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Draft Guidance for Industry on Assay Development for Immunogenicity Testing of Therapeutic Proteins; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Assay Development for Immunogenicity Testing of Therapeutic Proteins.'' The draft guidance provides recommendations to facilitate industry's development of immune assays for assessment of the immunogenicity of therapeutic proteins during clinical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DATES: Submit written or electronic comments on the draft guidance by February 2, 2010.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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