

Based on FDA's data on the number of sponsors that would be covered by the draft guidance, we estimate that approximately 180 SOPs related to

histologic evaluation will include the new procedures, and that sponsors will need approximately 30 minutes to

document, maintain, and update their SOPs with the new procedures.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED RECORDKEEPING BURDEN¹

	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
SOP New Procedures	30	6	180	0.5	90
Total	90

¹ There are no capital costs or operating and maintenance costs associated with this information collection.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-33553 Filed 12-29-11; 8:45 am]

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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this notice finalizes the draft guidance of the same title dated January 2009.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: Lori Jo Churchyard, 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: 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.

[FR Doc. 2011–33572 Filed 12–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 9, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, FAX: (301) 847–8533, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–(800) 741–8138; (301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss supplemental new drug application (NDA) 21790/010 for DACOGEN (decitabine) for injection, application submitted by Eisai, Inc. The proposed indication (use) for this product is for the treatment of acute myelogenous leukemia (AML) in adults 65 years of age or older who are not considered candidates for induction chemotherapy, which is the standard first phase of treatment for AML.

During the afternoon session, the committee will discuss NDA 022481, with the proposed trade name PIXUVRI (pixantrone dimaleate) injection, application submitted by Cell Therapeutics, Inc. The proposed indication (use) for this product is as a single agent treatment for patients with relapsed or refractory (difficult to treat), aggressive Non-Hodgkin's Lymphoma who received two or more prior lines of therapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting.

If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 25, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 17, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 18, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).