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 855 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Persons interested in obtaining a copy of the draft guidance may also do so using the Internet.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 the 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 guidances document 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 Web 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persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by May 8, 2002. 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 The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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: October 5, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3018 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0729]

Medical Devices; Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revision to the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submission of Washers and Washer-Disinfectors.'' (63 FR 59794). The revised guidance renamed ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' will serve as a special control for medical washers and medical washer-disinfectors if they are classified into class II. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify medical washers as class II (special controls).

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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 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 brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The intent of this guidance document for class II medical washers and medical washer-disinfectors is: (1) To provide applicants specific directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical washer-disinfectors intended to clean and provide high level disinfection, and (2) to provide recommendations on information and data to be held as part of the design control record for a medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either a low or intermediate level of disinfection for medical devices. The General Hospital and Personal Use Devices Advisory Panel met on September 14, 1998, and unanimously recommended that the medical washer and washer-disinfector be classified into class II.

FDA made the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions of Washers and Washer-Disinfectors'' available for comment on November 5, 1998 (63 FR 59794). The public comment period closed February 3, 1999. FDA reviewed the comments and revised the draft guidance as appropriate. The final guidance renamed ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' replaces the November 5, 1998, draft.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical washers and medical washer-disinfectors. 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). This guidance document is issued as level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' 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 1252 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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 Web 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 guidance at any time. 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 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 24, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3020 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. *Type of Information Collection Request:* EXTENSION, OMB control number 0925–0407, expiration date October 31, 2002. *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 251,000 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. The total sample size after more than 8 years of recruitment is 154,956. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectal, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information will be used to analyze the differential effectiveness of screening in high versus low risk individuals. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Adult men and women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 150,598; *Estimated Number of Responses Per Respondent:* 1.38; *Average Burden Hours Per Response:* 0.19; and *Estimated Total Annual Burden Hours Requested:* 39,597. The annualized cost to respondents is estimated at: $395,970. 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 are invited on 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. John Gohagan, Chief, Early Detection Branch, EDCOP, National Cancer institute, NIH, EPN Building, Room 3100, 6130 Executive Boulevard, Bethesda, MD 20892–7346, or call non-toll-free number (301) 496–3982 or e-mail your request, including your address to: *jg72p@mail.nih.gov*.

Comments Due Date: Comments regarding this information collections are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 28, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02–2904 Filed 2–6–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent application listed below may be obtained by contacting Catherine Joyce, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 258; fax: