for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Felix Frueh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4512, Silver Spring, MD 20993–0002, 301–796–1530; or

Raj K. Puri, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0471.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

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 drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products 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, Labour, 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 the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In October 2006, the ICH Steering Committee agreed that a draft guidance entitled ''E15 Terminology in Pharmacogenomics'' should be made available for public comment. The draft guidance is the product of the E15 Pharmacogenomics Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the E15 Pharmacogenomics Expert Working Group.

The draft guidance represents an international effort to harmonize pharmacogenomics definitions and sample coding. Inconsistent definitions make it difficult to achieve agreement on parameters for implementation of pharmacogenomics in global pharmaceutical development, and might lead to inconsistent assessments by regulators. The draft guidance contains definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. Timely harmonisation of terminology and definitions will create a common foundation for future guidance on pharmacogenomics.

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 on 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.

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: December 29, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5 Filed 1–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: GPRA Client Outcomes for the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0208)—Revision.

The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to improve the effectiveness and efficiency of substance abuse and mental health treatment and prevention services across the United States. All of SAMHSA's activities are designed to ultimately reduce the gap in the availability of substance abuse and mental health services and to improve their effectiveness and efficiency.

Data are collected from all SAMHSA discretionary services grants and contracts where client/participant outcomes are to be assessed at three points (for the Center for Substance Abuse Treatment (CSAT): Intake, discharge, and post-intake and for the Center for Substance Abuse Prevention (CSAP): pre-intervention, post-intervention, and follow-up). SAMHSA-funded projects are required to submit these data as a contingency of their award. The analysis of the data also will help determine whether the goal of reducing health and social costs of drug use to the public is being achieved.

The primary purpose of this data collection activity is to meet the reporting requirements of the Government Performance and Results Act (GPRA) by allowing SAMHSA to quantify the effects and

accomplishments of SAMHSA programs.

The burden for the Center for Mental Health Services (CMHS) will be transferred from this data collection to its own separate Office of Management and Budget (OMB) clearance. The 60-day **Federal Register** Notice for National Outcome Measures (NOMS) for Consumers Receiving Mental Health Services was published on Friday, June 9, 2006 (71 FR 33476).

The burden for the CSAP gradually reduces due to the fact that this clearance request only pertains to a continuation of data collection for those grantees initially funded prior to FY2006. The new grantees (FY2006 and beyond) are approved under the NOMS for CSAP (OMB No. 0930–0230).

CSAT has no revisions to the instrument and the data collection time will remain the same but there is an increase in the number of respondents due to identifying the seven Screening, Brief Intervention, and Referral to Treatment program grantees that provide data uploads. The estimated annual response burden for this effort is provided in the table below:

ESTIMATES OF ANNUALIZED HOUR BURDEN [1]

Center/form/respondent type	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Added burden proportion [2]	Total annual burden hours
CSAP GPRA Participant Outcome Measures for Discretionary Programs							
Participants:							
FY2007	7,000	3	21,000	.33	6,930	.72	4,990
FY2008	3,000	3	9,000	.33	2,970	.72	2,138
CSAP Subtotal	10,000	3	30,000	.33	9,900	.72	7,128
CSAP Annualized Subtotal	5,000		15,000				3,564
CSAT GPRA Client Outcome Measures for Discretionary Programs							
Clients							
Adults	28,000	3	84,000	.33	27,720	.33	9,148
Adolescents	3,900	4	15,600	.33	5,148	.33	1,699
Screening, Brief Intervention and Referral to Treatment (SBIRT): [3]							
Screening Only	150,618	1	150,618	.10	15,062	0	0
Brief Intervention	27,679	3	83,037	.16	13,286	0	0
Brief Tx & Referral to Tx	9,200	3	27,600	.33	9,108	.33	3,006
SBIRT Client Subtotal	187,497		261,255		37,456		3,006
Client Subtotal	219,397		360,855				13,853
Data Extract by Grants: [4]							
Adult Records	400 grants	70 × 3	210	.16	34		34
Adolescent Records	73 grants	53 × 4	212	.16	34		34
Screening, Brief Intervention and Referral to Tx (SBIRT) Records:							
Screening Only	7 grants	21,517 × 1	21,517	.05	1,076		1,076
Brief Intervention	7 grants	3,954 × 3	11,862	.08	949		949
Brief Tx & Referral to Tx	7 grants	1,314 × 3	3,942	.16	631		631
Data Extract Subtotal	480		37,743				2,724
Upload [5]	5 grants		171,639	1 hr. per 6,000 records	29		29
Upload Subtotal	5 grants		171,639				29
CSAT Subtotal	219,896		570,237				16,606
TOTAL	224,896		585,237				20,170

