FY 2013 ANNUAL REPORTING BURDEN

| Data collection activity | Number of respondents [1] | Responses per respondent [2] | Total responses | Average hours per response | Total hour burden |
|---|---|---|---|---|---|
| Semi-Annual Progress report | 12 | 2 | 24 | 15 | 360 |
| Overall Total | 12 | | 24 | | 360 |

[1] The respondents are the States.
[2] The Project Director for each Grantee is responsible for compiling and submitting the SAPR.

ANNUALIZED REPORTING BURDEN

| Data collection activity | Annualized number of respondents | Annualized total responses | Annualized total hour burden |
|---|---|---|---|
| Semi-Annual Progress Report | 12 | 21 | 315 |

Written comments and recommendations concerning the proposed information collection should be sent by January 4, 2010 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: 202–395–5806.

Dated: November 25, 2009.

**Elaine Parry,**

*Director, Office of Program Services.*

[FR Doc. E9–28953 Filed 12–3–09; 8:45 am]

**BILLING CODE 4162–20–P**

## 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: 2010 National Mental Health Services Survey (N–MHSS) (OMB No. 0930–0119)—Revision**

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) will conduct the 2010 N–MHSS. This national survey will update the previous biennial mental health facility survey conducted in 2008—the National Survey of Mental Health Treatment Facilities (NSMHTF) under OMB No. 0930–0119. Similar in design to the 2008 NSMHTF, the 2010 N–MHSS will survey all mental health service locations, instead of surveying each mental health organization as a whole. These separate mental health service locations (facilities) are in contrast to mental health organizations which may include multiple facilities (service locations). This survey will be (a) a 100-percent enumeration of all known facilities nationwide that specialize in mental health treatment services, (b) more consumer-oriented in describing services available at each facility location, and (c) patterned after SAMHSA's Office of Applied Studies National Survey of Substance Abuse Treatment Services (OMB No. 0930–0106).

The 2010 N–MHSS will utilize one questionnaire for all mental health facility types including hospitals, residential treatment centers, outpatient clinics, and multi-setting facilities. The information collected will include: intake telephone numbers for services, types of services offered, sources of payment for services, facility caseload characteristics, and facility bed counts, if applicable. This survey will use a multi-mode approach to data collection—mail and web with telephone follow up.

The resulting database will be used to provide both state and national estimates of facility types and their patient caseloads. Information from the 2010 survey will also be used to update SAMHSA's online Mental Health Facility Locator for use by consumers. In addition, data derived from the survey will be published by CMHS in SAMHSA publications such as *Mental Health, United States* and in professional journals such as *Psychiatric Services and the American Journal of Psychiatry.* The publication, *Mental Health, United States,* is used by the general public, State governments, the U.S. Congress, university researchers, mental health service providers, and mental health care professionals. The following Table summarizes the estimated response burden for the survey.

ESTIMATED TOTAL RESPONSE BURDEN FOR THE 2010 N MHSS

| Facility type | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hour burden |
|---|---|---|---|---|---|
| Public Psychiatric Hospitals | 305 | 1 | 305 | 1 | 305 |
| Private Psychiatric Hospitals | 536 | 1 | 536 | 1 | 536 |
| General Hospitals with Separate Psychiatric Units | 1,719 | 1 | 1,719 | 1 | 1,719 |
| Residential Treatment Centers for Adults | 833 | 1 | 833 | 1 | 833 |
| Residential Treatment Centers for Children | 1,191 | 1 | 1,191 | 1 | 1,191 |

ESTIMATED TOTAL RESPONSE BURDEN FOR THE 2010 N MHSS—Continued

| Facility type | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hour burden |
|---|---|---|---|---|---|
| Outpatient Clinics (including Hospital-Based) | 6,292 | 1 | 6,292 | 1 | 6,292 |
| Multi-Setting Community Facilities | 2,124 | 1 | 2,124 | 1 | 2,124 |
| Total | 13,000 | | 13,000 | | 13,000 |

Written comments and recommendations concerning the proposed information collection should be sent by January 4, 2010 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: 202–395–5806.

Dated: November 25, 2009.

**Elaine Parry,**

*Director, Office of Program Services.*

[FR Doc. E9–28950 Filed 12–3–09; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0539]**

### Draft Guidance for Industry on Assay Development for Immunogenicity Testing of Therapeutic Proteins; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Assay Development for Immunogenicity Testing of Therapeutic Proteins.'' The draft guidance provides recommendations to facilitate industry's development of immune assays for assessment of the immunogenicity of therapeutic proteins during clinical trials.

**DATES:** Submit written or electronic comments on the draft guidance by February 2, 2010. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Susan Kirshner, Center for Drug Evaluation and Research (HFD–122), Food and Drug Administration, 8800 Rockville Pike, Bldg. N29A, rm. 2D16, Bethesda, MD 20892, 301–827–1731; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assay Development for Immunogenicity Testing of Therapeutic Proteins.'' This guidance was created by a working group that consisted of staff from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Because clinicians rely on the observed immunogenicity rates listed in the ''Immunogenicity'' section of drug labeling, development of validated, sensitive immune assays is critical to patient care. This guidance discusses immunogenicity testing during drug product development and provides recommendations on assay development, clinical aspects of assay validation, assay validation, assay testing implementation, and other aspects of immunogenicity testing.

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 the development of immune assays for assessment of the immunogenicity of therapeutic proteins during clinical trials. 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 this document. 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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: December 1, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–28960 Filed 12–3–09; 8:45 am]

**BILLING CODE 4160–01–S**