

update on AHRQ's current research, programs, and initiatives. The Chair will officially welcome new members to the Council. The official agenda will be available on AHRQ's Web site at [www.ahrq.gov](http://www.ahrq.gov) no later than April 9, 2007.

Dated: March 26, 2007.

**Carolyn M. Clancy,**

*Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-07-06AC]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and

send comments to Joan F. Karr, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Low Back Exposure Assessment Tool for Mining—NEW—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Federal Mine Safety & Health Act of 1977, Section 501, enables CDC/NIOSH to carry out research relevant to the health and safety of workers in the mining industry. Mining has one of the

highest incidence rates for back pain of any industry, and back injuries are consistently the leading cause of lost work days in the industry. The objective of this project is to develop a self-administered, paper and pencil risk assessment tool for the development of low back disorders specifically directed towards use in the mining industry. Many current methods of assessing the risk of low back disorders do not address stressors that are relatively unique to the mining environment, including the restricted vertical spaces in many coal mines that require workers to adopt stooping or kneeling postures for extended periods of their workday.

The low back exposure assessment tool for mining will assess various occupational exposures associated with development of back disorders in the literature (postural demands, lifting, whole body vibration exposure, individual and psychosocial issues), as well as specific mining stressors and will develop a score that will be used to assess the degree of risk for the job and the individual. The tool will be useful in both prioritizing jobs that need interventions to reduce low back disorder risk, and in evaluating the effectiveness of interventions through tool administration before and after the implementation of an intervention. There will be no cost to the respondents other than their time.

*Estimated Annualized Burden Hours:*

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Surface and Underground Miners .....	320 miners .....	1	15/60	80

Dated: March 27, 2007.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E7-6139 Filed 4-2-07; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. 2006M-0411, 2006M-0512, 2006M-0412, 2006M-0396, 2006M-0460, 2006M-0456, 2006M-0459, 2006M-0455, 2006M-0457, 2006M-0473, 2006M-0490, 2006M-0492, 2006M-0529, 2006M-0530 and 2006M-0531]

**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:** Thinkh 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 Web site 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, 2006, through December 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 OCTOBER 1, 2006, THROUGH DECEMBER 31, 2006.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040027/2006M-0411	W.L. Gore & Associates	GORE VIATORR TIPS	December 6, 2004
P040023/2006M-0512	DePuy Orthopedics, Inc.	DURALOC OPTION CERAMIC HIP SYSTEM	May 3, 2005
P030047/2006M-0412	Cordis Corp.	CORDIS PRECISE NITINOL STENT	September 22, 2006
P050038/2006M-0396	Medafor, Inc.	ARISTA AH ABSORBABLE HEMOSTATIC, NON-COLLAGEN BASED	September 26, 2006
P970053(S9)/2006M-0460	Nidek, Inc.	NIDEK EC-5000 EXCIMER LASER	October 11, 2006
P050022/2006M-0456	Siemens Medical Solutions USA, Inc.	SYNGO LUNG COMPUTER ASSISTED DETECTION (CAD) SYSTEM	October 18, 2006
P050025/2006M-0459	Endotex Interventional Systems, Inc.	ENDOTEX NEXSTENT CAROTID STENT & DELIVERY SYSTEM; AND ENDOTEX NEXSTENT CAROTID STENT & MONORAIL DELIVERY SYSTEM	October 27, 2006
P020012/2006M-0455	Artes Medical USA, Inc.	ARTEFILL	October 27, 2006
P040050/2006M-0457	Uroplasty, Inc.	MACROPLASTIQUE IMPLANTS	October 30, 2006
P050031/2006M-0473	Paragon Vision Sciences	PARAGON Z CRT	November 16, 2006
P020056/2006M-0490	Allergan	INAMED SILICONE-FILLED BREAST IMPLANTS	November 17, 2006
P030053/2006M-0492	Mentor Corp.	MENTOR MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	November 17, 2006
P060010/2006M-0529	AbbeyMoor Medical, Inc.	THE SPANNER TEMPORARY PROSTATIC STENT	December 14, 2006
P040025/2006M-0530	Olympic Medical	OLYMPIC COOL-CAP	December 20, 2006
P050033/2006M-0531	Anika Therapeutics, Inc.	COSMETIC TISSUE AUGMENTATION PRODUCT	December 20, 2006

**II. Electronic Access**

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

Dated: March 22, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Oncologic Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.