ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14 Reporting of product deviations by licensed manufacturers.	3486	70	7.186	503	2.0	1,006
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services.	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products).	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	3486A [2]	127	6.50	826	0.25	207
Total				17,818		34,191

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents ((2,455 + 86) × 0.05 = 127).

Following publication of the 60-day notice, the Agency identified a multiplication and rounding error in the burden calculations. The corrected estimates are reflected in this 30-day notice. This revision does not reflect a substantive or programmatic change to the information collection. Our estimated burden for the information collection reflects an overall increase of approximately 4,612 hours and a corresponding increase of 2,642 responses. We attribute this adjustment to an increase in the number of product deviations we received in FY 2024 from licensed manufacturers, unlicensed registered blood establishments and transfusion services under § 606.171. This is likely due to the issuance of the revised guidance document titled, ''Biological Product Deviation Reporting for Blood and Plasma Establishments'' (85 FR 14682; March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18946 Filed 9–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8692]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Pathogen-Agnostic Sequencing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA. In addition, the Committee will meet to discuss and provide advice to FDA on examining the scientific, clinical, and public health dimensions of the use of pathogen-agnostic sequencing as it relates to emergency preparedness and response efforts, and to support discussion of opportunities, implementation considerations, and potential priorities for future coordination. The preparedness use could cover local and national outbreaks, known pathogens, or unknown pathogens. This meeting is being held to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The meeting will be open to the public. FDA is establishing a docket for public comment.

DATES: The meeting will be held on November 19, 2026, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: The public will have the option to participate, and all participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

The online web conference meeting will be available at the following link on the day of the meeting at: *https://youtube.com/live/pUjANlAc1ZQ?feature=share.*

The address for in-person attendance is FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2026–N–8692. The docket will close on November 12, 2026. 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 November 12, 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.

Comments received on or before November 3, 2026, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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):* 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–N–8692 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-Pathogen-agnostic sequencing.'' 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.'' FDA 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 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 the 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.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Advisory Committee Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm.3214, Silver Spring, MD 20993–0002, 301–796–6683, *CDRH_MDAC@fda.hhs.gov.* A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

On November 19, 2026, the Committee will discuss and make recommendations on information regarding the examination of scientific, clinical, and public health dimensions of the use of pathogen-agnostic sequencing as it relates to emergency preparedness and response efforts, and to support discussion of opportunities, implementation considerations, and potential priorities for future coordination. The preparedness use could cover local outbreaks, national outbreaks, known pathogens, or unknown pathogens. This meeting is being held to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). We are seeking input on the design of these tests and the opportunities and challenges associated with their development, including how to establish an agile but effective and validated bioinformatics system that can account for frequent sequence changes. FDA will provide an overview of the topics.

FDA intends to make background material available to the public no later than two (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include an online meeting platform in conjunction with the physical meeting room (see **ADDRESSES**) and slide presentations with audio and video components to allow the presentation of materials at the advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 3, 2026, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:00 p.m. and 2:00 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before October 28, 2026. 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, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory

committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by October 30, 2026. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the HHS Press Room at *https://www.hhs.gov/press-room/index.html* or 202–690–6343.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Evella Washington *CDRH_MDAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see **ADDRESSES**). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18920 Filed 9–15–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0473]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on the ICR must be received on or before October 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice via *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under Review'' and ''Select Agency: Department of Health and Human Services''.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, *Natalie.Klein@hhs.gov* or (240) 453–6900. If requesting information, please include the document identifier 0990–0473–30D and project title, ''Department of Health and Human Services (HHS) Subpart C Certification Form'' for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Subpart C Certification Form.

Type of Collection: Renewal.

OMB No.: 0990–0473.

Abstract: The Office for Human Research Protections (OHRP) is requesting a three-year extension of OMB No. 0990–0473, the HHS Subpart C Certification Form. The purpose of this form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to obtain authorization to include prisoners in HHS-conducted or supported human subjects research. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time.

Likely Respondents: Institutions or Organizations operating Institutional Review Boards (IRBs) that have enrolled or are planning to enroll prisoners in human subjects research conducted or supported by HHS.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Subpart C Certification Form	Institutions or Organizations operating Institutional Review Boards (IRBs).	40	2.13	1.0	85
Total		40	2.13	1.0	85

The estimate of the number of respondents is based upon the current number of institutions certifying HHS-conducted or -supported subpart C human subjects research to OHRP. In 2025, OHRP received fifty-one certifications from thirty-eight institutions or organizations, and one hundred percent of the respondents submitted their certification information electronically. We project that, annually, forty institutions will submit certifications. Most respondents will submit the form twice annually; however, some respondents may submit the form 3 times annually. Consistent with 5 CFR 1320.5(a)(1)(iv)(5), therefore, we believe this estimate represents the