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Dated: November 13, 2009.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. E9-27925 Filed 11-19-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0614]

#### Guidance for Industry on Changes to Approved New Animal Drug Applications—New Animal Drug Applications Versus Category II Supplemental New Animal Drug Applications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #191 entitled “Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs.” This guidance is intended to assist sponsors who wish to apply for approval of changes to approved new animal drugs that require FDA to reevaluate safety and/or effectiveness data. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by FDA’s Center for Veterinary Medicine (CVM).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance for industry #191 entitled “Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs.” This guidance is intended to assist sponsors who wish to apply for approval of changes to approved new animal drugs that require FDA to reevaluate safety and/or effectiveness data. The guidance explains how the Office of New Animal Drug Evaluation (ONADE) categorizes possible changes to approved new animal drugs that require reevaluation of safety and/or effectiveness data and explains which administrative vehicle—a new original new animal drug application (NADA) (new NADA) or a Category II supplemental application to the original new animal drug application (Category II supplemental NADA)—a sponsor should use when applying for approval of these changes. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by ONADE.

In the **Federal Register** of December 16, 2008 (73 FR 76363), FDA published the notice of availability for a draft guidance entitled “Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs,” which gave interested persons until February 17, 2009, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to some of the changes based on the comments received, CVM made a few minor changes to the guidance to add clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated December 16, 2008.

#### II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control no. 0910-0032 (expiration date April 30, 2010).

#### IV. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

Dated: November 13, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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 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 Institutes on Aging, Special Emphasis Panel Exceptional Aging.

*Date:* December 10, 2009.

*Time:* 9 a.m. to 12 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue 2C212, Bethesda, MD 20982 (Telephone Conference Call).

*Contact Person:* Alicja L. Markowska, PhD, DSC, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-496-9666, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

*Name of Committee:* National Institute on Aging, Special Emphasis Panel SYNTHESIS.

*Date:* December 14, 2009.

*Time:* 4:30 p.m. to 6 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ramesh Vemuri, PhD, Chief, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7700, [rv23r@nih.gov](mailto:rv23r@nih.gov).

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

Dated: November 13, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-27800 Filed 11-19-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; Notice of Closed Meeting

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 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 Drug Abuse Special Emphasis Panel; Conference Grant Application Review.

*Date:* December 3, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

*Contact Person:* Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401, 301-402-6626, [gm145a@nih.gov](mailto:gm145a@nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 12, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-27727 Filed 11-19-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

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 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 General Medical Sciences Special Emphasis Panel; Minority Biomedical Research Support.

*Date:* December 3, 2009.

*Time:* 9:30 a.m. to 10:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Room 3AN12, 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Helen R. Sunshine, PhD, Chief, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN12F, Bethesda, MD 20892, 301-594-2881, [sunshinh@nigms.nih.gov](mailto:sunshinh@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 12, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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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 (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:* Center for Scientific Review Special Emphasis Panel; ZRG1 IFCN-C (02) M Member Conflicts: Cognition and Neurotoxicology.

*Date:* December 10, 2009.

*Time:* 1:30 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301-435-1119, [msemanoff@csr.nih.gov](mailto:msemanoff@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-OD-09-008 BRDG-SPAN and RFA-OD-09-009 Catalyst ARRA Review Panel 17.

*Date:* December 10, 2009.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Lawrence E. Boerboom, PhD, Scientific Review Officer, Center for