ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 9, 2007, from 8 a.m. to 4 p.m. and May 10, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, 8727 Colesville Rd., Silver Spring, MD, 301–589–5200.

Contact Person: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–6761, FAX: 301–827–6776, e-mail: *johanna.clifford@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 9, 2007, the committee will do the following: (1) Discuss new drug application (NDA) 022–092, proposed trade name JUNOVAN (mifamurtide), IDM Pharma, Inc., proposed indication for the treatment of newly diagnosed resectable high grade osteosarcoma following surgical resection in combination with multiple agent chemotherapy; and (2) discuss NDA 022–062, proposed trade name ORBEC (beclomethasone dipropionate), DOR BioPharma, Inc., proposed indication for the treatment of graft versus host disease (GvHD) involving the gastrointestinal tract in conjunction with an induction course of high-dose prednisone or prednisolone. On May 10, 2007, the committee will discuss updated information on risks of erythropoeisis-stimulating agents (ARANESP, Amgen, Inc., EPOGEN, Amgen, Inc., and PROCRIT, Amgen, Inc.) for use in the treatment of anemia due to cancer chemotherapy.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 25, 2007. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 p.m. on May 9 and from 10:45 a.m. to 11:45 a.m. on May 10. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 19, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 18, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Johanna Clifford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 28, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–6171 Filed 4–2–07; 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; 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*.

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: March 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6170 Filed 4–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2005D–0468

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' This guidance document describes a means by which herpes simplex virus type 1 and 2 (HSV 1 and 2) serological assays may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III (premarket approval) into class II (special controls).

DATES: Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' 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 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 9, 2006 (71 FR 1399), FDA published a proposed rule to reclassify herpes simplex virus types 1 and 2 serological assays from class III (premarket approval) into class II (special controls). In addition, FDA issued a draft class II special controls guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' to support the proposed reclassification. Herpes simplex virus types 1 and 2 serological assays are in vitro diagnostic devices that test for specific antibodies. In conjunction with other clinical laboratory findings, the detection of these HSV type 1 and/or 2 -specific antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HSV type 1 and/or 2. FDA did not receive any comments on the proposed reclassification. FDA is now identifying the guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' as the guidance document that will serve as the special control for these devices.

The guidance document provides a means by which herpes simplex virus types 1 and 2 serological assays may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for herpes simplex virus type 1 and 2 serological assays will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on herpes simplex virus types 1 and 2 serological assays. 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 guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' 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 1305 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,