DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0305]

Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only.'' This guidance document is intended for manufacturers and distributors of ''for research use only'' (RUO) and ''for investigational use only'' (IUO) in vitro diagnostic (IVD) products and any other entities who label IVD products, as well as FDA staff.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH) Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or 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 that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664.

For questions relating to devices regulated by CBER, contact: 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

This guidance document is intended for manufacturers, and any other entities legally responsible for the labeling of IVD products that are distributing such products they have labeled RUO or IUO (subsequently referred to collectively as ''manufacturers''). This guidance is intended to provide the current thinking of CDRH and CBER on when IVD products are properly labeled RUO and IUO.

This guidance is being issued because FDA is concerned that the distribution of unapproved and uncleared IVD products labeled RUO or IUO, but intended for purposes other than research or investigation (for example, for clinical diagnostic use [1]), has led, in some cases, to the diagnostic use of products with unproven performance characteristics, and with manufacturing controls that are inadequate to ensure consistent manufacturing of the finished product. Use of such tests for clinical diagnostic purposes may mislead healthcare providers and cause serious adverse health consequences to patients who are not aware that they are being diagnosed with or treated based on the results of tests with research or investigational products. This guidance is thus intended to remind manufacturers that RUO and IUO labeling must be consistent with the manufacturer's intended use of the device.

In the **Federal Register** of June 1, 2011 (76 FR 31615), FDA announced the availability of the draft guidance document under the title ''Draft Guidance for Industry and Food and Drug Administration Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions.'' Interested persons were invited to comment by August 30, 2011. The FDA received 55 sets of comments regarding the guidance. As a result of these comments, FDA revised the guidance and changed its format. Due to these revisions, FDA also changed the name of the guidance document.

[1] Throughout this guidance document, references to ''clinical diagnostic use'' and ''use in clinical diagnosis'' include use in making medical treatment decisions.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1723 to identify the guidance you are requesting.

IV. 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 part 809.10 and part 812 have been approved under OMB control numbers 0910–0485 and 0910–0078, respectively.

V. 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.*

Dated: November 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28084 Filed 11–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1038]

Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products; 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: Preclinical Assessment of Investigational Cellular and Gene Therapy Products'' dated November 2013. The guidance document provides sponsors and individuals that design and implement preclinical studies with recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational products reviewed by the Office of Cellular, Tissue and Gene Therapies (OCTGT). The product areas covered by this guidance are cellular therapy, gene therapy, therapeutic vaccination, xenotransplantation, and certain biologic-device combination products, which OCTGT reviews. The guidance clarifies current expectations regarding the preclinical information that would support an investigational new drug application (IND) and a biologics license application (BLA) for these products. The guidance announced in this notice finalizes the draft guidance of the same title dated November 2012, and supersedes the recommendations in Section VIII in the guidance entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy'' dated March 1998.

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: Preclinical Assessment of Investigational Cellular and Gene Therapy Products'' dated November 2013. The guidance document provides sponsors and individuals that design and implement preclinical studies with recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational products reviewed by OCTGT. The product areas covered by this guidance include cellular therapy, gene therapy, therapeutic vaccination, xenotransplantation, and certain biologic-device combination products. The guidance is intended to clarify current expectations regarding the preclinical information that supports an IND and a BLA for these products.

In the **Federal Register** of November 29, 2012 (77 FR 71194), FDA announced the availability of the draft guidance of the same title dated November 2012. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. In response to these comments, several sections were reorganized and editorial changes throughout the document were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2012.

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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Comments

Interested persons may submit 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: November 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28173 Filed 11–22–13; 8:45 am]

BILLING CODE 4160–01–P