SUPPLEMENTARY INFORMATION:

Purpose and Background

The purpose of this announcement is to add 23 additional ports to the list of United States ports at which CDC will conduct rodent infestation inspections of ships, and issue Deratting and Deratting Exemption Certificates. While the United States does not require these certificates for ships to enter its seaports, CDC currently provides rodent infestation inspections and issues Deratting and Deratting Exemption Certificates for ships at 11 major ports upon request. These ports include: Baltimore, MD; Honolulu, HI; Houston, TX; Jacksonville, FL; Los Angeles, CA; Miami, FL; New Orleans, LA; New York, NY; San Francisco, CA; Savannah, GA; and Seattle, WA. Article 17 of the International Health Regulations, published by the World Health Organization, Geneva, Switzerland, requires that each Health Administration provide these services, and Article 82 outlines the criteria for charging fees. 42 CFR 71.46 authorizes the performance of these services by PHS as carried out by CDC. For many years, CDC provided these services at no cost to the owners or agents of ships requesting them. Consistent with the practice of most foreign countries and to reduce the cost of the inspection program, beginning on October 1, 1997, CDC consolidated its inspection activities to include only the ports listed above [63 FR 17427]. Further, beginning on June 6, 1999, CDC imposed user fees for inspections conducted at the above listed ports [64 FR 24658]. Now that the cost of providing these services is being passed along as a charge to those receiving them, and in the interest of facilitating the expeditious and economical movement of ships between the United States and countries that require a Deratting or Deratting Exemption Certificate for entry into their ports, CDC published a **Federal Register** notice on September 13, 2000 [65 FR 55253], soliciting requests to add additional ports to the list at which services will be provided.

Comments Received

A small number of comments were received during the comment period. Most of the comments included a request that CDC return to the past practice of conducting rodent infestation inspections and issuing deratting exemption certificates at virtually all U.S. seaports and/or a list of ports where inspection services would be most beneficial to them. Convenience and economy were cited as reasons for the addition of ports. One municipality cited a potential economic benefit to the community if inspections were available and additional traffic attracted because of their availability. None of the comments included the estimated number of inspections for the ports requested, and few provided an estimate of cost savings to the shipping industry. This supporting information was requested in the **Federal Register** notice.

Conclusion

In deciding where to expand these services, CDC considered the information submitted by respondents, the estimated demand for services, and the availability and suitability of potential vendors.

Effective July 1, 2001, rodent infestation inspections of ships will be conducted, and Deratting and Deratting Exemption Certificates issued at the following U.S. seaports. Inspections will be conducted upon request, subject to the availability of a CDC-designated inspector. A user fee of $150 will continue to be applicable to all rodent infestation inspections conducted by CDC or its vendors.

Boston, MA
New York, NY/Northern NJ
Philadelphia, PA
Norfolk/Hampton Roads Area, VA
Charleston, SC
Savannah, GA
Brunswick, GA
Jacksonville, FL
Cape Canaveral, FL
Port Everglades, FL
Miami, FL
Tampa, FL
Panama City, FL
Pensacola, FL
Mobile, AL
Pascagoula/Gulfport, MS
New Orleans/Metarie, LA
Beaumont/Port Arthur/Orange, TX
Houston/Galveston/Texas City, TX
Corpus Christi, TX
Brownsville/Port Isabel, TX
Chicago, IL
Toledo, OH
Detroit, MI
Cleveland, OH
San Diego/Pt. Hueneme, CA
Los Angeles/Long Beach/El Segundo, CA
San Francisco Bay Area, CA
Portland, OR
Seattle, WA
Tacoma, WA
Kalama, WA
Honolulu, HI
San Juan, PR

Dated: June 19, 2001.

Thena M. Durham,

Director, Executive Secretariat, Office of the Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–15825 Filed 6–22–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State Council on Developmental Disabilities Program Performance Report.

OMB No. 0980–0172.

Description: A Developmental Disabilities Council Program Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments. Information provided in the Program performance Report will be used (1) in the preparation of the Annual Report to the President, the Congress, and the National Council on Disabilities and (2) to provide a national perspective on program accomplishments and continuing challenges.

Respondents: State, Local or Tribal Government

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Council on Developmental Disabilities Program Performance Report ..	55	1	44	2420

Estimate Total Annual Burden Hours: 2420.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and

Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Report Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collection; and (3) ways to minimize the burden of the collection information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions within 60 days of this publication.

Dated: June 19, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–15802 Filed 5–22–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0129]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Implementation of the Biomaterials Access Assurance Act of 1998

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 25, 2001.

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 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Implementation of the Biomaterials Access Assurance Act of 1998

The Biomaterials Access Assurance Act of 1998 (BAA98) (21 U.S.C. 1601–1606) establishes a mechanism to protect biomaterial suppliers of implanted medical devices from liability in civil actions. BAA98 includes exceptions for when protection from liability is not available to suppliers. One of those exceptions is when a supplier acts as a manufacturer of the implanted device. BAA98 says that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that the supplier was required to register under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and failed to do so, or was required to list its device under section 520(j) of the act (21 U.S.C. 360(j)) and failed to do so.

BAA98 allows persons to petition FDA for a declaration that a biomaterials supplier should have registered its establishment or listed its device with FDA, and failed to do so. Petitioners are requested to include information about the prerequisites for filing a petition. This information includes the following: (1) A civil suit has been filed in State or Federal court alleging that an implant directly or indirectly caused harm; (2) the suit was filed after August 13, 1998; and (3) the manufacturer of the implant was named as a party to the civil action. Petitioners are also requested to include information to identify the following: (1) The final product and how it is intended to be used, (2) the activities the supplier performs on the device, and (3) the name as well as type of entity or person to which the supplier sends the device. These draft reporting requirements are intended to provide FDA with sufficient information to show that the prerequisites for filing the petition are met and determine whether a biomaterial supplier should have registered its establishment or listed its device with FDA, and failed to do so.

In the **Federal Register** of April 2, 2001 (66 FR 17562), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5	1	5	1	5

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

BAA98 became effective August 13, 1998. Up until the current date, no petitions for declaration have been filed with FDA. However, FDA believes that in future years a handful (estimated at 5) of petitioners may file with the agency. FDA estimates that respondents would take approximately 1 hour to gather the requisite information and draft a petition. The likely respondents to this collection of information are persons involved in civil actions based on harm arising from an implanted medical device.