

that labeling include a statement as to whether or not the lowest effective dose for the product has been identified.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on labeling for noncontraceptive estrogen drug products for the treatment of moderate to severe vasomotor symptoms and moderate to severe vulvar and vaginal atrophy symptoms. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Two copies of mailed 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 The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-3330 Filed 2-11-04; 11:58 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting. The meeting will be open to the public.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 16, 2004, 9 a.m.–1:15 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The full ACCV will meet on Tuesday, March 16, from 9 a.m. to 1:15 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1-800-619-2521 on March 16 and providing the following information:

Leader's Name: Thomas E. Balbier, Jr.

Password: ACCV.

Agenda: The agenda items for March 16 will include, but is not limited to: a presentation on the draft Tetanus and Diphtheria Vaccine Information Statements; an update on thimerosal lawsuits; a discussion of changes to the Vaccine Injury Table, including addition of Influenza vaccines; and updates from the Division of Vaccine Injury Compensation, the Department of Justice, and the National Vaccine Program Office. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C-17, Rockville, MD 20857 or by e-mail at clee@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period on the audio conference call. These persons will be allocated time as time permits.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443-2124 or e-mail: clee@hrsa.gov.

Dated: February 10, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-3335 Filed 2-13-04; 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 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 Special Emphasis Panel, Radionuclide Resource for Cancer Applications.

Date: March 16-18, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Chase Park Plaza, 212-232 North Kingshighway, St. Louis, MO 63108.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8068, Bethesda, MD 20892, (301) 435-1822.

(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: February 9, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-3303 Filed 2-13-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

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