collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Reports Clearance Officer.

[FR Doc. 2012–30686 Filed 12–19–12; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0482]

Guidances for Industry and Investigators on Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies, and a Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' and ''Safety Reporting Requirements for INDs and BA/BE Studies—Small Entity Compliance Guide.'' These guidances are intended to help sponsors and investigators comply with the requirements in the final rule entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans,'' published in the **Federal Register** on September 29, 2010 (75 FR 59935). FDA has prepared the Small Entity Compliance Guide in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses understand and comply with the regulations issued by FDA concerning safety reporting requirements for investigational new drug applications (IND) and bioavailability (BA) and bioequivalence (BE) studies.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances to the Office of Communications, 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; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

Submit electronic comments on the guidances to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephanie Shapley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6352, Silver Spring, MD 20993–0002, 301–796–4836; 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 two guidances for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' and ''Safety Reporting Requirements for INDs and BA/BE Studies—Small Entity Compliance Guide.'' These guidances are intended to help sponsors and investigators comply with the requirements for IND safety reporting and safety reporting for BA and BE studies. In addition, the Small Entity Compliance Guide is intended to help small businesses understand and comply with the regulations issued by FDA concerning the safety reporting requirements for INDs and BA/BE studies. FDA has prepared the Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act.

On September 29, 2010, FDA published a final rule amending the IND safety reporting requirements under 21 CFR part 312 and adding safety reporting requirements for persons conducting BA and BE studies under 21 CFR part 320. The requirements in the final rule are intended to improve the utility and quality of safety reports, expedite and strengthen FDA's ability to review critical safety information, and better protect human subjects enrolled in clinical trials. FDA also published a draft guidance entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' on September 29, 2010 (75 FR 60129), and the public was provided with an opportunity to comment on it until December 28, 2010. FDA carefully considered all of the comments received in developing the final guidance. The final guidance includes clarifications and additional detail regarding the draft guidance topics as well additional information on safety reporting issues raised in the comments.

The final guidance entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' contains the definitions used for IND safety reporting, makes recommendations on when and how to submit a safety report, and provides advice on other safety reporting issues that have generated questions from sponsors and investigators.

The Small Entity Compliance Guide provides answers to many frequently asked questions FDA has received from investigators and sponsors regarding the safety reporting requirements that are applicable to small entities.

In addition, on June 7, 2011, the Agency published a guidance describing enforcement discretion with the reporting requirements until September 28, 2011, to allow sponsors additional time to make process changes to implement the final rule (76 FR 32863; June 7, 2011). At this time, the Agency is withdrawing this guidance.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on safety reporting requirements for IND and BA/BE studies. They do not create or confer any rights for or on any person and do 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 either written comments regarding these documents to the Division of Dockets

Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

These guidances refer to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in these guidances have been approved under OMB control number 0910–0672.

IV. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: December 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30651 Filed 12–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at 301–443–1984.

Information Collection Request Title: National Health Service Corps Travel Request Worksheet (OMB No. 0915–0278)—Revision

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program use the online Travel Request Worksheet to request travel funds from the Federal Government to perform pre-employment interviews at sites on the NHSC's Opportunities List. The travel approval process is initiated when a scholar notifies the NHSC of an impending interview at one or more NHSC approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar has successfully been matched to an approved practice site. Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Scholar Travel Request Worksheet	180	2	360	.0667	24
Total	180	2	360	.0667	24

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: December 14, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–30690 Filed 12–19–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0052]

Agency Information Collection Activities: Application for Naturalization, Form Number N–400; Revision of a Currently Approved Collection

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.