NOTES:

1. This table represents the maximum additional burden if adult respondents provide three sets of responses/data and if CSAT adolescent respondents provide four sets of responses/data.

2. Added burden proportion is an adjustment reflecting customary and usual business practices programs engage in (e.g., they already collect the data items).

3. Screening, Brief Intervention, Treatment and Referral (SBIRT) grant program:
• 150,618 Screening Only (SO) respondents complete section A of the GPRA instrument, all of these items are asked during a customary and usual intake process resulting in zero burden; and
• 27,679 Brief Intervention (BI) respondents complete sections A & B of the GPRA instrument, all of these items are asked during a customary and usual intake process resulting in zero burden; and
• 9,200 Brief Treatment (BT) & Referral to Treatment (RT) respondents complete all sections of the GPRA instrument.
4. Data Extract by Grants: Grant burden for capturing customary and usual data.
5. Upload: 5 of the 7 SBIRT grants upload data; the other 2 grants conduct direct data entry.
6. Estimate based on $5.15 for program staff and $15 for IT staff.

Written comments and recommendations concerning the proposed information collection should be sent by February 5, 2007 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: December 22, 2006.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E6–22576 Filed 1–5–07; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

[USCG–2006–24685]

Long Range Aids to Navigation (LORAN) Program; Office of Navigation and Spectrum Management

AGENCY: Coast Guard, DHS, Office of the Secretary, DOT.

ACTION: Notice; request for public comments.

SUMMARY: The Department of Transportation in coordination with the Department of Homeland Security is considering the need to continue to operate or invest in the North American LORAN–C Radionavigation System beyond fiscal year 2007. Future investment decisions might include: Decommissioning the LORAN–C system, maintaining the LORAN–C system as currently configured, or developing a fully deployed Enhanced LORAN (eLORAN) system. Contributing factors to these decisions are (1) whether the Global Positioning System (GPS) and other available back-up systems are adequate for the public's navigation and timing needs, thus making the LORAN–C system redundant, and (2) whether the eLORAN investments made to date provide enhancements that now merit consideration as a complementary capability to GPS, and not merely as a GPS back-up. The Department of Transportation and the Department of Homeland Security seek public input on the various decisions currently under consideration. For more information on LORAN, you may visit *http://www.navcen.uscg.gov.*

DATES: Comments and related material must reach the Docket Management Facility on or before February 7, 2007.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2006–24685 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Web Site: http://dms.dot.gov.*

(2) *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(3) *Fax:* 202–493–2251.

(4) *Delivery:* Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call Mr. Greg Wheeler, Department of Transportation, Office of Navigation and Spectrum Policy, 202–366–4894, e-mail *Greg.Wheeler@dot.gov* or LT Michael Herring, Project Officer, Office of Navigation Systems, Coast Guard, telephone 202–372–1561, e-mail *Michael.L.Herring@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

You may obtain a copy of this notice by calling the U.S. Coast Guard Infoline at 1–800–368–5647 or read it on the Internet on the Coast Guard Navigation Center Web site at *http://www.navcen.uscg.gov* or at *http://dms.dot.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this notice (USCG–2006–24685) and give the reason for each comment. You may submit your comments by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period.

Viewing comments and documents: To view comments, go to *http://dms.dot.gov* at any time, click on ''Simple Search,'' enter the last five digits of the docket number for this notice, and click on ''Search.'' You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Background and Purpose

The North American LORAN–C system is a low frequency hyperbolic radionavigation system. It is approved for use in the U.S. Coastal Confluence Zone (CCZ) and as a supplemental air navigation aid. More information about LORAN–C is available at: *http://www.navcen.uscg.gov/loran/default.htm.*