written or electronic comments on the draft guidance by November 25, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Powell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4526, Silver Spring, MD 20993–0002, 301–796–1589

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''End-of-Phase 2A Meetings.'' This draft guidance will meet one of the performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV). Under section XI of the PDUFA IV Performance Goals, Expediting Drug Development, FDA agreed to publish by the end of fiscal year 2008 a draft guidance on end-of-phase 2A meetings (see section XI.A.4 at *http://www.fda.gov/oc/pdufa4/pdufa4goals.html*). This draft guidance is intended to facilitate early meetings (referred to as end-of-phase 2A meetings or EOP2A meetings) between FDA and sponsors who seek interaction or guidance related to the use of quantitative drug development methods (i.e., exposure-response, pharmacokinetic/pharmacodynamic (PK/PD) modeling, drug-disease modeling, genomic analysis) to inform drug development and regulatory decisions. The draft guidance provides recommendations to IND sponsors on the following topics:

- Objectives of an EOP2A meeting,
- Possible topics for discussion at EOP2A meetings,
- Useful information for an EOP2A meeting package, and
- Timing of EOP2A meetings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on end-of-phase 2A meetings. 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 statutes and regulations.

II. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. 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 part 312 and the guidance on ''Formal Meetings With Sponsors and Applicants for PDUFA Products'' have been approved under OMB control numbers 0910–0014 and 0910–0429, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: September 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22669 Filed 9–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–M–0207, FDA–2008–M–0243, FDA–2008–M–0244, FDA–2008–M–0283, FDA–2008–M–0335, FDA–2008–M–0311, FDA–2008–M–0342, FDA–2008–M–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 data 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, 240–276–4010.

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 April 1, 2008, through June 30, 2008. 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 APRIL 1, 2008, THROUGH JUNE 30, 2008

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P050020 FDA–2008–M–0207	Abbott Diabetes Care, Inc.	FREESTYLE NAVIGATOR CONTINUOUS GLUCOSE MONITORING SYSTEM	March 12, 2008
P010012 (S037) FDA–2008–M–0243	Guidant Corp.	Contak Renewal 3 AVT system & contak reviewal 3AVT HE System	March 13, 2008
P070027 FDA–2008–M–0244	Medtronic Vascular	The talent abdominal stent graft system	April 15, 2008
P060040 FDA–2008–M–0283	Thoratec Corp.	Thoratec Heartmate II Left ventricular assist	April 21, 2008
P070008 FDA–2008–M–0335	Biotronik, Inc.	Stratos LV CRT–P & stratos LV–T CRT–P, corox OTW BP lead & corox OTW-s bp lead	May 12, 2008
P070016 FDA–2008–M–0311	Cook, Inc.	Zenith TX2 Thoracic TAA endovascular graft with the H&LB One-shot introduction system	May 21, 2008
P070007 FDA–2008–M–0342	Medtronic Vascular	Talent Thoracic Stent Graft System	June 5, 2008
H070003 FDA–2008–M–0378	Synapse Biomedical, Inc.	NeuRx RA/4	June 17, 2008

II. Electronic Access

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

Dated: September 12, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–22668 Filed 9–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for Preparing *Bacillus anthracis* Protective Antigen for Use in Vaccines

Description of Technology: This invention relates to improved methods of preparing *Bacillus anthracis* protective antigen (PA) from a cell or organism, particularly a recombinant cell or microorganism, for use in vaccines. Production and purification methods of modified PA from a non-sporogenic strain of *Bacillus anthracis* are described. Specifically, a scalable fermentation and purification process is claimed that is suitable for vaccine development, and that produces almost three times more product than earlier-reported processes. This is accomplished using a biologically inactive protease-resistant PA variant in a protease-deficient non-sporogenic avirulent strain of *B. anthracis* (BH445). One of the PA variants described in the patent application lacks the furin and chymotrypsin cleavage sites.

Advantages: Bacillus anthracis protective antigen is a major component of the currently licensed human vaccine (Anthrax Vaccine Adsorbed, AVA). Although the current human vaccine has been shown to be effective against cutaneous anthrax infection in animals and humans and against inhalation anthrax in rhesus monkeys, the licensed vaccine has several limitations: (1) AVA