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.

[FR Doc. E9–6041 Filed 3–18–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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:

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.
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.

[FR Doc. E9–6026 Filed 3–18–09; 8:45 am]
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 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...