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, 2003, through December 31, 2003. 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, 2003, THROUGH DECEMBER 31, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P000028/2003M–0532	Medtronic, Inc. (Sofamor Danek)	AFFINITY CAGE SYSTEM (INTERVERTEBRAL CERVICAL DEVICE)	June 13, 2002
P020007/2003M–0487	Medtronic AVE, Inc.	MEDTRONIC AVE BRIDGE EXTRA SUPPORT OVER–THE–WIRE RENAL STENT SYSTEM	December 18, 2002
P020041/2003M–0488	Femcap, Inc.	FEMCAP BARRIER CONTRACEPTIVE DEVICE	March 28, 2003
P020047/2003M–0499	Guidant Corp.	MULTI-LINK RX/OTW VISION CORONARY STENT SYSTEM	July 16, 2003
P030009/2003M–0490	Medtronic Vascular	DRIVER OVER–THE–WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEM	October 1, 2003
P020050/2003M–0491	Wavelight Laser Technologies (SurgiVision Refractive Consultants, LLC)	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	October 7, 2003
P030008/2003M–0492	Wavelight Laser Technologies (SurgiVision Refractive Consultants, LLC)	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	October 10, 2003
P9900027(S6)/2003M–0533	Bausch & Lomb Surgical, Inc.	BAUSCH & LOMB TECHNOLAS 217Z ZYOPTIX SYSTEM FOR PERSONALIZED VISION CORRECTION	October 10, 2003
P020040/2003M–0524	Medinol Ltd.	NIRFLEX PRE–MOUNTED CORONARY STENT SYSTEM	October 24, 2003
H020003/2003M–0536	Medtronic, Inc.	CONTEGRA PULMONARY VALVED CONDUIT	November 21, 2003
D980003/2003M–0569	Encore Medical, LP	KERAMOS CERAMIC/CERAMIC TOTAL HIP SYSTEM	November 26, 2003
P030039/2003M–0560	Baxter Bio Science (Baxter Healthcare)	COSEAL SURGICAL SEALANT	December 12, 2003

II. Electronic Access

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

Dated: April 26, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–10459 Filed 5–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins.'' The goals of the public workshop are to provide a forum for sharing information and discussing strategies for safety and efficacy testing of therapeutics that target anthrax and its toxins in order to expedite the development of these FDA-regulated products; and to address the optimal studies for product characterization, proof of concept, and demonstration of safety and efficacy in postexposure prophylaxis and/or in the treatment of established disease. The workshop will cover therapies that

involve monoclonal antibodies, other recombinant proteins, polyclonal immune globulin (human or animal) and small molecules that inhibit toxins. The workshop will not cover the use of vaccines and antimicrobial drugs targeting anthrax and its toxins.

Date and Time: This 2-day public workshop will be held on June 10, 2004, from 8:30 a.m. to 5 p.m., and June 11, 2004, from 8:30 a.m. to 3 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), Natcher Auditorium, Bldg. 45, 45 Center Dr., Bethesda, MD 20894.

The NIH campus is accessible via the Washington, DC Metro Transit System, Red Line, at the Medical Center Station. The Natcher Conference Center is a short walk from the metro station, or you may take a shuttle bus that runs from the metro station to the various buildings on the campus. Because of security measures, visitors' parking is extremely limited and use of private vehicles may cause significant delays in entering the campus. Additionally, you will be required to show a photo ID upon entry to the campus and the Natcher Conference Center.

Contact Person: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–3841, FAX: 301–827–3079, e-mail: *Whelan@cber.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone number, e-mail address, and FAX number) to the contact person by Friday, May 21, 2004. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Melanie Whelan (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research; the National Institutes of Health, National Institute of Allergy and Infectious Diseases; the Centers for Disease Control and Prevention; and the Department of Health and Human Services, Office of Research and Development Coordination are cosponsoring a public workshop. The public workshop will provide a forum for sharing information and discussing strategies for safety and efficacy testing of therapeutics, including monoclonal antibody-based therapies, other recombinant proteins, polyclonal immune globulins (human and animal derived), and small molecules, that target anthrax and its toxins in order to expedite the development of these FDA-regulated products. The use of vaccines and antimicrobial drugs targeting anthrax and its toxins will not be covered. The public workshop is intended to address the optimal studies for product characterization, proof of concept, and demonstration of safety and efficacy in postexposure prophylaxis and/or in the treatment of established disease.

Mail or fax your issues and questions to Melanie Whelan (see *Contact Person*) by Friday, May 28, 2004. (There will be an opportunity to raise additional questions and issues for discussion at the public workshop.) The agenda for this public workshop, when finalized, will be posted on the Center for Biologics Evaluation and Research's Web site at *http://www.fda.gov/cber/scireg.htm*.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: April 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–10460 Filed 5–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

SAMHSA Application for Peer Grant Reviewers (OMB No. 0930–0255, revision)—Section 501(h) of the Public Health Service (PHS) Act [42 U.S.C. 290aa] directs the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) to establish such peer review groups as are needed to carry out the requirements of Title V of the PHS Act. SAMHSA administers a large discretionary grants program under authorization of Title V, and for many years SAMHSA has funded grants to provide prevention and treatment services related to substance abuse and mental health.

SAMHSA efforts to make improvements in the grants process have been shown by the restructuring of discretionary award announcements. In support of these efforts, SAMHSA desires to expand the types of reviewers it uses on these grant review committees. To accomplish that end, SAMHSA has determined that it is important to proactively seek the inclusion of new and qualified representatives on its peer review groups, and accordingly SAMHSA has developed an application form for use by individuals who wish to apply to serve as peer reviewers.

The application form has been developed to capture the essential information about the individual applicants. Although consideration was given to requesting a resume from interested individuals, it is essential to have specific information from all applicants about their qualifications; the most consistent method to accomplish this is completion of a standard form by all interested persons. SAMHSA will use the information about knowledge, education and experience provided on the applications to identify appropriate peer grant reviewers. Depending on their experience and qualifications, applicants may be invited to serve as either grant reviewers or review group chairpersons. Revisions are the addition of: a check item to identity the address to which grant applications to be reviewed should be mailed, and allowance for individuals who are consumers or family members of consumers to choose two rather than one professional affiliation. The following table shows the estimated annual response burden.