Submit electronic comments on the guidance 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: Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5170, Silver Spring, MD 20993–0002, 301–796–8345.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled, ''Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators.'' This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators. This guidance provides FDA's responses to the most frequently asked questions regarding financial disclosure by clinical investigators.

This guidance also responds to recommendations made by the Office of the Inspector General (OIG), Department of Health and Human Services, in their report entitled ''The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information.'' [1] The OIG's recommendations were intended to strengthen FDA's oversight and review of clinical investigators' financial disclosures. Specifically, the guidance describes: (1) The sponsor's responsibility to collect the financial disclosure information prior to an investigator participating in a study and ensure that all required forms and attachments are submitted in marketing applications, (2) what is meant by ''due diligence'' in obtaining financial disclosures from investigators, and (3) how FDA will review financial disclosure information. FDA also reiterates its policy on public release of individual clinical investigator financial disclosure information and states its intention to provide summary information about clinical investigator financial interests/arrangements in the new product reviews FDA posts for an approval decision.

In the **Federal Register** of May 24, 2011 (76 FR 30175), FDA announced the availability of the draft guidance of the same title dated May 2011. FDA received several comments on the draft guidance, and those comments were considered in preparing the final guidance. Changes include: Clarifications related to the terms ''due diligence,'' ''covered clinical study,'' and ''material support;'' identification of a dependent child for purposes of part 54; and explanation of FDA's review of clinical investigator financial disclosure information. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 2011 and replaces the guidance entitled, ''Guidance for Industry: Financial Disclosure by Clinical Investigators,'' dated March 2001.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995

This guidance refers 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 21 CFR parts 54, 312, and 812 have been approved under OMB control numbers 0910–0396, 0910–0014, and 0910–0078.

III. Comments

Interested persons may submit either electronic regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm* or *http://www.regulations.gov.*

[1] OIG report OEI–05–07–00730 available at *https://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register.**)

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04386 Filed 2–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0487]

Guidance for Industry: Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma'' dated February 2013. The guidance document recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.2 dated September 2012, as an acceptable mechanism that is consistent with FDA's requirements and recommendations for collecting Source Plasma donor history information. The Plasma Protein Therapeutics Association (PPTA) Source Plasma donor history questionnaires and accompanying materials (SPDHQ documents) will provide blood establishments that collect Source Plasma with a specific process for administering questions to Source Plasma donors to determine their eligibility to donate. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2011.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests.

The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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: Tami Belouin, 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 document entitled ''Guidance for Industry: Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma'' dated February 2013. The guidance document recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.2 dated September 2012, prepared by the PPTA, as an acceptable mechanism that is consistent with FDA's requirements and recommendations for collecting Source Plasma donor history information. The SPDHQ documents will provide blood establishments that collect Source Plasma with a specific process for administering questions to Source Plasma donors to determine their eligibility to donate. The guidance also advises Source Plasma manufacturers who choose to implement the acceptable SPDHQ documents on how to report the manufacturing change consisting of the implementation of the SPDHQ under 21 CFR 601.12.

In the **Federal Register** of July 22, 2011 (76 FR 44013), FDA announced the availability of the draft guidance of the same title dated July 2011. FDA received no comments on the draft guidance. A summary of changes includes: Referencing the most current version of the acceptable SPDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and making a few editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995

This guidance refers 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 21 CFR 601.12 have been approved under OMB control number 0910–0338 and the collections of information in 21 CFR 640.63 have been approved under OMB control number 0910–0116.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see ADDRESSES). 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.*

IV. Electronic Access

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

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04384 Filed 2–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Seventh Annual Drug Information Association/Food and Drug Administration Statistics Forum—2013; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the Drug Information Association (DIA), is announcing a public conference entitled ''Seventh Annual DIA/FDA Statistics Forum—2013.'' The purpose of the conference is to discuss relevant statistical issues associated with the development and review of therapeutic drugs and biologics. This meeting is intended to be an open forum for the timely discussion of topics of mutual theoretical and practical interest to statisticians and clinical investigators who are involved in the development of new drugs and biologics. A primary focus for this meeting will be to establish an ongoing dialogue regarding FDA's ''Critical Path'' initiative—emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data and measuring the progress being made in designing and implementing innovative solutions.

DATES: The public conference will be held on April 28, 2013, to May 1, 2013, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public conference will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852, 1–301–822–9200.

FOR FURTHER INFORMATION CONTACT:

Constance Burnett, Drug Information Association, 800 Enterprise Rd., Horsham, PA 19044, 1–215–293–5800, email: *Constance.Burnett@diahome.org;* or

Stephen Wilson, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0579, email: *Stephen.Wilson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This annual FDA/DIA statistics forum will establish a unique, open, international forum for statisticians and clinicians from industry, academia, contract research organizations, and