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of the **Federal Register**, FDA is publishing a related document entitled ''International Conference on Harmonisation; Draft Guidance on S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; Availability.''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.

To address this healthcare crisis in a timely manner, eligibility for the cooperative agreement is limited to ASAM to establish a national mentoring network and to carry out the dissemination of information and education as it relates to methadone use in the treatment of opioid addiction and chronic pain. ASAM presently provides a parallel service under a SAMHSA cooperative agreement to operate a Physician Clinical Support System (PCSS) to assist physicians with issues related to office-based treatment of opioid dependence with buprenorphine. As a result, ASAM is in the unique position to have the infrastructure and capacity in place to expeditiously meet the specific and unique needs outlined in this announcement. In addition, ASAM has demonstrated in the past (through the PCSS project) the capability to implement and achieve the goals of this program.

FOR FURTHER INFORMATION CONTACT: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1081, Rockville, MD 20857; telephone: (240) 276–2321; E-mail: *shelly.hara@samhsa.hhs.gov.*

Toian Vaughn,

SAMHSA Committee Management Officer.

[FR Doc. E8–6084 Filed 3–25–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

60-Day Notice of Information Collection Under Review: Form I–102, Application for Replacement/Initial Nonimmigrant Arrival-Departure Document; OMB Control No. 1615–0079

Agency Information Collection Activities: Form I–102, Extension of a Currently Approved Information Collection; Comment Request.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until May 27, 2008.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352, or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by e-mail add the OMB Control Number 1615–0079 in the subject box.

During this 60-day period USCIS will be evaluating whether to revise the Form I–102. Should USCIS decide to revise the Form I–102 it will advise the public when it publishes the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30-days to comment on any revisions to the Form I–102.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Application for Replacement/Initial Nonimmigrant Arrival-Departure Document.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–102. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and households. This form is used by the USCIS to determine eligibility for a waiver.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 12,195 responses at 25 minutes (.416) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 5,073 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit: *http://www.regulations.gov/search/index.jsp.*

We may also be contacted at: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529, telephone number 202–272–8377.

Dated: March 20, 2008.

Stephen Tarragon,

Acting Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. E8–6103 Filed 3–25–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0170]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0004

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) and Analysis to the Office of Management and Budget (OMB) requesting a reinstatement, with change, of a previously approved collection for which approval has expired for the following collection of information: 1625–0004, United States Coast Guard Academy Application and Supplemental Forms. Before submitting this ICR to OMB, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before May 27, 2008.

ADDRESSES: To prevent duplicate submissions to the docket [USCG–2008–0170], please submit them by only one of the following means:

(1) Online: *http://www.regulations.gov.*