adoption of the standard (such as technical violations of debt covenant agreements, planned or intended changes in business practices, etc.) is encouraged.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, and 640

[Docket No. 85N-0032]

General Biological Products Standards, Additional Standards for Human Blood and Blood Products; Test for Antibody to Human Immunodeficiency Virus (HIV)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to require that each unit of human blood and blood components intended for use in preparing a product be tested and found negative by an approved test for antibody to human immunodeficiency virus (HIV). HIV, also known as human immunodeficiency virus type (HIV-1), lymphadenopathy-associated virus (LAV), or human T-lymphotropic virus type III (HTLV-III), is the etiologic agent of acquired immunodeficiency syndrome (AIDS). FDA believes that the voluntary routine testing of blood by an approved test for antibody to HIV is already decreasing the risk of transmitting HIV through the transfusion of blood and blood components and by the parenteral use of certain plasma derivatives.

DATES: Effective February 4, 1988. For human blood and blood component products collected on or after January 5, 1989, the product shall be labeled and instruction circulars shall be provided consistent with this final rule. Licensed establishments should submit draft revised labeling by March 7, 1988.

ADDRESS: Draft revised labeling should be sent to the Director, Office of Biologics Research and Review (HFN-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steve F. Falter, Center for Biologics Evaluation and Research (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of February 21, 1986 (51 FR 6362), FDA proposed to amend the biologics regulations to require that each donation of human blood or blood components intended for use in a product be tested by a serologic test for HTLV-III, approved for such use by the Director, Office of Biologics Research and Review. (As discussed elsewhere in this preamble, FDA has decided that the virus should be identified as "Human Immunodeficiency Virus" or "HIV" and the required test should be identified as "a test for antibody to HIV." This nomenclature is used throughout the remainder of this preamble and in the final regulations.) The proposed requirements would apply to all human blood and blood components intended for use for any product, including products not subject to licensure as a biological product, such as human blood source material used in the manufacture of in vitro diagnostic reagents. In the February 21, 1986, proposal, FDA also proposed requirements concerning the proper labeling of human blood and blood components found nonreactive to a test for antibody to HIV, the qualifications of facilities that may conduct the testing, and restrictions on use of human blood and blood components that are repeatably reactive to a test for antibody to HIV or were collected from a donor whose blood is known to be repeatably reactive to a test for antibody to HIV.

In the preamble to the proposed rule, FDA also discussed the effect of the proposed rule on certain existing regulations, recommendations, and regulatory policies. FDA discussed its requirements and policies concerning the proper storage and disposition of human blood and blood components that are initially reactive or repeatably reactive, the maintenance of written standard operating procedures and records concerning the test, and the recommended procedures for notifying donors of repeatably reactive test results.

Blood establishments began testing human blood and blood components for antibody to HIV consistent with FDA recommendations in early 1985. Through routine inspections and special surveys, FDA has determined that blood establishments have instituted testing programs consistent with these regulations. In accordance with FDA recommendations, blood establishments are also conducting donor screening procedures designed to assure that persons at increased risk of HIV infection do not donate blood or blood components for transfusions or further manufacture. FDA issued the most recent recommendations on donor screening procedures to all registered blood establishments by a letter dated October 30, 1986. By a letter of April 29, 1987, FDA also issued to all registered blood establishments recommendations concerning a test protocol to clarify the status of donors with a reactive test for antibody to HIV. The agency is considering revising the donor suitability regulations in connection with HIV infection to codify existing policies. The purpose of this rulemaking is to establish in the regulations policies already in effect for assuring the continued safety of the blood supply by testing for antibody to HIV. The regulations thus reflect accepted procedures related to the test for antibody to HIV necessary for assuring the continued safety of the blood supply. The regulations will also provide FDA clear enforcement authority in the event that deviations from the accepted testing procedures are discovered.

II. Comments

FDA provided interested persons 30 days to submit written comments on the proposed rule. FDA received 31 letters of comment in response to the proposal. All of the letters supported, in general, FDA's proposed actions. A summary of the comments and FDA's responses follow.

A. Legal Issues

1. Three comments requested that FDA indicate clearly in the final regulations that the Federal requirements for determining donor suitability, product labeling, and the conduct and interpretation of HIV antibody testing are intended to preempt State and local regulation in those specific areas.

