Dated: March 1, 2002.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

[FR Doc. 02–5363 Filed 3–6–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–02–29]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: National Healthcare Safety Network (NHSN)—New—National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC). In 1970, OMB first approved the information collection now known as the ''National Nosocomial Infections Surveillance (NNIS) System'' (OMB No. 0920–0012) and in 1999 approved the ''Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers'' (OMB No. 0920–0442). These two data collections have been modified and merged to create the NHSN and constitute the first phase of this national surveillance system to collect data on adverse events associated with healthcare. The NHSN will evolve with the addition of modules and healthcare institutions from a wide spectrum of settings.

The NHSN is a knowledge system for accumulating, exchanging, and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and to promote healthcare safety. Specifically, the data will be used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients with similar risks. They will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing patient risks.

Healthcare institutions that participate in NHSN voluntarily report their data to CDC through the National Electronic Disease Surveillance System that uses a web browser-based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. The cost to participating institutions is the salaries of data collector and data entry personnel, a computer capable of supporting an internet service provider (ISP), and access to an ISP. The amount expended for annual salaries will vary widely depending on the module(s) selected. Salaries will range from approximately $940.00 for collection of dialysis incident data to $3500.00 for collection of bloodstream infections data using the Device-associated Module in 2 ICUs. The table below shows the estimated annual burden in hours to collect and report data by form for the entire NHSN project. The estimated annualize cost to respondents will be $6,900.

Title	Number of respondents	Number of responses/respondent	Avg. burden per response (in hours)	Total Burden (in hours)
NHSN Application Annual Survey	350	1	1	350
Dialysis Application/Annual Survey	80	1	1	80
Patient Safety Monthly Reporting Plan	350	9	25/60	1,313
Patient Data	350	111	5/60	3,238
Surgical Site Infection (SSI)	200	27	25/60	2,250
Pneumonia (PNEU)	200	54	25/60	4,500
Primary Bloodstream Infection (BSI)	230	54	25/60	5,175
Urinary Tract Infection (UTI)	150	45	25/60	2,813
Dialysis Incident (DI)	80	90	12/60	1,440
Custom Event (not reported to CDC)	125			
Denominator for Procedure	200	540	5/60	9,000
Denominator for Specialty Care Area (SCA)	75	9	5	3,375
Denominator for Neonatal Intensive Care Unit (NICU)	100	9	4	3,600
Denominator for Intensive Care Unit (ICU)/Other locations (Not NICU or SCA)	245	18	5	22,050
Denominator for Outpatient	80	9	5/60	60
Antimicrobial Use and Resistance (AUR)—Microbiology Lab	20	45	3	2,700
Antimicrobial Use and Resistance (AUR)— Pharmacy	20	36	2	1,440
Total				63,384

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.

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.