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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 1271**

**[Docket No. 00N-1380]**

**Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH), is announcing a public meeting entitled "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair." The purpose of the meeting is to provide a public forum for gathering scientific information and views from the public to help FDA in clarifying the regulation of human bone allograft.

**DATES:** The public meeting will be held on Wednesday, August 2, 2000, from 8:30 a.m. to 5 p.m. Submit registration information by July 24, 2000. Submit written comments by September 1, 2000.

**ADDRESSES:** The public meeting will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit registration information to Kathy

A. Eberhart (address below).  
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**FOR FURTHER INFORMATION CONTACT:**

For registration and meeting information: Kathy A. Eberhart, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-1317, FAX 301-827-3079, e-mail: eberhart@cber.fda.gov.

For information about presentations: Martha A. Wells, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6106.

For information about this notice: Nathaniel L. Geary, 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 began regulating tissue establishments in 1993 when it issued an interim rule entitled “Human Tissue Intended for Transplantation” that was codified in 21 CFR 1270 (58 FR 65514, December 14, 1993). In 1997 the agency replaced the interim rule with a final rule entitled “Human Tissue Intended for Transplantation” (62 FR 40429, July 29, 1997). FDA announced a plan for a new approach to regulate cells and tissue-based products in February 1997 with two documents: “Reinventing the Regulation of Human Tissue” and “A Proposed Approach to the Regulation of Cellular and Tissue-Based Products.” FDA requested written comments on the proposed approach and on March 17, 1997, held a public meeting to solicit information and views from the interested public (62 FR 9721, March 4, 1997). FDA is implementing its regulatory plan for human cellular and tissue-based products with publication of a series of proposed regulations. On May 14, 1998, FDA published a proposed regulation entitled “Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products” (63 FR 26744). On September 30, 1999, FDA published a proposed rule entitled “Suitability Determination for Donors

of Human Cellular and Tissue-Based Products” (64 FR 52696). The comment period for the 1999 proposed rule was reopened on April 18, 2000 (65 FR 20774), and will close on July 17, 2000.

The proposed rule for establishment registration and listing also proposed criteria that human cellular and tissue-based products must meet for regulation solely under section 361 of the Public Health Service Act. One of the criteria is that these products be “minimally manipulated.” “Minimal manipulation” is defined in proposed § 1271.3(g) for structural tissue, as processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement. Another criterion, “homologous use,” is defined in proposed § 1271.3(d). “Homologous use” means the use of a cellular or tissue-based product for replacement or supplementation or for structural tissue-based products, used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs. FDA has received numerous comments to the dockets of both proposed rules (Docket Nos. 97N-484R and 97N-484S) about the application of the definitions for minimal manipulation and homologous use in the regulation of human allograft bone products. Many of these comments request that FDA clarify how these definitions will be applied to bone products that are preshaped for use in spinal fixation. Other comments cite the long history of safe use of bone products.

This public meeting is being organized by CBER and CDRH to provide stakeholders with the opportunity to provide additional information to the agency. The agency is requesting information concerning the characteristics of various bone products as they relate to the agency’s proposed definitions for “minimal manipulation” and “homologous use.” Such information will be considered for future guidance to industry in conjunction with the regulations discussed above. Stakeholders are encouraged to provide information about the following issues:

1. Which processing procedures applied to human bone allograft fall within, or outside of, FDA’s proposed definition for “minimal manipulation?”
2. Which uses of human bone allograft fall within, or outside of, FDA’s proposed definition for “homologous use?”

3. What risks to health have been identified and characterized for human bone allograft products?

4. What controls have been identified to adequately address the risk to health of human bone allograft products?

5. What industry standards for bone allograft products are available, and what standards will be needed in the future?

## **II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments by September 1, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document. FDA is requesting that those persons making oral presentations at the public meeting also submit in writing comments based on their statements by September 1, 2000, to ensure their adequate consideration. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## **III. Registration and Requests for Oral Presentations**

