

Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (Centers for Disease Control), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone (770) 488-2757, E-mail address: coc9@cdc.gov.

For program technical assistance, contact: Elijah West, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K-44, Atlanta, GA 30341-3724, Telephone 404-488-5549, E-mail address: ejw1@cdc.gov.

Dated: April 28, 2000.

**Henry S. Cassell, III,**

*Acting Director, Procurement and Grants Office, Center for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1220]

#### **The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH); Notice of Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use" to solicit information and receive comments on the future of the ICH. The purpose of the meeting is to solicit public input prior to the next Steering Committee meeting in Brussels, Belgium, July 2000, at which discussion of the future of the ICH will be continued.

**DATES:** The public meeting will be held on May 16, 2000, from 10 a.m. to 2 p.m. Registration must be received by May 9, 2000. Written and electronic comments regarding the public meeting must be submitted by May 20, 2000.

**ADDRESSES:** The public meeting will be held in the Center for Drug Evaluation and Research, Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Written submissions must be sent to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic submissions must be sent to the Dockets Management Branch at <http://www.fda.gov/scripts/oc/dockets/comments/commentsmain.cfm>.

#### **FOR FURTHER INFORMATION CONTACT:**

Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, FAX 301-827-6801, or e-mail: [Topperk@cder.fda.gov](mailto:Topperk@cder.fda.gov).

**Registration:** There is no registration fee for this public meeting, but registration by May 9, 2000, is required. Participation is limited to the first 140 registrants due to limited space. FDA employees are required to register to attend the meeting. Interested persons may register with the contact person via e-mail at: [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov) or fax 301-827-6801 and provide the following information: Name, affiliation, address, phone, fax, and e-mail address. Interested persons may also register by mail with the contact person (address above).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with

harmonization among the following 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 and Welfare, the Japanese Pharmaceutical Manufacturers Association, 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Therapeutics Products 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>.

The ICH will present the Common Technical Document and other significant achievements at the ICH 5 Conference in San Diego in November 2000. In preparing for this meeting, the ICH Steering Committee is evaluating the future direction for the ICH, including structure, processes, work program, and global cooperation. FDA is soliciting public input at this time to assist the agency in these deliberations.

##### **II. Issues To Be Discussed at the Public Meeting**

The issues to be discussed include the following: (1) Administrative and technical issues, (2) future participation, (3) global cooperation, and (4) new topic areas.

Interested persons may present data, information, or views, orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 9, 2000, and submit: A brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The full agenda for the public meeting will be available on May 10, 2000, at the Dockets Management Branch (address above). Requests should be identified with the Docket Number 00N-1220.

Dated: April 28, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00-11246 Filed 5-2-00; 11:30 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-452]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### Type of Information Collection

**Request:** Reinstatement, with change, of a previously approved collection; **Title of Information Collection:** Ambulatory Surgical Center Payment Rate Survey; **Form No.:** HCFA-452 (OMB# 0938-0434); **Use:** Section 1833(i)(2)(A)(i) of the Act requires that, for the purpose of estimating Medicare Part B payment amounts for ASCs, the Secretary take a survey not later than January 1, 1995, and every five years thereafter, of the audited costs incurred by ASCs, based upon a representative sample of procedures and facilities; **Frequency:** Once; **Affected Public:** Business or other for-profit, Not-for-profit institutions; **Number of Respondents:** 2,200; **Total Annual Responses:** 2,200; **Total Annual Hours:** 77,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 11, 2000.

**John P. Burke, III,**

*Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00-11134 Filed 5-3-00; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Aquatic Nuisance Species Task Force Great Lakes Panel

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a meeting of the Aquatic Nuisance Species Task Force Great Lakes Panel on Aquatic Nuisance Species. The meeting topics are identified in the **SUPPLEMENTARY INFORMATION.**

**DATES:** The Great Lakes Panel on Aquatic Nuisance Species will meet from 1:00 pm to 5:00 pm on May 10, 2000, and from 8:00 am to 12:00 noon on May 11, 2000.

**ADDRESSES:** The meeting will be held at the Holiday Inn—Downtown Waterfront, Duluth, Minnesota.

**FOR FURTHER INFORMATION CONTACT:** Sharon Gross, Executive Secretary, Aquatic Nuisance Species Task Force at 703-358-2308 or Kathe Glassner-Schwayder at 734-665-9135.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Aquatic Nuisance Species Task Force Great Lakes Panel on Aquatic

Nuisance Species. The Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (16 U.S.C. 4701-4741).

Topics to be addressed at this meeting include updates from subcommittees on information/education, research coordination and policy and legislation; review and discussion of the information/education strategy for aquatic nuisance prevention and control; review and discussion of the Great Lakes Action Plan; and discussion of current policy initiatives including reauthorization of NISA, ballast water standards, and Michigan State Ballast Water Legislation.

Minutes of the meeting will be maintained by the Executive Secretary, Aquatic Nuisance Species Task Force, Suite 851, 4401 North Fairfax Drive, Arlington, Virginia 22203-1622. Minutes for the meetings will be available at this location for public inspection during regular business hours, Monday through Friday.

Dated: April 28, 2000.

**Cathleen I. Short,**

*Aquatic Nuisance Species Task Force Co-Chair, Assistant Director—Fisheries.*

[FR Doc. 00-11091 Filed 5-3-00; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[CO-934-5700; COC62391, COC62392, COC62431]

#### Notice of Proposed Reinstatement of Terminated Oil and Gas Leases

Pursuant to the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas leases, COC62391, COC62392, and COC62431, for lands in San Miguel and Montrose counties, Colorado, were timely filed and were accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10.00 per acre, or fraction thereof, per year and 16 2/3 percent, respectively.

The lessee has paid the required \$500 administrative fee and \$125 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and Bureau of Land Management is proposing to reinstate leases