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

describes a means by which herpes simplex virus types 1 and/or 2 (HSV 1 and/or 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 proposed rule to reclassify these devices from class III into class II (special controls).

DATES: Submit written or electronic comments on this draft guidance by April 10, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft 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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft 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, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this draft guidance document as a special control to support the classification of in vitro diagnostic devices for the laboratory diagnosis of herpes simplex virus (HSV) infection into class II (special controls). HSV (types 1 and/or 2) serological assays are intended for testing specimens from individuals who have signs and symptoms of infection consistent with HSV 1 and/or 2; determining if an individual has been previously infected with HSV 1 and/or 2; or providing epidemiological information about these infections. The detection of these antibodies aids in the clinical diagnosis of an infection by HSV 1 and/or 2 in conjunction with other clinical laboratory findings.

This draft guidance document identifies the classification regulation and product codes for HSV 1 and/or 2 serological assays. In addition, other sections of this guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these assays and lead to a timely premarket notification (510(k)) review and clearance. This document supplements other FDA documents regarding the specific content of a premarket notification submission.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on class II special controls for HSV 1 and/or 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

To receive ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1305) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number (1305) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. 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, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807.87 have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR 801.109 have been approved under OMB Control No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–174 Filed 1–6–06; 8:45 am]

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