Dated: September 28, 2001.

Nancy E. Cheal,

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

[FR Doc. 01–25073 Filed 10–4–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–50–01]

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: Human Exposure to Cyanobacterial (blue-green algal) Toxins in Drinking Water: Risk of Exposure to Microcystins from Public Water Systems—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

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, 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 cyanobacteria 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. The estimated annualized burden is 350 hours.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Telephone Contact	300	1	10/60
Survey	200	1	1
Tap Water Sample Collection	200	1	30/60

Dated: September 28, 2001.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

ICD–9–CM Coordination and Maintenance Committee Meeting

National Center for Health Statistics (NCHS), Data Policy and Standards Staff, announces the following meeting.

Name: ICD–9–CM Coordination and Maintenance Committee meeting.

Times and Dates: 9 a.m.–5 p.m., November 1–2, 2001.

Place: Centers for Medicare and Medicaid Services (CMS)(formerly The Health Care Financing Administration) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD–9–CM Coordination and Maintenance (C&M) Committee will hold its final meeting of the 2001 calendar year cycle on Thursday and Friday Nov. 1–2, 2001. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters To Be Discussed: Agenda items include:

Discussion on use of V codes for procedures
Heart failure
Aftercare codes
Vascular disease
Facial droop following CVA
Ectopic pregnancy with uterine pregnancy
Pulmonary complications of cystic fibrosis
Asthma
Severe sepsis
West Nile Virus
Paint ball injury
Abnormal pap smear
ICD–10-PCS Update
Implantation of intramuscular electrodes
Brain wafer chemotherapy
Cardiac resynchronization therapy
Implantation of neosphincter
Spinal procedures-360 fusion, Interbody Fusion Devices, InFUSE bone grafts
Repair of Aneurysm/Arteriovenous malformation
Hepatic hemodialysis
Therapeutic ultrasound
Infusion of Drotrecogin Alfa (Activated)
Adhesion barriers for abdominal surgery
Extra-corporeal immunoadsorption (ECI)
Intraoperative MRI
Administration of inhaled nitric oxide
Drug-Eluting stent
Injection or infusion of Human B-type natriuretic peptide (hBNP)
Addenda

For Further Information Contact: Amy Blum, Medical Classification Specialist, Data Policy and Standards Staff, NCHS, 6526 Belcrest Road, Room 1100, Hyattsville, Maryland 20782, telephone 301/458–4106 (diagnosis), Amy Gruber, Health Insurance Specialist, Division of Acute Care, CMS, 7500

Security Blvd., Room C4–07–07, Baltimore, Maryland, 21244 telephone 410–786–1542 (procedures).

Notice: In the interest of security, (CMS) has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room the meeting will be closed.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 1, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–25050 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Mine Safety and Health Research Advisory Committee (MSHRAC).

Time and Date: 9 a.m.–4 p.m., November 1, 2001.

Place: National Institute for Occupational Safety and Health (NIOSH), 626 Cochrans Mill Road, Building 140, Pittsburgh, Pennsylvania 15236, telephone 412/386–6602.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), section 102(b)(2).

Matters To Be Discussed: Agenda for this meeting will focus on NIOSH updates and overviews from various regional offices, international and stakeholder collaboration, and alternate fuels for mining systems.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Lewis V. Wade, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715–H, Hubert Humphrey Building, P12 Washington, DC 20201–0004, telephone 202/401–2192, fax 202/260–4464.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 1, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–25049 Filed 10–4–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0402]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/ European Community Mutual Recognition Agreement

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 extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical devices; third-party premarket submission review and quality system inspections under United States/ European Community (U.S./EC) Mutual Recognition Agreement (MRA).

DATES: Submit written or electronic comments on the collection of information by December 4, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under U.S./ EC Mutual Recognition Agreement (OMB Control No. 0910–0378)—Extension

The third-party program under the U.S./EC MRA is intended to implement that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical