

Appendix VI—Researcher Affidavit of Confidentiality

I certify that no confidential data or information viewed or otherwise obtained while I am a researcher in the National Center for Health Statistics (NCHS) Research Data Center (RDC) will be removed from NCHS. Further, I understand that NCHS will perform a disclosure review and must provide approval to me before I remove any data from the RDC, whether they are in electronic or paper form. I acknowledge NCHS Confidentiality Statute, Sec. 308(d) of the Public Health Service Act (42 U.S.C. 242m) stated below and fully understand my legal obligations to NCHS to protect all confidential data. Further, I understand that any violation may be punishable by fine or imprisonment for up to 5 years or both under Title 18 U.S.C. 1001.

NCHS Confidentiality Statute—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 304, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

Title 18 U.S.C. 1001—Deliberately making a false statement in any matter within the jurisdiction of any Department or Agency of the Federal Government violates Title 18 U.S.C. 1001 and is punishable by a fine or up to 5 years in prison or both.

Researcher's Signature

Date

NCHS Witness

Date

Dated: November 9, 2004.

James D. Seligman,

*Associate Director for Program Services,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Oncologic Drugs Advisory Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 2004, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy/Adams Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, Fax: 301-827-6776, e-mail: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss these items: (1) New drug application (NDA) 21-673, proposed trade name CLOLAR (clofarabine) Ilex Products, Inc., proposed indication for the treatment of pediatric patients 1 to 21 years old with refractory or relapsed acute leukemias, and (2) NDA 21-600, proposed trade name MARQIBO (vincristine sulfate liposome injection) Inex Pharmaceuticals Corp., proposed indication for the treatment of patients with aggressive non-Hodgkin's lymphoma previously treated with at least two combination chemotherapy regimens.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 23, 2004. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and between approximately 2:30 p.m. and 3 p.m.

Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 23, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Trevelin Prysock at 301-827-7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 9, 2004.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Office of the Director, National Institutes of Health; 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 the meeting of the Advisory Committee to the Director, National Institutes of Health (NIH).

The meeting will be open to the public as indicated below, 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.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in the Government in the Sunshine Act, sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C., as amended, because the disclosure of which would constitute a clearly unwarranted invasion of personal property and the premature disclosure of information and the discussions are likely to significantly