

Glomerular Basement Membrane Disease)” to the List.¹⁴ The petition’s validity was established by references to two peer-reviewed, published studies that provide a medical basis for the association between anti-GBM glomerulonephritis—a type of kidney disease—and hydrocarbon exposure. Several hydrocarbons (including organic solvents and fuels such as pristane, phytane, and benzo(a)pyrene) are identified as 9/11 agents. The following referenced studies (a literature review and a case study) each individually establish a medical basis:

- *Hydrocarbon Exposure May Cause Glomerulonephritis and Worsen Renal Function: Evidence Based on Hill’s Criteria for Causality*, by Ravnskov [2000],¹⁵ is a peer-reviewed, published literature review discussing the role of hydrocarbons in causing glomerulonephritis and end-stage renal failure.

- *Anti-Glomerular Basement Membrane Disease*, by Pusey [2003],¹⁶ is a peer-reviewed, published case review discussing the role of hydrocarbons in anti-GBM disease.

These two studies suggest a potential association between exposure to 9/11 agents (specific hydrocarbons) and anti-GBM glomerulonephritis and thus provided a sufficient medical basis to consider the submission a valid petition.

D. Evaluation of Scientific Evidence: Findings and Conclusion

In response to Petition 026, and pursuant to the *Policy and Procedures*, the Administrator of the WTC Health Program directed the Science Team to conduct a systematic search of the scientific literature to identify all peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis among 9/11-exposed populations. These types of studies are evaluated to determine if they provide evidence to support the likelihood of a causal association between 9/11 exposure and the health condition under consideration. The Science Team provided a paper to the Administrator describing its findings, *Evaluation of Scientific Evidence Supporting the Addition of Anti-Glomerular Basement Membrane Disease (Anti-GBM) Glomerulonephritis to the List of WTC-Related Health Conditions*. This paper is available in the docket for this

¹⁴ See Petition 026, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

¹⁵ Ravnskov U [2000], *Hydrocarbon Exposure May Cause Glomerulonephritis and Worsen Renal Function: Evidence Based on Hill’s Criteria for Causality*, *Q J Med* 93(8):551–556.

¹⁶ Pusey CD [2003], *Anti-Glomerular Basement Membrane Disease*, *Kidney Int* 64(4):1535–1550.

activity¹⁷ and on the Program’s website.¹⁸

Neither the systematic literature search nor the references provided in the petition, including those described above, identified any peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis in 9/11-exposed populations. In accordance with the WTC Health Program’s *Policy and Procedures*, because no such peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis in 9/11-exposed populations were found, the Program was unable to conduct an evaluation of scientific evidence to determine the likelihood of a causal association between 9/11 exposures and the petitioned health condition.

Upon finding no evidence available in peer-reviewed, published, epidemiological studies regarding anti-GBM glomerulonephritis among 9/11-exposed populations, the Science Team concluded that there is inadequate evidence to determine the likelihood of a causal association¹⁹ between 9/11 exposures and anti-GBM glomerulonephritis (Category V).

E. Administrator’s Final Decision on Whether To Propose the Addition of Anti-GBM Glomerulonephritis to the List

Pursuant to the PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), and in accordance with Sec. VIII.B. of the *Policy and Procedures*, the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of anti-GBM glomerulonephritis to the List (pursuant to the PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to the PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator also determined that requesting a recommendation from the STAC (pursuant to the PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 026 request to add “Anti GBM Disease Glomerulonephritis (Anti-Glomerular Basement Membrane Disease)” to the List of WTC-Related Health Conditions is denied.

¹⁷ <https://www.cdc.gov/niosh/docket/archive/docket094.html>.

¹⁸ <https://www.cdc.gov/wtc/received.html>.

¹⁹ See *supra* note 5 at 17.

F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Acting CDC Director Jay Bhattacharya, MD, Ph.D., approved this document for publication on March 11, 2026.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2026–05421 Filed 3–18–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1849]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notifications Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the applicable regulations, and the guidance documents and agency forms related to Premarket Notifications of Devices.

DATES: Either electronic or written comments on the collection of information must be submitted by May 18, 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 May 18, 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-N-1849 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notifications Submission." 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 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: 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, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Notifications Submission 510(k)—21 CFR, Part 807, Subpart E

OMB Control Number 0910-0120—Extension

This information collection helps support implementation of statutory provisions that govern premarket clearance of devices. Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), establish premarket notification procedures. Persons who intend to market a medical device, for which a premarket approval application (PMA) is not required, must submit a premarket notification to FDA, unless the device is exempt from 510(k) requirements and does not exceed the limitations of exemptions of the device classification regulations, at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device. If a device is determined to be not substantially equivalent to a legally marketed device, it must have an approved PMA, product development

protocol, humanitarian device exemption (HDE), request for an evaluation of automatic class III designation (De Novo request), or be reclassified into class I or class II before being marketed. The information collection also helps support section 510(l) of the FD&C Act, which provides for exemption from premarket notification.