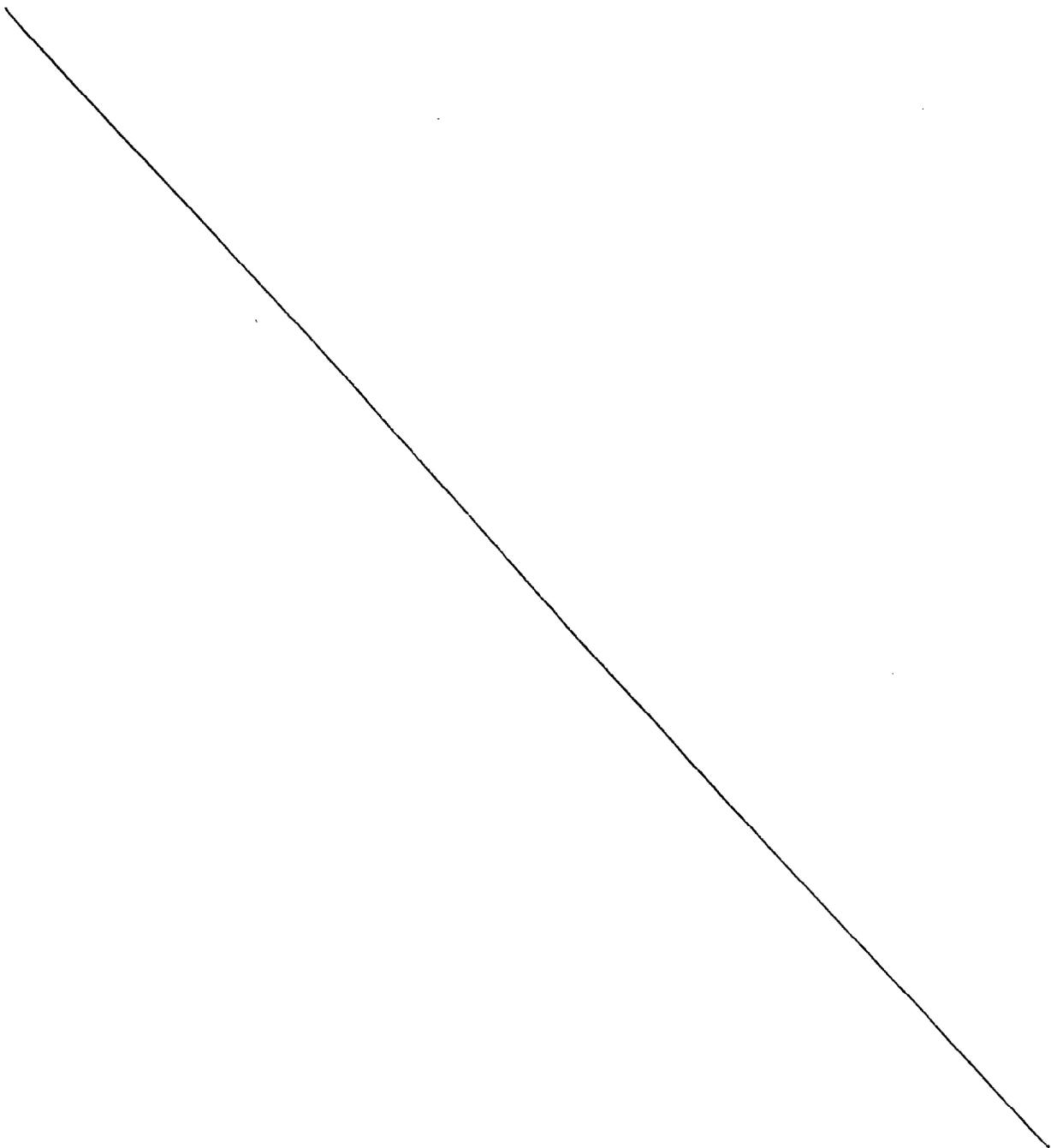
Those persons interested in attending the public meeting should fax or e-mail their registration information (including name, title, firm name, address, and telephone and fax numbers), a summary of their presentation, and a notice of intent to make an oral presentation, to Kathy Eberhart (address above) by Monday, July 24, 2000. Registration is not required for attendees not making a presentation. However, all interested persons are encouraged to preregister because space is limited. An announcement of the public meeting and the notice of intent to participate may be accessed at <http://www.fda.gov/cber/scireg/htm>. FDA will post a draft agenda on this web site about a week before the meeting.

If time permits, those who did not submit a notice of participation will be given an opportunity to speak at the end of the meeting.

If you need special accommodations due to a disability, please contact Kathy Eberhart at least 7 days in advance.

**IV. Transcripts**

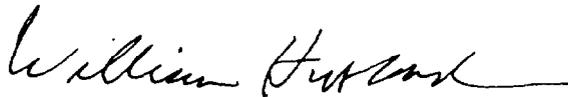
Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD



20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available at <http://www.fda.gov/ohrt/minutes/workshop-min.htm>.

Dated: \_\_\_\_\_

July 16, 2000



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William K. Hubbard,  
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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