Dated: December 8, 2000.

Kenneth C. Clayton,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 00–31762 Filed 12–11–00; 10:11

BILLING CODE 3410-02-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 32

RIN 3038-AB61

Trade Options on Enumerated Agricultural Commodities

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is proposing to amend the exemption from its agricultural trade option rule, to clarify its operation in light of amendments to the exemption for bilateral transactions, published elsewhere in this issue of the Federal Register.

DATES: Comments must be received by December 28, 2000.

ADDRESSES: Comments should be sent to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, attention: Office of the Secretariat. Comments may be sent by facsimile transmission to (202) 418—5521 or by e-mail to secretary@cftc.gov. Reference should be made to "Amendment to Rule 32.13(g)."

FOR FURTHER INFORMATION CONTACT: Paul M. Architzel, Chief Counsel, or Nancy E. Yanofsky, Assistant Chief Counsel, Division of Economic Analysis, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone: (202) 418–5260. Email: PArchitzel@cftc.gov or NYanofsky@cftc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission is proposing a technical revision to its agricultural trade option rule to clarify the requirements for an exemption therefrom. As revised, the exemption from the agricultural trade option rule will be based only on the net worth requirement in the current rule. See Rule 32.13(g)(1)(iii). A revised part 35,

published elsewhere in this issue of the Federal Register, establishes an exemption from the regulatory requirements of the Commodity Exchange Act (Act) and the Commission's regulations for certain bilateral transactions between eligible participants. In adopting part 35, however, the Commission reserved the applicability of rule 32.13. Today's proposal is designed to make the operation of the exemption from rule 32.13 consistent with the broader exemption of part 35. Transactions between counterparties meeting the net worth requirement although not subject to the requirements of rule 32.13 remain subject to the provisions of part 35.

II. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 et seq. (RFA), requires that agencies consider the impact of their rules on small businesses. The proposed rule amendment simply clarifies the scope of an existing regulatory exemption available to high net worth entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that this proposed amendment will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3504(h) (PRA), which imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA, does not apply to the proposed amendment to this rule. The Commission believes the proposed amendment does not contain information collection requirements which require the approval of the Office of Management and Budget. The purpose of the proposed amendment is to clarify the scope of an existing regulatory exemption.

exemption therefrom. In addition to the net worth requirement, the rule requires that: (a) the option be offered to a producer, processor, or commercial user of, or a merchant handling, the commodity which is the subject of the option transaction, or the products or byproducts thereof; and (b) such producer, processor, commercial user of or merchant is offered or enters into the option solely for purposes related to its business as such. See Rule 32.13(g)(1)(i) and (ii). The Commission is proposing to remove these latter two requirements and make the exemption from the agricultural trade option rule available to parties based solely on their ability to meet the net worth requirement.

List of Subjects in 17 CFR Part 32

Commodity futures, Commodity options, Prohibited transactions, Trade options.

In consideration of the foregoing, and pursuant to the authority contained in the Act, and in particular sections 2(a)(1)(A), 4c and 8a of the Act, 7 U.S.C. 2, 6c and 12a, as amended, the Commission hereby proposes to amend Chapter I, Part 32 of Title 17 of the Code of Federal Regulations as follows:

PART 32—REGULATION OF COMMODITY OPTION TRANSACTIONS

1. The authority section for part 32 continues to read as follows:

Authority: 7 U.S.C. 2, 6c and 12a.

2. Section 32.13 is proposed to be amended by revising paragraph (g) to read as follows:

§ 32.13 Exemption from prohibition of commodity option transactions for trade options on certain agricultural commodities.

* * * * *

(g) Exemption. The provisions of this section shall not apply to a commodity option entered into between counterparties that have a reasonable basis to believe that each has a net worth of not less than \$10 million or the party's obligations on the option are guaranteed by a person which has a net worth of \$10 million and has a majority ownership interest in, is owned by, or is under common ownership with, the party to the option; provided, however, that part 35 of this chapter and § 32.9 apply to such option transactions.

Issued in Washington, D.C., this 7th day of December, 2000, by the Commission.

Jean A. Webb,

Secretary of the Commission. [FR Doc. 00–31732 Filed 12–12–00; 8:45 am] BILLING CODE 6351–01–U

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,

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

 $^{^{1}}$ The Commission's agricultural trade option rule currently provides a three-prong test for an

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 February 12, 2001.

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 February 12, 2001. 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: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.
[FR Doc. 00–31653 Filed 12–12–00; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-00-221]

RIN 2115-AA97

Safety Zone: New York Harbor, Western Long Island Sound, East River, and Hudson River Fireworks

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish ten permanent safety zones for fireworks displays located in the Port of New York/New Jersey, to expand the size of one current safety zone, and to modify effective times and notice requirements of existing permanent safety zones. This action is necessary to provide for the safety of life on navigable waters during the events. This action establishes permanent exclusion areas that are only active prior to the start of the fireworks display until shortly after the fireworks display is completed, and is intended to restrict vessel traffic in the affected waterways, expand the effective times of the zones to allow for earlier displays during daylight savings time, and to require one sign that may be used for displays from a barge or onshore.

DATES: Comments and related material must reach the Coast Guard on or before February 12, 2001.

ADDRESSES: You may mail comments and related material to Waterways Oversight Branch (CGD01-00-221), Coast Guard Activities New York, 212 Coast Guard Drive, room 204, Staten Island, New York 10305. The Waterways Oversight Branch of Coast Guard Activities New York maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room 204, Coast Guard Activities New York, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4012.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01-00-221), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the Waterways Oversight Branch at the address under ADDRESSES explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the Federal Register.

Background and Purpose

The Coast Guard proposes to establish ten permanent safety zones that will be activated for fireworks displays occurring throughout the year that are not held on an annual basis but are normally held in one of these ten locations. The ten locations are south of