Corporate Blvd., Rockville, MD 20850, 301–594–2186, ext. 152.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's Web site at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2006, through December 31, 2006. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2006, THROUGH DECEMBER 31, 2006.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040027/2006M–0411	W.L. Gore & Associates	GORE VIATORR TIPS	December 6, 2004
P040023/2006M–0512	DePuy Orthopedics, Inc.	DURALOC OPTION CERAMIC HIP SYSTEM	May 3, 2005
P030047/2006M–0412	Cordis Corp.	CORDIS PRECISE NITINOL STENT	September 22, 2006
P050038/2006M–0396	Medafor, Inc.	ARISTA AH ABSORBABLE HEMOSTATIC, NON-COLLAGEN BASED	September 26, 2006
P970053(S9)/2006M–0460	Nidek, Inc.	NIDEK EC–5000 EXCIMER LASER	October 11, 2006
P050022/2006M–0456	Siemens Medical Solutions USA, Inc.	SYNGO LUNG COMPUTER ASSISTED DETECTION (CAD) SYSTEM	October 18, 2006
P050025/2006M–0459	Endotex Interventional Systems, Inc.	ENDOTEX NEXSTENT CAROTID STENT & DELIVERY SYSTERM; AND ENDOTEX NEXSTENT CAROTID STENT & MONORAIL DELIVERY SYSTERM	October 27, 2006
P020012/2006M–0455	Artes Medical USA, Inc.	ARTEFILL	October 27, 2006
P040050/2006M–0457	Uroplasty, Inc.	MACROPLASTIQUE IMPLANTS	October 30, 2006
P050031/2006M–0473	Paragon Vision Sciences	PARAGON Z CRT	November 16, 2006
P020056/2006M–0490	Allergan	INAMED SILICONE-FILLED BREAST IMPLANTS	November 17, 2006
P030053/2006M–0492	Mentor Corp.	MENTOR MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	November 17, 2006
P060010/2006M–0529	AbbeyMoor Medical, Inc.	THE SPANNER TEMPORARY PROSTATIC STENT	December 14, 2006
P040025/2006M–0530	Olympic Medical	OLYMPIC COOL-CAP	December 20, 2006
P050033/2006M–0531	Anika Therapeutics, Inc.	COSMETIC TISSUE AUGMENTATION PRODUCT	December 20, 2006

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: March 22, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–6166 Filed 4–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

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