

other electrical continence devices; protective garment for incontinence; surgical mesh; electrosurgical cutting and coagulation device and accessories; perineometer; gynecologic laparoscope and accessories; and vaginal pessary.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on clinical investigations of devices intended to treat urinary incontinence. 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence," you may either send an e-mail request to [ds mica@fda.hhs.gov](mailto:ds mica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1636 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 in 21 CFR part 812 have

been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in parts 50 and 56 have been approved under OMB control number 0910-0130.

## V. Comments

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: September 2, 2008.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0394]

### Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document (GFI#187) entitled "Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs." This draft guidance is intended to clarify FDA's requirements and recommendations for producers and

developers of genetically engineered (GE) animals and their products. The draft guidance describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the act) apply with respect to GE animals, including FDA's intent to exercise enforcement discretion regarding requirements for certain GE animals.

Elsewhere in this same issue of the **Federal Register**, the Animal and Plant Health Inspection Service (APHIS) is soliciting public comment on any potential implications of activities such as the importation or interstate movement of GE animals on the health of the U.S. livestock population under the authority of the Animal Health Protection Act (AHPA).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 18, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document 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 draft 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 draft guidance document.

### FOR FURTHER INFORMATION CONTACT:

Larisa Rudenko, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8247, e-mail: [larisa.rudenko@hhs.fda.gov](mailto:larisa.rudenko@hhs.fda.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

For the purpose of this guidance, FDA defines "genetically engineered (GE) animals" as those animals modified by recombinant DNA (rDNA) techniques. The term GE animal can refer to both animals with heritable rDNA constructs and animals with non-heritable rDNA constructs (e.g., those modifications intended to be used as gene therapy). Although much of this guidance will be relevant to non-heritable rDNA constructs, and FDA intends to regulate non-heritable constructs in much the

same way as described in this guidance for heritable constructs, this guidance only pertains to GE animals containing heritable rDNA constructs. We may issue a separate guidance on the regulation of GE animals bearing non-heritable constructs to discuss when those constructs would be under FDA jurisdiction and the kinds of information that would be relevant for FDA's review.

FDA's authority over new animal drugs comes from the Federal Food, Drug, and Cosmetic Act. The definition of a drug, in section 201(g) of the act (21 U.S.C. 321(g)), includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the act drug definition. The draft guidance describes how the new animal drug provisions of the act apply with respect to GE animals, including FDA's intent to exercise enforcement discretion regarding requirements for certain GE animals.

FDA is one of several Federal agencies that share regulatory oversight of GE organisms. In 1986, the Office of Science and Technology Policy (OSTP) under the Executive Office of the President published a policy document known as the Coordinated Framework for the Regulation of Biotechnology (the Coordinated Framework).<sup>1</sup> This policy document describes the system for coordinating the activities of the Federal agencies responsible for regulating all GE organisms.<sup>2</sup>

In addition to FDA's role in oversight of GE animals, APHIS is authorized, under the AHPA (7 U.S.C. 8301 *et seq.*), to protect the health of U.S. livestock by preventing the introduction and spread of livestock diseases and pests into and within the United States. Based on that authority, APHIS may broadly consider the potential effects of animals with GE

traits on the health of the overall U.S. livestock population, while FDA is more focused on the direct effects of genetic engineering on individual animals based on its authority under the act. Given these complementary authorities, FDA and APHIS have been discussing their respective roles in overseeing GE animals for some time. In conjunction with FDA's release for public comment of its guidance on GE animals, APHIS is soliciting public comment in this same issue of the Federal Register on any potential implications of activities such as the importation or interstate movement of GE animals on the health of the U.S. livestock population.

## II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's Good Guidance Practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent 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 method may be used as long as it satisfies the requirements of applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This draft 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 Nos. 0910–0032, 0910–0045, 0910–0117, and 0910–0284. FDA seeks public comment on the agency's determination that the previously approved collections of information referred to previously adequately account for the collections of information referenced in this guidance. Although the collections of information burden estimates previously approved by OMB were derived for new animal drug applications (NADAs) in general, FDA believes that such estimates are applicable to NADAs for GE animals. In particular, FDA previously determined that preparing the paperwork required for an NADA under 21 CFR 514.1 will take approximately 112 hours. Over the past 5 fiscal years, FDA has received an average of 19 NADAs per year.

## IV. Comments

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

## V. Electronic Access

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

Dated: September 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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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. Appendix 2), 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:* Oncological Sciences Integrated Review Group, Cancer Etiology Study Section.

*Date:* September 29–30, 2008.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

*Contact Person:* Najma Begum, PhD, Scientific Review Officer, Center for

<sup>1</sup>Coordinated Framework for the Regulation of Biotechnology; June 26, 1986; 51 FR 23302; <http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf>.

<sup>2</sup>In addition to discussing the regulatory responsibilities of these agencies for GE organisms and other products, the Coordinated Framework also discusses the responsibilities of agencies with jurisdiction over GE research (the National Institutes of Health, the National Science Foundation, the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture's (USDA's) Agricultural Research Service).