has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness. Finally, an NDA for a similar amphetamine/dextroamphetamine salt combination was recently approved after the product was found to be safe and effective for the treatment of ADHD.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Delcobese tablets and capsules, approved under ANDAs 83–563 and 83–564, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Delcobese tablets and capsules in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. As a result, ANDAs that refer to Delcobese tablets and capsules may be approved by the agency for appropriate indications.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28193 Filed 11–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0498]

Compliance Program Guidance Manual 7371.009; Bovine Spongiform Encephalopathy/Ruminant Feed Ban Inspections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance program guidance manual (CP) entitled ''Bovine Spongiform Encepholopathy/Ruminant Feed Ban Inspections.'' This CP is intended to assist investigators in determining compliance with the FDA regulation prohibiting the use of specified animal proteins in ruminant feeds (21 CFR 589.2000). The purpose of this regulation is to prevent the establishment and/or amplification within the United States of bovine spongiform encephalopathy (BSE), a fatal degenerative nerve disease of cattle.

DATES: Submit written or electronic comments on the CP at any time.

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

Copies of the CP also may be downloaded to a personal computer with access to the Internet. The CVM home page includes a link to the CP and may be accessed at *http://www.fda.gov/cvm*. Submit written comments on the CP to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this compliance program: Neal Bataller, Center for Veterinary Medicine, HFV–230, Food and Drug Administration, 7500 Standish Pl., Rm. E441, Rockville, MD 20855, 301–827–0163, e-mail: *nbatalle@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 4, 1997, the ruminant feed ban regulation in § 589.2000 (21 CFR 589.2000) became effective. This regulation prohibits the use of certain proteins derived from mammalian tissues in the feeding of ruminant animals. The regulation is intended to prevent the establishment and/or amplification within the United States of BSE, a fatal degenerative nerve disease of cattle.

BSE is the bovine form of a group of uniformly fatal neurological diseases known as transmissible spongiform encephalopathies (TSEs). BSE appears to be spread through the feeding to cattle of protein derived from TSE-infected animal tissues. Specifically, epidemiologic evidence gathered in the United Kingdom suggests an association between BSE and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE. BSE represents a public health concern based on the possible connection between BSE and a form of human TSE, new variant Creutzfeldt-Jacob disease (nv-CJD), that is believed to have resulted from people eating ruminant tissues infected with the BSE agent. BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected. BSE has not been diagnosed in the United States.

The regulation in § 589.2000 affects renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders. Based on the acute need to prevent the entry and spread of BSE, FDA has set a goal of full compliance with the regulation. This CP is intended to assist in the conduct of inspections to enforce § 589.2000 and thereby minimize risk to human or animal health.

II. Significance of Guidance

This CP is being issued as a level 1 guidance consistent with our good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance and instructions to both agency and state investigators in conducting inspections under § 589.2000 for preventing the introduction and amplication of BSE in the United States. Such guidance is presently not available. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

The CP represents the FDA's current thinking on the subject. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance 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.

IV. Electronic Access

Copies of the CP may also be downloaded to a personal computer with access to the Internet. The CVM home page includes a link to the CP and may be accessed at *http://www.fda.gov/cvm*.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28192 Filed 11–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Pediatric Preclinical Testing Program.

Date: December 2, 2003.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lalita D. Palekar, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8105, Bethesda, MD 20892–7405, (301) 496–7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support, 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 4, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–28237 Filed 11–7–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 materials, 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 Cancer Institute Initial Review Group, Subcommittee D—Clinical Studies.

Date: December 10–11, 2003.

Time: 8 AM to 2 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 10814.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., 8th Floor, Bethesda, MD 20892–8328, 301–496–9767, *wm63f@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 4, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–28238 Filed 11–7–03; 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: National Institute of General Medical Sciences Special Emphasis Panel, Trauma and Burn.

Date: December 3–5, 2003.

Time: 8 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Loews Hotel, 4150 East Mississippi Avenue, Denver, CO 80246.

Contact Person: Carole H. Latker, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–18B, Bethesda, MD 20892, 301–594–2848, *latkerc@nigms.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: November 4, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–28229 Filed 11–7–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice