

Veterinary Medicine (HFV-236), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 515-318-8075.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #272 entitled “Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.” This draft guidance contains much of the information found in the CPGs Sec. 680.500 “Unsafe Contamination of Animal Feed from Drug Carryover” and 680.600 “Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds” but includes updates and additional information. We intend to withdraw the CPGs after this guidance is finalized. Drug carryover generally occurs when a drug used in the manufacture of a batch of medicated feed, for which the drug is approved, gets inadvertently included in a subsequent batch of: (1) A non-medicated feed, (2) a different medicated feed for which the drug is not approved (*e.g.*, medicated feed for another species), or (3) a medicated feed that contains the same drug that can result in a higher drug level than is stated on the labeling. This carryover can occur for multiple reasons, including the use of the same equipment to manufacture both medicated and non-medicated feed, inadequate cleanout practices for manufacturing and distribution equipment between sequential batches, or human error.

We understand that an absolute avoidance of all batch-to-batch drug carryover may not be possible. However, measures can be implemented to avoid unsafe contamination of animal feed from drug carryover. In this draft guidance, unsafe contamination of an animal feed refers to a degree of contamination, by a drug approved for a medicated feed use, that poses an unacceptable risk to human or animal health. Human health may be at risk if humans consume a product derived from animals that have consumed animal feed contaminated from drug carryover and there is drug residue in the edible tissues of that animal (*e.g.*, milk, meat, or eggs). Unsafe contamination from drug carryover in animal feed can impact animal health when an animal consumes the contaminated feed, *e.g.*, horses consuming feed contaminated with the drug monensin. Horses are sensitive to ionophore drugs like monensin, and

ingestion can result in severe illness or death.

Our regulation “Current Good Manufacturing Practice for Medicated Feeds,” 21 CFR part 225, contains requirements for equipment cleanout procedures to avoid unsafe contamination of feeds with drugs (see 21 CFR 225.65 and 225.165). In this guidance, we provide information on some ways to comply with these requirements to help prevent unsafe contamination of animal feed from drug carryover.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on some practices that can be used in feed mills manufacturing medicated feed to prevent unsafe contamination of animal feed from drug carryover. 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-09939 Filed 5-9-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) 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: Brain Disorders and Clinical Neuroscience Integrated Review Group Developmental Brain Disorders Study Section

Date: June 8–9, 2022.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 408-9866, manospa@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group Nanotechnology Study Section.

Date: June 9–10, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9694, petersonjt@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group Integrative Myocardial Physiology/Pathophysiology B Study Section.

Date: June 14–15, 2022.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kirk E Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, (301) 867-5309, dineleyke@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group Maximizing Investigators’ Research Award C Study Section.

Date: June 14–15, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for

Scientific Review, 6107 Rockledge Drive, Bethesda, MD 20892, (301) 402-8559, jimok.kim@nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group Macromolecular Structure and Function B Study Section.

Date: June 14–15, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alexei A Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-443-0552, yeliseeva@mail.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: May 4, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-09965 Filed 5-9-22; 8:45 am]

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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 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 Allergy and Infectious Diseases Special Emphasis Panel NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: June 7, 2022.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20852, (240) 292-0189, sandip.bhattacharyya@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-09988 Filed 5-9-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Study Section.

Date: June 23–24, 2022.

Time: 10:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Heart, Lung, and Blood Institute, RKL1, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajiv Kumar, Ph.D., Chief, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Bethesda, MD 20892, (301) 827-4612, rajiv.kumar@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Study Section.

Date: June 23–24, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda MD 20817 (Virtual Meeting).

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209-A, Bethesda, MD 20892-7924, (301) 827-7912, copeka@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

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