

**I. Background**

FDA is announcing the availability of a final guidance entitled “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions.” This guidance describes FDA’s general recommendations for limited modifications to devices required to have an approved PMA or HDE to help address manufacturing limitations or supply chain disruptions. This guidance supersedes “Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (Revised)”, issued in May 2020 and updated in May 2022 (COVID–19 PMA/HDE guidance). In the **Federal Register** of March 13, 2023 (88 FR 15417), FDA announced that COVID–19 PMA/HDE guidance was being revised to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration issued under the Public Health Service Act, during which time FDA intended to further revise the guidance.

Following expiration of the PHE declaration on May 11, 2023, FDA has continued to observe supply chain challenges and shortages of medical devices remain widespread. Therefore, consistent with the **Federal Register** of March 13, 2023, FDA is issuing this final guidance. Although this guidance has been revised to remove any expiration date for the enforcement policy, the Agency will continue to monitor the situation and may make

further revisions to the guidance, withdraw the guidance, or pursue other regulatory actions, as appropriate.

FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this less burdensome policy is neither feasible nor appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)) because delaying this policy is likely to exacerbate ongoing supply chain issues. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

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 “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions.” 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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00020028 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Use Devices; Humanitarian Device Exemption.	0910–0332
800, 801, and 809 .....	Medical Device Labeling Requirements; Unique Device Identification.	0910–0485
820 .....	Current Good Manufacturing Practice; Quality Systems.	0910–0073
807, subparts A through D .....	Medical Device Registration and Listing ..	0910–0625
“Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program”.	Medical Devices—Voluntary Improvement Program.	0910–0922

Dated: October 30, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**2023 Publication of Senior Executive Service Candidates for Health and Human Services Performance Review Board**

**AGENCY:** Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members (PRB) who are reviewing performance of Senior Executive Service members, title 42 executives, Senior Level, and Scientific Professional employees for fiscal year 2023

**FOR FURTHER INFORMATION CONTACT:** Monique Pollard, Program Manager, Executive Performance Management, Department of Health and Human

Services, 330 C Street SW, Washington, DC 20201, (202) 729-8797.

**SUPPLEMENTARY INFORMATION:** Title 5 U.S.C. 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95-454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following individuals are being appointed to a roster, from which the PRB members will be appointed to serve on the HHS PRB from CY 2023 through CY 2025. The PRB provides performance rating and rating-based compensation recommendations to the HHS Secretary based on the individual performance appraisals for Senior Executive Service, Senior Level/Senior Technical, and Title 42 executive equivalent employees and the organizational assessments of the Operating and Staff Divisions they serve.

Last name	First name
ADAMS	STEVEN.
AKPA	STEPHANIE.
ALTMAN	BRIAN.
ALVAREZ	KATHRYN.
AMES	KAREN.
ANOKA	JEFFERY.
ANTHONY	ELISE.
ARNOLD	SHARON.
BACKFIELD	KATLIN.
BALLANCE	CHRISTINA.
BARKOFF	ALISON.
BARLOW	AMANDA.
BARRY	DANIEL.
BELL	WILLIAM.
BENFORD	JOFFREY.
BHARGAVA	DEEPAK.
BLACKWELL	EDITH.
BLUM	JONATHAN.
BOATENG	SARAH.
BODDEN	CHERYL.
BOTTICELLA	ANGELA.
BRATCHER-BOWMAN.	NIKKI.
BRAXTON	MAKOTO.
BRISBON	HENRIETTA.
BROWN	MARK.
BRUCE	DUANE.
BURNS	SAMIRA.
BURNSZYNSKI	JENNIFER.
BUSH	LAINA.
CABEZAS	MIRIAM.
CALSYN	MAURA.
CAMPBELL	CHERYL.
CANNISTRA	JENNIFER.
CARNIVAL	DANIELLE.
CHA	STEPHEN.
CHAMBERS	GEORGE.
CHAMP-GELBMANN	JANE.
CHESLEY	FRANCIS.
CHESSON	SONIA.
CLIFFORD	CHAD.
COCHRAN	NORRIS.
COMFORT	KAREN.
CONLEY	MARY.
COOPER	RENEE.
CRONIN	KELLY.
CURTIS	MICHAEL.

