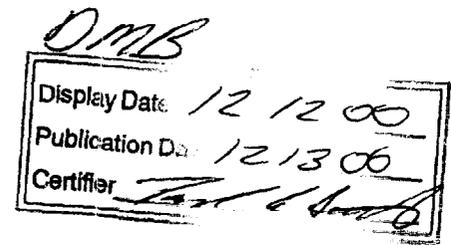


DEPARTMENT OF HEALTH AND HUMAN SERVICES

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; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for a public meeting entitled "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair" that was held on August 2, 2000. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments to FDA on the issues discussed at the public meeting.

DATES: Submit written comments by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 18, 2000 (65 FR 44485), FDA published a notice of public meeting that would give the public an opportunity to provide additional

information to the agency about the characteristics of various bone products as they relate to the agency's proposed definitions for "minimal manipulation" and "homologous use." Such information would be considered for future guidance to industry in conjunction with regulations that have been proposed. Interested persons were given until September 1, 2000, to submit written comments. The agency received several requests for an extension of the comment period to allow interested parties additional time to address the complex issues concerning FDA's proposed regulatory framework for bone allografts used for reconstruction and repair, to provide adequate time to review the transcript of the meeting, and to conduct research into the issues discussed at the meeting in formulating comments to submit to FDA. FDA finds these requests are reasonable, and, therefore, is reopening the comment period for an additional 60 days. Stakeholders are encouraged to provide information about the following issues:

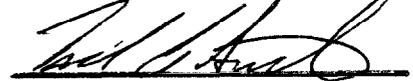
1. Which processing procedures applied to human bone allograft fall within, or outside of, FDA's proposed definition for "minimal manipulation?"
2. Which uses of human bone allograft fall within, or outside of, FDA's proposed definition for "homologous use?"
3. What risks to health have been identified 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?

Interested persons may submit to the Dockets Management Branch (address above) written comments on the issues discussed at the public meeting by *[insert date 60 days after date of publication in the **Federal Register**]*. Two copies of any comments are to be submitted,

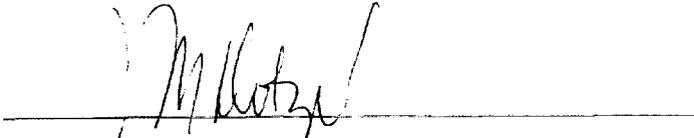
except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11-28-00
November 28, 2000

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



Bill Hurd



Margaret M. Dotzel
Associate Commissioner for Policy

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

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