practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the content and format of the ISE. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under 0910–0001. The collections of information for submission of data in a BLA under 21 CFR 601.2 have been approved under 0910–0338.

III. 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*.

IV. Electronic Access

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

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19906 Filed 8–27–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–M–0084, FDA–2008–M–0100 (formerly 2008M–0013), FDA–2008–M–0182, FDA–2008–M–0109, FDA–2008–M–0207]

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: Samie Allen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013.

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 January 1, 2008, through March 31, 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 JANUARY 1, 2008, THROUGH MARCH 31, 2008

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P040021 (S004) FDA–2008–M–0084	St. Jude Medical, Inc.	SJM EPIC VALVE AND SJM SUPRA VALVE	November 15, 2007

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2008, THROUGH MARCH 31, 2008—Continued

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P070001 FDA–2008–M–0100 (formerly 2008M–0013)	Synthes Spine, Inc.	PRODISC–C TOTAL DISC PEPLACEMENT	December 17, 2007
P050045 FDA–2008–M–0182	Dako Denmark a/s	DAKO TOP2A FISH PHARM DX KIT	January 11, 2008
P060033 FDA–2008–M–0109	Medtronic Vascular	ENDEAVOR ZOTAROLIMUS-ELUTING CORONARY STENT ON THE OVER THE WIRE (OTW), RAPID EXCHANGE (RX), OR MULTI-EXHANGE II (MX^2) STENT DELIVERY SYSTEM	February 1, 2008

II. Electronic Access

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

Dated: August 14, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–19907 Filed 8–27–08; 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.

Identification and Characterization of Folliculin-Interacting Protein 2, FNIP2

Description of Technology: The invention describes the identification and characterization of a FNIP1 homolog, folliculin-interacting protein 2 (FNIP2), that interacts with folliculin, the protein encoded by the FLCN gene, which is responsible for the Birt-Hogg-Dube' (BHD) syndrome. BHD is a dermatologic disorder associated with an increased risk for developing renal cancer, spontaneous pneumothorax and lung cysts. FNIP2 binds to the C-terminus of folliculin and to AMPK. Importantly, FNIP2 expression was elevated in renal tumors seen in BDH patients. This finding suggests that FNIP2 may serve as a biomarker for BHD.

Applications: Research tool; Diagnostic applications.

Advantages: Could facilitate the development of therapeutic drugs to treat the skin lesions and renal tumors that develop in BHD patients.

Development Status: Early stage of development.

Market: Dermatologic products; Diagnostic applications.

Inventors: Laura S. Schmidt *et al.* (NCI).

Relevant Publication: H Hasumi *et al.* Identification and characterization of a novel folliculin-interacting protein FNIP2. (2008) Gene, in press.

Patent Status: HHS Reference No. E–213–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for biological materials licensing only.

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov*.

Collaborative Research Opportunity: The Urologic Oncology Branch at the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize detection methods specific for FNIP2 to be used to screen FNIP2 as a biomarker for renal cancer. This may include development of an efficient FNIP2 antibody which does not cross react with FNIP1 for immunhistochemical screening of renal tumors for FNIP2 expression. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Immunotoxins Made With Modified Cholix Toxin and Uses Thereof

Description of Technology: Immunotoxins are chimeric molecules comprising an antibody targeting moiety and a toxin domain capable of killing a cell. Immunotoxins represent an important therapeutic tool for the treatment of cancer because they are able to specifically target cancer cells while ignoring healthy cells. The major drawback to immunotoxins is the development of neutralizing antibodies against the toxin portion of the immunotoxin. Many patients treated with *Pseudomonas* exotoxin A (PE) based immunotoxins develop neutralizing antibodies after the first administration. As a result, only one effective administration of a PE-based immunotoxin is often possible.

NIH inventors have created a novel immunotoxin, where the toxin portion is a truncated Cholera exotoxin (cholix toxin). Although cholix toxin retains strong functional and structural similarity to PE, neutralizing antibodies to PE do not affect the truncated cholix toxin. As a result, cholix toxin-based immunotoxins are of potential utility after a patient has developed neutralizing antibodies to PE. The ability to deliver two rounds of immunotoxins to a patient will increase the successful treatment of various diseases, including cancer.

Application: