cell products for transplantation and to provide an opportunity for interested persons to submit written comments on the draft document. This document is in response to numerous inquiries regarding the agency's regulatory approach to cord blood stem cell products. The draft document was distributed at the public workshop held on December 13, 1995, as announced in the Federal Register of November 24, 1995 (60 FR 58088). FDA has since made editorial changes to the draft document but the content and technical information remains unchanged.

DATES: Written comments by April 26, 1996.

ADDRESSES: Submit written requests for single copies of the draft document entitled ''Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products for Transplantation or Further Manufacture into Injectable Products'' to the Division of Congressional and Public Affairs (HFM–44), Office of Communication, Training and Manufacturers Assistance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or call FDA's automated information system at 1–800–835–4709. Send one self-addressed adhesive label to assist that office in processing your requests. Persons with access to the INTERNET may request the document be sent by return E-mail by sending a message to ''CORDSTEM@A1..CBER.FDA.GOV''. The draft document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requesters should connect to the Center for Drug Evaluation and Research (CDER) FTP using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDVS2.CDER.FDA.GOV'' (150.148.24.202). The ''READ.ME'' file in that subdirectory describes the available documents, which may be available as an ASCII text file (*.TXT), or WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a test based FTP program would be:

FTP CDVS2.CBER.FDA.GOV
LOGIN ANONYMOUS
<ANY PASSWORD> <''YOUR EMAIL ADDRESS''>
BINARY
CD CBER
GET READ.ME
EXIT

The draft document may also be obtained by calling the CBER FAX information system (FAX-On-Demand) at 1–800–835–4709 from a touch tone telephone. Submit written comments on the draft document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of all comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft 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: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

Traditional bone marrow transplantation, involving the extraction of bone marrow by aspiration from bone cavities and processing by density gradient centrifugation, is increasingly being supplanted by novel sources of stem cells and biotechnologic procedures to purify and expand hematopoietic stem cells. Human cord blood, which is enriched with pluripotent hematopoietic stem cells, has recently emerged as an alternative source of hematopoietic stem cells for patients who are unable to obtain stem cells from allogeneic donors. Although availability of cord blood stem cells may reduce some constraints on bone marrow transplantation, the ultimate safety and efficacy of cord blood stem cell transplantation has yet to be determined.

Recently, the agency has received numerous inquiries regarding the regulatory approach to cord blood stem cell products. Cord blood stem cells for transplantation in autologous or allogeneic recipients is an emerging area with complex medical issues, including issues raised by the banking of such cells for possible future transplantation. Unlike bone marrow donors who are at least several years old with a medical history, cord blood is obtained from a newborn donor without an established medical history. Existing FDA statutory authorities apply to these new products and allow FDA to see that areas such as quality control, quality assurance, safety, purity, potency, and efficacy are appropriately addressed prior to marketing.

FDA is announcing the availability of a draft document that includes discussions of the following: (1) The applicable legal authorities in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act; (2) FDA's approach to the regulation of human cord blood stem cells intended for transplantation; (3) FDA's approach to the regulation of cord blood stem cells as source material for further manufacture; (4) FDA's approach to the regulation of ancillary products used for production of cord blood stem cells; and (5) a request for public comments on the regulatory approach.

II. Comments

FDA is providing for comment the draft document prepared by the Office of Blood Research and Review and the Office of Therapeutics Research and Review in CBER. FDA does not intend the draft document to be all-inclusive. This draft document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person.

FDA recognizes that cord blood stem cell products used for hematologic transplantation constitute a new and emerging scientific area. FDA will review and consider written comments on the regulatory approach set forth in the draft document. FDA specifically invites public comment on the approach for regulation of cord blood stem cells as source material for further manufacture and for regulation of ancillary products used in the production of cord blood stem cells, as discussed in the draft document.

Interested persons may, on or before April 26, 1996, submit to the Dockets Management Branch (address above) comments on the draft document. 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. A copy of the draft 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.

FDA will consider any written comments received in determining whether amendments to, or revisions of, the document are warranted.

Dated: February 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4065 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 203, 256, and 260

Announcement of Public Meeting on Public Law 104–58, Outer Continental Shelf (OCS) Deep Water Royalty Relief Act, and Its Effect on OCS Natural Gas and Oil Resource Management

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The Outer Continental Shelf Deep Water Royalty Relief Act (Act) authorized the Secretary of the Interior to modify the terms of certain existing leases and to establish new terms for leases in water depths of 200 meters or greater in the Gulf of Mexico west of 87 degrees 30 minutes West longitude. The Minerals Management Service (MMS) will hold a public meeting at the Westin Canal Place, Vieux Carré Theatre, 100 Rue Iberville, New Orleans, Louisiana 70130, on March 12–13, 1996 to receive written and oral comments on this topic.

