DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005M–0435, 2005M–0475, 2005M–0473, 2005M–0478, 2005M–0454, 2005M–0399, 2005M–0477, 2005M–0476, 2005M–0492, 2005M–0474, 2005M–0504]

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: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 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 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 October 1, 2005 through December 31, 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 October 1, 2005 through December 31, 2005

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P960040(S28)/2005M–0435	Guidant CRM Corp.	VENTAK PRIZM AVT AICD SYSTEM	March 27, 2003
P020045/2005M–0475	CryoCath Technologies, Inc.	7F FREEZOR CARDIAC CRYOBLATION CATHETER & CCT.2 CRYOCONSOLE SYSTEM	April 17, 2003
P040003/2005M–0473	InSightec—North America	EXABLATE 2000 SYSTEM	October 22, 2004
P030056/2005M–0478	Bayer Healthcare, LLC	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	December 22, 2004
P980022(S11)/2005M–0454	Medtronic MiniMed	GUARDIAN RT CONTINUOUS GLUCOSE MONITORING SYSTEM	July 18, 2005
P020016/2005M–0399	Walter Lorenz Surgical, Inc.	TOTAL TEMPOMANDIBULAR JOINT REPLACEMENT SYSTEM	September 21, 2005
P040047/2005M–0477	Bioform Medical, Inc.	COAPTITE	November 10, 2005
P040042/2005M–0476	Irvine Biomedical, Inc.	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM	November 18, 2005
P030054(S10)/2005M–0492	St. Jude Medical CRMD	EPIC & ATLAS + HF CRT–D SYSTEMS	November 18, 2005
P040013/2005M–0474	Biomimetic Therapeutics, Inc.	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX)	November 18, 2005

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040045/2005M–0504	Vistakon, Division of Johnson & Johnson Vision Care, Inc.	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	December 20, 2005

II. Electronic Access

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

Dated: March 7, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–3850 Filed 3–16–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the meeting of the Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science scheduled for April 18 and 19, 2006. This meeting was announced in the **Federal Register** of February 16, 2006 (71 FR 8307).

FOR FURTHER INFORMATION CONTACT: Mimi T. Phan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *mimi.phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138(301–443–0572 in the Washington, DC area) code 3014512539.

Dated: March 10, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–3851 Filed 3–16–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institutes; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Training Programs (T32s and T35s).

Date: May 26, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda, Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Charles Joyce, PhD, Scientific Review Administrator, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892. 301–435–0288. *cjoyce@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: March 9, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–2575 Filed 3–16–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclosed confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 06–50, Review FRA DE–06–005, Orofacial Pain.

Date: April 20, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: H. George Hausch, Ph.D., Acting Director, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892. (301) 594–2904, *george_hausch@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 06–69, Review R21s.

Date: April 24, 2006.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lynn M. King, Ph.D., Scientific Review Administrator, Scientific Review Branch, 45 Center Dr., Rm. 4AN–32F, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892–6402. (301) 594–5006, *lynn.king@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 06–59, Review RFA DE–06–007.