considered by FDA and the Quality Expert Working Group.

The draft guidance provides recommendations on data expectations for drug substances and drug products to support marketed drug products including those with registration submissions, lifecycle/postapproval changes, and when applicable, master files. This draft guidance consolidates and updates the recommendations made in the ICH Q1A(R2), Q1B, Q1C, Q1D, Q1E, and Q5C series of stability guidances (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*), by addressing consistency of interpretation, clarification of technical components of stability concepts, recommendations for new technologies and tools used to facilitate an enhanced product understanding, and applicability of recommendations across the lifecycle of a product. This draft guidance can apply to all marketing authorization applications of prescription and nonprescription drugs (*e.g.,* new, abbreviated) for a broad range of drug substances and products (*e.g.,* chemically synthesized, therapeutic and well-characterized proteins and polypeptides, vaccines, cell and gene therapy, drug-device combinations, natural health products).

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''Q1 Stability Testing of Drug Substances and Drug Products'' and will supersede the ICH Q1A(R2), Q1B, Q1C, Q1D, and Q1E guidances. 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR part 314 for submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for the submission of biological license applications under 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information for OTC monograph drug products have been approved under OMB control number 0910–0340. The collections of information for the submission and review of biosimilar product applications and related biosimilar user fee requirements have been approved under OMB control number 0910–0718. The collections of information for the submission and review of correspondence for generic drug products and related generic drug user fee requirements have been approved under OMB control number 0910–0727. The collections of information for current good manufacturing practice in the manufacture, processing, packing and storage of finished pharmaceuticals in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 201 for labeling of prescription drug and biological products have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, 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,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11552 Filed 6–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Guidance on Referrals for Potential Criminal Enforcement

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: This notice describes the Department of Health and Human Services' (HHS or the Department) plans to address regulations that impose criminal liability under the recent Executive Order (E.O.) on *Fighting Overcriminalization in Federal Regulations.*

FOR FURTHER INFORMATION CONTACT: Bob Foster, Deputy General Counsel, (202) 260–3324, *robert.foster@hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 9, 2025, President Donald J. Trump issued E.O. 14294, *Fighting Overcriminalization in Federal Regulations;* 90 FR 20363 (published May 14, 2025). Section 7 of E.O. 14294 provides that within 45 days of the E.O., and in consultation with the Attorney General, each agency should publish guidance in the **Federal Register** describing its plan to address regulations that impose criminal liability.

Consistent with that requirement, HHS advises the public that by May 9, 2026, the Department, in consultation with the Attorney General, will provide to the Director of the Office of Management and Budget a report containing: (1) a list of all criminal regulatory offenses [1] enforceable by the Department or the Department of Justice (DOJ); and (2) for each such criminal regulatory offense, the range of potential criminal penalties for a violation and the applicable mens rea [2] for the criminal regulatory offense.

This notice also announces a general policy, subject to appropriate exceptions and to the extent consistent with law, that when HHS is deciding whether to refer alleged violations of criminal regulatory offenses to DOJ, officers and employees of HHS should consider, among other factors:

- the harm or risk of harm, pecuniary or otherwise, caused by the alleged offense;
- the potential gain to the putative defendant that could result from the offense;
- whether the putative defendant held specialized knowledge, expertise, or was licensed in an industry related to the rule or regulation at issue; and
- evidence, if any is available, of the putative defendant's general awareness of the unlawfulness of his conduct as well as his knowledge or lack thereof of the regulation at issue.

This general policy is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies,

[1] ''Criminal regulatory offense'' means a Federal regulation that is enforceable by a criminal penalty. E.O. 14294, sec. 3(b).

[2] ''Mens rea'' means the state of mind that by law must be proven to convict a particular defendant of a particular crime. E.O. 14294, sec. 3(c).

or entities, its officers, employees, or agents, or any other person.

Eric J. Osterhues,

Deputy General Counsel, U.S. Department of Health and Human Services.

[FR Doc. 2025–11543 Filed 6–23–25; 8:45 am]

BILLING CODE 4150–26–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: Population Sciences and Epidemiology Integrated Review Group; Reproductive, Perinatal and Pediatric Health Study Section.

Date: July 23–24, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lisa Anne Deroo, Ph.D., MPH, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4994, *lisa.deroo@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle and Rehabilitation Sciences.

Date: July 23, 2025.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Erick Omar Hernandez Ochoa, Ph.D., MD, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *erick.hernandezochoa@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurotoxicology, Alcohol, Neurobiology, Motivated Behavior, Mental Health, Cognitive Decline, Aging and Training Grant Applications.

Date: July 23–24, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mamatha Garige, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2118, Bethesda, MD 20817, (301) 443–9737, *mamatha.garige@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Clinical and Translational Exploratory/Developmental Studies in Cancer.

Date: July 23–24, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W–116, National Cancer Institute, Rockville, MD 20892–9750, 240–276–5413, *klaus.piontek@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Addiction Risks and Mechanisms.

Date: July 23, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Li Jia, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH, 6001 Executive Boulevard, Room 3208D, Rockville, MD 20852, 301 451–2854, *li.jia@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Therapeutic approaches for central nervous system disorders.

Date: July 23–24, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Division of Extramural Research, Scientific Review Branch, National Institute on Drug Abuse, NIH 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in CNS Infection and Immunology.

Date: July 23, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Iqbal Sayeed, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496–9223, *iqbal.sayeed@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Cancer Prevention, Control and Treatment Research.

Date: July 23, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Erica Charlot Spears, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–3211, *spearsec@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; HIV Coinfections and HIV Associated Cancers Study Section.

Date: July 23–24, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Joshua D. Powell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5370, *josh.powell@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 20, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–11571 Filed 6–23–25; 8:45 am]

BILLING CODE 4140–01–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