practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on non-clinical and clinical investigation of devices used for the treatment of BPH. 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1724 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27919 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2330]

Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers; 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 final guidance for industry entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during good laboratory practice (GLP)-compliant toxicology studies. This guidance finalizes the draft guidance ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers'' issued on September 30, 2019. This revision includes editorial changes to improve the clarity of the document.

DATES: The announcement of the guidance is published in the **Federal Register** on December 27, 2021.

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–2019–D–2330 for ''Pathology Peer Review in Nonclinical Toxicology

Studies: Questions and Answers.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. 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: Tahseen Mirza, Office of Study Integrity and Surveillance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993, 301–796–7645; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Judy Davis, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993, 301–796–6636; Hilary Hoffman, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rm. 389, Rockville, MD 20855, 240–402–8406; Yuguang Wang, Office of the Center Director, Center for Food Safety and Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A035, College Park, MD 20740, 240–402–1757; Hans Rosenfeldt, Office of Science, Center for Tobacco Products, Food and Drug Administration, 11785 Beltsville Dr., Bldg. BELT1, Rm. 5322, Beltsville, MD 20705–3121, 301–796–2202; or Tony Taube, Division of Operational Policy, Office of Regulatory Affairs, 12420 Parklawn Dr., Rm. 4044, Rockville, MD 20857 email: *ORAPolicyStaffs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during GLP-compliant toxicology studies.

The histopathological assessment of tissue samples is one of the key activities performed during GLP-compliant toxicology studies. Commonly, histopathological assessment includes an initial read of tissue slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist. Pathology peer review may be particularly useful in situations where unique or unexpected findings are noted or when the peer-review pathologist has a particular expertise relevant to the study. When pathology peer review occurs as part of a nonclinical study conducted in compliance with GLP regulations, it should be well-documented. However, documentation practices during pathology peer review have not been clearly defined and vary among nonclinical testing facilities.

Although the current regulations include general requirements for histopathology evaluation (for example, it requires that standard operating procedures be established to cover histopathology), pathology peer review is not specifically addressed in the current regulations. This Q&A document is intended to clarify FDA's recommendations concerning the management and conduct of pathology peer review performed during GLP-compliant toxicology studies.

This guidance finalizes the draft guidance entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers'' issued on September 30, 2019 (84 FR 37646). FDA considered comments received on the draft guidance as the guidance was finalized. Editorial changes were made to improve clarity.

This 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 ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 (Good Laboratory Practice for Non-Clinical Laboratory Studies) have been approved under OMB control number 0910–0119; and submission of information for FDA review under an investigational new drug application for human drug or

biologic products is approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: December 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28051 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes And Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: May 11–12, 2022.

Open: May 11, 2022, 10:00 a.m. to 1:30 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive, Bethesda, MD 20892.

Closed: May 12, 2022, 1:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31 Conference Rooms C, D&E, and F&G 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Digestive Diseases and Nutrition Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31 Conference Rooms C, D&E, and F&G 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 12:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 12:15 p.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS).

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28000 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P