Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 20, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 6, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 11, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–26563 Filed 10–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0411]

Bovine Spongiform Encephalopathy (BSE) in Products for Human Use; Guidance for Industry on the Sourcing and Processing of Gelatin to Reduce Potential Risk; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use.'' This guidance is intended to provide information to industry on reducing the risk of transmission of BSE in gelatin for human use.

DATES: Submit written comments on this guidance by December 22, 1997.

ADDRESSES: Submit written requests for single copies of the guidance document to the Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Linda H. Gangloff, Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4450.

SUPPLEMENTARY INFORMATION: In 1994, representatives of the gelatin industry presented preliminary data to FDA concerning an experimental study of the infectivity of tissue infected with a transmissible spongiform encephalopathy (TSE). TSE's are rare, fatal, neurological diseases that occur in a number of animals (e.g., scrapie in sheep) and in humans (e.g., Creutzfeldt-Jakob disease). Based on the data presented, FDA decided that recommendations concerning bovine ingredients from countries that have reported BSE in FDA-regulated products would not include gelatin. A notice in the **Federal Register** of August 29, 1994 (59 FR 44584), summarized FDA's recommendations to reduce any potential BSE risk to humans from FDA-regulated products and clarified that FDA did not object at that time to gelatin for human use produced from bovine materials from countries reporting BSE.

FDA is committed to amending previous guidance to industry as new information becomes available. On April 23 and 24, 1997, FDA's TSE Advisory Committee discussed information on gelatin manufacturing practices and final results of the research study. At the end of the meeting, a majority of the advisory committee members agreed that current scientific evidence did not justify continued exemption of gelatin from restrictions recommended by FDA for other bovine-derived materials from BSE countries. They also stated that the potential risk of BSE transmission from bovine-derived gelatin varies depending on the country of origin of the raw materials, type of tissue used, the gelatin processes used, and the route of administration or exposure.

FDA has adopted ''Good Guidance Practices'' (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The guidance announced in this document is issued as a Level 1 guidance consistent with GGP's. The agency is accepting public comments, but it is implementing this guidance immediately because of public health concerns related to the use of gelatin. This guidance represents the agency's current thinking on reducing the potential risk of transmission of BSE related to the use of gelatin in FDA-regulated products for human use. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before December 22, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the guidance document using the World Wide Web (WWW). For WWW access, go to ''http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm''.

Dated: October 1, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–26501 Filed 10–2–97; 12:02 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 National Center for Research Resources Special Emphasis Panel (SEP) meeting:

Name of SEP: Resource Related Research Project—R24.

Date: October 21, 1997.

Time: 9:30 a.m.—Until Adjournment.

Place: Woodfin Suites Hotel, Virginia Room, 1380 Piccard Drive, Rockville, MD 20850 (301) 590–9880.

Contact Person: Dr. Jill Carrington, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965 (301) 435–0811.

Purpose/Agenda: To evaluate and review grant applications.

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

(Catalog of Federal Domestic Assistance Program No. 93.306, Laboratory Animal Science and Primate Research.)

Dated: October 1, 1997.

Laverne Y. Stringfield,

Committee Management Office, NIH.

[FR Doc. 97–26505 Filed 10–6–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Research Resources Initial Review Group—General Clinical Research Centers Review Committee, October 15–16, 1997, Bethesda Ramada Hotel, Ambassador 2 Room, 8400 Wisconsin Avenue, Bethesda, Maryland, which was published in the **Federal Register** on September 23 (62 FR 49697).

This committee was scheduled to meet on October 15–16, 1997, from 8:00 a.m. to 9:30 a.m. in open session, and from 9:30 a.m. until adjournment in closed session. The meeting has been changed to add an additional open session on October 16, 1997.

The session on October 16 will be open to the public from 10:30 a.m. to 11:30 a.m., and will be closed from 11:30 a.m. until adjournment for the review, discussion, and evaluation of individual grant applications.

Dated: October 1, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–26506 Filed 10–6–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Purusant 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 National Center for Research Resources Special Emphasis Panel (SEP) meeting:

Name of SEP: General Clinical Research Centers

Date: October 30, 1997

Time: 8:00 a.m.–Until Adjournment

Place: City of Hope National Medical Center, 1500 East Duarte Road, Duarte, CA 90027, (626) 301–8434

Contact Person: Dr. Charles Hollingsworth, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, (301) 435–0806

Purpose/Agenda: To evaluate and review grant applications.

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

(Catalog of Federal Domestic Assistance Program No. 93.306, Laboratory Animal Science and Primate Research.)

Dated: September 30, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–26507 Filed 10–6–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following National Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of SEP: Perinatal Studies of Disorders of Fetal Metabolism.

Date: October 6–7, 1997.

Time: October 6–7:30 p.m.–10:00 p.m.; October 7—8:30 a.m.–adjournment.

Place: The Glidden House Inn, 1901 Ford Drive, Cleveland, Ohio 44106.

Contact Person: Gopal Bhatnagar, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, 6100 Building–Room 5E01, Rockville, Maryland 20852; Telephone: 301–496–1485.

Purpose/Agenda: To evaluate and review a grant application.

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

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

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research and No. 93.865, Research Mothers and Children], National Institutes of Health.)

Dated: October 1, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–26503 Filed 10–6–97; 8:45 am]

BILLING CODE 4140–01–M