

Dated: February 16, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-3455 Filed 2-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Barrett's Esophagus.

Date: March 12, 2010.

Time: 3:30 p.m. to 5 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: Maria E. Davila-Bloom, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, davila-bloomm@extra.niddk.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary R01 Application Review.

Date: March 19, 2010.

Time: 10:30 a.m. to 11:30 a.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: Xiaodu Guo, MD, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard,

Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.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: February 16, 2010.

Jennifer Spaeth,

Director, 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Research Program Project in Cardiac Fibrillation.

Date: March 2, 2010.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: William J Johnson, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725 johnsonwj@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Randomized Evaluation of VAD InterVention before Inotropic Therapy (REVIVE-IT)

Date: March 3, 2010.

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

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: YingYing Li-Smerin, PhD, MD, Scientific Review Officer, Review

Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892-7924, 301-435-0277, lismerein@nhlbi.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: February 16, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-3457 Filed 2-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Guidelines for Human Stem Cell Research

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on a revision to the definition of human embryonic stem cells (hESCs) in the "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

On July 7, 2009, NIH issued Guidelines (<http://edocket.access.gpo.gov/2009/pdf/E9-15954.pdf>) to implement Executive Order 13505, as it pertains to NIH-funded stem cell research, to establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

In Section II of the final Guidelines, hESCs are defined as: "For the purpose of these Guidelines, 'human embryonic stem cells (hESCs)' are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers."

This definition had the unintended consequence of excluding certain hESCs which may otherwise be appropriate for Federal funding. For example, the current definition excludes hESCs from an embryo which fails to develop to the blastocyst stage.

Therefore, the NIH proposes replacing the current definition of hESCs in Section II with the following: "For the purpose of these Guidelines, 'human embryonic stem cells (hESCs)' are pluripotent cells that are derived from

early stage human embryos, up to and including the blastocyst stage, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.”

This proposed change in no way alters the rigorous ethical standards set forth in the Guidelines.

DATES: Written comments on this proposed change must be received by NIH on or before March 25, 2010 in order to be considered.

ADDRESSES: Public comments may be entered at: <http://hescregapp.od.nih.gov/comments/add.htm>.

Comments may also be mailed to: NIH Stem Cell Guidelines, MSC 7997, 9000 Rockville Pike, Bethesda, Maryland 20892–7997. Comments will be made publicly available. Personally identifiable information (except for organizational affiliations) will be removed prior to making comments publicly available.

Dated: February 16, 2010.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2010–3527 Filed 2–19–10; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0085]

Preventive Controls for Fresh Produce; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to obtain information about current practices and conditions for the production and packing of fresh produce. FDA is establishing this docket in order to provide an opportunity for interested parties to provide information and share views that will inform the development of safety standards for fresh produce at the farm and packing house and strategies and cooperative efforts to ensure compliance.

DATES: Submit electronic or written comments by May 24, 2010.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2024.

SUPPLEMENTARY INFORMATION:

I. Background

On March 19, 2009, President Barack Obama established a new Food Safety Working Group (FSWG), chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture. In announcing creation of the FSWG, the President said the group would advise him on how to upgrade U.S. food safety laws for the 21st century, foster coordination of food safety efforts throughout the Government, and ensure laws are being adequately enforced to keep the American people safe from foodborne illness (Ref. 1).

On July 1, 2009, the FSWG recommended a new public health-focused approach to food safety based on three core principles: (1) Prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery (Ref. 1). The FSWG announced steps to be taken by FDA and other Federal agencies to achieve these goals.

With regard to fresh produce, the FSWG announced that FDA would issue “commodity-specific draft guidance on preventive controls that industry can implement to reduce the risk of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens” (Ref. 1). The FSWG also announced that FDA, over the next 2 years, would “seek public comment and work to require adoption of these approaches through regulation” (Ref. 1).

On August 3, 2009, FDA made available draft guidances to industry for leafy greens, melons, and tomatoes (Refs. 3 through 5). FDA is now establishing a docket in order to provide an opportunity for interested parties to provide information and share views that will inform the development of: (1) Safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance.

II. Request for Comments and Information

We are requesting comments that will inform the development of: (1) Safety standards for fresh produce at the farm and packing house and (2) strategies and

cooperative efforts to ensure compliance. In particular, we welcome input on any of these general categories:

- Role of the good agricultural practice guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (GAPs Guide, Ref. 6);
 - Standards for domestic and foreign growers and packers;
 - Identification and prioritization of risk factors;
 - Environmental assessment of hazards and possible pathways of contamination;
 - The impact of scale of growing operations on the nature and degree of possible food safety hazards;
 - Methods to tailor preventive controls to particular hazards and conditions affecting an operation;
 - Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations;
 - Coordination of produce food safety practices and sustainable and/or organic production methods;
 - Coordination of produce food safety practices and environmental and/or conservation goals or practices;
 - Coordination of produce food safety practices and Federal, State, local and tribal government statutes and regulations;
 - Microbial testing;
 - Post-harvest operations and the role of the current good manufacturing practices in 21 CFR part 110;
 - Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce; and
 - Strategies to enhance compliance.
- The agency will consider information submitted to the docket in developing safety standards for fresh produce. Comments previously submitted to the Division of Dockets Management for the following dockets will also be considered by FDA and do not need to be resubmitted:
- “Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Availability” (74 FR 38438, August 3, 2009; Docket No. FDA–2009–D–0346);
 - “Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons” (74 FR 38437, August 3, 2009; Docket No. FDA–2009–D–0347);
 - “Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Availability” (74 FR 38439, August 3, 2009; Docket No. FDA–2009–D–0348); and