document, which among other things, includes the disclosure document's table of contents, as well as an admonition to download or otherwise preserve document's table of contents, as well as an admonition to download or otherwise preserve the electronic disclosure document. The proposed instructions would also specify the general formal for an electronic disclosure document, ensuring that the disclosure document could be downloaded or otherwise preserved, and that the disclosures are clear, conspicuous, and do not contain extraneous or distracting features (such as animation or pop-up screens). The proposal would permit franchisors to insert navigational tools that aid in the reviewing a disclosure document, including scroll bars, search features, and internal links.

The NPR comment period closed at the end of January, 2000. Forty comments, including five rebuttal comments, were submitted, several of which address the Commission's proposed Internet compliance instructions. Commission staff are currently analyzing the various comments and are preparing recommendations to the Commission on Internet compliance and other disclosure issues.

The Commission recognizes that, to date, few franchisors have sought to use the Internet or other electronic technologies to comply with the Franchise Rule. One reason is that the Rule itself requires franchisors to ''furnish'' a ''written'' disclosure document. Arguably, these requirements would preclude the use of the Internet until such time as the Commission clarifies the term ''furnish'' and revises the definition of ''written'' to include electronic communications. Another reason is fear of liability. Franchisors appear unwilling to incur the costs associated with developing an online disclosure mechanism without some assurances that their mechanism will pass Commission muster. This reluctance is understandable in light of the Commission's evolving policy in this area, as developed through the ongoing Franchise Rule amendment process.

The Commission believes that demonstration projects of the NPR's proposed Internet instructions would be in the public interest. In light of the franchise community's lack of practical experience with Internet disclosure, it is critical to probe the strengths and weaknesses of the NPR proposed instructions before they are incorporated into the final revised Rule. Through demonstration projects, the Commission can be alerted to any technological problems with the proposed instructions, receive feedback on whether franchisors are able to comply with the proposed instructions efficiently, as well as to identify areas where the proposed instructions might need fine-tuning. As a result, the final Rule's Internet instructions are likely to be much more precise, enabling franchisors to comply with the Rule efficiently and with significant cost reductions.

Accordingly, the Commission solicits all interested parties to submit petitions to the Commission for permission to implement a demonstration project, consistent with proposed section 436.7 of the NPR. The Commission will consider all such petitions on a case-by-case basis. To gain approval, the interested party must be able to demonstrate that its proposal meets the standards specified in proposed section 436.7 of the NPR. All demonstration projects will be on a trial basis only, and the Commission specifically reserves its right to terminate any demonstration project for any reason. To enable the Commission and the public to benefit from a demonstration project, an approved party must file written reports to appropriate Commission staff of its progress on at least a quarterly basis, describing any problems it has encountered with the proposed Internet instructions, any complaints from franchisors and franchisees, as well as any suggested improvements. Such reports will be placed on the public record.

List of Subjects in 16 CFR Part 436

Advertising, Business and industry, Franchising, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 00–17994 Filed 7–17–00; 8:45 am]

BILLING CODE 6750–01–M

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.

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).

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/cber/minutes/workshop-min.htm.

Dated: July 10, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–17942 Filed 7–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA–98–4350]

RIN 2125–AE45

Administration of Engineering and Design Related Services Contracts

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to revise its regulation on the administration of engineering and design related services contracts in order to establish procedures to be followed when using Federal-aid highway funds for the procurement of engineering and design related services, materials, equipment, or supplies. The proposed regulation describes procurement methods contracting agencies are to use when acquiring these services or related items. This proposed rule implements 23 U.S.C. 112(b), as amended by section 307 of the National Highway System Designation Act of 1995 (NHS Act) and section 1205(a) of the Transportation Equity Act for the 21st Century (TEA–21), by requiring States to award Federal-aid highway engineering and design service contracts: In accordance