

1. In 1996, MACDP was still obtaining assistance from more than 10 Atlanta hospitals to conduct birth defects surveillance. Therefore, MACDP renewed its OMB approval at that time. In 1997, however, the State of Georgia exercised its option to require the reporting of birth defects under the state's disease reporting regulations, which list birth defects as a condition whose reporting is required by law. The Georgia Division of Health authorized the CDC to serve as its agent in the collection of these case reports. MACDP findings are shared with the state. Since birth defects surveillance in Atlanta is now a state requirement, the CDC is no longer requesting OMB clearance for

this activity. Therefore, the Division of Birth Defects and Pediatric Genetics is not seeking renewal of its OMB clearance for the surveillance activities involved in MACDP.

2. The BDRFS is now called the National Birth Defects Prevention Study. The major components of this study have not changed. Infants with birth defects are identified through MACDP. Control infants are selected from birth hospitals in the same population. Mothers of case and control infants are interviewed by phone about their medical history, pregnancies, environmental exposures and lifestyle. The interview still takes about 1 hour but it is now a computer-based

interview and answers are entered directly into the database instead of recorded on paper. Another change from the BDRFS is that we are no longer asking participants to come to a clinic for blood drawing. Instead of using blood to study genetic risk factors for birth defects, we will be studying DNA from cheek cells. After completing the interview, participants are sent a packet in the mail and are asked to collect cheek cells using small brushes from the mother, father, and infant. The brushes containing cheek cells are then sent back to the lab by mail. The cheek cell kits will include \$20.00 as an incentive to complete them and send them back. The cost to the respondents is \$0.00.

Forms	No. of respondents	No. of responses/re-spondents	Avg. burden/response (in hrs.)	Total Burden (in hrs.)
NBDPS case/control interview	400	1	1	400
Biologic specimen collection	1,200	2	.1666	400
Total				800

2. Case-Control Study of Lifetime Exposure to Drinking Water Disinfection By-products (DBPs) and Bladder Cancer in Pet Dogs—New—National Center for Environmental Health (NCEH). Current drinking water treatment practices in the U.S. typically include disinfection to control the pathogenic organisms responsible for waterborne diseases. Chlorine is the most commonly used chemical for drinking water disinfection; however, chlorine reacts with other drinking water contaminants

to generate compounds that may cause cancer (e.g., bladder cancer) in people. The long latency period for the development of bladder cancer and the difficulty in reconstructing water consumption and exposure history make it difficult to verify the association between DBPs exposure and bladder cancer occurrence that has been reported in human epidemiologic studies. It would be useful to have an alternative method to examine this association. We propose to conduct a

case-control study of pet dogs to test the hypothesis that consumption of water containing chlorination DBPs increases the dogs' risk for canine bladder cancer in a dose-dependent manner. Specifically, we are interested in examining the type of water disinfection treatment (chlorination, chloramination, or no disinfection) of the tap water consumed by dogs with and without bladder cancer. The total cost to respondents is \$0.00.

Respondents	No. of respondents	Responses/ respondents	Avg. burden per respondent (in hrs.)	Total burden (in hrs.)
Recruiting Project Participants	430	1	.26666	115
Telephone Interview	400	1	.08333	33
Total				148

Nancy Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-11-99]

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) 639-7090. 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

1. Evaluation of Customer Satisfaction of the Centers for Disease Control and Prevention (CDC) Internet Home Page and Links—New—CDC proposes to conduct consumer satisfaction research

around its Internet site in order to determine whether the information, services, and materials on this web-site are presented in an appropriate technological format and whether it meets the needs, wants, and preferences of visitors or "customers" to the Internet site.

Information on the site focuses on disease prevention, health promotion,

and epidemiology. The site is designed to serve the general public, persons at risk for disease, injury, and illness, and health professionals. This research will ensure that these audiences have opportunity to provide "customer feedback" regarding the value and effectiveness of the information, services, and products of the CDC web-

site and whether these materials are easy to access, clear, and informative. The initial 60 day **Federal Register** Notice was solely for the evaluation of the National Center for HIV, STD, and TB Prevention (NCHSTP) website, but has since been modified to include the entire Agency. The total annual burden hours are 30,667.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Visitors to CDC Internet Site	184,000	1	0.1

Nancy Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The 2000 FDA Science Forum—FDA and the Science of Safety: New Perspectives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Office of Science, is announcing the following meeting entitled "The 2000 FDA Science Forum—FDA and the Science of Safety: New Perspectives." The forum is devoted to the presentation and sharing of data, knowledge, and ideas among the diverse disciplines of risk management. The forum will bring FDA scientists together with industry, academia, government agencies, consumer groups, and the public to explore the scientific and practical issues related to the safety evaluation and risk management of FDA-regulated products.

Co-sponsored by FDA's Office of Science, the American Association of Pharmaceutical Scientists, FDA's Office of Women's Health, FDA's Chapter of Sigma Xi, and the Scientific Research Society.

Date and Time: The forum will be held on Monday, February 14, 2000, from 8:30 a.m. to 6 p.m., and Tuesday, February 15, 2000, from 8:30 a.m. to 5 p.m.

Location: Washington Convention Center, rms. 29 to 32 (lower level), and Hall C (upper level), 900 Ninth St. NW., Washington, DC 20001.

Contact: Susan A. Homire, Food and Drug Administration, Office of Science (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3366, e-mail "shomire@oc.fda.gov".

Registration: Registration information will be provided at a later date.

SUPPLEMENTARY INFORMATION: Speakers and panelists will address emerging issues in the safety assessment of foods, drugs, biologics, and medical devices. Plenary lectures and discussion groups will provide perspectives on the following topics: (1) Walking and Talking: The Art and Science of Risk Communication, (2) Contemporary Issues in Risk Assessment, (3) Postmarket Surveillance—Beyond Passive Surveillance, (4) The Food Safety Initiative—The Risk Perspective, (5) Risk and Gender Effects, and (6) Risk Assessment in Action.

Dated: April 26, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: The Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on May 20, 1999, 9:45 a.m. to 6:30 p.m., and May 21, 1999, 8:30 a.m. to 4:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD. 20850, 301-594-2096, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 20, 1999, the committee will discuss and make recommendations on a premarket notification submission for a qualitative in vitro diagnostic assay intended for the detection of human cytomegalovirus (CMV) deoxyribonucleic acid (DNA) in human peripheral white blood cells and its labeling. The focus of the discussion will be the appropriate use of signal amplification terminology. The committee will also discuss, make recommendations, and vote on a premarket approval application (PMA) supplement for an in vitro diagnostic target-amplified nucleic acid probe test used for the detection of *Mycobacterium tuberculosis* complex in sediments prepared from sputum (induced or expectorated), bronchial specimens, or tracheal aspirates. The device as modified is indicated for use of acid-fast bacilli (AFB) smear negative and AFB smear positive respiratory specimens for the diagnosis of active pulmonary tuberculosis disease. On May 21, 1999, the committee will discuss, make recommendations, and vote on a PMA for an in vitro diagnostic qualitative