

Respondents	Activity	No. of respondents	No. of responses/respondent	Average burden/re-sponse (in hrs)	Total burden hours
State Health Departments	Typing and gathering of the data	16	10,000	2/60	5,333
	Transmission of the data	16	52	1	832
Total					6,165

Dated: January 22, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-1843 Filed 1-28-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Notice

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a request for information only. It is not a request for proposal and does not commit the government to issue a solicitation, make an award, or pay any costs associated with responding to this announcement. All submitted information shall remain with the government and will not be returned.

The Centers for Disease Control and Prevention (CDC), National Center for Infectious Disease (NCID), Division of Bacterial and Mycotic Diseases (DBMD) through its component Branches has lead technical responsibility for a number of Category A, B and C bioterrorism agents and their associated toxins (*Bacillus anthracis*, *Clostridium botulinum*, *Brucella* spp., *Burkholderia* spp., *Staphylococcus* enterotoxin B, other food- or waterborne bacterial pathogens, and other bacterial agents). DBMD uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent bacterial and mycotic infectious disease. The Division also conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

DBMD is seeking to evaluate commercial products, or products in development, for *in vitro* comparison of immunotherapeutic and immunoprophylactic antibody treatments for anthrax. Specifically these may include monoclonal and polyclonal antibody toxin inhibitors and

inhibitors of intracellular anthrax toxin function. CDC will coordinate the evaluation of products in a range of *in vitro* and *in vivo* models. Data obtained from this comparative analysis will be used by CDC and DHHS in making recommendations and decisions on development of an appropriate procurement strategy to meet the nation's bioterrorism defense needs.

Interested organizations that have candidate products are invited to submit documentation for CDC to assess whether the offered product(s) are at a sufficient stage of development to be included in this comparative analysis. As a minimum, submitted information should be sufficient for CDC to assess the following for each candidate product:

- Pre-clinical animal efficacy studies.
- Pre-clinical pharmacokinetic studies.
- Biochemical analysis to include:
 - Binding affinity measurements for monoclonal antibodies.
 - Animal species (if applicable).
 - Epitope or domain binding targets (if available).
 - Mass value assignment for antigen-specific antibody levels (e.g. Anti-PA specific IgG concentration).

Organizations that have products selected by CDC for this comparative analysis will be required to submit data packages with as much detail as possible for the pre-clinical studies, and to enter into an appropriate agreement prior to the transfer of any material to CDC.

Sample agreements may be viewed at the following Web site: <http://www.cdc.gov/od/ads/techtran/forms.htm>. All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552), and the Trade Secrets Act (18 U.S.C. 1905). Only information submitted by February 1, 2004, will be reviewed to determine if the offered product(s) will be acceptable for possible inclusion in this comparative analysis.

Responses are preferred in electronic format and can be e-mailed to the attention of Michael J. Detmer at MDetmer@cdc.gov. Mailed responses

can be sent to the following address: Michael J. Detmer, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE., Mail Stop C-09, Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT:

Technical: Dr. Conrad Quinn, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mail Stop D-11, Atlanta, GA 30333. Telephone (404) 639-2858, e-mail at cquinn@cdc.gov.

Business: Lisa Blake-DiSpigna, Technology Development Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mail Stop E-51, Atlanta, GA 30333. Telephone (404) 498-3262, e-mail at lblake-dispigna@cdc.gov.

Dated: January 22, 2004.

Joseph R. Carter,

Deputy Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 68 FR 62456-62459, dated November 4, 2003) is amended to reorganize the Management Analysis and Services Office, Office of the Chief Operating Officer.

Section C-B, Organization and Functions, is hereby amended as follows:

Revise the functional statement for the *Management Analysis and Services*

Office (CAJ6), *Office of the Chief Operating Officer (CAJ)*, by deleting item (1) and inserting the following: (1) Plans, coordinates, and provides CDC-wide management and information services in the following areas: policy development and consultation, studies and surveys, delegations of authorities, organizations and functions, Privacy Act, confidentiality management, records management, Paperwork Reduction Act and OMB clearance, printing procurement and reproduction, and meeting management, forms design and management, publications distribution, mail services, public inquires, information quality, and Federal advisory committee management.

