DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0077]

Agency Emergency Processing Under OMB Review; Emergency Medical Device Shortage Program Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a telephone survey used to assist FDA in implementing an emergency medical device shortage program so that the agency can respond quickly to medical device shortages that might arise in the aftermath of a bioterrorist attack.

DATES: Submit written comments on the collection of information by April 25, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 10503, Attn: Stuart Shapiro, Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can respond quickly to medical device shortages that might arise in the aftermath of a terrorist attack.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Medical Device Shortage Program Survey

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the Commissioner of FDA is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with FDA. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical devices usage that are not foreseen or apparent during the premarket notification and review process.

FDA is compiling a list of medical devices that would be needed to treat patients in the event of a biological or chemical weapon attack. FDA plans to collect manufacturing and inventory information concerning the devices on this list, starting with those devices that are considered critical to patient care. This information will allow FDA to identify quickly sources and locations of medical devices in the event that they are needed in an emergency. It will also help to identify logistical problems in the event that borders are closed or transportation has been disrupted. In addition, FDA plans to maintain a list of telephone contacts for the manufacturers so that communication channels with manufacturers will be in place in the event that they are needed.

This telephone survey's primary respondents will be medical device manufacturers and wholesalers.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of Respondents	Annual Frequency per-Response	Total Annual Responses	Hours per Response	Total Hours
Telephone Survey	7,000	1	7,000	.1	700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has based these estimates on conversations with industry and trade association representatives, and from internal FDA estimates.

The total number of manufacturers is estimated to be 70,000. FDA estimates that approximately 10 percent of these manufacturers would be contacted in a 1-year period, due to limitations on FDA staff. It is estimated also that the survey will take approximately 6 minutes to complete over the telephone. Therefore, 7,000 respondents (10 percent of the FDA manufacturer base) times 1/10 of an hour (i.e., 6 minutes) would equal a total of 700 hours.

Dated: March 19, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information

collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Hepatitis B and C Among Health Care for the Homeless Program Clients—New

The Health Care for the Homeless Clinicians' Network (HCHCN) of the National Health Care for the Homeless Council, Inc., through a cooperative agreement with the Bureau of Primary Health Care, Health Resources and Services Administration, proposes to conduct epidemiological research regarding hepatitis B and C. The study will be of adult homeless clients and will be conducted using laboratory tests and patient interviews. The study is designed to estimate the prevalence of lifetime hepatitis B and C infection among homeless adults and the rate of comorbidity of hepatitis B and C infection, identify high-risk groups, describe health service utilization specific to hepatitis B and C, and assess patient knowledge and attitudes regarding hepatitis B and C. The participants will be recruited from eight clinics of the national Health Care for the Homeless Program.

The estimated response burden is as follows:

Respondent	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Clients	400	1	1	400

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 20, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–7181 Filed 3–25–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Support Center; Statement of Organization, Functions and Delegations of Authority

Part P (Program Support Center) of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) (60 FR 51480, October 2, 1995, and as last amended at 66 FR 58740–41, dated November 23, 2001) is being amended to reflect the following changes in Chapter PG within Part P, Program Support Center, HHS.

The changes to the above chapter establish Division-level organizations for the *Federal Occupational Health Service.*

Program Support Center

Under *Part P, Section P–20, Functions,* after the title and statement for *Chapter PG, Federal Occupational Health Service (PG)* add the following:

Office of the Director (PGA)

Provides executive direction, policy, guidance and supervision, and coordinates long- and short-range planning for the Federal Occupational Health Service (FOHS). In addition the office provides management expertise to the FOHS divisions in the areas of: fiscal controls, management information, program support services, operations support, and is responsible for FOHS' strategic planning and performance measurement. Operations consist of: (1) Evaluation and consultation of Federal managers concerning the management and delivery of the full scope of agency occupational health programs; (2) nationwide assistance in planning, implementing and monitoring health programs for Federal agencies on a reimbursable basis including improved environmental, educational, promotional, clinical, information management, and managerial services; (3) health evaluations, science and engineering assessments training, and demonstration projects; (4) developing standards and criteria; (5) promoting workforce productivity and reducing absenteeism, lost time and related Federal liability; (6) development and operation of shared services for contracting, cost comparison, analysis and program formulation; (7) maintaining relationships with health officials in other Federal agencies and private organizations; and (8) participating in Federal occupational health related policy and program development and implementation.

Division of Clinical Services (PGB)

Designs and delivers comprehensive occupational health clinical services (including wellness/fitness) throughout the Nation to assist client agencies to improve and maintain the physical health of their workforce and meet or exceed regulatory compliance standards regarding occupational health. Services are aimed at promoting healthy work and lifestyle habits and detecting and intervening in those conditions which are deleterious to wellness and productivity. Specifically: (1) Adopts standards of practice, protocols, and procedures by which clinical services are provided that meet or exceed the highest standards established by professional bodies representing appropriate clinical disciplines; (2) maintains a formal, written system of ancillary program policies to ensure that clinical services are delivered to all clients in accordance with interagency agreements, regardless of location or actual provider of service; (3) conducts periodic reviews and program audits, and uses total quality management/continuous quality improvement techniques to assure that the highest quality clinical services are delivered in a compliant, effective, efficient, and consistent manner; (4) conducts applied research, training, and demonstration projects to address clinical needs, including specific programs requested by clients; (5) designs and delivers customized programs and services including facility and workplace designs for clients with special needs; (6) develops methods for evaluation of clinical services and conducts such evaluations on request; (7) maintains clinical services information and records; and (8) assures that all clinical consultation and services have been fully reimbursed by customers.