pharmaceuticals. 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 approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before June 2, 1997, submit written comments on the draft guideline to the Dockets Management Branch (address above). 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. The draft guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this draft guideline is available via the Internet using the World Wide Web (WWW). To connect to the CDER home page, type http://www.fda.gov/cder and go to the ''Regulatory Guidance'' section.

The text of the draft guideline follows:

Addendum to ''Dose Selection for Carcinogenicity Studies of Pharmaceuticals''

Limit Dose

Under a defined set of conditions, it would be considered acceptable to limit the high dose administered for nongenotoxic pharmaceuticals in long-term carcinogenicity testing to a maximum, e.g., 1000 mg/kg/day in rats. This approach is only considered appropriate where the other accepted methods of dose selection have been evaluated and each has been considered not applicable based on scientific justification. Use of this alternative is considered appropriate when:

1. Neither a toxicity-based endpoint (MTD) nor a pharmacodynamic-based dose selection endpoint can be achieved; and

2. Determination of pharmacokinetic parameters needed to apply pharmacokinetic endpoints (the 25-fold ratio of rodent to human AUC or saturation of absorption) is not feasible or is inappropriate due to scientific or technical limitations.

Under such circumstances, it would be considered acceptable to use the maximum feasible dose (e.g., 5 percent of diet) for selection of the high dose. However, if in addition to meeting the criteria 1. and 2. above, the dose of the pharmaceutical for use in humans is 50 mg/day, a ''limit dose'' of 1000 mg/kg/day is considered acceptable for high dose selection (see NOTE). This endpoint is consistent with the principles set forth in the paragraphs on pharmacokinetic endpoints, achieving approximately the same margin of safety as specified there based on a mg/m^2 basis. For those pharmaceuticals used at maximum daily human doses higher or lower than 50 mg/day it is considered acceptable to limit the top dose in a rat carcinogenicity study proportionally.

NOTE

The dose of 50 mg/day in humans (leading to 1 mg/kg on an assumed human weight of 50 kg) is an approximate calculation based upon the following: A conversion from mg/kg to mg/m^2, the AUC ratio of 25, and a multiplication factor of 6 to account for the variance (approximately 95 percent confidence interval) for estimation of the AUC ratio from mg/m^2 ratio (rodent to human) (see, for the data, Contrera, et al., *Journal of the American College of Toxicology*, 14:1–10, 1995). A similar rationale and calculation can be applied for other rodent species.

Dated: March 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–8353 Filed 4–1–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Center for Research Resources; Closed Meetings

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) meetings:

Name of SEP: General Clinical Research Centers.

Date: May 13–14, 1997.

Time: 8 a.m.

Place: Holiday Inn Iowa City, Johnson 1 & 2 Conference Room, 210 South Dubuque Street, Iowa City, IA 52240, (319) 337–4058.

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

Name of SEP: Biomedical Research Technology.

Date: May 27–29, 1997.

Time: 8 a.m.

Place: Doubletree Hotel, Conference Rooms—Twinbrook, Montrose, and Parklawn, 1750 Rockville Pike, Rockville, MD 20852, (301) 468–1100.

Contact Person: Dr. Sharon Moss, 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.

The meetings will be closed in accordance with the provisions set forth in sections 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. 93.371, Biomedical Research Technology; 93.333, Clinical Research, National Institutes of Health, HHS)

Dated: March 27, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 97–8294 Filed 4–1–97; 8:45 am]

BILLING CODE 4140–01–M

National Center for Research Resources; 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:

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Dates of Meeting: May 28–30, 1997.

Time: 8 a.m.–until adjournment.

Place of Meeting: Doubletree Hotel, Halpine Room, 1750 Rockville Pike, Rockville, MD 20892, Tel: (301) 468–1100.

Scientific Review Administrator: Dr. D. G. Patel, National Institutes of Health, 1 Rockledge Center, Room 6018, 6705 Rockledge Drive, MSC 7965, Bethesda, MD 20892–7965, Telephone: (301) 435–0822.

Purpose/Agenda: To review and evaluate grant applications. The meeting will be closed in accordance with the provisions set forth in sections 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. 93.167 Research Facilities Improvement Program, National Institutes of Health, HHS)

Dated: March 27, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 97–8297 Filed 4–1–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Closed Meetings

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 meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: April 3, 1997.

Time: 3 p.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis D. Artis, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.