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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Draft Animal Cloning Risk Assessment; Proposed Risk Management Plan; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 3, 2007, the comment period for the notice of availability that appeared in the **Federal Register** of January 3, 2007 (72 FR 136). In the notice, FDA requested comments on the draft risk assessment, the proposed risk management plan, and the draft guidance for industry on animal cloning. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by May 3, 2007.

ADDRESSES: Submit written comments on the draft risk assessment, proposed risk management plan, or draft guidance for industry to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*.

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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 to evaluate the health effects 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 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the availability for public comment of a proposed risk management plan for animal clones and their progeny and a draft guidance for industry describing FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed.

The agency has received requests for an extension of the comment period for the draft risk assessment, proposed risk management plan, and draft guidance. These requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the cloning documents.

FDA has considered the requests and is extending the comment period for the draft risk assessment, proposed risk management plan, and draft guidance until May 3, 2007. The agency believes this extension allows adequate time for interested persons to submit comments.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these documents. 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.

Dated: 3/27/07
March 27, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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