

0242); *Frequency*: Weekly; *Affected Public*: Individuals or households and State, Local or Tribal Government; *Number of Respondents*: 54; *Total Annual Responses*: 2442; *Total Annual Hours*: 4884. (For policy questions regarding this collection contact JoAnn Perry at 410-786-3336. For all other issues call 410-786-1326.)

7. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Rehabilitation Hospital Criteria Worksheet and Rehabilitation Hospital Criteria Worksheet; *Use*: The rehabilitation hospital and rehabilitation unit criteria worksheets are necessary to verify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system. *Form Number*: CMS-437A and 437B (OMB# 0938-0986); *Frequency*: Annually; *Affected Public*: Business or other for-profit; *Number of Respondents*: 1227; *Total Annual Responses*: 1227; *Total Annual Hours*: 307. (For policy questions regarding this collection contact Georgia Johnson at 410-786-6859. For all other issues call 410-786-1326.)

8. *Type of Information Collection Request*: New collection; *Title of Information Collection*: State Plan Amendment Template for 1915(i) State Plan Home and Community-Based Services (HCBS) Benefit; *Use*: Section 6086 of the Deficit Reduction Act (DRA), expanded access to HCBS for the elderly and disabled and added a new section 1915(i) to the Social Security Act. Under 1915(i), States can amend their State plans to add these services. The template includes the information needed by CMS to determine whether the State's services will meet the requirements under 1915(i). *Form Number*: CMS-10259 (OMB# 0938-NEW); *Frequency*: Once; *Affected Public*: State, Local or Tribal Governments; *Number of Respondents*: 56; *Total Annual Responses*: 3; *Total Annual Hours*: 240. (For policy questions regarding this collection contact Kathy Poisal at 410-786-5940. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to

Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on April 20, 2009.

OMB, Office of Information and Regulatory Affairs.

Attention: CMS Desk Officer.

Fax Number: (202) 395-6974.

E-mail:

OIRA_submission@omb.eop.gov.

Dated: March 12, 2009.

Michelle Shortt,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2008-M-0535, FDA-2008-M-0547, FDA-2008-M-0536, FDA-2008-M-0563, FDA-2008-M-0593, FDA-2008-M-0601, FDA-2008-M-0562, FDA-2008-M-0596, FDA-2008-M-0579, FDA-2008-M-0594, FDA-2008-M-0608, FDA-2008-M-0645, FDA-2008-M-0646]

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 October 1, 2008, through December 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 OCTOBER 1, 2008, THROUGH DECEMBER 31, 2008.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P070015 FDA-2008-M-0535	Abbott Vascular Inc.	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM & PROMUS ELUTING CORONARY STENT SYSTEM	July 2, 2008
P030025 (S28) FDA-2008-M-0547	Boston Scientific Corp.	TAXUS EXPRESS2 PACLITAXEL ELUTING CORONARY STENT SYSTEM	September 24, 2008
P080004 FDA-2008-M-0536	Hoya Surgical Optics, Inc.	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	September 26, 2008
H070004 FDA-2008-M-0563	Levitronix, LLC	LEVITRONIX CENTRIMAG RIGHT VENTRICULAR ASSIST SYSTEM (RVAS)	October 7, 2008
P060008 FDA-2008-M-0593	Boston Scientific Corp.	TAXUS LIBERTE' PACLITAXEL ELUTING CORONARY STENT SYSTEM	October 10, 2008
P050029 FDA-2008-M-0601	Stereotaxis, Inc.	HELIOS II ABLATION CATHETER	October 10, 2008
H040004 FDA-2008-M-0562	Medtronic Sofamor Danek USA, Inc.	INFUSE/MASTERGRAFT POSTEROLATERAL REVISION DEVICE	October 10, 2008
P050019 FDA-2008-M-0596	Boston Scientific Corp.	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	October 23, 2008
H060002 FDA-2008-M-0579	Spiration, Inc.	IBV VALVE SYSTEM	October 24, 2008
P060025 FDA-2008-M-0594	ATS Medical, Inc.	ATS 3F AORTIC BIOPROSTHESIS	October 30, 2008
P080011 FDA-2008-M-0608	Coopervision Manufacturing, Ltd.	BIOFINITY COMFILCON A (EXTENDED WEAR SOFT CONTACT LENSES)	November 19, 2008
P080007 FDA-2008-M-0645	Bard Peripheral Vascular Inc.	BARD E-LUMINEXX VASCULAR STENT	December 4, 2008
P060006 FDA-2008-M-0646	Boston Scientific Corp.	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	December 11, 2008

II. Electronic Access

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

Dated: March 10, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Simulations for Drug Related Science Education

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has

submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 26, 2008, (Vol. 73 No. 124, page 36337) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after November 15, 2008, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Simulations for Drug Related Science Education. **Type of Information Collection Request:** NEW. **Need and Use of Information Collection:** This is a request for a one-time clearance to evaluate an interactive multimedia

module developed by *ArchieMD*. This evaluation seeks to determine whether the multimedia module *Archie MD: The Science of Drugs* (1) Increases students' knowledge in brain and heart biology and the effects drugs have on the body (2) Increases positive attitudes towards science education for high school students (3) Reinforce or instill negative attitudes towards substance abuse. In order to test the effectiveness of the interactive multimedia module, data will be collected in the form of pre and post test surveys from 10th and 11th grade high school students utilizing the developed module. The findings will provide valuable information regarding information pertaining to the use of interactive multimedia educational modules in high school science classrooms and their ability to increase knowledge and change attitudes and perceptions.

Frequency of Response: 4. **Affected Public:** High school students engaged with the *ArchieMD: The Science of*