FDA believes that the actions requested by the comments are beyond the scope of this rulemaking. In the proposed rule, FDA did not discuss the possible preemptive effect of any of the regulations in this final rule. Nor did FDA propose to revise existing regulations concerning donor suitability or product labeling other than in connection with HIV antibody testing. The comments requested Federal preemption of donor suitability and blood product labeling requirements in general, as well as requirements related to HIV antibody testing. To assure an adequate opportunity for all interested persons, including State and local authorities as well as the blood industry, to consider the issues concerning preemption raised by these comments,

FDA intends to publish in the **Federal Register** a notice that will discuss these issues and provide an opportunity for public comment on them.

2. One comment requested further information on the authority of FDA's Office of Biologics Research and Review (OBRR) to place restrictions on the sale of certain in vitro diagnostic products that are regulated as medical devices and are manufactured from blood components that are reactive for a test for antibody to HIV.

The regulations in this final rule do not apply directly to the sale of in vitro diagnostic products. The regulations apply to blood establishments that collect blood and blood components and place restrictions on the uses of human blood materials that test repeatably reactive for antibody to HIV. The sections of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act (the act) authorizing promulgation of these regulations are listed in the authority citations in paragraphs 1 and 3 on page 6367 and in paragraph 5 on page 6368 of the proposal in the **Federal Register** of February 21, 1986, and are repeated in the authority citations listed below. The regulations require that all human blood intended for further manufacturing be tested and found negative for antibody to HIV; therefore, source blood or plasma that is untested or that tests repeatably reactive would be unavailable for use in manufacturing in vitro diagnostic products without an exception approved by OBRR under § 610.45(c)(1) of the final rule.

FDA is amending the final rule by removing specific references to the Director, Office of Biologics Research and Review. FDA is amending the regulations so that they will not have to be amended again in the event that the title of the organizations or the delegation of authority is changed in the future.

Finished products determined by FDA to be appropriately regulated as medical devices would be regulated under the provisions of the 1976 Medical Device Amendments of the act and implementing regulations in 21 CFR Part 800. Implementation of the requirements concerning medical devices would be by FDA's Center for Devices and Radiological Health or OBRR, in accordance with the delegations of authority in 21 CFR 5.47 through 5.59.

B. Terms and Definitions

3. Five comments recommended that the viral agent be identified as "Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus (HTLV-III/LAV)" wherever the term appears in the regulations. Several other comments recommended that the viral agent be identified as "Lymphadenopathy-Associated Virus/ Human T-Lymphotropic Virus Type III (LAV/HTLV-III)." One of these comments, from a manufacturer of test kits, stated that the current term discriminates unfairly against its serologic test product, which identifies the virus as LAV.

FDA has decided to identify the virus as human immunodeficiency virus (HIV) in the regulations. FDA used the term "HTLV-III" in the proposed rule because it was the term used most widely in the United States at the time. HIV is now used most widely in scientific literature and is the term recommended by the international body charged with assigning nomenclature.

In May 1986, a subcommittee of the International Committee on the Taxonomy of Viruses (ICTV) proposed that the term "Human Immunodeficiency Virus (HIV)" be recognized as the name for the AIDS virus. The term "Human Immunodeficiency Virus" and the acronym "HIV" are used increasingly in scientific literature and are now accepted widely. Accordingly, FDA is amending the regulations by using the terms "Human Immunodeficiency Virus" and "HIV" to identify the virus. The term "HIV," as used in this regulation, is intended to encompass the terms "LAV" (now "LAV-I"), "HTLV-III," and "HIV-I," which have also been used to describe the AIDS virus.

FDA has already notified manufacturers of test kits that the proper name of the licensed reagent will be changed to "Human Immunodeficiency Virus." The new proper name should appear on product labeling shortly. Manufacturers of test kits may continue to identify the virus as an HTLV-III or LAV isolate in the product labeling and to incorporate either term in the trade name of the product.

Similarly, FDA is requiring that blood establishments revise their product labeling consistent with 21 CFR 606.122(e) and 640.70(a)(11) of the final rule. FDA discusses the procedures and schedule for these labeling revisions in the response to the following comment.

4. One comment asked that for clarity and accuracy the regulations refer to "a serologic test for antibody to HIV" rather than "a serologic test for HIV."

FDA agrees with the comment. In the proposed rule, FDA omitted the word "antibody" to provide flexibility in the regulations in case tests other than tests for antibody become available in the future. However, on review, FDA finds it important to emphasize in the regulations and product labeling that the current test is a test for antibody to HIV and does not detect directly the virus that causes AIDS. In addition, FDA finds that by specifying that the test is for the detection of antibody, the term "serologic" is no longer necessary for adequately identifying the test and is omitting the term in the final rule. Finally, in the proposed rule, FDA used the term "nonreactive" in certain proposed testing and labeling requirements. Upon review, FDA believes the term "negative" is more appropriate to designate blood samples in which antibody to HIV is not detected. "Negative" is a more general term that will be applicable regardless of the types of tests for detecting the presence of antibody to HIV that may be used in the future. Furthermore, the term "negative" more directly relates to the interpretation of the test results that antibody is not present in the test sample. See also FDA's response to the next comment. Accordingly, FDA is amending the final rule, including the product labeling requirements in §§ 606.122(e) and 640.70(a)(11), to refer to "a test for antibody to HIV" or "Negative by a test for antibody to HIV," as appropriate.

