those effects, to examples of testing that might be considered as part of the overall safety evaluation of finished devices or constituent materials.

FDA published a notice of availability of the original draft guidance in the **Federal Register** of March 18, 1997 (62 FR 12832). Comments were received from 28 respondents, including medical device manufacturers, industry trade groups, and individuals. These comments were reviewed by the CDRH Immunotoxicology Working Group. Based on these comments, the draft guidance was revised to include additional didactic and technical information. The revised draft guidance was reviewed by a group of regulatory reviewers as well as senior CDRH management to obtain the final version of ''Immunotoxicity Testing Guidance.''

II. Significance of Guidance

This guidance represents the agency's current thinking on immunotoxicity testing of medical devices and constituents. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Immunotoxicity Testing Guidance'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (635) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Immunotoxicity Testing Guidance,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Immunotoxicity Testing Guidance'' document will be available at ''http://www.fda.gov/cdrh/ost/ostggp/immunotox.html''.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the contact person listed previously. Such comments will be considered when determining whether to amend the current guidance.

Dated: April 28, 1999.

Linda S. Kahan,

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

[FR Doc. 99–11345 Filed 5–5–99; 8:45 am]

BILLING CODE 4160–01–F

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 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 Cancer Institute Initial Review Group Subcommittee C—Basic & Preclinical.

Date: June 11, 1999.

Time: 1:30 PM to 4:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Office of Advisory Activities, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN 609, Rockville, MD 20892, 301/496–2378.

(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: April 30, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–11430 Filed 5–5–99; 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 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 Cancer Institute Initial Review Group Subcommittee H—Clinical Groups.

Date: June 7–8, 1999.

Time: 8:00 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Deborah R. Jaffe, PHD, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496–7221.

(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: April 30, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–11431 Filed 5–5–99; 8:45 am]

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