listing information under the regulations, and exhibit vendor SPL authoring tools that may be used in the creation and manipulation of SPL content of labeling.

Date and Time: The public workshop will be held on November 17, 2008, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at the Universities at Shady Grove, Multipurpose Room, Building II, 9630 Gudelsky Dr., Rockville, MD 20850.

Contact Person: Donna Lipscomb, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079; e-mail: *spl@fda.hhs.gov* (Subject line: CBER SPL Public Workshop).

Registration: Mail, FAX, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 30, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m.

Vendor Registration: Vendors wishing to exhibit their SPL authoring tools at this public workshop must register and submit their registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 30, 2008, via e-mail to *spl@fda.hhs.gov*.

If you need special accommodations due to a disability, please contact Donna Lipscomb (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop to provide the biologics industry with guidance on submitting to FDA content of labeling in SPL format and to present an overview of FDA's voluntary pilot program for electronic submission of drug establishment registration and drug listing information under the regulations in part 207 (21 CFR part 207).

FDA's Center for Biologics Evaluation and Research (CBER) has stated in a memorandum, posted on July 11, 2008, to Docket No. FDA–1992–S–0039 (formerly 1992S–0251), that beginning October 15, 2008, SPL in XML (extensible markup language) is the acceptable presentation in electronic format for the submission of content of labeling that CBER can process, review, and archive. This applies to the content of labeling with original submissions, supplements, and annual reports. Individuals may electronically access CBER's notification on the submission of SPL content of labeling at *http://www.fda.gov/oc/datacouncil/spl.html*.

In the **Federal Register** of July 11, 2008 (73 FR 39964), FDA announced the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' This draft guidance established a pilot program for industry to voluntarily submit drug establishment registration and drug listing information in SPL format. The draft guidance only applies to drug establishments that currently register their establishments and list their products under the regulations in part 207 and explains how to transition from submitting the required information on paper to submitting the required information using the SPL standard. The draft guidance also describes how to voluntarily submit additional useful, but not required, information that currently is often included by industry in their registration and listing paper submissions. FDA plans to complete the voluntary pilot program and begin receiving drug establishment and drug listing information only electronically and only in SPL format (including labeling) beginning June 1, 2009, unless a waiver is granted.

This public workshop will feature presentations by FDA experts on SPL content of labeling and electronic drug establishment registration and drug listing. In addition, registrants will have access to a vendor exhibition of SPL authoring tools.

Dated: September 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21968 Filed 9–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0457]

Draft Guidance for Industry and Food and Drug Administration Staff; Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence.'' This draft guidance document describes FDA's proposed recommendations for clinical investigations of medical devices indicated for the treatment of urinary incontinence. This draft guidance is not final nor is it in effect at this time.

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 December 18, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4130.

SUPPLEMENTARY INFORMATION:

I. Background

Urinary incontinence is defined as the involuntary loss of urine. This draft guidance is intended to assist device manufacturers who plan to conduct clinical investigations of devices intended to treat urinary incontinence in support of premarket approval (PMA) applications or premarket notification (510(k)) submissions. The draft guidance describes FDA's proposed recommendations for human clinical trials that involve the use of any type of urinary incontinence device, including, but not limited to, urological clamp for males; nonimplanted, peripheral and

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 *dsmica@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.

[FR Doc. E8–21971 Filed 9–18–08; 8:45 am]

BILLING CODE 4160–01–S

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*.

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