reduced by direct medical intervention. Termination of an ectopic gestation or a heterotopic pregnancy is not considered a therapeutic reduction. Therapeutic reduction is used in women with multiple gestations, usually three or more, to decrease the number of fetuses a woman carries usually to two.

Tubal embryo transfer (TET)—Transfer of an early stage embryo to the fallopian tube.

Tubal factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury of one or both fallopian tubes; the following are included: (1) tubal ligation, not reversed; (2) hydrosalpinx (in place); (3) any other tubal disease including but not limited to pelvic or peritubal adhesive disease, prior tubal surgery, prior ectopic pregnancy, or tubal occlusion (partial or complete without hydrosalpinx).

Ultrasound—A technique for visualizing the follicles in the ovaries and the gestational sac or fetus in the uterus, allowing the estimation of size.

Unexplained infertility—Infertility in which no etiology (male infertility, endometriosis, tubal factor, ovulatory disorders/PCO, diminished ovarian reserve, uterine factor or other factors such as immunologic, chromosomal, cancer chemotherapy or other systemic disease) has been identified.

Unstimulated cycle—An ART cycle in which the woman does not receive medication to stimulate follicular development such as clomiphene citrate or follicle stimulating hormone. Instead, natural follicular development occurs.

Uterine factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury to the uterus whether repaired or not; includes septum, myoma, Diethylstilbestrol (DES) exposure, intrauterine adhesions, congenital anomalies.

Zygote—A normal (2 pronuclei) fertilized egg before cell division begins.

Zygote intra fallopian transfer (ZIFT)—Eggs are collected and fertilized, and the resulting zygote is then transferred to the fallopian tube.

D. Updating Data To Be Reported

Specific data items and definitions will be provided to clinics each year along with all other reporting requirements at least 90 days in advance of the reporting deadline. Data items and definitions will be periodically reviewed and updated. Such review will include consultation with professional and consumer groups and individuals.

IV. Content of Published Reports

The data reported will be used to provide a picture of the national rates of pregnancy and live birth achieved using ART as well as clinic-specific live birth rates. The annual report will have four components:

(A) A national component which will provide a comprehensive picture of success rates given a variety of factors including age, reason for ART, type of ART procedure, number of embryos transferred etc. This is possible because the large number of cycles at the national level allow accurate statistical reporting of success rates which is not possible with the smaller number of cycles carried out in individual clinics.

(B) A clinic-specific component which will provide success rates for all ART cycles using fresh, non-donor embryos, success rates for ART cycles using thawed embryos, and success rates for ART cycles using donor oocytes or embryos. Success rates will be reported by specific age groups. In addition, the clinic-specific component will provide other information which may be useful to the consumer such as types of services the clinic offers (e.g. gestational surrogacy, single women), the number of cycles carried out, the percent distribution of types of ART, the types of infertility problems the clinic sees, the frequency of cancellations, the average number of embryos transferred per cycle and the percentage of multiple pregnancies and births (twins and triplets or greater).

Pregnancy and live birth success rates will be defined and characterized as described below.

For fresh, non-donor cycles success rates will be defined as—

1. The rate of *pregnancy* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

2. The rate of *live birth* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

b. Oocyte retrieval procedures.

c. Embryo (or zygote, or oocyte) transfer procedures.

For cycles using thawed embryos and cycles using donor oocytes or embryos success rates will be defined as—

1. The rate of *live birth* after completion of ART according to the number of:

a. Embryo (or zygote, or oocyte) transfer procedures.

(C) An appendix containing a consumer-oriented explanation of all medical and statistical terms used in the report.

(D) An appendix containing a list of all reporting clinics and a list of all clinics that did not report data (See above, WHO REPORTS section, for a full description of clinics that will be considered to not be in compliance with the federal reporting requirements of FCSRCA; such clinics will be listed as non-reporters in the published report.) This appendix will contain the names, addresses and telephone numbers for all reporting and non-reporting clinics.

The entire annual report will be available to the general public. As resources allow, additional information may also be published.

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BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research, Subcommittee for Management Review of the Chernobyl Studies: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER), Subcommittee for Management Review of the Chernobyl Studies.

Times and Dates: 9 a.m.–5 p.m., September 20, 1999; 9 a.m.–12 Noon, September 21, 1999.

Place: Washington Court Hotel, 525 New Jersey Avenue, NW, Washington, DC 20001, telephone 202/628–2100, fax 202/879–7918.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 30 people.

Purpose: This subcommittee is charged with providing guidance to the scientific reviewers and staff, and reporting back to the full ACERER on the charge from the Department and Congress to assess the management, goals, and objectives of the National Cancer Institute (NCI) Chernobyl studies.

Matters To Be Discussed: Agenda items will include: a briefing from the National Cancer Institute's Management Staff on the approach to the site visit; a review of the NCI documentation; a discussion on public input; and a decision on the task list.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michael J. Sage, Deputy Director, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 4770 Buford Highway, NE, (F–28), Atlanta, Georgia 30341–3724, telephone 770/488–7300, fax 770/488–7310.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 24, 1999.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–22988 Filed 9–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2875]

Agency Information Collection Activities; Proposed Collection; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions relating to the blood establishment registration and product listing requirements in 21 CFR part 607 and relating to Form FDA 2830.

DATES: Submit written comments on the collection of information by November 2, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607 (OMB Control Number 0910–0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business and all such establishments, and submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood product in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December. Section 607.22 requires the use of Form FDA 2830 for registration and blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires for certain changes an amendment to the establishment registration to be made within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their blood product listing information every June and at the annual registration. Section 607.31 requires that additional blood product listing information be provided upon FDA request.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. Form FDA 2830, Blood Establishment Registration and Product Listing, is used to collect this information. The likely respondents are blood banks, blood collection facilities, and blood component manufacturing facilities.

FDA estimates the burden of this collection of information based upon the past experience of the Center for Biologics Evaluation and Research, Division of Blood Applications, in regulatory blood establishment registration and product listing. Most blood banks are familiar with the regulations and registration requirements to fill out this form.