

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.
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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:

- a. Pre-clinical animal efficacy studies.
- b. Pre-clinical pharmacokinetic studies.
- c. 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*