Last name	First name	Last name	First name
DALY	MADELINE.	LANKFORD	DAVID.
DAVIS	MICHELLE.	LEAVITT	WILLIAM.
DEL VECCHIO	PAOLO.	LEE	PAULA.
DELEW	NANCY.	LESKO	MAX.
DESPRES	SARAH.	LIMAGE	JULIA.
DISRAELLY	DEENA.	LONNERDAL	NILS.
DOOLEY	SEAN.	LOPEZ	ELIZABETH.
DORN	ALAN.	LYNCH-SMITH	MIRANDA.
DRIGGS	SCOTT.	LYONS	SUSAN.
DUNN MARCOS	ROBIN.	MALONEY	CAROL.
DUPRE	BRIAN.	MARCELLA	JESSICA.
ESPINOSA	KIMBERLY.	MATAKA	ARSENIO.
FIGUEROA	MARVIN.	MATHIAS	KARL.
FINK	DOROTHY.	MAZANEC	BRIAN.
FITZGERALD	DENIS.	MCCLUSKIE	SEAN.
FLAGG	ANN.	MCDANIEL	EILEEN.
FORBER-PRATT	ANJALI.	MCIFF	COLIN.
FRIEDMAN	RUTH.	MIRANDA	TERESA.
FROHBOESE	ROBINSUE.	MOHIUDDIN	SYED.
FROSS	CAITLIN.	MOTSIPOULOS	CHRISTOS.
FRYE	EUGENE.	MUSE	AVERY.
GALLOWAY	SUMMER.	NAIMON	DAVID.
GARRITY	SHEILA.	NICHOLLS	RICHARD.
GARVIN	KHARI.	NOLAN	JANET.
GOLDHABER	BEN.	NOONAN	TIMOTHY.
GOLDSTEIN	ANDREA.	NOVY	STEVEN.
GOTTLICH	VICKI.	PACE	LOYCE.
GOULDING	MICHAEL.	PARK	RACHEL.
GRAF	ALEXANDER.	PARKER HALVERSON.	PAMELA.
GRAMLING	ELIZABETH.		
GRAY	TANGULER.	PECK	JOSHUA.
GREENBERG	MARK.	PEREZ	LUIS.
GREENE	JONATHAN.	PERSON	LISA.
GRIFFIN	ELIZABETH.	PETILLO	JOHN.
GROSSMAN	JORDAN.	PIERCE	JULIA.
GUERRERO	BERTHA.	POSNACK	STEVEN.
HAFFAJEE	REBECCA.	PRYOR	RACHEL.
HALL	RANDALL.	PURDUE	MICHELE.
HALL	WAYNE.	RABIN	BRIAN.
HAMAMOTO	PAMELA.	RAINER	MELANIE.
HAMM	KATHLEEN.	RAMIREZ	ANGELA.
HANDERHAN	LAWRENCE.	RATHGEB	COLLEEN.
HARPER	VICTOR.	RECHTER	PETER.
HAYES WALLER	BERNITA.	ROBINSON	WILMA.
HENDERSON	GRAEME.	RODRIGUEZ	PAUL.
HERNANDEZ	PATRICK.	ROSENTHAL	SARAH.
HILD	STEVEN.	SANDERS	STACY.
HILL	KRISTI.	SAUNDERS	MICHAEL.
HOFFMAN	JANICE.	SCHOMBURG	AYSHA.
HOLLAND	HOWARD.	SCHUHAM	AARON.
HOLZERLAND	WILLIAM.	SCOTT	MARIE.
HORN	DAVID.	SESHASAI	KARUNA.
HOWARD	LANIKQUE.	SHA	LYNN.
HUTCHINSON	KIM.	SHANBHAG	KRISHNAKANT.
JACKSON	SHANNON.	SHERRY	TISAMARIE.
JACOBS	JILL.	SKEADAS	CHRISTOS.
JEE	LAUREN.	SMITH	JENNIFER.
JOHN	KURT.	SMITH	JESSICA.
JOHNSON	DAVID.	STEIDE	KIMBERLY.
JOHNSON	DEBRA.	SULLIVAN	MEG.
JOHNSON	JENNIFER.	SULLIVAN	ROSE.
JONES	CHRISTINE.	SUPPLEE	LAUREN.
JONES	KAMARA.	TAYLOR	CAROLYN.
JONES	WANDA.	TOBIAS	CONSTANCE.
JOYNER	ARLENE.	TOMOYASU	NAOMI.
KACHINSKI	KEVIN.	TOVEN	JEFFREY.
KADISH	ANDREA.	TRAUTMAN	TRACEY.
KENNEDY	GAVIN.	TRESS	DEBORAH.
KEVENEY	SEAN.	TRIPATHI	SUHAS.
KIM	HANNAH.	VALDEZ	ROBERT.
KIM	SUSAN.	WALKER	EDWIN.
KOSSALLY	CONSTANCE.	WALLER	KIMBERLY.
KRAM	ANTHONY.	WEAVER	GRETCHEN.
KRAMER	DEBORAH.	WEBB	SANDRA.

Last name	First name
WENDEL .....	JENNIFER.
WESLEY .....	KENYATA.
WILLIAMS .....	CARLIS.
WILLIAMS .....	RASHEED.
WULFF .....	KATHARINE.
YARBOROUGH .....	LA MONTE.

**Michelle Monroe,***Director, Executive Resources.*

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BILLING CODE 4151-17-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDDK.

The meeting 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 meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIDDK.

*Date:* April 19–20, 2024.

*Open:* April 19, 2024, 10:00 a.m. to 10:20 a.m.

*Agenda:* Introductions and Overview.

*Place:* National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

*Closed:* April 19, 2024, 10:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael W. Krause, Ph.D., Scientific Director, NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Building 5, Room B104, Bethesda, MD 20892-1818, (301) 402-4633, [mwkrause@helix.nih.gov](mailto:mwkrause@helix.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:* October 27, 2023.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2023-24139 Filed 11-1-23; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Cancer Institute; 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:* National Cancer Institute Special Emphasis Panel; Molecular and Cellular Analysis Technologies.

*Date:* December 14–15, 2023.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850 (Virtual Meeting).

*Contact Person:* Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240-276-5856, [nadeem.khan@nih.gov](mailto:nadeem.khan@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Survivorship Needs of Individuals Living with Advanced Cancer (R01).

*Date:* January 11, 2024.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850 (Virtual Meeting).

*Contact Person:* Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240-276-6343, [schweinfestcw@mail.nih.gov](mailto:schweinfestcw@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; IMAT Biospecimen Research.

*Date:* January 11, 2024.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850 (Virtual Meeting).

*Contact Person:* Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850, 240-276-5460, [jfang@mail.nih.gov](mailto:jfang@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Technologies for Cancer Research.

*Date:* January 25–26, 2024.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850 (Virtual Meeting).

*Contact Person:* Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240-276-5856, [nadeem.khan@nih.gov](mailto:nadeem.khan@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Transition Career Development Award and Institutional Research Training and Education Grants.

*Date:* January 25, 2024.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Virtual Meeting).

*Contact Person:* Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240-276-6368, [Stoicaa2@mail.nih.gov](mailto:Stoicaa2@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review SEP-II.

*Date:* February 1–2, 2024.

*Time:* 9:30 a.m. to 5:30 p.m.