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]

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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.

Proposed Collection:

Title: National Kidney Disease Education Program Evaluation Survey.

Type of Information Collection Request: New.

Need and Use of Information Collection: NIDDK will conduct a survey to monitor and evaluate the effects of a pilot kidney disease education program. This will be accomplished through baseline and follow-up surveys of the primary target audience members, i.e. African American adults and primary care providers, in four pilot site locations. The research is designed to assess the overall impact of the program, but also to provide information that will be useful in developing and refining this and future programs.

Frequency of Response: A baseline and follow-up survey will each require a onetime response.

Affected Public: Individuals or households, clinics or doctor's offices.

Type of Respondents: African-American adults, and Primary Care Providers (e.g., physicians, physician assistants, and nurse practitioners, etc.).

The annual reporting burden is as follows:

Estimated Number of Respondents: 2,000.

Estimated Number of Responses per Respondent: 1 (Respondents will answer a single survey: African American adults will complete a 20 minute computer assisted telephone interview (CATI); Primary care providers will complete a 10 minute faxed survey.

Average Burden Hours Per Response: .298

Estimated Total Annual Burden Hours Requested: 596.

The annualized total cost of respondents' time is estimated at $10,684. All respondents will be contacted via telephone. To reduce respondent burden and overall costs of administering the study, it is expected that random digit dialing will be used to contact African American adults and telephone lists will be used to contact primary care providers. Because different program materials will be developed for each audience the questionnaires will be tailored such that respondents will be asked only target-audience pertinent questions. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
African Americans	1,600	1.0	.33	528
Primary Care Providers	400	1.0	.17	68
Total	2,000			596

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mimi Lising, Project Officer, NIDDK National Kidney Disease Education Program, NIH, Building 31, Room 9A04, Bethesda, MD 20892–2560, or call non-toll-free number (301) 496–3583 or e-mail your request, including your address, to: *lisingm@extra.niddk.nih.gov*.

Comments Due Date: Comments regarding this information are best assured of having their full effect if received within 60 days following the date of this publication.

Dated: July 17, 2002.

Barbara Merchant,

Executive Officer, NIDDK.

[FR Doc. 02–19726 Filed 8–2–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

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 Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Collection: Title: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants.

Type of Information Collection Request: EXTENSION, OMB No. 0925–0496, expiration date 10–31–2002.

Need and Use of Information Collection: The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening conducted among 9,211 male smokers from 1971 to 1983. No reduction in lung cancer mortality was observed in the MLP with an intense regimen of x-ray and sputum cytology screening. Recent analysis of updated mortality and case survival data (through 1996) suggests that lesions with little-to-no clinical relevance (over-diagnosis may have been detected through screening in the MLP intervention arm. Over-diagnosis leads to unnecessary medical interventions, including diagnostic and treatment procedures that carry with them varying degrees of risk. Consequently, over-diagnosis can result in considerable harm, including premature death, that would not have occurred in the absence of screening. The persistence, after screening ends, of an excess of lung cancer cases in the intervention arm is the strongest evidence in support of over-diagnosis, but this information cannot be adequately obtained with available MLP data. Therefore, we propose to re-contact the MLP participants and/or their next-of-kin to determine the participants who were diagnosed with lung cancer after the formal end of the Project. These data will allow the NCI to either more-convincingly state or perhaps refute the