

Good Manufacturing Practices versus Quality System Regulation) applicable to combination products?

6. What scientific and policy principles should be followed in determining the appropriate adverse event reporting requirements (e.g., the drugs and biologics adverse event reporting system, Medical Device Reporting) to be applied to a combination product?

7. What other comments do you have concerning other issues related to FDA regulation of combination products? (Examples may include cross labeling of products intended to be used together, though manufactured by different companies; and application of promotion and advertising policies to combination products.)

IV. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15. The hearing will have a presiding officer, who will be accompanied by senior management from CBER, CDER, CDRH, and the agency's Combination Products Program.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Dockets Management Branch (see **ADDRESSES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number listed at the head of this notice along with the statement "Combination Products Hearing." Groups should submit two written copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation (including the specific discussion questions that will be addressed); and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The

hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under the docket number listed at the head of this notice.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available on the Internet at <http://www.fda.gov/ohrms/dockets>, and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions to which they refer (see section III of this document). Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number at 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. Transcripts of the hearing also will be available for review at the Dockets Management Branch.

VI. Electronic Access

Persons with access to the Internet may obtain more information about this hearing or combination products in general at <http://www.fda.gov/oc/ombudsman/combination.html>.

Dated: October 18, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-27267 Filed 10-25-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, 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 Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.
Date: November 19, 2002.

Time: 2 p.m. to 4 p.m.

Agenda: To discuss the next steps for the DCLG with Dr. von Eschenbach and to get an update on the CARRA program.

Place: 6166 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Elaine Lee, Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594-3194.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the

record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/dclg/dclg.htm, where an agenda and any additional information for the meeting will be posted when available.

(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: October 22, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27404 Filed 10-25-02; 8:45 am]

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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 section 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: December 5-6, 2002.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Philadelphia Airport, One Arrivals Road, Philadelphia, PA 19153.

Contact Person: Deborah R. Jaffee, PhD., Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8038, MSC

8328, Bethesda, MD 20892, (301) 496-7721, dj86k@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: October 22, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27405 Filed 10-25-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Obesity and Nutrition Research Centers.

Date: December 3-4, 2002.

Time: 8 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Maria E. Davila-Bloom, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 758, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594-7637, davila-bloom@extra.nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 22, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27399 Filed 10-25-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of 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.

The meetings 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 Mental Health Special Emphasis Panel, Research Career Award for Transition to Independence.

Date: November 15, 2002.

Time: 12:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Benjamin Xu, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6143, MSC 9608, Bethesda, MD 20892-9608, 301-443-1178, benxu1@mail.nih.gov.

Name of Committee: National Institutes of Mental Health Special Emphasis Panel, T32 Services and Interventions Applications.

Date: November 25, 2002.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard E. Weise, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6140, MSC 9606, Bethesda, MD 20892-9606, 301-443-1225, rweise@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development