The following instruments are included in the information collection:

- Form FDA 3514, “CDRH Premarket Review Submission Cover Sheet”
- Form FDA 3881, “Indications for Use”
- Voluntary eSTAR Program Interactive PDF Form and instructional web page
- Form FDA 4062, “Electronic Submission Template and Resource (eSTAR)” (for non-In Vitro Diagnostic (IVD) 510(k) submissions)
- Form FDA 4078, “Electronic Submission Template and Resource (eSTAR)” (for In Vitro Diagnostic (IVD) 510(k) submissions)

We are revising the information collection to include Form FDA 3674, “Certification of Compliance, Under 42 U.S.C. 282(j)(5)(B), with Requirements of *ClinicalTrials.gov*.” Under applicable authorities, applications under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the Public Health Service Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers.

The information collection also includes an “Acceptance Checklist.” As discussed in the guidance document “Refuse to Accept Policy for 510(k)s” (April 2022), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>, we believe the checklist can be a helpful resource for

510(k) submitters and may simplify preparation of the 510(k). Similarly, the guidance document “Recognition and Withdrawal of Voluntary Consensus Standards” (September 2020), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards>, communicates procedures followed by the Center for Devices and Radiological Health (CDRH) when requests for recognition of a voluntary consensus standard for medical products are received. The guidance document outlines principles for recognizing a standard wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard. Section 514 of the FD&C Act (21 U.S.C. 360d) allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions, including premarket notifications or other requirements. We publish and update the list of recognized standards regularly at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. As instructed in the guidance document, any interested party may submit a request for recognition of a standard by mail directed to the CDRH Standards Program (*i.e.*, paper copy) or electronically via email.

For efficiency of Agency operations, we are also revising the information to include activities associated with section 520(b) of the FD&C Act, governing custom devices. Regulations in 21 CFR 812.3 define a custom device and implementing regulations in 21 CFR 807.85 provide for exemption from premarket notification. Section 520(b) of the FD&C Act also provides for the issuance of guidance. The guidance document entitled, “Custom Device Exemption” (September 2014), and available for download at <https://www.fda.gov/media/89897/download>,

explains how FDA interprets provisions in section 520(b)(2)(B) of the FD&C Act, describes what information should be submitted in a Custom Device Annual Report (“annual report”), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption.

Finally, we discuss the guidance document entitled, “Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency,” announced in the **Federal Register** of March 27, 2023 (88 FR 18153), which describes a phased approach intended to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements. The recommendations discussed in the guidance document result in the one-time collection of information intended to ensure an orderly and transparent transition from temporary policies established during the COVID-19 public health emergency to normal operations. Because the information collection recommendations apply to specific medical devices already in distribution, we believe the information discussed is appropriately characterized as nonstandardized followup designed to clarify responses to approved collections of information (*i.e.*, plans for compliance with applicable requirements unique to that distributed device). We therefore believe the activity constitutes the collection of non-identical and/or followup information, as defined under 5 CFR 1320.3. At the same time, we expect some degree of fluctuation in future submissions under part 807, subpart E, as a result of implementation of the medical device transition plan.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity and 21 CFR part/section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 CFR Part 807, Subpart E, PREMARKET NOTIFICATION PROCEDURES						
510(k) submission (807 subpart E)	FDA 3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87)	FDA 3514	1,906	1	1,906	0.5	953
Status request (807.90(a)(3))	1	1	1	0.25	1
510(k) summary (807.92)	2,742	1	2,742	4	10,968
510(k) statement (807.93)	130	1	130	.08 (5 minutes)	10
510(k) submission (807 subpart E)—using eSTAR format ...	FDA 4062, FDA 4078 ..	3,800	1	3,800	40	152,000
Guidance Document Recommendations						
Request for recognition of a voluntary consensus standard	5	1	5	1	5
Annual reporting for custom devices under 520(b) of the FD&C Act.	31	1	31	40	1,240

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

Activity and 21 CFR part/section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance “Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions”						
Certification to accompany 510(k) submissions	FDA 3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Electronic Submission Template and Resource (eSTAR)						
eSTAR setup—one-time burden	80	1	80	0.08 (5 minutes) ...	6
Total	16,295	469,183

The information collection reflects program changes and adjustments. We have also made nominal adjustments on individual provisions to reflect expected fluctuations in submissions. Cumulatively these actions result in an overall increase of 145,804 hours and a corresponding increase of 3,625 responses annually. The increase was attributed to the 510(k) submissions increase from 100 to 3,800.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation,
and International Affairs.
[FR Doc. 2026-05329 Filed 3-18-26; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-D-6131]

General Considerations for the Use of New Approach Methodologies in Drug Development; 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 entitled “General Considerations for the Use of New Approach Methodologies in Drug Development.” The purpose of this draft guidance is to provide drug developers with a validation framework and general recommendations for using new approach methodologies (NAMs) in drug development. Although animal toxicity studies have proved to be a critical method to identify potential risks to human health, finding ways to improve human relevance while reducing the use of animals by developing reliable NAMs furthers an important Center for Drug Evaluation and Research (CDER) priority to move

away from reliance on animal testing. The recommendations in this draft guidance are intended to highlight scientific principles of study design and reporting that can be applied broadly and flexibly in the validation of NAMs used in drug development. This draft guidance is not intended to address specific NAMs and does not address the use of NAMs in drug discovery; rather, it encourages the use of NAMs in regulatory submissions, especially when they improve the predictivity of nonclinical studies for increased safety in clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by May 18, 2026 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:

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-2025-D-6131 for “General Considerations for the Use of New Approach Methodologies.” 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