§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

* * * * *

AAL AK E5 Klawock, AK [Revised]

Klawock Airport, AK
(Lat. 55°34′48″ N, long. 133°04′30″ W)
Klawock NDB/DME
(Lat. 55°34′07″ N, long. 133°04′46″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Klawock Airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME extending to 16 miles southwest of the NDB/DME; and that airspace extending upward from the 1,200 feet above the surface within 6.7 miles northwest and 9.5 miles southeast of the 039° bearing from the airport extending from the airport to 6.7 miles northeast of the airport and within 6.7 miles northwest and 9.5 miles southeast of the 219° bearing from the airport extending from the airport to 32 miles southwest of the airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME beginning 16 miles west of the NDB/DME and extending to 35 miles west of the NDB/DME.

* * * * *

Issued in Anchorage, AK, on February 25, 1997.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 97–5292 Filed 3–3–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 97N–0068]

Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of proposed regulatory approach; public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled, ''Proposed Approach to Regulation of Cellular and Tissue-Based Products.'' In addition, FDA is announcing a public meeting to solicit information and views from the interested public on the agency's proposed regulatory approach for such products. These actions are taken in response to the Administration's ''Reinventing Government'' initiative which seeks to streamline regulatory requirements to ease the burden on regulated industry, while providing adequate protection to the public health.

DATES: Written comments may be submitted at any time; however, comments should be submitted by April 17, 1997, to ensure their adequate consideration in preparing FDA's final approach to the regulation of cellular and tissue-based products.

The public meeting will be held on March 17, 1997, from 8 a.m. to 4:30 p.m. Submit written notices of participation by March 10, 1997, including a summary of the presentation, which will be submitted to the docket, and approximate time requested.

Registration is not required; however, groups are asked to limit the number of individuals attending because of the anticipated broad interest in the meeting and the limited available seating.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857.

Submit written requests for single copies of the document ''Proposed Approach to Regulation of Cellular and Tissue-Based Products'' to the Office of Communication, Training and Manufacturer's Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. The document may also be obtained by mail or by calling the CBER Voice information System at 1–800–835–4709, or 301–827–1800, or FAX at 1–888–CBER–FAX, or 301–827–3844.

Persons with access to the Internet may obtain the document using the world wide web (WWW) or bounce-back-e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''CELL TISSUE@a1.CBER.FDA.GOV''.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch, address above, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information regarding the meeting or to submit a notice of intent to participate: Martha A. Wells, Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0967, FAX 301–827–2844.

For information regarding this document: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

FDA is announcing the availability of a document entitled ''Proposed Approach to Regulation of Cellular and Tissue-Based Products.'' This document is being issued as a part of FDA's continuing effort to reduce unnecessary burdens for industry without diminishing public health protection.

FDA has designed a new regulatory framework for cells and tissues. The document describes this new approach, which FDA believes would provide adequate protection of public health, both from the risks of transmission of communicable disease and from the risks of therapies that may be ineffective or dangerous, while enabling investigators to develop new therapies and products with as little regulatory burden as possible. The proposed approach would encompass, but not be limited to, the regulation of the following: Human tissue intended for transplantation, currently regulated under 21 part CFR 1270; demineralized bone; reproductive tissue; heart valves; peripheral blood hematopoietic stem cells; placental/umbilical cord blood hematopoietic stem cells; somatic cell therapy products; and gene therapy products.

The approach does not encompass vascularized organs or minimally-manipulated bone marrow, transfusable blood products (e.g., whole blood, red blood cells, platelets, and plasma), tissues derived from animals, products used in the propagation of cells or tissues, or products that are secreted by or extracted from cells or tissues (e.g., human milk, collagen, urokinase, cytokines, and growth factors and hormones). Such products generally raise different safety and effectiveness issues, and generally are covered by other rules, regulations, and/or

standards. The agency intends to implement this regulatory plan in a step-by-step fashion and to issue through notice and comment rulemaking new regulatory requirements.

The regulatory approach focuses on five overarching public health and regulatory concerns, which can be stated as the following questions:

(1) How can the transmission of communicable disease be prevented?

(2) What processing controls are necessary, e.g., to prevent contamination that could result in an unsafe or ineffective product, and to preserve integrity and function so that products will work as they are intended?

(3) How can clinical safety and effectiveness be assured?

(4) What labeling is necessary, and what kind of promotion is permissible, for proper use of the product?

(5) Should manufacturers notify FDA when they process and market tissue products?

With these concerns in mind, FDA categorized cells and tissues and their uses by their risk relative to each concern, so as to enable the agency to provide only that level of oversight relevant to each of the individual areas of concern. Thus, under the plan, cells and tissues would be regulated with a tiered approach based on risk and the necessity for FDA review.

In addition to making this document available, FDA is announcing a public meeting to discuss the proposed approach to the regulation of cellular and tissue-based products. At the public meeting FDA intends to present a brief overview of the proposed regulatory approach and provide an opportunity for public comments on the approach. Individuals who wish to make a presentation should contact Martha A. Wells, address above. FDA will determine the time available for presentations based on the number of participants. As time permits, those who did not submit a notice of participation will be given an opportunity to speak at the end of the meeting. FDA is requesting that those persons making oral presentations also submit their statements in writing, as described below, to ensure their adequate consideration.

Although all members of the public will have an opportunity to comment on the proposed regulations when they are published, interested persons who wish to comment on the agency's proposed approach to the regulation should submit written comments on the document, ''Proposed Approach to Regulation of Cellular and Tissue-Based Products,'' and written comments in response to the public meeting to Dockets Management Branch (address above). Written comments may be submitted at anytime, however, comments should be submitted by April 17, 1997, to assure their adequate consideration. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments and information are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Written comments on this document and comments received in response to the public meeting will be considered in determining whether revisions to the document are warranted and in preparing any future rulemaking.

Dated: February 26, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5240 Filed 2–28–97; 2:13 pm]

BILLING CODE 4160–01–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA–7210]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Frederick H. Sharrocks, Jr., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–2796.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act

This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act.

The Executive Associate Director, Mitigation Directorate, certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.