FDA is requiring that human blood and blood components collected on or after January 5, 1989 be labeled and revised instruction circulars be made available consistent with the final regulations. Blood establishments are currently labeling these blood products consistent with the proposed rule. Blood and blood components collected before the effective date need not be relabeled to reflect the change in terminology. Licensed blood establishments should submit draft revised labeling to the Director, Office of Biologics Research and Review, by March 7, 1988, to assure the timely review and approval of the labeling.

FDA continues to believe that the regulations should provide adequate flexibility to allow the immediate use of newly approved tests, other than a test for antibody, for the screening of blood and blood components for evidence of HIV. Accordingly, FDA is amending § 610.45(a) in the final rule by redesignating proposed § 610.45(a) as § 610.45(a)(1) and adding new § 610.45(a)(2) to provide for the use of other tests approved by FDA in place of a test for antibody to HIV, as specified by FDA. FDA emphasizes that tests alternative to a test for antibody to HIV are not currently in use for screening blood, nor may they be used without FDA approval. However, these

amendments will provide for immediate use of an alternative test upon FDA approval without requiring concurrent amendment of the regulations.

5. One comment on proposed §§ 606.122(e) and 640.70(a)(11) requested that the term "nonreactive" be defined in the regulations to include "nonrepeatably reactive" as well as "initially nonreactive" test results.

As discussed in response to the previous comment, FDA has decided to use the term "negative" in place of the term "nonreactive" in the regulations. FDA believes it is inappropriate to define "negative" in the regulations. For currently approved test systems, a blood sample that tests reactive upon initial testing but does not react in successive repeat tests, i.e., is not repeatably reactive, is considered negative for antibody. The labeling accompanying licensed test kits describes the criteria for determining that a blood sample is negative. (Some test kit labeling may still use the term "nonreactive," but manufacturers of these test kits are now revising the labeling to use the term "negative.") As current tests are improved or new tests become available, the definition of "negative," as defined in the test kit labeling, may be changed. Because the term negative is adequately defined in test kit labeling and the definition is subject to change, FDA believes it is inappropriate to define the term in the regulations.

6. Two comments on § 610.45(c)(1) and the preamble to the proposed rule contended that the terms "positive" and "repeatedly positive" should not be used with regard to HIV antibody test results because of the frequency of inconsistent and discrepant results using currently available test kits. One of the comments recommended that the terms "repeatably reactive" and "confirmed" should be used in place of "positive" and "repeatably positive," respectively.

FDA agrees that the term "repeatably reactive" should be used in place of "positive" in the regulations. The term "repeatably positive" was used only in the preamble of the proposed rule and not in the regulations; therefore, no further action is necessary with respect to that phrase. The agency is requiring that blood reacting by two independent tests, i.e., that is repeatably reactive, shall not be used for transfusion or the manufacture of a product except upon specific FDA approval. Accordingly, FDA is amending § 610.45(c)(1) to require that blood, plasma, or other blood components that are repeatably reactive to a test for antibody to HIV shall not be shipped or used in the manufacture of any product, except as provided in the regulations. (See also FDA's response to the next comment.)

C. Testing Requirements and Procedures

7. Twelve comments on proposed § 610.45(c) asked that the regulations provide for use of a means of determining false-positive tests for antibody to HIV so that persons testing false-positive are not deferred permanently from donating blood. Many of the comments cited cases of blood samples that initially were repeatably reactive and then did not react by other licensed tests, Western blot, or tests using blood samples obtained subsequent to the first, repeatably reactive, sample. In other cases, the repeatably reactive test results were shown to be false-positive because of human leukocyte locus A (HLA) antibody cross-reactivity. Some comments stated that the responsible physician at the blood establishment should have the discretion of deciding whether such donors could be reinstated in the donor pool. Some comments recommended that blood be considered positive for antibody to HIV only when confirmed by Western blot or other appropriate, more specific tests. Other comments recommended that the deferral for donors testing positive should not be permanent because methods may soon be developed to identify false positive tests and those donors whose blood sample tested false-positive should be allowed to return to routine blood donation.

