Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and 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 (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, Health Canada, and the European Free Trade Area.

In February 2008, the ICH Steering Committee agreed that a draft guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use'' should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance provides guidance on optimizing the standard genetic toxicology battery for the prediction of potential human risks, and on interpreting the results. The ultimate goal of this guidance is to improve risk characterization for carcinogenic effects induced by changes in the genetic material. The draft guidance is intended to help facilitate drug development programs, ensure patient safety, and reduce animal usage.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: March 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08–1076 Filed 3–21–08; 3:05 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0145]

Preparation for International Conference on Harmonization Meetings in Portland, Oregon; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Meetings in Portland, Oregon'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Portland, Oregon. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Portland, Oregon, June 2–5, 2008, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on Friday April 4, 2008, from 12:30 pm to 5 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Room G and H, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 12:25 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Room G and H.

Contact Person: All participants must register with Tammie Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *Tammie.bell@fda.hhs.gov* or FAX: 301–480–0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations, to the contact person by April 3, 2008.

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

SUPPLEMENTARY INFORMATION: 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. 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 Centers for Drug Evaluation and Research and 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH

sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. 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 at the following Web site: *http://www.ich.org*.

The agenda for the public meeting will be made available via the internet at *http://www.fda.gov/cder/meeting/ICH_20080404.htm*.

One of the agenda items that will be discussed at the meeting will be the revised ICH S2 (R1) guidance. Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled ''International Conference on Harmonisation; Draft Guidance on S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; Availability.''

The revised ICH S2 Guidance proposes a new set of options for genetic toxicity testing. A primary impetus for these new testing options has been the occurrence of a high frequency of in vitro mammalian cell assay positive results and questions of the relevance of these positive results. The proposed new test battery consists of a bacterial mutation (Ames) assay followed by a choice of two options. The first option is similar to the present battery although the limit dose for the in vitro mammalian cell assays has been lowered 10-fold to 1 millimolar and the in vitro micronucleus test is introduced as an alternative for the in vitro mammalian test. The second option consists of two in vivo endpoints. The in vitro mammalian tests are not required for option 2. The first in vivo test is the micronucleus endpoint; however, the identity of the second in vivo test has been left open.

The rationale and scientific data to support the proposed changes in the revised ICH S2 Guidance will be discussed.

Specific Questions for the Public Meeting on Revised ICH S2 Guidance

1. The perceived problem with the current battery, as articulated in the new guidance, is that there are too many irrelevant (false) in vitro mammalian cell assay positive results. Are there sufficient scientific data (preferably published) that support the proposed changes in the revised guidance? Does the new battery address this issue without missing genotoxicants?

2. Most regulatory agencies use the same battery of genetic toxicology tests as described in the ICH S2A and SB Guidances. What is the rationale for having a different genetic toxicity battery to support safety determinations for pharmaceuticals, versus for other chemical substances?

3. Is it reasonable, as part of ICH Guidance, to give sponsors an option of two test batteries? Are option 1 and option 2 test batteries equivalent? When would you use one and when would you use the other?

4. FDA has put in place new recommendations (''Guidance for Industry and Review Staff Recommended Approaches to Integration of Genetic Toxicology Study Results,'' published in January 2006) concerning the interpretation of genotoxicity data (weight-of-evidence approach). Have standards and recommendations for interpretation of current genetox batteries sufficiently addressed interpretation of results to obviate the need for changing the battery itself? Supporting data would be helpful.

5. Is the lowering of the maximum concentration in the in vitro mammalian assays by an order of magnitude scientifically justified?

6. Do the changes in the ICH Guidance adequately address accuracy (which requires both sensitivity and specificity)?

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. The public oral presentations schedule can be found on the ICH public meeting agenda. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 3, 2008, 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.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08–1077 Filed 3–21–08; 3:05 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2008 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to the American Society of Addiction Medicine (ASAM).

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $500,000 (total costs) per year for up to three years to the American Society of Addiction Medicine (ASAM). This is not a formal request for applications. Assistance will be provided only to the American Society of Addiction Medicine (ASAM) based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: TI–08–014.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 509 of the Public Health Service Act, as amended.

Justification: Only the American Society of Addiction Medicine (ASAM) is eligible to apply. The Substance Abuse and Mental Health Services Administration (SAMHSA) is seeking to award a single source grant to the American Society of Addiction Medicine (ASAM) to establish a national mentoring network offering support (clinical updates, evidence-based outcomes and training) free of charge to physicians and other medical professionals in the appropriate use of methadone for the treatment of chronic pain and opioid addiction. SAMHSA is responsible for certifying over 1,000 Opioid Treatment Programs (OTPs) that use methadone and buprenorphine in the treatment of opioid addiction. This initiative will help address the nation's rise in methadone-associated deaths that has been spurred by misuse/abuse and fatal drug interactions involving methadone.

According to the National Center for Health Statistics (NCHS), methadone poisoning deaths nationwide increased 390% from 786 deaths in 1999 to 3,849 deaths in 2004, and on going data indicate that the number of deaths in many states continued to increase in 2005 and 2006. Thus, prompt and direct implementation of this cooperative agreement is necessary to help ensure public health and safety.