have no further questions for which we would need to see additional data to address; to

• Category 3 products for which FDA will review and, where the data supports it, approve a product using data requirements that are proportionate to the risk associated with the particular product.

Draft GFI #187B, ''Heritable Intentional Genomic Alterations in Animals: The Approval Process,'' whose notice of availability is published elsewhere in this edition of the **Federal Register**, describes how the FDA approval process applies to heritable IGAs in animals.

FDA received comments on the draft guidance that came from industry (companies that produce IGAs and trade associations), individual consumers, academics, non-governmental organizations (consumer, environmental), other Federal and State government agencies, and individual developers of IGAs in animals. In the **Federal Register** notice announcing availability of the draft guidance, FDA posed questions regarding whether there

are categories of IGAs in animals that pose less risk and, if so, what data or information supports that contention. No commenters provided data to address the Agency's questions other than scientific literature references that were not directly applicable or conclusive.

In the notice announcing availability of the draft guidance, FDA also asked for comment on the appropriate terminology for animals with intentional genomic alterations. Commenters expressed different preferences, but there was no general consensus on an appropriate term. FDA has adopted ''intentional genomic alteration'' or ''IGA'' in animals as the term it will use to refer to intentional genomic alterations in animals regardless of whether they are developed with genetic engineering, including genome editing, or some other modern molecular technology. This term is simple and sufficiently broad to encompass intentional genomic alterations achieved through means that currently exist and those yet to be developed. Moreover, section 740(d)(4)(B) of the Federal Food, Drug, and Cosmetic Act uses this term (21 U.S.C. 379j-12(d)(4)(B)). However, the scope of the guidance does not include induction of polyploidy by heat, pressure, or chemical treatment, or selective breeding or other assisted reproductive technologies. Non-heritable intentional genomic alterations in animals are also outside the scope of this guidance document.

Changes FDA has made in response to comments include:

- Reorganization and use of plain language to make FDA's regulatory approach clearer to stakeholders;
- Expansion of IGAs for which FDA may decide it does not expect submission of an application for approval following a review of data and a determination that the IGA meets the Category 2 description in the guidance. The new types of IGAs include:
  - IGAs that are equivalent to genomic sequences that are found in animals of the same species with a history of safe use in animal agriculture food production and
  - IGAs that are equivalent to what could be theoretically achieved through conventional breeding under certain conditions,

including that the IGAs are not expected to result in changes to food composition and their intended use does not include any effect on disease or other health outcome;

- Clarification that if you are:
  - ;a farmer, grower, or other entity that just has animals with IGAs that FDA has approved or determined are Category 2 on your farm or other premises, including the offspring of those animals,
  - and you are not the developer of the IGA in the animal or marketing the animals with any new claims,

then, as a general matter, you do not have to register or list with FDA and you can engage in your ordinary activities (*e.g.,* breeding, growing, etc.) without contacting FDA; and

- Clarification that those who breed an animal containing an IGA that FDA has approved or has determined is Category 2:
  - with another animal containing an IGA that FDA has approved or also determined is Category 2 or
  - with an animal that does not contain an IGA

and make no new claims do not need to contact FDA and nothing further is required.

The guidance announced in this notice finalizes the draft guidance dated January 2017.

This level 1 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 ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information regarding environmental analysis in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of information regarding applications in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information regarding investigational exemptions in 21 CFR part 511 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09278 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2648]

Heritable Intentional Genomic Alterations in Animals: The Approval Process; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' This draft guidance is intended to clarify FDA's requirements and recommendations for developers of intentional genomic alterations (IGA) in animals. The draft guidance is being issued as one of two companion documents. ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the FDA approval process applies to heritable IGAs in animals. FDA is issuing GFI #187B as a draft guidance to solicit comments that will enable the Agency to update, and make as efficient as possible, the approval process for IGAs in animals. In addition, FDA requests comments on questions that it intends to address in the final version of this guidance document. The companion final guidance, GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals. This means that, for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get approval before marketing their product.

DATES: Submit either electronic or written comments on the draft guidance by July 31, 2024 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: