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