

Respondents	Number of respondents	Number of responses/ respondent	Average burden/re-sponse (in hours)	Total burden (in hours)
People with Arthritis (quantitative survey)	2000	1	20/60	667
People with Arthritis (qualitative data collection, ie., focus groups)	100	1	90/60	150
MDs and other health care professionals	24	1	90/60	36
Total				853

Dated: September 18, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-02-82]

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) 498-1210.

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: Human Exposure to Cyanobacterial (blue-green algal) Toxins in Drinking Water: Risk of Exposure to Microcystin from Public Water Systems (OMB. No. 0920-0527)—Extension—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background

Cyanobacteria (blue-green algae) can be found in terrestrial, fresh, brackish, or marine water environments. Some species of cyanobacteria produce toxins that may cause acute or chronic illnesses (including neurotoxicity, hepatotoxicity, and skin irritation) in humans and animals (including other mammals, fish, and birds). A number of human health effects, including gastroenteritis, respiratory effects, skin irritations, allergic responses, and liver damage, are associated with the ingestion of or contact with water containing cyanobacterial blooms. Although the balance of evidence, in conjunction with data from laboratory animal research, suggests that cyanobacterial toxins are responsible for

a range of human health effects, however, there have been few epidemiologic studies of this association. We plan to recruit 100 people whose tap water comes from a source with a current cyanobacterial bloom (*i.e.*, *M. aeruginosa*) and who report drinking unfiltered tap water. We also plan to recruit 100 people who report drinking unfiltered tap water but whose tap water source is groundwater that has not been contaminated with cyanobacteria. This population will serve as our referent population for the analysis of microcystins in blood and for the clinical assays. We will administer a questionnaire and collect blood samples from all study participants. Blood samples will be analyzed using a newly developed molecular assay for levels of microcystins—the hepatotoxin produced by *Micocystis aeruginosa*. We also will analyze blood samples for levels of liver enzymes (a biological marker of hepatotoxicity) and for a number of clinical parameters including hepatitis infection (a potential confounder in our study). We will evaluate whether we can (1) Detect low levels of microcystins (<10 ng/ml of blood), in the blood of people who are exposed to very low levels of this toxin in their drinking water, (2) utilize clinical endpoints such as blood liver enzyme levels as biomarkers of exposure and biological effect, and (3) compare the analytical results for the exposed population with the results from the referent population. There is no cost to respondents.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/re-sponse (in hours)	Total burden (in hours)
Telephone Contact	300	1	10/60	50
Survey	200	1	1	200
Tap water sample collection	200	1	30/60	100
Total				350

Dated: September 19, 2002.
Nancy E. Cheal,
Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-47-02]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written

comments should be received within 30 days of this notice.
Proposed Project: Hospital Bioterrorism Needs Assessment—New—National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC). In October-November 2001, following the reports of anthrax cases, the infection control community indicated to the Division of Healthcare Quality Promotion that there was a need for more bioterrorism-related information. A needs assessment was created and pilot tested in eight hospitals to assist DHQP in providing guidance to hospitals for preparedness and response. The needs assessment will gather information that will help the Division and other areas of CDC in evaluating CDC strategies for identifying and developing the materials and communication mechanisms that hospitals need most to adequately prepare for and respond to possible bioterrorism events in the future. The Division of Healthcare Quality Promotion has a more than 30-year history of being seen as a reliable source of information to the infection control community. Our objective is to determine the needs of hospitals so they are adequately prepared to recognize

and treat bioterrorism-related diseases and prevent further transmission of disease. This will ultimately enable them to do their jobs better, identify bioterrorism events more quickly, and prevent morbidity and mortality.
The needs assessment will assess the bioterrorism planning and preparedness, resources and communication, impact of anthrax events, surveillance for bioterrorism-related diseases, education and training, and information needs in hospitals. The data from responding hospitals will be used to develop improved methods of communication to healthcare providers and facilities, establish the best way for CDC to disseminate materials, assure disaster plans are in place, and determine what information from CDC is of greatest need to healthcare facilities.
The data collection will use web-based technology to gather information in a systematic fashion to better assist hospitals. These topics were chosen for the needs assessment by staff members of the Division of Healthcare Quality Promotion, who provided expertise to healthcare facilities after the September 11th attacks. The estimated annualized burden is 1,000 hours.

Title	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)
Bioterrorism needs assessment for healthcare facilities	4,000	1	15/60

Dated: September 19, 2002.
Nancy Cheal,
Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 1, 2002 (67 FR 49945). The

amendment is being made to reflect a change in the *Agenda* portion of the document. The meeting was originally scheduled for September 25, 26, and 27, 2002. However, due to administrative complications, the discussions on September 26 and 27, 2002, will be postponed until a later date. There are no other changes.
FOR FURTHER INFORMATION CONTACT: Kathleen Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536, for up-to-date information on this meeting.
SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 2002, FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on September 25, 26, and 27, 2002. On page 49945, in the first column, the

Agenda portion of the meeting is amended to read as follows:
Agenda: On September 25, 2002, the committee will discuss appropriate designs for clinical trials of new osteoporosis treatments.
This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.
Dated: September 23, 2002.
Linda Arey Skladany,
Senior Associate Commissioner for External Relations.
[FR Doc. 02-24561 Filed 9-23-02; 5:02 pm]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as