The annual reporting estimate is based on information received from representatives of the food packaging and processing industries and agency records. In the past, FDA has typically received 60 threshold of regulation exemption requests per year. However, it is estimated that up to 90 percent of the requests that would have been previously submitted under § 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910–0495). The main advantages of the premarket notification process is that notifiers are guaranteed a decision by FDA within 120 days of receipt of an acceptable notification and, once approved, an effective notification is exclusive to the manufacturer or supplier who submitted the request. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is identical to that required under § 170.39, the burden on industry for premarket notifications will be similar to the burden for requests submitted under the existing threshold of regulation process.

As indicated previously in this document, it is estimated that approximately six requests per year will be submitted under the threshold of regulation exemption process of § 170.39. The threshold of regulation process offers one advantage over the premarket notification process in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at *http://www.cfsan.fda.gov*. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: September 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23561 Filed 9–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0186]

Guidance for Industry on Use of Material From Deer and Elk in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance (#158) entitled ''Use of Material From Deer and Elk in Animal Feed.'' This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from deer and elk that are positive for chronic wasting disease (CWD) or are considered at high risk for CWD.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20855. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of this guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0177, e-mail: *bpritche@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 16, 2003 (68 FR 26628), FDA published a notice of availability for a draft guidance entitled ''Use of Material from Deer and Elk in Animal Feed'' giving interested persons until June 16, 2003, to submit comments. FDA considered all comments received.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This level 1 guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the final guidance at any time. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the final guidance document entitled ''Use of Material From Deer and Elk in Animal Feed'' from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: August 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23559 Filed 9–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following 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). The grant applications 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 Center on Minority Health and Health Disparities Special Emphasis Panel, ZMD1 (07) S Loan Repayment Program Competing Continuation Applications.

Date: September 12, 2003.

Time: 8:30 am to 3 pm.

Agenda: To review and evaluate grant applications.

Bethesda Marriott, 5151 Pooke Hill Road, Bethesda, MD 20814.

Contact Person: Lorrita Watson, PhD, National Center on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd, Suite 800, Bethesda, MD 20892–5465, (301) 594–7784, *watson@ncmhd.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: September 9, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–23520 Filed 9–15–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

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 Contract 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 Council on Drug Abuse.

Date: September 17–18, 2003.

Closed: September 17, 2003, 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, neuroscience center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: September 18, 2003, 9 a.m. to 3 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Teresa Levitin, PhD, Director, Office of Extramural Affairs, National Institute on Drug Abuse, national Institutes of Health, DHHS, Bethesda, MD 20892–9547, (301) 443–2755.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's Home page: *http://www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: September 5, 2003.

Anna Snouffer, Acting,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–23519 Filed 9–15–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following 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: Minority Programs Review Committee; MARC Review Subcommittee A.

Date: October 8–10, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Richard I. Martinez, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12B, 45 Center Drive MSC 6200, Bethesda, MD 20892–6200, 301–594–2849, *rm63f@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: September 9, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–23522 Filed 9–15–03; 8:45 am]

BILLING CODE 4140–01–M