currently unapproved marketed drugs? For which drugs might this be feasible? What attributes make published literature of sufficient quality to contribute to such an evaluation?

B. Limiting the Use of Enforcement Discretion

As stated previously, the Agency acknowledges that the practice of exercising enforcement discretion in certain circumstances is necessary to ensure the availability of some essential animal drug products. This practice of exercising enforcement discretion (i.e., a decision on the part of the Agency to not take enforcement action in certain circumstances) is not only important for managing limited Agency resources related to compliance activities but is also important for assuring that certain animal drug products remain available for addressing the health needs of animals. However, FDA’s goal is to limit, to the extent possible, its use of enforcement discretion for unapproved animal drugs.

What factors should the Agency consider when determining which unapproved animal drug products or categories of products should be the subject of enforcement discretion?

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31889 Filed 12–17–10; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB; Comment Request; National Epidemiologic Survey on Alcohol and Related Conditions—III

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), 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 October 15, 2010, 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 you are not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: National Epidemiologic Survey on Alcohol and Related Conditions—III. Type of Information Collection Request: NEW. Need and Use of Information Collection: This study will determine the prevalence of alcohol use patterns and alcohol use disorders and their associated disabilities in a representative sample of adults in the United States population. The primary objectives of this study are to: (1) Understand the relationships between alcohol use patterns and alcohol use disorders and their related psychological and medical disabilities with a view toward designing more effective treatment, prevention and intervention programs; (2) Identify subgroups at high risk for alcohol use disorders that are complicated by associated disabilities; (3) Understand treatment utilization, unmet treatment need, barriers to treatment, health disparities, and economic costs of alcohol use disorders and their associated disabilities; and (4) Identify environmental and genetic risk factors and their interactions that are associated with harmful consumption patterns and alcohol use disorders and their associated disabilities.


The annualized cost to respondents is estimated to be $936,684.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974. Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory General Medical Sciences Council.
Date: January 27–28, 2011.
Closed: January 27, 2011, 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Hormone Therapy and Cognitive Aging.
Date: January 11, 2011.
Time: 11 a.m. to 12 p.m.
Agenda: To review and evaluate contract proposals.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2010–0057; OMB No. 1660–0072]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, OMB No. 1660–0072; Mitigation Grants Program/eGrants

AGENCY: Federal Emergency Management Agency, DHS.
ACTION: Notice: 30-day notice and request for comments; extension, without change, of a currently approved