

Dated: August 30, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

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

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## 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#### **Medical Devices; Draft Guidance; Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis." This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented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 This draft guidance is neither final nor is it in effect at this time.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**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" to the Division of Small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Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented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

document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2001.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 01-22287 Filed 9-5-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 30, 2001, page 21404, Volume 66, No. 83 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection:** Title: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants. **Type of Information Collection Request:** NEW. **Need and Use of Information Collection:** The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening conducted among 9,211 male smokers from 1971 to 1983. No reduction in lung cancer mortality was observed in the MLP with an intense regimen of x-ray and sputum cytology screening. Recent analysis of update mortality and case survival data (through 1996) suggests that lesions with little-to-no clinical relevance (over-diagnosis) may have been detected through screening in the MLP intervention arm. Over-diagnosis leads to unnecessary medical interventions, including diagnostic and treatment procedures that carry with them varying

degrees of risk. Consequently, over-diagnosis can result in considerable harm, including premature death, which would not have occurred in the absence of screening. The persistence, after screening ends, of an excess of lung cancer cases in the intervention arm is the strongest evidence in support of over-diagnosis, but this information cannot be adequately obtained with available MLP data. therefore, we propose to re-contact the MLP participants and/or their next-of-kin to determine the participants who were diagnosed with lung cancer after the formal end of the Project. These data will allow the NCI to either more-convincingly state or perhaps refute the possibility of over-diagnosis in lung cancer screening, and may be used to guide future research agendas and lung cancer screening policies. **Frequency of Response:** Once. **Affected public:** Individuals. **Type of Respondents:** MLP participants or their next-of-kin. The annual reporting burden is as follows: **Estimated Number of Respondents:** 6,223; **Estimated Number of Responses per Respondent:** 1. **Average Burden Hours Per Response:** 0.25; **Estimated Total Annual Burden Hours Requested:** 1,556. The annualized cost to respondents is estimated at \$27,230. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Request for Comments:** Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk

Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Pamela Marcus, Epidemiologist, Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, Suite 344 EPN, 6130 Executive Blvd, Bethesda, MD 20892-7354; or call non-toll free 301-496-7468; or email [pm145q@nih.gov](mailto:pm145q@nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 27, 2001.

**Reesa L. Nichols,**

*NCI Project Clearance Liaison.*

[FR Doc. 01-22352 Filed 9-5-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel.

**Date:** September 4, 2001.

**Time:** 10 am to 12 pm.

**Agenda:** To review and evaluate grant applications.

**Place:** NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Gloria B. Levin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, (301) 435-1017, [leving@csr.nih.gov](mailto:leving@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel.

**Date:** September 5, 2001.