

that a collection of information entitled "Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities; Survey" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of June 24, 2004 (69 FR 35379), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0548. The approval expires on March 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee for Reproductive Health Drugs; 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:* Advisory Committee for Reproductive Health Drugs.

*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 2, 2004, from 8 a.m. to 5:30 p.m.

*Location:* Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Teresa Watkins, 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: [watkinst@cder.fda.gov](mailto:watkinst@cder.fda.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug application (NDA) 21-769, Testosterone Transdermal System (proposed tradename, Intrinsa) by Procter and Gamble, indicated for the treatment of hypoactive sexual desire disorder in surgically menopausal women receiving concomitant estrogen therapy. Background materials for this meeting when available will be posted on the Internet 1 business day before the meeting at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

*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 17, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 17, 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 Teresa Watkins 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: October 21, 2004.

**Sheila Dearybury Walcott,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-24068 Filed 10-27-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001D-0584]

#### "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Human Immunodeficiency Virus Type 1 and Hepatitis C Virus;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated October 2004. The guidance provides recommendations to all establishments that manufacture Whole Blood and blood components (including Source Plasma and Source Leukocytes) on the implementation of licensed nucleic acid tests (NAT) to identify human immunodeficiency virus type 1 (HIV-1) ribonucleic acid (RNA), and hepatitis C virus (HCV) RNA in donations of Whole Blood and blood components to reduce the risk of transmission of these agents; and the reporting to FDA of such implementation. The guidance announced in this notice finalizes the draft guidances entitled "Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated December 2001 and "Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated March 2002.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug

Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated October 2004. FDA's final rule (66 FR 31146, June 11, 2001) entitled "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Diseases" became effective on December 10, 2001. The regulations under § 610.40(b) (21 CFR 610.40(b)) require that establishments that collect or manufacture Whole Blood and blood components "must perform one or more screening tests to adequately and appropriately reduce the risk of transmission of communicable disease agents" (66 FR 31146 at 31162). As we noted in the preamble to the final rule, the standard for adequate and appropriate testing will change as new testing technology is approved by FDA. We explained, " \* \* \* we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents" (66 FR 31146 at 31149).

The guidance announced in this notice finalizes the draft guidances entitled "Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated December 2001, and "Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion

to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated March 2002. This guidance recommends that establishments implement these recommendations as soon as feasible, but not later than 6 months after publication of this notice.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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. The Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 601.12 and § 610.40 of this guidance were approved under OMB control numbers 0910-0315 and 0910-0472.

##### **III. Comments**

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **IV. Electronic Access**

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

Dated: October 20, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-24067 Filed 10-27-04; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 2004D-0462]

#### **Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry entitled Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes" dated October 2004. The draft guidance provides sponsors or investigators, with criteria for testing the efficacy and safety of oxygen therapeutics as substitutes for red blood cells, and guidance on the design of clinical trials to assess risk/benefit ratio of such use. The draft guidance, when finalized, would supercede the "Points to Consider on the Safety Evaluation of Hemoglobin-Based Oxygen Carriers," dated August 27, 1990, and replaces the draft "Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers" dated September 1997.

**DATES:** Submit written or electronic comments on the draft guidance by January 26, 2005 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the

**SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics