

with other statutory and regulatory provisions that pertain to devices. Therefore, stakeholders are invited to submit comments on timelines necessary for this transition and how FDA can facilitate this transition in a way that does not disrupt the supply of these important medical products or place undue burden on manufacturers or on the healthcare delivery system.

4. User Fee Transitions

CDER assesses user fees for certain new drug applications (NDAs) and products approved under those NDAs under the Prescription Drug User Fee Amendments (PDUFA). CDER also assesses user fees for certain abbreviated new drug applications (ANDAs) and products approved under those ANDAs under the Generic Drug User Fee Amendments (GDUFA). The PDUFA and GDUFA user fee programs both include specific fees assessed annually for certain marketed approved products.

In the case of PDUFA, with certain exceptions or exemptions, annual prescription drug program fees are assessed for each strength of a prescription drug identified in an approved NDA, as of October 1 of each fiscal year (FY), provided the product is included in the "Prescription Drug Product List" (the "active section") of *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

In the case of GDUFA, annual GDUFA program fees are assessed with respect to approved ANDAs, and fee amounts are tiered based on the number of approved ANDAs owned by an entity (including its affiliates) as of October 1 of each fiscal year. GDUFA also includes an annual facility fee for each facility referenced in an approved ANDA as a producer of an active pharmaceutical ingredient or finished dosage form covered by the ANDA.

FDA does not anticipate that the identification and transitioning of products from drug status to device status pursuant to the *Genus* decision will be completed before October 1, 2021. Persons assessed an annual fee with respect to a product identified in an approved NDA or ANDA as of that date should pay the assessed FY 2022 fees by the due date to avoid being placed on the arrears list and incurring other penalties associated with failure to pay user fees by the due date. Payors of the annual FY 2022 fee with respect to a product that the payor believes should transition to device status under *Genus* are encouraged to request refunds of user fees attributable to those products. FDA anticipates that, for approved

products that transition from drug status to device status under the process described above, refund requests for PDUFA and GDUFA fees that are received on time under section 736(i) or 744B(m) of the FD&C Act (21 U.S.C. 379h(i) or 379j-42(m)), respectively, will be granted. This would include requests for refund of the FY 2022 prescription drug program fees assessed under PDUFA, or FY 2022 generic drug applicant program fees assessed under GDUFA that may result in a lower fee tier for an ANDA holder, as well as any GDUFA facility fees for a facility referenced in one or more ANDAs that will transition, if that facility is not also reported in other ANDAs that will not transition. Under PDUFA, to qualify for consideration for a refund, a written request must be submitted to FDA not later than 180 calendar days after the fee is due (see section 736(i) of the FD&C Act). Under GDUFA, to qualify for a return of a fee, a written request justifying the return must be submitted within 180 calendar days from the date of the fee payment (see section 744B(m) of the FD&C Act).

More information about PDUFA and GDUFA fees and the submission of refund requests is available on FDA's website at <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments> (PDUFA) and <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments> (GDUFA).

5. Determining Drug or Device Status

FDA intends to establish a process for the orderly and efficient determination of which products currently regulated as drugs must be regulated as devices under *Genus*. We encourage sponsors of potentially affected products to comment on this notice, await the publication of our future notice identifying products that we have tentatively determined should transition to device status, and, in the meantime, reach out to FDA with time-sensitive questions.

FDA has established the following contact point for all questions concerning the *Genus* decision and transition activities: *Drug_Device_Transition_Inquiry@fda.hhs.gov*.

Dated: August 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16944 Filed 8-6-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0868]

Development and Submission of Near Infrared Analytical Procedures; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (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 "Development and Submission of Near Infrared Analytical Procedures." This guidance provides recommendations to applicants to aid the development, validation, and use of near infrared (NIR)-based analytical procedures in evaluating the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplemental NDAs and ANDAs for small molecule drugs. The principles in this guidance also apply to drug substances and drug products covered in Type II drug master files. This guidance finalizes the draft guidance of the same title issued on March 31, 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on August 9, 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-2015-D-0868 for “Development and Submission of Near Infrared Analytical Procedures.” 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. 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:

Eugenia Nashed, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4154, Silver Spring, MD 20993-0002, 301-796-1723.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Development and Submission of Near Infrared Analytical Procedures.” This guidance provides recommendations to applicants to aid the development, validation, and use of NIR-based analytical procedures in evaluating the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to NDAs, ANDAs, and supplemental NDAs and ANDAs for small molecule drugs. The principles in this guidance also apply to drug substances and drug products covered in Type II drug master files. FDA intends to issue recommendations specific to NIR methods used for biological products under biologics license applications in a future revision to this guidance. Specifically, this guidance, among other things, (1) addresses the development and submission of NIR analytical procedures used during and for the manufacture and analysis of pharmaceuticals (including raw materials, in-process materials and intermediates, drug substances, and finished products); (2) provides

recommendations to manufacturers for applying the concepts described in the guidance for industry entitled “PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance” (<https://www.fda.gov/media/71012/download>) and the International Council for Harmonisation guidance for industry entitled “Q2(R1) Validation of Analytical Procedures: Text and Methodology” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1-validation-analytical-procedures-text-and-methodology>) to NIR analytical procedures that use chemometric models; and (3) describes the type of information that should be submitted about NIR analytical procedures in applications.

This guidance pertains only to the development and validation of NIR analytical procedures and does not provide recommendations concerning the setup, qualification, maintenance, or calibration of NIR instruments. Although this guidance specifically addresses NIR spectroscopy, this guidance’s concepts of validation can be applied to other multivariate analytical technics, including, for example, Raman.

This guidance finalizes the draft guidance entitled “Development and Submission of Near Infrared Analytical Procedures” issued on March 31, 2015 (80 FR 17057). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates to reflect Agency regulatory experience and technological advancements in the industry, as well as management of NIR procedures over the life cycle of the products.

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 the development and submission of NIR analytical procedures. 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 314 for NDAs and in 21 CFR parts 314 and 601 for annual reports, ANDAs, and supplements to applications have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively. The collections of information in 21 CFR part 211 for current good manufacturing practices for finished pharmaceuticals and medical gases have been approved under OMB control number 0910-0139.

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> or <https://www.regulations.gov>.

Dated: August 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16930 Filed 8-6-21; 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 Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR19-319: NIDDK Central Repositories Non-Renewable Sample Access (X01) Review.

Date: September 13, 2021.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@nidk.nih.gov.

(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: August 4, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-16901 Filed 8-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 Institute on Aging Special Emphasis Panel; T32/T35 Review January 2022 Council.

Date: October 20, 2021.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-827-7428, anita.undale@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 4, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-16951 Filed 8-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, September 09, 2021, 10:00 a.m. to September 10, 2021, 12:45 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on June 02, 2021, FR Doc 2021-11516, 86 FR 29592.

The meeting notice is amended to change the meeting time from September 9-10, 2021, 10:00 a.m. to 1:45 p.m. To September 9-10, 2021, 10:00 a.m. to 12:45 p.m. The meeting is partially closed to the public.

Dated: August 4, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-16952 Filed 8-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special