development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many IVD device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions (IDEs), under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (parts 50 and 56 (21 CFR parts 50 and 56)) apply to all clinical investigations that are regulated by FDA (see §§ 50.1 and 56.101, and section 520(g)(3)(A) and (g)(3)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)(A) and (g)(3)(D))).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

FDA intends to notify the public, in a level 1 guidance document issued under the good guidances practices regulation (21 CFR 10.115), of the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs. In the guidance document, FDA recommends that sponsors of studies that meet the conditions maintain documentation of how these conditions were met and of the types of human subject protection procedures followed by the specimen provider to ensure that the subject cannot be identified.

Sponsors that wish to follow the recommendations of the guidance will substitute use of records to demonstrate conformance to this enforcement discretion policy in place of the more detailed and patient-specific records for obtaining and documenting informed consent. Most fundamentally, this means collecting and maintaining information about the protections that are in place to prevent the identification of the specimens, since making sure that the specimens are not identifiable is key to obtaining FDA's enforcement discretion.

FDA intends to exercise enforcement discretion when all the following are true:

- The investigation meets the IDE exemption criteria at § 812.2(c)(3);
- The study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded if not used in the study;
- The specimens provided to the investigator are accompanied by only minimal clinical information such as age, gender, and existing laboratory result;
- The specimens are not individually identifiable;
- The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information;
- The individuals caring for the patients are different from, and do not share information with, those conducting the investigation; and
- The study has been reviewed by an IRB in accordance with 21 CFR part 56.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| No. of Recordkeepers | Annual Frequency per Record | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|
| 600 | 1 | 600 | 4 | 2,400 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 600 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,400 hours ($600 \times 4 = 2,400$).

Dated: January 3, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–73 Filed 1–6–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 2005M–0320, 2005M–0289, 2005M–0387, 2005M–0270, 2005M–0379, 2005M–0388, 2005M–0284, 2005M–0283, 2005M–0328, 2005M–0308, 2005M–0380, 2005M–0321, 2005M–0339, 2005M–0359, 2005M–0382, 2005M–0381, 2005M–0378]**

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200

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

**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 home page 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 July 1, 2005, through September 30, 2005. 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 JULY 1, 2005, THROUGH SEPTEMBER 30, 2005

| PMA No./Docket No. | Applicant | Trade name | Approval date |
|---|---|---|---|
| P040043/2005M–0320 | W.L. Gore & Associates, Inc. | GORE TAG THORACIC ENDOPROSTHESIS | March 23, 2005 |
| P030035(S3)/2005M–0289 | St. Jude Medical | FRONTIER MODEL 5508L AND FRONTIER II MODEL 5586 CARDIAC RESYNCHRONIZATION THERAPY PACEMAKERS (CRT-P) SUPPORTED ON THE MODEL 3510 PROGRAMMER PLATFORMS WITH THE MODEL 3307, V4.8M PROGRAMMER SOFTWARE | April 29, 2005 |
| P040005/2005M–0387 | DakoCytomation Denmark A/S | DAKOCYTOMATION HER2 FISH PHARMDX KIT | May 3, 2005 |
| P030049/2005M–0270 | Bayer Healthcare, LLC | ADVIA CENTAUR HBSAG READY PACK REAGENTS/CONFIRMATORY READY PACK REAGENTS/QUALITY CONTROL MATERIAL | May 26, 2005 |
| P040037/2005M–0379 | W.L. Gore & Associates, Inc. | VIABAHN ENDOPROSTHESIS | June 14, 2005 |
| P040011/2005M–0388 | DakoCytomation California, Inc. | DAKOCYTOMATION C-KIT PHARMDX | June 27, 2005 |
| P950042(S3)/2005M–0284 | Xillix Technologies Corp. | ONCO-LIFE ENDOSCOPIC LIGHT SOURCE AND VIDEO CAMERA | June 30, 2005 |
| P970003(S50)/2005M–0283 | Cyberonics, Inc. | VNS THERAPY SYSTEM | July 15, 2005 |
| P030004/2005M–0328 | Micro Therapeutics, Inc. | ONYX LIQUID EMBOLIC SYSTEM | July 21, 2005 |
| H050001/2005M–0308 | Boston Scientific Smart | WINGSPAN STENT SYSTEM WITH GATEWAY PTA BALLOON CATHETER | August 3, 2005 |
| P030036/2005M–0380 | Medtronic, Inc. | MEDTRONIC SELECTSECURE | August 3, 2005 |
| P040021/2005M–0321 | St. Jude Medical, Inc. | SJM BIOCOR VALVE/SJM BICOR SUPRA VALVE | August 5, 2005 |
| P040039/2005M–0339 | Orthometrix, Inc. | ORBASONE PAIN RELIEF SYSTEM | August 10, 2005 |

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2005, THROUGH SEPTEMBER 30, 2005—Continued

| PMA No./Docket No. | Applicant | Trade name | Approval date |
|---|---|---|---|
| P040044/2005M–0359 | Access Closure, Inc. | MATRIX VSG SYSTEM MODEL MX–100 | August 17, 2005 |
| P930016(S21)/2005M–0382 | Visx, Inc. | STAR S4 IR EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS) | August 30, 2005 |
| P040038/2005M–0381 | Abbott Vascular Devices | XACT CAROTID STENT SYSTEM | September 6, 2005 |
| P930014(S15)/2005M–0378 | Alcon Laboratories | ACRYSOF TORIC POSTERIOR CHAMBER INTRAOCULAR LENS | September 14, 2005 |

**II. Electronic Access**

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

Dated: December 20, 2005.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6–59 Filed 1–6–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Cellular, Tissue and Gene Therapies 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). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Cellular, Tissue and Gene Therapies 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 February 9, 2006, from 8 a.m. to approximately 5:30 p.m. and on February 10, 2006, from 8 a.m. to approximately 1 p.m.

*Location*: Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person*: Gail Dapolito or Rosanna L. Harvey, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, 301–827–0314 or FDA Advisory Committee Information Line, 1–800–741–8138 (301)–443–0572 in the Washington, DC area), code 301–451–2389. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On February 9, 2006, in open session, the committee will conduct a scientific discussion of potency measurements for cellular and gene transfer products. On February 10, in open session, the committee will (1) Discuss the National Toxicology Program on Retroviral Mutagenesis and (2) receive a brief update on the recent review of the research program of the Office of Cellular, Tissue and Gene Therapies, FDA.

*Procedure*: On February 9, 2006, from 8 a.m. to approximately 5:30 p.m., and on February 10, 2006, from 8 a.m. to approximately 11:30 a.m., the meeting is open to the public. 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 by February 2, 2006. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. on February 9, 2006, and between approximately 9:40 a.m. and 10:10 a.m. on February 10, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2006, 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.

*Closed Committee Deliberations*: On February 10, 2006, from approximately 11:30 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)); and where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the Research Subcommittee of the Cellular, Tissue and Gene Therapies Advisory Committee related to a review of the research program in the Office of Cellular, Tissue and Gene Therapies.

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 Gail Dapolito 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: January 3, 2006.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. E6–71 Filed 1–6–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005D–0468]**

### Draft 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 draft guidance entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' This draft guidance document