

(c) *Microbial contamination.* All processing steps shall be conducted in a manner to minimize the risk of contamination from microorganisms, pyrogens, or other impurities. * * *

* * * * *

(e) * * * Heat treatment shall be conducted so that the solution is heated continuously for not less than 10 or more than 11 hours at an attained temperature of 60±0.5 °C.

(f) *Stabilizer.* Either 0.08±0.016 millimole sodium caprylate, or 0.08±0.016 millimole sodium acetyltrypophanate and 0.08±0.016 millimole sodium caprylate per gram of protein shall be present as a stabilizer(s). Calculations of the stabilizer concentration may employ the labeled value 5 percent for the protein concentration of the product.

* * * * *

8. Section 640.92 is amended by revising the headings of paragraphs (a) and (c), and by revising paragraphs (d) and (e) to read as follows:

§ 640.92 Tests on final product.

* * * * *

(a) *Protein concentration.* * * *

* * * * *

(c) *pH.* * * *

(d) *Sodium concentration.* The sodium concentration of the final product shall be 130 to 160 milliequivalents per liter.

(e) *Potassium concentration.* The potassium concentration of the final product shall not exceed 2 milliequivalents per liter.

* * * * *

9. Section 640.94 is amended by revising paragraph (a) to read as follows:

§ 640.94 Labeling.

* * * * *

(a) The osmotic equivalent in terms of plasma, and the sodium concentration in terms of a value or a range in milliequivalents per liter.

* * * * *

10. Section 640.100 is amended by revising the last sentence in paragraph (a), and by revising paragraphs (b) and (c) to read as follows:

§ 640.100 Immune Globulin (Human).

(a) * * * The product is defined as a sterile solution containing antibodies derived from human plasma.

(b) *Source material.* The source material of Immune Globulin (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.

(c) *Additives in source material.* The source material shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity, and potency of the product will not be affected adversely.

§ 640.101 [Amended]

11. Section 640.101 *General requirements* is amended by removing the heading of paragraph (b) "*Hydrogen ion concentration*" and by adding in its place "*pH*" and by removing paragraphs (e)(3), (e)(4), and (f).

12. Section 640.102 is amended by revising the last sentence of paragraph (e) to read as follows:

640.102 Manufacture of Immune Globulin (Human).

* * * * *

(e) * * * At no time during processing shall the product be exposed to temperatures above 45 °C and after sterilization the product shall not be exposed to temperatures above 32 °C for more than 72 hours.

13. Section 640.103 is amended by revising paragraph (b) to read as follows:

§ 640.103 The final product.

* * * * *

(b) *Protein composition.* At least 96 percent of the total protein shall be immunoglobulin G (IgG), as determined by a method that has been approved for each manufacturer by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

14. Section 640.104 is amended by revising paragraphs (b)(2), (b)(3), (c)(1), and (c)(2) to read as follows:

§ 640.104 Potency.

* * * * *

(b) * * *

(2) A measles neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(3) A poliomyelitis Type 1, Type 2, or Type 3 neutralizing antibody level that, when compared with that of a reference

material designated by the Center for Biologics Evaluation and Research, Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(c) * * *

(1) Reference Immune Globulin for correlation of measles antibody titers.

(2) Reference Immune Globulin for correlation of poliomyelitis antibody titers, Types 1, 2, and 3.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99-11898 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-106905-98]

RIN 1545-AW09

Allocation of Loss With Respect to Stock and Other Personal Property; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to the allocation of loss recognized on the disposition of stock and other personal property.

DATES: The public hearing originally scheduled for Wednesday, May 26, 1999, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Michael L. Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622-7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking; notice of proposed rulemaking by cross-reference to temporary regulations; and notice of public hearing that appeared in the **Federal Register** on Monday, January 11, 1999 (64 FR 1571), announced that a public hearing was scheduled for

Wednesday, May 26, 1999, at 10 a.m., in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is proposed regulations under sections 861 and 865 of the Internal Revenue Code. The public comment period for these proposed regulations expired on Wednesday, May 5, 1999. The outlines of topics to be addressed at the hearing were due on Wednesday, May 5, 1999.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of May 10, 1999, no one has requested to speak. Therefore, the public hearing scheduled for Wednesday, May 26, 1999, is cancelled.

Michael L. Slaughter,

Acting Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 99-12167 Filed 5-13-99; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05-99-006]

RIN 2115-AE47

Drawbridge Operation Regulations; Sassafras River, Georgetown, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: At the request of the Maryland Department of Transportation (MDOT), the Coast Guard is proposing to change the regulations that govern the operation of the Maryland Route 213 drawbridge across the Sassafras River, Mile 10.0, at Georgetown, Maryland. The proposed rule would restrict drawbridge openings from November 1 through March 31, from midnight to 8 a.m., by requiring a six-hour advance notice for drawbridge openings. This change is intended to eliminate the need to have the bridge constantly manned during times of minimal use while still providing for the reasonable needs of navigation.

DATES: Comments must reach the Coast Guard on or before July 13, 1999.

ADDRESSES: Comments may be mailed to Commander (Aowb), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004, or may be hand delivered to the same address between 8 a.m. and 4:30 p.m., Monday through Friday,

except Federal holidays. The telephone number is (757) 398-6222. Comments will become a part of this docket and will be available for inspection and copying at the above address.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at 757-398-6222.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested parties to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD05-99-006) and the specific section of this proposal to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If not practical, a second copy of any bound material is requested. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

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 the Commander, Fifth Coast Guard District, at the address under **ADDRESSES**. The request should include reasons why a hearing would be beneficial. If it determines 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**.

Background and Purpose

The Maryland Route 213 drawbridge across the Sassafras River, Mile 10.0, at Georgetown, Maryland, is currently required to open on signal year-round. The Maryland Department of Transportation (MDOT) has requested that the Coast Guard change the operating schedule for the drawbridge by requiring a six-hour advance notice to open the bridge from November 1 to March 31, from midnight to 8 a.m. Review of MDOT's bridge logs from 1993 to 1997 reveals a total of 29 bridge openings for the five year period during the months from November 1 through March 31, an average of 1.2 openings per month. Considering the low number of openings that have occurred during the November through March time period, the Coast Guard believes that

these proposed changes will not unduly restrict navigation.

Discussion of Proposed Amendment

The Coast Guard proposes a new regulation governing the operation of the Maryland Route 213 drawbridge across the Sassafras River, mile 10.0, at Georgetown, Maryland. The proposed regulation would restrict openings of the Sassafras River drawbridge from November 1 through March 31, from midnight to 8 a.m. During this period, the bridge need only open if a six-hour notice is given to MDOT. A sign would be posted at the bridge to provide MDOT's 24-hour telephone number.

Regulatory Evaluation

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard reached this conclusion based on the fact that the proposed changes will not prevent mariners from transiting the bridge, but merely require mariners to adhere to the proposed new operation procedures during times of minimal use of the bridge. The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this proposed rule, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Because it expects the impact of this proposal to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization qualifies as a small entity and that this proposed rule will have a significant economic impact on your business or organization, please submit a comment (see **ADDRESSES**) explaining why you think it qualified