4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0659]

Guidance for Industry: Current Good Tissue Practice and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based 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: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated December 2011. The guidance document provides recommendations to establishments for complying with CGTP and additional requirements for manufacturers of HCT/Ps. The guidance is intended for any HCT/P establishment that performs a manufacturing step and is responsible for complying with CGTP requirements. The guidance also addresses whether the establishment registration and HCT/P listing requirements apply in certain instances. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2009.

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 that 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:

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Center for Biologics Evaluation and Research (HFM-17),

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1401 Rockville Pike, suite 200N,

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated December 2011. The guidance provides recommendations for complying with the CGTP requirements under part 1271 (21 CFR part 1271), subpart D, and additional requirements for manufacturers of HCT/Ps under part 1271, subpart E. The guidance is intended for any HCT/P establishment that performs a manufacturing step and is responsible for complying with CGTP requirements. However, at this time, part 1271, subpart D (with the exceptions of §§ 1271.150(c) and

1271.155) and subpart E do not apply to reproductive HCT/P establishments regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) (the PHS Act). In consideration of the input FDA received from stakeholders, this guidance provides recommendations for establishments that manufacture HCT/Ps that meet the criteria listed in § 1271.10 and are regulated solely under section 361 of the PHS Act and the regulations in part 1271. CGTP requirements also apply to HCT/Ps regulated as drugs, devices, and/or biological products under section 351 of the PHS Act (42 U.S.C. 262) and/or the Federal Food, Drug, and Cosmetic Act (see § 1271.1(b)(2)). The guidance also addresses whether the establishment registration and HCT/P listing requirements under part 1271, subparts A and B, apply in certain instances.

In the Federal Register of January 16, 2009 (74 FR 3055), FDA announced the availability of the draft guidance of the same title dated January 2009. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 2009.

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

The 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 1271 have been approved under OMB control number 0910-0543, and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

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: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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