NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0573]

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

Wednesday, January16, 2008

AGENCY: Food and Drug Administration, HHS.

***2923** ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a risk assessment on animal cloning. FDA's Center for Veterinary Medicine (CVM) developed this 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 a risk management plan for animal clones and their progeny. The risk management plan takes into account the risks identified in the risk assessment and sets out measures that FDA will use to manage those risks. In addition, FDA is announcing availability of guidance for industry 179. This 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 agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the risk assessment, risk management plan, or the 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 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, 240-276-8245, e-mail: clones@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 3, 2007 (72 FR 136), FDA published a notice of availability with a 90-day comment period to request comments on a draft risk assessment on animal cloning. FDA also announced the availability for public comment of a proposed risk management plan for animal clones and their progeny and a draft guidance for industry describing FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed. In response to requests to extend the comment period on these documents, FDA subsequently published a notice in the Federal Register (72 FR 15887, April 3, 2007) extending the comment period for an additional 30 days.

The draft risk assessment evaluated the health effects to animals involved in the process of cloning and evaluated the food consumption risks that may result from edible products derived from animal clones or their progeny. The proposed risk management plan described proposed measures that the agency might use to address animal health and food consumption risks identified in the draft risk assessment that were within the agency's purview. It also described the agency's plans with regard to issues that were not within the agency's authority to manage (e.g., ethics) regarding animal cloning. The draft guidance for industry described FDA's recommendations regarding the introduction of edible products from animal clones and their progeny into the food and feed supply.

FDA has completed a thorough analysis of all comments and additional information received and has updated the documents appropriately. FDA has concluded that meat and milk from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals. FDA, however, in its guidance for industry, is recommending that edible products from clones from animals other than cattle, swine, or goat (e.g., sheep) not be introduced into the human food supply. Whereas the scientific data supports the safety of edible products from clones of cattle, swine, or goat, there is insufficient scientific data to reach this conclusion for edible products from other types of animals.

II. Significance of Guidance

The guidance for industry is a level 1 guidance that 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. The 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. Paperwork Reduction Act of 1995

For this level 1 final guidance, FDA concludes that there are no collection of information requirements under the Paperwork Reduction Act of 1995.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the guidance for industry. 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 in January 2008 the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a Federal Register notice announcing that date.

V. Electronic Access

Persons with access to the Internet may obtain the documents at http:// www.fda.gov/cvm/cloning.htm.

***2924** Dated: January 3, 2008.

Jeffrey Shuren, Assistant Commissioner for Policy.

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