Fishers Lane, Rockville, MD 20857, 301–827–6430.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. In most cases to date, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some drug effects also may be difficult to detect in clinical trial or during routine postmarketing surveillance.

The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It describes how juvenile animal studies can be useful in monitoring, timing, and phasing of trials for initial enrollment in pediatric clinical studies. The draft guidance is intended to serve as a resource for general considerations in animal testing and to provide recommendations based on the available science and pragmatic considerations. The scope of animal studies is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Managment Branch between 9 a.m. and 4 p.m., Monday through Friday.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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2376 Filed 1–31–03; 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: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: SAMHSA/HRSA Collaboration to Link Health Care for the Homeless Programs and Community Mental Health Agencies—(New)—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS); the Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC); and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) propose to conduct a longitudinal, multi-site evaluation assessing their initiative to foster collaborations between Health Care for the Homeless programs (HCH) and community mental health agencies (CMHA). In 12 designated communities, an HCH site and a CMHA site will collaborate to increase the availability of mental health and primary care services for persons with serious mental illness and co-occurring substance use disorders who are homeless. The evaluation of these collaborative efforts will advance knowledge on elements of the implementation process associated with establishment of a successful collaboration, such as partnering mechanisms, success of referral links, intensity of services, the effects of collaboration on client outcomes, and plans for sustainability.

Data collection will be conducted over a 30-month period. In each community, both a process and an outcome evaluation will be conducted to address the following questions: How is the project being implemented? What are the identified collaboration mechanisms? What are the service/agency level outcomes? What are the system-level outcomes? What are the client-level outcomes? To what extent do the various collaboration strategies predict outcomes?

To reduce burden and increase uniformity across the study sites, a common case study protocol will be used to guide the evaluation. Information for the service/agency and system level evaluations will be collected by staff from the central Evaluation Center (EC) during annual site visits and through activity logs. Common site visit protocols will dictate what data collection methods will be used. Site visitors will rely on focus groups and interviews to obtain information from project directors, local evaluators, project staff, and clients. Activity logs monitoring each community's efforts to implement collaboration strategies, will be completed by program administrators and submitted to the EC quarterly. Key outcomes to be examined at the service/agency level through these data collection methods include increased availability of mental health, substance abuse, specialty care, housing and services; increased access to primary care, mental health, and substance abuse services; more comprehensive assessment of and services for individual needs; increased integrated delivery of services; and increased engagement and retention in services. System-level outcomes to be examined include increased cross-agency activity;

increased mental health capacity at Hch sites; less redundancy in data collection; and enhanced screening for multi-dimensional issues.

The estimated response burden for this project is as follows:

Instrument	Number of responses	Responses/ respondent	Burden/response (Hrs.)	Total burden hours
Administrative Interviews	24	3	1.5	108
Evaluator Interviews	12	3	1.0	36
Line Staff Interviews	48	3	1.0	144
Consumer Focus Groups	84	3	1.0	252
Other Key Informants	48	3	1.0	144
Activity Logs	12	10	2.0	240
Total	228	.....	.....	924
3-yr. Annual Average	228	.....	.....	308

A total of approximately 6,500 program participants are expected to be recruited from the 12 sites. Each site will collect GPRA data on these participants using the CMHS GPRA Core Client Outcome measures approved by the Office of Management and Budget under control number 0930–0208, which cover such domains as drug and alcohol use, family and living conditions, education, employment, and income, crime and criminal justice status, and mental and physical health problems and treatment. To obtain information on client-level outcomes the central Evaluation Center will work with each site to develop methods for obtaining relevant material from the GPRA data. It is expected that client-level data will be submitted to the Evaluation Center via electronic means. The Evaluation Center will provide training and technical assistance to all sites on data submission procedures.

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 27, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–2392 Filed 1–31–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at the following websites: *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–6870, (Formerly: Jewish Hospital of Cincinnati, Inc.).

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866 / 800–433–2750.

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917.

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652 / 417–269–3093, (Formerly: Cox Medical Centers).

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200 / 800–735–5416.