

Radionuclides Rules: Lead and Copper Rule Amendment, EPA ICR No. 1896.04, OMB Control No. 2040-0204. This amendment will update burden and costs associated with the LCR and move the burden from the National Primary Drinking Water Regulations for Lead and Copper; Final Rule, EPA No. 1912.01, OMB Control No. 2040-0210, which expires September 2002, to the Disinfectants/Disinfection Byproducts, Chemical and Radionuclides Rules ICR, EPA ICR No. 1896.03, OMB Control No. 2040-0204. The Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rules ICR is the result of a consolidation of activities covered in the 1998 Stage 1 Disinfectants/Disinfection Byproduct Rule (DBPR) ICR, some rules and activities covered in the 1993 Public Water Systems Supervision (PWSS) program ICR and activities and rules previously covered in other Office of Ground Water and Drinking Water (OGWDW) standalone ICRs. As part of the consolidation effort, the Disinfectants/Disinfection, Chemical, and Radionuclides Rules ICR will be amended to include burden and costs associated with the Lead and Copper Rule. The National Primary Drinking Water Regulations (NPDWRs) for Lead and Copper (The Lead and Copper Rule or LCR), promulgated by EPA in 1991, is a regulatory program mandated by the Safe Drinking Water Act (SDWA). The LCR's goal is to reduce the levels of lead and copper at the tap to as close to the maximum contaminant level goals of 0 parts per billion (ppb) of lead and 1.3 ppb of copper as possible. To accomplish this, the LCR requires community and non-transient non-community water systems to conduct periodic monitoring to optimize corrosion control and, under specified conditions, install source water treatment, conduct public education, and/or replace lead service lines in the distribution system.

In January 2000, EPA published the Lead and Copper Rule Minor Revisions (LCRMR) which eliminated unnecessary requirements, streamlined and reduced reporting burden, and promoted consistent national implementation. The LCRMR do not affect the lead or copper rule maximum contaminant level goals, action levels, or the basic regulatory requirements. Monitoring, reporting and recordkeeping are required at both the system and State levels under the National Primary Drinking Water Regulations (NPDWRs). EPA has chosen to require the least frequent collection that remains consistent with overall public health preservation objectives. An agency may not conduct or sponsor,

and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on April 9, 2002 (67 FR 17070-17071), no comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this amendment to a collection of information is estimated to average 2.3 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Public Water Systems and Primacy Agents.

Estimated Number of Respondents: 74,587.

Frequency of Response: Bi-weekly, monthly, quarterly, annually, semi-annually, triennially, and every nine years.

Estimated Total Annual Hour Burden: 1,780,049 hours.

Estimated Total Annualized Capital, O&M Cost Burden: \$11,456,047.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 1896.04 and OMB Control No. 2040-0204 in any correspondence.

Dated: July 26, 2002.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 02-19696 Filed 8-2-02; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:30 a.m. on Tuesday, August 6, 2002, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, pursuant to sections 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of Title 5, United States Code, to consider matters relating to the Corporation's enforcement and corporate activities.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550-17th Street, NW., Washington, DC:

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at (202) 898-3742.

Dated: August 1, 2002.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 02-19811 Filed 8-1-02; 2:18 pm]

BILLING CODE 6714-01-M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011812.

Title: Contship/CMA CGM-Safmarine Space Charter Agreement.

Parties: Contship Containerlines, CMA CGM, S.A., Safmarine Containerlines N.V.

Synopsis: The proposed agreement authorizes Contship and CMA CGM to charter space to Safmarine on the service they operate between the Indian Subcontinent/Middle East and the U.S. East Coast. The parties request expedited review.

By Order of the Federal Maritime Commission.

Dated: July 30, 2002.

Bryant L. VanBrakle,
Secretary.

[FR Doc. 02-19615 Filed 8-2-02; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0330]

International Conference on Harmonisation Workshop on Gene Therapy; Public Meeting

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Public Meeting: ICH Workshop on Gene Therapy." The purpose of the meeting is to solicit input and conduct discussion on gene therapy issues regarding the development of viral vector reference materials, adenovirus shedding, and the safe use of Lentivirus vectors in clinical trials.

Date and Time: The meeting will be held on September 9, 2002, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the Sheraton Premiere Tysons Corner, McLean, VA.

Contact: Stephanie Simek, Division of Cellular and Gene Therapies (HFM-591), Food and Drug Administration, Woodmont Office Complex One, 1401 Rockville Pike, suite 380 North, Rockville, MD 20852, 301-827-5102, FAX 301-827-5397.

Registration and Request for Oral Representations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by August 26, 2002. To register electronically, please see the Pharmaceutical Research and Manufacturers of America at <http://www.phrma.org/meetings/> and register by August 16, 2002.

If you need special accommodations due to a disability, please contact Stephanie Simek at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The International Conference on Harmonisation (ICH) was organized to provide an opportunity for harmonization initiatives to be developed with input from both

regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at <http://www.ifpma.org/ich1.html>.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of gene therapy regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to participating with the international community in the development and clinical use of safer and more effective gene therapy products.

The ICH held its first workshop on Gene Therapy in Chiba Japan, May 21 through 24, 2001. The workshop was held as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for sharing information on the development of gene therapy products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

At this workshop, it was agreed that the scientific principles for the regulation of gene therapy or gene therapy products are currently harmonized in the three ICH regions. Because the field of gene therapy is extremely complex and rapidly evolving, the group suggested that an exchange of scientific expertise and experience among the ICH partners could foster prospective harmonization of technical requirements.

It was then agreed that an ICH scientific workshop would be held in conjunction with the Spring ICH Steering Committee and Expert Working Group meetings in Washington, DC.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) Development of viral vector reference standards, and (2) safe use of Lentivirus vectors in gene therapy clinical trials.

Interested persons may take part in an open discussion at two sessions during the September 9, 2002, meeting. The morning panel discussion will be between approximately 9:45 a.m. and 10:45 a.m. and will be focused on the development of viral vector reference standards. The afternoon discussion panel will be scheduled between approximately 3:40 p.m. and 4:40 p.m. and will focus on the safe use of Lentivirus vectors in gene therapy clinical trials.

The agenda for the public meeting will be made available on August 26, 2002, at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under docket number 02N-0330.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: July 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-19728 Filed 8-2-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Kidney Disease Education Program Evaluation Survey

SUMMARY: 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 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management (OMB) for review and approval.