

set of principles and related requirements that have been deemed by the European Commission as providing “adequate” privacy protection. These principles include notice, choice, onward transfer, security, data integrity, access, and enforcement. Commerce maintains a public Web site, www.export.gov/safeharbor, where it posts the names of companies that have self-certified to the Safe Harbor framework. The listing of companies indicates whether their self-certification is “current” or “not current.” Companies are required to re-certify every year in order to retain their status as “current” members of the Safe Harbor framework.

Fantage developed and operates a massively multiplayer online role-playing game directed at children ages 6–16. According to the Commission’s complaint, since June 2011, except for a one-month period from November to December 2013, Fantage set forth on its Web site, www.fantage.com, privacy policies and statements about its practices, including statements related to its participation in the U.S.-EU Safe Harbor Framework.

The Commission’s complaint alleges that Fantage falsely represented that it was a “current” participant in the U.S.-EU Safe Harbor Framework when, in fact, from June 2012 until January 2014, Fantage was not a “current” participant in the Safe Harbor Framework. The Commission’s complaint alleges that in June 2011, Fantage submitted a Safe Harbor self-certification. Fantage did not renew its self-certification in June 2012 and Commerce subsequently updated Fantage’s status to “not current” on its public Web site. In January 2014, Fantage renewed its self-certification to the Safe Harbor Framework, and its status was changed to “current” on Commerce’s Web site.

Part I of the proposed order prohibits Fantage from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the U.S.-EU Safe Harbor Framework.

Parts II through VI of the proposed order are reporting and compliance provisions. Part II requires Fantage to retain documents relating to its compliance with the order for a five-year period. Part III requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part IV ensures notification to the FTC of changes in corporate status. Part V mandates that Fantage submit an initial compliance

report to the FTC, and make available to the FTC subsequent reports. Part VI is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed complaint or order or to modify the order’s terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0797]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Human Tissue Intended for Transplantation” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, PRASaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 20, 2013, the Agency submitted a proposed collection of information entitled “Human Tissue Intended for Transplantation” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0302. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0103]

Draft Guidance for Industry on Analytical Procedures and Methods Validation for Drugs and Biologics; 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 “Analytical Procedures and Methods Validation for Drugs and Biologics.” This revised draft guidance supersedes the 2000 draft guidance for industry on “Analytical Procedures and Methods Validation” and, when finalized, will also replace the 1987 FDA guidance for industry on “Submitting Samples and Analytical Data for Methods Validation.” This draft guidance discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug 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 May 20, 2014.

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; or to 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 draft guidance document.

Submit electronic comments on the draft guidance to <http://>