

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 97N-0513]

**Agency Information Collection Activities; Announcement of OMB Approval; Orphan Drugs—21 CFR Part 316****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Orphan Drugs—21 CFR Part 316" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 18, 1998 (63 FR 27299), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0167. The approval expires on July 31, 2001.

Dated: September 2, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-24240 Filed 9-9-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 98D-0670]

**Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k); Draft; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of the draft guidance entitled "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)." This draft guidance is neither final nor is it in effect at this time. This draft guidance outlines the information to be submitted in a premarket notification submission (510(k)) for medical devices that are intended to be used for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), intracytoplasmic sperm injection (ICSI), embryo transfer (ET), and related assisted reproduction technology (ART) procedures.

**DATES:** Written comments concerning this draft guidance must be submitted by December 9, 1998.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FURTHER INFORMATION CONTACT:** Elisa D. Harvey, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

**SUPPLEMENTARY INFORMATION:****I. Background**

This draft guidance outlines the information to be submitted in a 510(k) for medical devices that are intended for use in IVF, GIFT, ZIFT, ICSI, ET, and ART procedures. On January 29, 1988, and October 21, 1995, FDA consulted with the Obstetrics and Gynecology Devices Panel (the Panel) regarding its regulatory strategy and the classification of these devices. Both times the Panel agreed that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices used for IVF and ART.

Therefore, in the **Federal Register** of September 4, 1997 (62 FR 46686), FDA published a proposed rule to reclassify instrumentation intended for use in IVF and related ART procedures from class III to class II. FDA also proposed to reclassify assisted reproduction microscopes and microscope accessories from class III to class I and to exempt them from the requirement of premarket notification (510(k)).

**II. Significance of Guidance**

This draft guidance represents the agency's current thinking on the information needed in a 510(k) intended to be used for ART procedures. 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 applicable statute, regulations, or both.

The agency has developed good guidance practices (GGP's) to set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is a level 1 document consistent with the GGP's.

**III. Electronic Access**

In order to receive "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 620 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic

submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The draft guidance entitled "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)" will be available at <http://www.fda.gov/cdrh/ode/ed—rp.html>.

#### IV. Comments

Interested persons may, on or before December 9, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1998.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 98-24243 Filed 9-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-3432-N]

#### Medicare Program; September 25, 1998, Open Town Hall Meeting To Discuss the Medicare Coverage Process

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a meeting to solicit comments from the public on proposed revisions to the process we use to make administrative coverage decisions in the Medicare program. Advance registration is required due to space limitations.

**DATES:** The meeting is scheduled for September 25, 1998 from 8:30 a.m. until 5:30 p.m., e.s.t.

**ADDRESSES:** The meeting will be held in the HCFA headquarters auditorium, 7500 Security Boulevard, Baltimore, Maryland, 21244.

**FOR FURTHER INFORMATION CONTACT:** Ron Milhorn (410) 786-5663

**SUPPLEMENTARY INFORMATION:** At present, in accordance with section 1862(a)(1)(A) of the Social Security Act,

we use a variety of mechanisms to make coverage decisions, including internal staff review, meetings and discussions with medical experts, and technology assessments. Until last year, we also used a Technology Advisory Committee, comprised of both HCFA and non-HCFA personnel, to discuss and receive advice about coverage issues. We disbanded the Technology Advisory Committee last year following concerns raised by the General Accounting Office about whether the Committee complies with the Federal Advisory Committee Act. We have developed a plan for establishing a new committee that fully complies with the Federal Advisory Committee Act. This committee will be more open and responsive to public participation. We are also taking other steps to make the coverage review process more open and to offer a more accessible and systematic means for advising the public about ongoing actions regarding coverage issues.

The meeting will consist of short HCFA presentations on several major topics central to the development of revisions to the coverage process followed by public discussion. The meeting will conclude with a question and answer session during which the public may raise any issues related to the topics discussed. While the meeting is open to the public, attendance is limited to space available. Therefore, individuals must register in advance, as described below.

#### Registration

Casals and Associates in Arlington, Virginia will handle registration for the meeting. Individuals may register by contacting Stacey Young at Casals and Associates by mail, fax, or Internet electronic mail. Please provide your name, title, firm name, address, telephone, fax, and Internet electronic mail address (if applicable).

- For mail registration, the address is: Casals and Associates, 2231 Crystal Drive, Suite 814, Arlington, Virginia, 22202, Attention: Stacey Young.
- For fax registration, the number is 703-920-5750.
- For registration by Internet electronic mail, the address is [SYoung@Casals.com](mailto:SYoung@Casals.com).

Casals and Associates will provide all registrants with a confirmation packet and background papers prior to the meeting.

We will accept written questions, comments, or other materials, either prior to, or within 14 days after the meeting. Address comments to: Ron Milhorn (S3-02-01), HCFA, 7500 Security Blvd., Baltimore, Md. 21244,

Telephone: 410-786-5663, FAX: 410-786-6857, E-Mail: [Rmilhorn@hcfa.gov](mailto:Rmilhorn@hcfa.gov)

There is no special format for the materials; however, we request that commenters be clear about the issue or aspect of the proposed process on which they have a question, comment, or suggestion.

After reviewing and analyzing the comments and suggestions we receive, we intend to prepare a notice for publication in the **Federal Register** setting forth the process for making administrative coverage decisions. Although our plans are to publish this notice in final form, we anticipate that we will provide a comment period and make any necessary revisions in the notice based on the comments we receive.

**Authority:** Federal Advisory Committee Act (5 U.S.C. App.2)

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 26, 1998.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 98-24291 Filed 9-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Council Notice of Re-establishment

Pursuant to the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. Appendix 2), the Secretary, Department of Health and Human Services, announces the re-establishment of the following advisory committee.

**Designation:** HRSA AIDS Advisory Committee.

**Purpose:** Advises the Secretary and the Health Resources and Services Administration (HRSA) on its activities related to the support of health care services to persons living with HIV/AIDS and education of health professionals about HIV/AIDS. The Committee will support the Agency's process of identifying and responding to the health service delivery needs of affected communities and to the needs of individuals living with this disease.

**Structure:** The Committee shall consist of the Administrator, HRSA as Chair; ex-officio members: Director, Centers for Disease Control and