21–368 was approved on November 21, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 679 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 21, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 19, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–9899 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006M–0075, 2006M–0009, 2006M–0014, 2006M–0015, 2006M–0163]

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 January 1, 2006, through March 31, 2006. 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, 2006, THROUGH MARCH 31, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020024/2006M–0075	AGA Medical Corp.	AMPLATZER DUCT OCCULUDER AND 180 DELIVERY SYSTEM	May 14, 2003
P020001/2006M–0009	Neoventa Medical AB	STAN S31 FETAL HEART MONITOR	November 1, 2005
P040001/2006M–0014	St. Francis Medical Technologies, Inc.	X STOP INTERSPINOUS PROCESS DECROMPRESSION SYSTEM	November 21, 2005
P050009/2006M–0015	Biomet, Inc.	C2 A-TAPER ACETABULAR SYSTEM	December 16, 2005

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2006, THROUGH MARCH 31, 2006—Continued

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P050007/2006M–0016	Abbott Vascular Devices (AVD)	STARCLOSE VASCULAR CLOSURE SYSTEM	December 21, 2005
H040005/2006M–0163	Karl Storz Endoscopy-America, Inc.	KARL STORZ RIGID TTTS FETOSCOPY INSTRUMENT SET WITH 0 AND 12 DEGREE SCOPE, KARL STORZ RIGID TTTS FETOSCOPY INSTRUMENT SET WITH 30 DEGREE SCOPE, AND KARL STORZ SEMI-RIGID TTTS FETOSCOPY INSTRUMENT SET	March 31, 2006

II. Electronic Access

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

Dated: June 13, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–9898 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Medical Staff Credentials and Privileges Files

AGENCY: Indian Health Service, HHS.

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the IHS is providing a 60-day advance opportunity for public comment on a proposed new collection of information to be submitted to the Office of Management and Budget for review.

Proposed Collection

Title: 0917–0009, ''Indian Health Service Medical Staff''

Typed of Information Collection Request: Extension, without revision, of currently approved information collection, 0917–0009, ''Indian Health Service Medical Staff Credentials and Privileges Files.''

Form Numbers(s): None.

Need and Use of Information Collection: This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. The HHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: Physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. The IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with IHS; (2) contractors who will not seek to become IHS employees; and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Center for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and other accrediting organizations required health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. To meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: Former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, JCAHO standards require that a review of the medical staff be conducted not less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is not optional; such records must be established and maintained at all health care facilities in the United States that are accredited by JCAHO. Prior to the establishment of this JCAHO requirement, the degree to which medical staff applications were verified for completeness and accuracy varied greatly across America.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

Burden Hours: The table below provides the estimated burden hours for this information collection: