

Dated: February 28, 2002.

Julie Fishman,

Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02-5396 Filed 3-6-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0039]

Medical Devices; Draft Guidance for Industry and FDA on Premarket Notification Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA." This document provides guidance concerning the content and format of 510(k) submissions for medical sterilization packaging systems intended for the sterilization of medical devices in health care facilities. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by June 5, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5 diskette of the draft guidance entitled "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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FOR FURTHER INFORMATION CONTACT:

Chiu S. 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

Medical sterilization packaging systems encompass sterilization wrap, sterilization pouches or packages, sterilization containers, trays, cassettes, including mats, holders, or any other related component that is used for sterilization of medical devices. These devices are class II devices, regulated under 21 CFR 880.6850. The draft guidance provides advice on the kind of information and data needed to demonstrate the substantial equivalence of a medical sterilization packaging system device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA." 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 requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive the draft guidance entitled "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA" 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 (1388) 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>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by June 5, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02-5489 Filed 3-6-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects [section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13], the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: Health Care for the Homeless Program User/Visit Surveys—New

The Bureau of Primary Health Care (BPHC) of HRSA is planning to conduct User/Visit Surveys of the Health Care for Homeless Program (HCHP). The

purpose of this study is to conduct nationally representative surveys, which have the following components: (1) A personal interview survey of HCHP site users; and (2) a record-based study of visits to HCHP sites.

The HCHP is the Federal program with the sole responsibility for addressing the critical primary health care needs of homeless individuals. The HCHP is administered by the BPHC. The BPHC is interested in knowing more about the general and specific characteristics of the HCHP users and their visits to the HCHP sites. As a consequence, a personal interview survey (User Survey) will be administered to a nationally representative sample of HCHP users and a representative sample of medical visits of HCHP sites (Visit Survey) will be examined as well. These surveys are designed and intended to be primary sources of information on the health and

visits of the HCHP users. The information will provide policymakers with a better understanding of the services that HCHP users are receiving at HCHP sites and how well these sites are meeting the needs of HCHP users.

Data from the surveys will provide quantitative information on the homeless population served by the HCHP, specifically: (a) Sociodemographic characteristics, (b) health care access and utilization, (c) health status and morbidity, (d) health care experiences and risk behaviors, (e) content of medical encounters, (f) preventive care, and (g) living conditions. These surveys will provide data useful to the HCHP and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993.

The estimated burden on respondents and HCHP site staff is as follows:

Form	Number of respondents	Hours per respondent	Total hour burden
Users of HCHP Sites	1000	1	1000
Abstraction of Visit Records by HCHP Site Staff	1000	.25	250
Total	1000	1,250

Send comments to Susan Queen, Ph.D., HRSA Reports Clearance Officer, Room 11-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 4, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-5488 Filed 3-6-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meetings; Addendum

In **Federal Register** Document 01-28108, appearing on pages 56689-56690 in the issue for Friday, November 9, 2001, the following meetings for the Health Professions and Nurse Education Special Emphasis Panel have been added:

Name: Allied Health Projects.
Date and Time: April 8-11, 2002.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.
Open on: April 8, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: April 8, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 9-11, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Quentin N. Burdick Program for Rural Interdisciplinary Training.

Date and Time: April 8-11-2002.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.
Open on: April 8, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: April 8, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 9-11, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Residency Training in Primary Care.
Date and Time: April 22-25, 2002.
Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: April 22, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: April 22, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 23-25, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Physician Assistant Training in Primary Care.
Date and Time: April 22-25, 2002.
Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.
Open on: April 22, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: April 22, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 23-25, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Faculty Development Training in Primary Care.

Date and Time: April 29-May 2, 2002.
Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.
Open on: April 29, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: April 29, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 30-May 2, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Geriatric Education Centers.
Date and Time: April 29-May 2, 2002.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.
Open on: April 29, 8:00 a.m. to 10:00 a.m.
Closed on: April 29, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); April 30-May 2, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Residency Training in Primary Care.
Date and Time: May 6-9, 2002.
Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.
Open on: May 6, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: May 6, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); May 7-9, 2002, 8:00 a.m. to adjournment (approximately 6:00 p.m.).

Name: Residencies in the Practice of Pediatric Dentistry and Residencies and Advanced Education in the Practice of General Dentistry.
Date and Time: May 6-9, 2002.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.
Open on: May 6, 2002, 8:00 a.m. to 10:00 a.m.

Closed on: May 6, 2002, 10:00 a.m. to adjournment (approximately 6:00 p.m.); May