DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 28, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Paul E. Levine, Jr., 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 document entitled, ''Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated March 2013. The draft guidance document provides revised recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The recommendations described in the document are for blood establishments that use either non-treponemal or treponemal screening assays to test donors for serological evidence of syphilis infection.

In the **Federal Register** of June 26, 2003 (68 FR 38083), FDA announced the availability of the draft guidance entitled, ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis,'' dated June 2003. The draft guidance announced in this notice replaces the 2003 draft guidance and when finalized, is intended to supersede the FDA memorandum to all registered blood establishments dated December 12, 1991, entitled, ''Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.''

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 630.6 and 606.160 have been approved under OMB control number 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: February 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04281 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–1999–D–0742] (formerly 1999D–4396)

Guidance for Clinical Investigators, Industry, and Food and Drug Administration Staff: Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance 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. The guidance announced in this notice finalizes the draft guidance of the same title dated May 2011 and replaces the guidance entitled, ''Guidance for Industry: Financial Disclosure by Clinical Investigators,'' dated March 2001.

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 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 (1–888–463–6332 or 301–796–3400), 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 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. 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: 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]

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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.