

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Evidence Based Assisted Reproductive Technologies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) in cosponsorship with the National Institutes of Health (NIH), and Department of Health and Human Services (DHHS), Office of Women's Health is announcing the following public workshop entitled: "Evidence Based Assisted Reproductive Technologies (ART)." The topics to be discussed include: (1) The FDA regulatory framework; (2) methods of supporting research in this area by NIH; and (3) scientific, social, ethical and policy issues concerning ART.

Date and Time: The public workshop will be held on September 18, 2002, from 8:30 a.m. to 4:30 p.m., and September 19, 2002, from 8 a.m. to 12 a.m.

Location: The public workshop will be held at Lister Hill Center, Bldg. 38A, NIH, 8600 Rockville Pike, Bethesda, MD.

Contact Person: For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210, FAX 301-594-1944.

For information about the public workshop: Melanie Whelan, Center for Biologics Evaluation and Research (HFM-40), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3079, FAX 301-827-3843, or e-mail: whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Melanie Whelan (see *Contact Person*) by Friday, September 6, 2002. The registration form is available at <http://www.fda.gov/cber/meetings.htm>. There is no registration fee for the public workshop. Space is limited, therefore interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Melanie Whelan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This public workshop will provide a forum

for discussion of scientific, social, ethical, and policy issues related to ART. The public workshop will be of primary interest to consumers, researchers, academia, ART practitioners, and sponsors of clinical trials evaluating novel ART. The goals of the public workshop are to: (1) Assess the usefulness of animal models in evaluating the safety and efficacy of human ART, and (2) identify social and ethical issues specific to ART. These issues are of interest to FDA, NIH, and DHHS to guide development of scientific initiatives, policy, and regulations in this area and to identify areas where research funding may be needed.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the workshop will also be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: July 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-17584 Filed 7-11-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the American Academy of Pediatrics (AAP), regarding pediatric oncology drug development. The public workshop is intended to provide information for and perspective from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of drug development in pediatric oncology, including prioritization of new and emerging therapeutic alternatives, clinical trial design, and access to new therapeutic agents. The input from this public workshop will be used in developing topics for discussion at future meetings of the Pediatric Subcommittee of the Oncologic Drugs

Advisory Committee (the subcommittee).

Date and Time: The public workshop will be held on Thursday, July 18, 2002, from 8 a.m. to 4 p.m.

Location: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857. Seating is limited and available only on a first-come, first-served basis. Please note there is very limited parking in the vicinity of 5630 Fishers Lane, but it is near the Twinbrook Metro station. Please bring picture identification in order to clear building security.

Contact: Steven I. Hirschfeld, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1532, e-mail: HIRSCHFELDS@CDER.FDA.GOV.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with the AAP, regarding pediatric oncology drug development. On January 4, 2002, the President signed into law the Best Pharmaceuticals for Children Act (Public Law 107-109). Section 15 of the Best Pharmaceuticals for Children Act (Section 15) relates to the subcommittee.

Section 15 directs the subcommittee, in carrying out "the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers," to:

- Evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;

- Provide recommendations and guidance to help ensure that children with cancer have timely access to the most promising new cancer therapies; and

- Advise on ways to improve consistency in the availability of new therapeutic agents.

The agency is seeking public input to inform its future decisionmaking in regard to Section 15.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Requests to Make Oral Presentations: The public workshop agenda allows opportunities for oral presentations from interested persons. If you desire to make a formal oral presentation, please notify the contact person (see the *Contact* section of this document) before July 17, 2002, and provide your name,