Dated: December 22, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–22450 Filed 12–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0573]

Draft Animal Cloning Risk Assessment; Proposed Risk Management Plan; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and is requesting comment on, a draft risk assessment on animal cloning. FDA's Center for Veterinary Medicine (CVM) developed this draft risk assessment to evaluate the health risks to animals involved in the process of cloning and to evaluate the food consumption risks that may result from edible products derived from animal clones or their progeny. FDA is also announcing the availability of, and is requesting comment on, a proposed risk management plan for animal clones and their progeny. The proposed risk management plan takes into account the risks identified in the draft risk assessment and sets out proposed measures that FDA might use to manage those risks. In addition, FDA is announcing availability of draft guidance for industry #179 for public comment. This draft guidance describes FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed.

DATES: Submit written or electronic comments on the draft risk assessment document, the proposed risk management plan, and the draft guidance for industry by April 3, 2007. FDA will accept comments, data, and information after the deadline, but to ensure consideration by the agency in any final documents, comments must be received by this date. Comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft risk assessment, proposed risk management plan, or the draft guidance for industry to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send a self-addressed, adhesive label to assist that office in processing your request. Submit written comments on the draft risk assessment, proposed risk management plan, or draft guidance for industry to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–453–6842, e-mail: *clones@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2001, FDA's CVM issued an update on livestock cloning (available at *http://www.fda.gov/cvm/CVM_Updates/clones.htm*) and indicated its intention to work with stakeholders to assess potential risks presented by cloning food-producing animals. It also requested that companies voluntarily refrain from introducing animal clones, their progeny, or their food products (such as milk or meat) into the human or animal food supply, pending completion of the risk assessment process. The public participation phase of this process begins with the release of draft documents entitled ''Animal Cloning: A Draft Risk Assessment,'' ''Animal Cloning: Proposed Risk Management Plan for Clones and Their Progeny,'' and ''Draft Guidance for Industry #179: Use of Edible Products From Animal Clones or Their Progeny for Human Food or Animal Feed.''

Among the goals of our draft risk assessment were the determination of whether somatic cell nuclear transfer (SCNT), the process used to produce the clones being considered in the risk assessment, poses any unique risks to animals involved in cloning relative to other assisted reproductive technologies, and whether foods derived from animal clones or their progeny pose consumption risks greater than those posed by foods derived from their conventional counterparts. It specifically does not consider risk issues that may be posed by genetically engineered animals.

The draft risk assessment has been peer reviewed in accordance with the Office of Management and Budget's Information Quality Peer Review Bulletin. The peer reviewers' comments and the agency's response to them are posted on the Internet with the draft risk assessment (see the Electronic Access section of this document).

The proposed risk management plan describes proposed measures that the agency might use to address animal health and food consumption risks identified in the draft risk assessment that are within the agency's purview. It also describes the agency's plans with regard to issues that are not within the agency's authority to manage (e.g., ethics) regarding animal cloning.

The draft guidance for industry describes FDA's recommendations regarding the introduction of edible products from animal clones and their progeny into the food and feed supply. FDA will consider information received during the comment period in its preparation of a final risk assessment. To that end, FDA requests that any producers or breeders of clones who have additional data on the health of the clones or their progeny or composition of food products (i.e., meat or milk) derived from clones or their progeny share those data with us. Additionally, the agency reiterates that the release of these draft documents does not affect its request to industry to continue to refrain from introducing food products from clones and their progeny into the marketplace.

II. Significance of Guidance

The draft guidance for industry is a level 1 draft guidance that is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the topic. The draft guidance document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft risk assessment document, the proposed risk management plan, and the draft guidance for industry. For convenience in reviewing the comments, FDA requests that comments be separately identified as to which document they address. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cvm/cloning.htm*. In an effort to better ensure broad awareness of this **Federal Register** notice, FDA will announce it and make copies available through the FDA Dockets Listserv (*http://www.fda.gov/ohrms/dockets/FDAMAIL/DMBemaillist.htm*). To be added to any of FDA's free e-mail subscription services go to *http://www.fda.gov*. Click on ''Subscribe to FDA's E-mail Lists,'' then follow the instructions provided.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–9927 Filed 12–28–06; 11:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0504]

Draft Guidance for Industry and Food and Drug Administration Staff; Radio-Frequency Wireless Technology in Medical Devices; 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 ''Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices.'' This draft guidance document addresses issues relevant to the safe and effective use of radio frequency (RF) wireless technology in medical devices, including wireless coexistence, performance, data integrity, security, and electromagnetic compatibility (EMC). These issues involve all stages of the product life cycle and should be considered in preparing premarket submissions; identifying, documenting, and implementing product design requirements, as well as design verification and validation; and risk management processes and procedures.

DATES: Submit written or electronic comments on the draft guidance by April 2, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Draft Guidance for Industry and FDA Staff: Radio-Frequency Wireless Technology in Medical Devices'' 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.

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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Donald Witters, Center for Devices and Radiological Health (HFZ–130), Food and Drug Administration, 12725 Twinbrook Pkwy., Rockville, MD 20852, 301–827–4955.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance document to assist industry, systems and service providers, consultants, FDA staff, and others in the design, development, and evaluation of RF wireless technology in medical devices. The RF wireless emissions from one product or device can affect the function of another, the electromagnetic environments where medical devices are used may contain many sources of RF energy, and the use of RF wireless technology in and around medical devices is increasing. As a result, the draft guidance recommends that manufacturers address concerns about the potential effects of the use of RF wireless technology in and around medical devices on the ability of medical devices to function properly and the resultant safety of patients and operators.

This draft guidance references national and international standards and discusses some of FDA's regulatory requirements, including premarket requirements (21 CFR parts 807 and 814). The draft guidance document also discusses quality system requirements as they specifically apply to RF wireless technology in medical devices, including design and development activities (21 CFR part 820).

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 RF wireless technology in and around medical devices. 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 ''Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices'' 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 1618 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 on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

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 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807 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