(6) Federal contractors cannot use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

You can use Federal facilities (e.g., laboratories) or speak with Federal employees during the contest only if those same Federal facilities and employees are equally available to everyone participating in the contest (for example, such availability could be announced on a public Web site).

If laboratory work is required to support your submission, all work should be performed under appropriate biosafety level 2 (BSL2) conditions, and in accordance with standard precautions for the handling and processing of clinical specimens.

By participating in this contest, contestants agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this contest, contestants agree to indemnify the Federal Government against third party claims for damages arising from or related to contest activities.

Contestants warrant that their submissions are wholly original and do not infringe upon any rights of any third party of which Contestants are aware.

Registration Process for Participants: All participants for the Culture-Independent Straintyping and Characterization Challenge must register before submitting a proposal. Registration instructions are available at *http://www.cdc.gov/amd/cidtchallenge.* Deadline for registration is October 1, 2014.

Additional Information: More information on or about CDC's Advanced Molecular Detection and Response to Outbreaks of Infectious Diseases initiative can be found at: *www.cdc.gov/amd.*

Regarding Copyright/Intellectual Property: When you submit your entry, you must certify that you are the person who developed the submission and that you maintain intellectual property rights to the process and solution that you propose. You also must ensure that you did not use any copyrighted material or affect the rights of any third party to the best of your knowledge.

Submission Rights: Once you submit your solution, you give HHS/CDC permission to review and evaluate your submission, and to post and share information about your solution in the context of the contest, its participants and its awardee. You cannot take this permission back or ask us for money to use your submission for these purposes. You can, however, give other people permission to use your method or solution to this challenge while the contest is ongoing, and may keep all other intellectual property rights to your solution and your work.

Compliance With Rules and Contacting Contest Winners: In order to win the contest, you must meet all terms and conditions of these Official Rules. You can be named a winner only if you meet all the requirements. We will contact the winner using the contact information provided (by email, telephone, or mail after the date of the judging). You may need to pay Federal income taxes on any prize money. The Department of Health and Human Services will follow the Internal Revenue Service withholding and reporting requirements, where applicable.

Privacy: If you provide personal information to use when you register for the contest at the Challenge.gov Web site, we will use that information to contact you about your entry, and to announce updates and the final contest winner. We will not use the information for commercial marketing.

General Conditions: HHS/CDC can cancel, suspend, or change the contest, or any part of it, for any reason.

Dated: August 22, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–20428 Filed 8–27–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0128 (Legacy ID: FDA–2003D–0236)]

Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; 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: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated September 2014. The guidance document provides recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The guidance is intended for blood establishments that collect Whole Blood or blood components, including Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title, dated March 2013 (2013 draft guidance), and supersedes the memorandum of December 12, 1991, entitled ''Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.''

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, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. 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 240–402–7800. 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: Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 September 2014. The guidance document provides 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 nontreponemal or treponemal screening assays to test donors for serological evidence of syphilis infection.

In the **Federal Register** of February 26, 2013 (78 FR 13069), FDA announced the availability of the 2013 draft guidance. FDA received several comments on the 2013 draft guidance and those comments were considered as the guidance was finalized. In summary, FDA modified the recommendations provided in the 2013 draft guidance concerning the use of an FDA-cleared nontreponemal donor screening assay to test donations from reentered donors. In addition, FDA made editorial changes to recommendations in the guidance to improve clarity. The guidance announced in this notice finalizes the 2013 draft guidance.

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 requirement 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 21 CFR 606.121, 606.160, 610.40, 630.6, 640.3, 640.65, and 640.71 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: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20483 Filed 8–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1177]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Electronic Exchange of Documents: File Format Recommendations; 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 (GFI #225) entitled ''Draft Guidance for Industry, Electronic Exchange of Documents: File Format Recommendations'' (VICH GL53). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance is intended to provide recommendations to industry on electronic file format specifications for individual documents and collections of multiple related documents that need no subsequent editing and are utilized for electronic exchange between industry and regulators in the context of regulatory approval of veterinary medicinal products.

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 October 27, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Scott Fontana, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0656, *Scott.Fontana@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #225) entitled ''Draft Guidance for Industry, Electronic Exchange of Documents: File Format Recommendations'' (VICH GL53). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission;