information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; *Number of Respondents:* 750; *Total Annual Responses:* 380; *Total Annual Hours:* 1,643.47. (For policy questions regarding this collection contact April Forsythe at 410–786–8493 or *April.Forsythe@cms.hhs.gov.*)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Acute Hospital Care at Home (AHCAH) Quantity, Intensity, and Mix of Services (QIMS) Data Collection Tool; *Use:* This is a new information collection request. The Consolidated Appropriations Act (CAA) of 2026 Section 6210(c) requires CMS to evaluate care provided to patients served through the Acute Hospital Care at Home (AHCAH) initiative, including the quantity, intensity, and mix of services (QIMS) furnished. This includes, but not limited to, the number of clinician visits, food services, and pharmacy services provided to patients while on the hospital-at-home service.

To participate in the AHCAH initiative hospitals are granted individual waivers at the CMS Certification Number (CCN) level. The AHCAH initiative waives specific Hospital Conditions of Participation (CoPs), 42 CFR 483, which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient.

In-patient healthcare services are provided to patients served under the AHCAH initiative. CMS has developed a tool to quantify the mix and intensity of the services for the purposes of analysis as required by CAA 2026. CMS is seeking OMB approval for information collection via this tool.

CMS will use this information to describe the quantity, mix, and intensity of services (QIMS) provided to patients in the AHCAH initiative. This includes patients admitted from an emergency department (ED) and patients transferred from an inpatient hospital unit. CMS will use this data to report to Congress. *Form Number:* CMS–10971 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; Federal Government and State, Local or Tribal Governments; *Number of Respondents:* 365; *Total Annual Responses:* 13,000; *Total Annual Hours:* 13,000. (For policy questions regarding this collection contact Cheryl Lehane at (617) 461–4888.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–24024 Filed 11–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8482]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 28, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910–0769—Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to FDA's Center for Devices and Radiological Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (*https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form*), by email, or by regular mail.

In the **Federal Register** of August 26, 2026 (91 FR 55101), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that was PRA related.

The commenter questioned the usefulness of the form, citing submission concerns and recommended publishing submissions with identifying information removed. The comment did not address the proposed changes to the

burden estimate. FDA appreciates this feedback. Reports submitted through the form help FDA identify potential regulatory misconduct, assess risks to patients, and determine whether further investigation or action is warranted. CDRH prioritizes its review based on potential risks to patients. Depending on the assessment, FDA may take regulatory action, request additional information, or continue monitoring the allegation.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH ..	2,800	1	2,800	0.25 (15 minutes) ..	700

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

Our estimated burden for the information collection reflects an overall increase of 75 hours and a corresponding increase of 300 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–24046 Filed 11–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–11783]

Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance for industry titled ''Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management'' that appeared in the **Federal Register** of October 28, 2026. In the notice of availability for the draft guidance, FDA requested comments on the draft guidance. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance for industry published October 28, 2026 (91 FR 67838). Either electronic or written comments must be submitted by December 28, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2026–D–11783 for ''Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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