Both individual and joint MMS-industry panel discussions will be used to cover the full range of options. The first day will concentrate on tracts offered for lease after November 28, 1995. The second day will be reserved for detailed discussion of options for royalty volume suspensions on existing leases. Topics will include options for: (1) Application and eligibility requirements; (2) review and approval process; (3) economic viability; and (4) definition of ''new production.'' These topics are also the subject of an Advance Notice of Proposed Rulemaking, which will be published in the Federal Register February 23, 1996 and which will be accessible on the MMS homepage on the World Wide Web.

All interested parties are invited to attend both sessions, but it would be especially valuable for those who may prepare the bids for upcoming Gulf of Mexico lease sales or who may want to apply for relief on existing leases to attend. Those wishing to attend any part of the 2-day session may register in advance and should indicate which day(s) they plan to be present. (Seating is limited to 295.) Reservations should be made no later than March 6, 1996, to Mary Carter, Gulf of Mexico Regional Office, Minerals Management Service, Elmwood Towers Building, 1201 Elmwood Park Boulevard, Jefferson, Louisiana 70123—(504) 736–2675, or facsimile (504) 736–2647.

DATES: Tuesday, March 12 and Wednesday, March 13, 1996, 9 a.m. to 4:30 p.m.

ADDRESSES: The Westin Canal Place, Vieux Carré Theatre, 100 Rue Iberville, New Orleans, Louisiana 70130—(504) 566–7006 or 1–800–228–3000. Contact person: Mary Carter, (504) 736–2675.

FOR FURTHER INFORMATION CONTACT: Mr. Walter Cruickshank, Chief, Offshore Minerals Analysis Division, Minerals Management Service, at either Mail Stop 4013, 1849 C Street, NW., Washington, DC 20240 or telephone: (202) 208–3822. You may access the text of the Advance Notice of Proposed Rulemaking from the MMS homepage on the World Wide Web at http://www.mms.gov/whatsnew.html.

Dated: February 20, 1996.

Thomas Gernhofer,

Associate Director for Offshore Minerals Management.

[FR Doc. 96–4215 Filed 2–23–96; 8:45 am]

BILLING CODE 4310–MR–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01–96–008]

RIN 2115–AE46

Special Local Regulation: Winter Harbor Lobster Boat Race, Winter Harbor, ME

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a permanent special local regulation for the Winter Harbor Lobster Boat Race. The event is held annually on the second Saturday in August, in the waters of Winter Harbor, Winter Harbor, ME. This regulation is needed to protect the boating public from the hazards associated with high speed powerboat racing in confined waters.

DATES: Comments must be received on or before April 26, 1996.

ADDRESSES: Comments should be mailed to Commander (b), First Coast Guard District, Captain John Foster Williams Federal Building, 408 Atlantic Ave., Boston, MA 02110–3350, or may be hand delivered to Room 428 at the same address, between 8 a.m. and 4 p.m., Monday through Friday, except federal holidays. Comments will become part of this docket and will be available for inspection or copying at the above address.

FOR FURTHER INFORMATION CONTACT: Lieutenant (jg) B.M. Algeo, Chief, Boating Affairs Branch, First Coast Guard District, (617) 223–8311.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD01–96–008), the specific section of the proposal to which each comment applies, and give reasons for each comment. The Coast Guard requests that all comments and attachments be submitted in an 8½″ x 11″ unbound format suitable for copying and electronic filing. If that is not practical, a second copy of any bound material is requested. Persons requesting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Commander (b), First Coast Guard District at the address under **ADDRESSES**. The request should include reasons why a hearing would be beneficial. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Discussion of Proposed Amendments

The Winter Harbor Lobster Boat Race is a local, traditional event that has been held for more than thirty years in Winter Harbor, ME. In the past, the Coast Guard has promulgated individual regulations for each year's running of the race. Given the recurring nature of the event, the Coast Guard desires to establish a permanent regulation for this event. The proposed regulation would establish a regulated area on Winter Harbor and would provide specific guidance to control vessel movement during the race.

This event includes up to 50 power-driven lobster boats and draggers competing in heats on a marked course at speeds approaching 25 m.p.h. The event typically attracts approximately 75 spectator craft. The Coast Guard will assign a patrol to the event, and the race course will be marked. However, due to the speed, large wakes, and proximity of the participating vessels, it is necessary to establish a special local regulation to