Delete the functional statement for the *Office of the Director (CAJ61)* and insert the following:

Plans, directs, coordinates, and implements activities of the Management Analysis and Services Office (MASO). (1) Plans, directs, and coordinates requirements of OMB Circulars to conduct competitive sourcing activities, management review and FAIR Act activities and to determine whether certain Agency functions might be more appropriately carried out through or by commercial sources; (2) plans, develops, and implements policies and procedures in these areas, as appropriate; (3) provides forms management services, including development, coordination of clearances, and inventory management.

Delete in their entirety the title and functional statement for the *Committee Management and Program Panels Activity (CAJ62)*.

Delete in their entirety the title and functional statement for the *Management Procedures Branch (CAJ63)*.

Delete the title and functional statement for the *Management Analysis Branch (CAJ64)*, and insert the following:

Management Analysis and Policy Branch (CAJ64). (1) Provides management and oversight of CDC Federal advisory committees including the CDC-wide special emphasis panel that is the primary review mechanism for assuring scientific and programmatic review of applications and cooperative agreements for grant support and contracts; (2) provides consultation and assistance to CDC program officials on the establishment, modification, or abolishment of organizational structures and functions; reviews and analyzes organizational changes; and develops documents for approval by appropriate CDC or HHS officials; (3) coordinates IG/GAO audit activities; (4) conducts

management and operational studies for CDC to improve the effectiveness and efficiency of management and administrative systems techniques, policies, and organizational structures; (5) interprets, analyzes, and makes recommendations concerning delegations and redelegations of program and administrative authorities, and develops appropriate delegating documents; (6) manages the CDC policy issuance system to include policy development, dissemination, and advisory services; interprets HHS and other directives and assesses their impact on CDC policy, and maintains the official CDC library of administrative management policy and procedures manuals; (7) directs the agency-wide confidentiality management function to process applications for approval to collect sensitive research data in accordance with special confidentiality authorities in Sections 301(d) and 308(d) of the Public Health Service Act; (8) provides consultation and assistance to CDC program officials and staff in complying with the requirements of the Privacy Act, the Paperwork Reduction Act and OMB clearance, and accompanying guidelines and regulations; (9) plans, develops, and implements policies and procedures in these areas, as appropriate; (10) conducts a CDC-wide records management program, including provision of technical assistance in the development and conduct of electronic records management activities.

Delete the title and functional statement for the *Management Services Branch (CAJ65)* and insert the following:

Management and Information Services Branch (CAJ65). (1) Plans and conducts a publications management program, including development, production, procurement, distribution, and storage of CDC publications; (2) plans, directs, coordinates, and implements CDC-wide information distribution services and mail and messenger services, including the establishment and maintenance of mailing lists and OPS Announcements; (3) maintains liaison with contract suppliers, HHS, the Government Printing Office, and other Government agencies on matters pertaining to printing, copy preparation, reproduction, and procurement of printing; (4) manages all functions of the auditoriums at the Roybal Campus and specific meeting rooms at Roybal and other CDC campuses provides conference management support and audio-visual expertise to CIO customers; plans, develops, and implements policies and procedures in these areas, as appropriate; (5) serves as the focal

point for recommending policies and establishing procedures for matters pertaining to energy conservation of white office paper recycling; (6) receives and reviews requests received from the public or information and publications; and responds to the requests or triages them to the appropriate organization (CDC or other agencies) for action; (7) manages the CDC-wide subject matter database which serves as a resource for CIOs, call management services and hotlines within CDC; (8) manages the current food service facilities at the Roybal and Chamblee Campuses as well as future planned food service facilities; (9) responsible for the planning, coordination and management of the Conference Center located in the Scientific Communication Center on the Roybal Campus; manages the infrastructure support for functions within the Scientific Communication Center provided by a contractor; (10) manages the receipt and response to complaints by the public questioning the accuracy of any scientific information disseminated by CDC; implements established government guidelines contained in Public Law 106-554, Section 515, for ensuring the Quality of Information disseminated to the public by Government Agencies.

Dated: January 22, 2004.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04-1905 Filed 1-28-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0026]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Form FDA 3356

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed