approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Heparin Sodium Injection 5000 USP IU/mL is the subject of NDA 017029, held by Fresenius Kabi USA LLC, and initially approved on January 1, 1982. Heparin Sodium Injection is an anticoagulant indicated for:

- Prophylaxis and treatment of venous thrombosis and pulmonary embolism.
- Prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease.
- Atrial fibrillation with embolization.
- Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation).
- Prevention of clotting in arterial and cardiac surgery.
- Prophylaxis and treatment of peripheral arterial embolism.
- Use as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

In May 1991, FDA moved the Heparin Sodium Injection 5000 USP IU/mL to the ''Discontinued Drug Product List'' section of the Orange Book. BE Pharmaceuticals AG, submitted a citizen petition dated October 18, 2022 (Docket No. FDA–2022–P–2952), under 21 CFR 10.30, requesting that the Agency determine whether Heparin Sodium Injection 5000 USP IU/mL was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Heparin Sodium Injection 5000 USP IU/mL was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Heparin Sodium Injection 5000 USP IU/mL was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Heparin Sodium Injection 5000 USP IU/mL from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Heparin Sodium Injection 5000 USP IU/mL in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Heparin Sodium Injection 5000 USP IU/mL may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11157 Filed 5–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1268]

Use of Whole Slide Imaging 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 ''Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the use of whole slide images during good laboratory practice (GLP)-compliant toxicology studies. Documentation practices during generation, use, and retention of whole slide images have not been clearly defined and vary among nonclinical testing facilities. This question-and-answer document is intended to clarify FDA's recommendations concerning the management, documentation, and use of whole slide images in histopathology assessment and/or pathology peer review for nonclinical studies conducted in compliance with the GLP regulations. This guidance finalizes the draft guidance of the same title issued on April 8, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on May 25, 2023.

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–2021–D–1268 for ''Use of Whole Slide Imaging 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 the 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; Diane Maloney, 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 Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2220, 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 Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A012, College Park, MD 20740, 240–402–1757; Hans Rosenfeldt, Office of Science, Center for Tobacco Products, Food and Drug Administration, 11785 Beltsville Dr., Calverton Tower, Rm. 5322, Beltsville, MD 20705, 301–796–2202; Eric S. Myskowski, Office of Bioresearch Monitoring Operations, Office of Regulatory Affairs, Food and Drug Administration, Resident Post—Maplewood, 15 Sunnen Dr., Maplewood, MO 63143, 612–758–7187.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.'' The histopathological assessment of tissue samples is one of the key activities conducted during GLP-compliant nonclinical laboratory studies. Commonly, the histopathological assessment includes an initial evaluation of glass histology slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist, group of pathologists, or Pathology Working Group. The current regulations (21 CFR part 58) include general requirements for histopathology evaluation (*e.g.,* standard operating procedures), but the use of whole slide images in lieu of glass slides is not expressly addressed. This guidance provides information to sponsors and nonclinical laboratories regarding the management, documentation, and use of whole slide images during histopathology assessment and/or pathology peer review performed for GLP-compliant nonclinical toxicology studies using non-human specimens. The guidance does not cover the use of whole slide imaging for clinical applications.

When whole slide images are used in lieu of glass slides as part of a nonclinical study conducted in compliance with the GLP regulations, adequate documentation is critical. Documentation practices during whole slide imaging generation and use have not been clearly defined and vary among nonclinical testing facilities. Use of whole slide images in casual consultations, opinion exchanges, and mentoring among pathologists are not covered by this guidance document.

This guidance finalizes the draft guidance entitled ''Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers'' issued on April 8, 2022 (87 FR 20872). FDA considered comments received on the draft guidance as the guidance was finalized. This revision includes editorial changes to improve the clarity of the document.

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 ''Use of Whole Slide Imaging 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 pertaining to good laboratory practice for non-clinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

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

Dated: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11211 Filed 5–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics Meeting

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: *https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/.*

NAME: National Committee on Vital and Health Statistics (NCVHS) Meeting

DATES: Wednesday, June 14, 2023: 10:00 a.m.–4:30 p.m. EDT.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to *vgh4@cdc.gov;* or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the NCVHS website *https://ncvhs.hhs.gov/*, where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION:

Purpose: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[1] NCVHS advises the Secretary on administrative simplification standards, including those for privacy, security, adoption and implementation of transaction standards, unique identifiers, code sets, and operating rules adopted under the Patient Protection and Affordable Care Act (ACA).[2]

The purpose of this meeting is to provide a public forum for the Committee to consider what comments it will make on the April 17, 2023, Notice of Proposed Rulemaking (NPRM) ''HIPAA Privacy Rule to Support Reproductive Health Care Privacy'' which is available at *https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy.*

In addition, the Committee will consider what recommendations it will make in response to updated and new operating rules proposed by the Council for Affordable Quality Health Care (CAQH), Committee on Operating Rules for Information Exchange (CORE), to support adopted HIPAA standards, and an updated version of the X12 standard for claims and electronic remittance advice transactions (Version 8020) proposed by X12. The Committee developed these recommendations in response to formal proposals received from CAQH CORE [3] and X12 [4] respectively, informed by a Request for Comment (RFC) and two-day hearing held January 18–19, 2023.[5] Details on the recent RFC and hearings are available on the Committee's website here: *https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/.*

The Committee will reserve time on the agenda for public comment. Meeting times and topics are subject to change. Please refer to the agenda posted on the NCVHS website for updates: *https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/.*

Sharon Arnold,

Associate Deputy Assistant Secretary, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2023–11207 Filed 5–24–23; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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: Center for Scientific Review Special Emphasis Panel; Small

[1] Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at *https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf.*

[2] Public Law 111–148, 124 Stat.119, available at *https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.*

[3] Letter from CAQH CORE to NCVHS, May 23, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf.*

[4] Letter from X12 to NCVHS, June 7, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf.*

[5] See, Subcommittee on Standards, National Committee on Vital and Health Statistics, Hearing on Requests for New and Updated Transaction Standards and Operating Rules, available at *https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/.*