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.

[FR Doc. 2014–03532 Filed 2–18–14; 8:45 am]

BILLING CODE 6750–01–P

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, *PRAStaff@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.

[FR Doc. 2014–03502 Filed 2–18–14; 8:45 am]

BILLING CODE 4160–01–P

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://*

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: Lucinda Buhse, Center for Drug Evaluation and Research, Food and Drug Administration, 1114 Market St., Suite 1002, St. Louis, MO 63101, 314–539–2134; 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 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.'' It 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 and how to assemble information and present data to support analytical methodologies. The recommendations in this guidance apply to new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications. The principles in this revised draft guidance also apply to Type II drug master files. This draft guidance does not address investigational new drug application (IND) methods validation specifically, but the principles being discussed may be helpful to sponsors preparing INDs.

This draft guidance complements the International Conference on Harmonisation guidance ''Q2(R1) Validation of Analytical Procedures: Text and Methodology.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on analytical procedures and methods validation. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 part 211, 21 CFR part 314, and 21 CFR part 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338.

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 document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or *http://www.regulations.gov.*

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03580 Filed 2–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1041]

Fibromyalgia Public Meeting on Patient-Focused Drug Development; Rescheduling of Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is rescheduling a December 10, 2013, public meeting on Patient-Focused Drug Development for fibromyalgia, announced in the **Federal Register** on September 23, 2013. Due to inclement weather, the Federal Government was closed on December 10, 2013. We are rescheduling the public meeting to March 26, 2014, and extending the comment period for the public docket.

DATES: The public meeting will be held on March 26, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by March 20, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit either electronic or written comments by May 27, 2014.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Sections B and C of the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm363203.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, email: *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2013 (78 FR 58313), FDA announced a public meeting on December 10, 2013, to obtain patients' perspectives on the impact of fibromyalgia on daily life as well as the available therapies for fibromyalgia. Due to the Government closure on December 10, 2013, the meeting was postponed. We are rescheduling the public meeting to March 26, 2014, and extending the comment period to May 27, 2014 (see