Division of HIV/AIDS Prevention, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–46, Atlanta, GA 30333; Phone: 404–639–6166; Fax: 404–639–8640; e-mail BBranson@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

**Technology Sought**

One mission of the Division of HIV/AIDS Prevention/NCHSTP is to develop new alternatives to increase the number of persons who know their HIV infection status. The Prevention Services Research Branch is seeking rapid diagnostic tests for HIV that are suitable for commercial distribution and that are simple: preferably, tests that: use direct unprocessed specimens (e.g., whole blood or oral fluid); can be performed in 30 minutes or less by persons with minimal training; include all necessary reagents in the test kit; can be stored at temperatures between 25 and 39°C; and have a minimum 1-year shelf life.

NCHSTP and Collaborator Responsibilities

The NCHSTP role may include, but will not be limited to, the following:

(1) Providing scientific, and technical expertise needed for the research project;

(2) Planning and conducting research studies of the diagnostic tests and interpreting results; and

(3) Publishing research results.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing tests that can be used in the evaluation; and

(2) Providing NCHSTP access to necessary data in support of the research activities.

**Selection Criteria**

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data available on the performance of the tests in different populations;

(2) Information on the technology used for the test;

(3) Information on the time required to perform the test, whether the test is preformed on whole blood, sera, plasma or saliva, and the steps involved in performing the test;

(4) Information on the storage requirements and stability of the test;

(5) Interest by the company to seek FDA approval and market the test in the United States; and

(6) Documentation of production capacity to provide at least 500,000 tests annually, and the ability to deliver a minimum of 45,000 tests within 90 days of order.

Dated: August 29, 2001.

**James D. Seligman,**

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

[FR Doc. 01–22431 Filed 9–5–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

**Proposed Projects**

*Title:* Evaluation of the Early Head Start Fatherhood Demonstration.

*OMB No.:* New Collection.

*Description:* ACYF, in partnership with the Office of Child Support Enforcement (OCSE), recently funded 21 Early Head start grantees to develop and implement creative practices to increase the involvement of fathers in their Early Head Start program and in the lives of their children. This submission requests approval to conduct the survey of demonstration staff and to collect father participation data from the demonstration programs.

*Respondents:* To reduce of the burden of demonstration staff, the survey will be configured in four versions. The Director Version will be completed by the Early Head Start program directors. The Father Coordinator Version will be completed by the staff member responsible for father activities. The Family Specialist version will be completed by the staff member who works most closely with the Early Head Start families in the home. The Teacher Version will be completed by the staff member working with families of children participating in the Early Head Start child care programs.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Director Version | 21 | 2 | .5 | 18.9 |
| Father Coordinator Version | 21 | 2 | .5 | 17.8 |
| Family Specialist Version | 21 | 2 | .4 | 14.2 |
| Teacher Version | 13 | 2 | .4 | 8.8 |
| Estimated total Annual Burden Hours: | | | | 59.7 |

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 30, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01–22347 Filed 9–5–01; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01D–0318]**

### Medical Devices; Draft Guidance; Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; 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 ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.'' This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis into class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments concerning this guidance by December 5, 2001.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in the brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis into class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type. This draft guidance may not be implemented until the reclassification process undergoes notice and comment and completes final rulemaking to reclassify this device. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the hip joint metal/polymer constrained cemented or uncemented prosthesis. If the device is reclassified, a manufacturer who intends to market a device of this generic type must: (1) Conform with the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in FDA regulations (21 CFR 807.81); (2) address the specific risks to health associated with the hip joint metal/polymer constrained cemented or uncemented prosthesis; and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control draft guidance document identifies the classification, product code, and classification definition for the generic hip joint metal/polymer constrained cemented or uncemented prosthesis. In addition, it identifies the risks to health and serves as a special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely section 510(k) of the act (21 U.S.C. 360(k)) review and clearance.

#### II. Significance of Guidance

This draft guidance document represents the agency's current thinking about the hip joint metal/polymer constrained cemented or uncemented prosthesis. 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 and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

#### III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1328) followed by the pound sign (#). 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 Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets/default.htm.

#### IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance on or before [*insert date 90 days after date of publication in the* **Federal Register**]. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this