FDA agrees in part with the comments. As demonstrated by the comments, blood establishments have studied a variety of methods for identifying those blood samples that test repeatably reactive for reasons other than exposure to the HIV virus, i.e., blood samples testing falsely-positive. To be considered for use in assuring the safety of blood products, any such test system must be shown by appropriate trials to identify only falsely-positive tests while assuring that blood containing antibody to HIV is removed from the blood supply.

FDA has now approved for licensure a standardized test system that is appropriate for use as a more specific test for identifying falsely-positive test results. By a letter of April 29, 1987, to all registered blood establishments, FDA issued recommendations for the use of the newly licensed Western blot test as part of a testing protocol to clarify the status of donors with a reactive test for antibody to HIV. Other test systems may be approved for similar purposes in the future, and FDA will continue to advise blood establishments of the conditions under which these test systems may be used. FDA agrees that the regulations should provide for the use of such test systems upon FDA approval. Accordingly, FDA is adding under § 610.45(c)(2)(i) a provision that the restrictions on use of blood and blood components that test repeatably reactive or from a donor known to be repeatably reactive do not apply when the blood or donor is shown to be negative for antibody to HIV or otherwise free from HIV infection by a method or process approved for such purpose by FDA. As FDA approves an appropriate test or process, FDA will advise blood establishments of the circumstances and conditions under which the newly approved method or process may be used. This amendment will allow blood establishments to adopt immediately newly approved methodologies for detecting false-positive reactions to the test for antibody to HIV while assuring the continued safety of the blood supply. Proposed § 610.45(c)(2)(i), (ii), and (iii) are redesignated in the final rule as § 610.45(c)(2)(ii), (iii), and (iv), respectively.

8. One comment from the New York State Department of Health urged that donor notification be made only if the initial screening tests have been confirmed by a more specific assay, such as the Western blot technique. The comment advised that New York State regulations prohibit donor notification without such verification. Another comment asked that FDA strongly endorse the use of Western blot as a confirmatory test before notification of a donor whose blood was repeatably reactive to the test for antibody to HIV.

Currently, blood establishments are using any of several donor notification procedures. For example, many establishments perform additional testing, including testing by the Western blot technique, before notifying a donor. Other establishments notify a donor when the blood sample tests repeatably reactive upon initial testing for antibody for HIV; however, these establishments inform the donor that the test results do not mean that the person will get AIDS and, indeed, that additional testing will be necessary to determine whether the person has even been exposed to the viral agent of AIDS. Such notification also provides the donor guidance for further medical evaluation and counseling.

The requirements in this rulemaking are to assure that blood and blood components containing antibody to HIV are not used for purposes that may be hazardous to the public health. FDA

does not believe it necessary to include requirements at this time concerning the notification of donors testing repeatably reactive for antibody to HIV. The Public Health Service has issued recommendations regarding appropriate procedures for notification of any person testing repeatably reactive to a test for antibody to HIV (*Morbidity and Mortality Weekly Report*, March 14, 1986; 35:152–155). As additional information becomes available, the Public Health Service will issue revised notification recommendations, if appropriate.

9. One comment on proposed § 610.45(a) asked that the regulations clearly prohibit the human use of blood and blood components before the completion of testing for antibody to HIV.

FDA does not agree that the use of incompletely tested blood should be prohibited in all circumstances. Blood and blood components are frequently life-saving products. On occasion, a physician may determine it necessary in a life-threatening situation to transfuse blood and blood components for which testing has not been completed because adequate supplies of completely tested blood of suitable blood type are not immediately available. Except in such emergency situations or in other specific circumstances subject to the approval of FDA, the regulations will effectively prohibit the use of blood and blood products until testing is completed.

10. One comment on proposed § 610.45 (a) and (c) asked that blood labeled "For Autologous Use Only" be specifically exempted from testing requirements and restrictions on use because the testing of an autologous unit for antibody to HIV does not increase the safety of that unit for the donor/recipient.

At many blood establishments, blood may be collected from a person for later infusion into the same person, i.e., for autologous use. In some cases, a blood establishment may elect to use for other purposes blood originally intended for autologous use, but found to be unnecessary for the treatment of the donor/patient. The blood establishment may use such blood or components for other purposes only if the donor was found to meet all suitability requirements related to product safety and the blood has been tested and found suitable by all required tests, including a test for antibody to HIV. When a blood establishment collects blood exclusively for autologous use, the blood or any components of the blood must be prominently and permanently labeled in place of the blood group label as being for autologous use only as required by 21 CFR 606.121(i)(4) of the blood labeling regulations. Blood so labeled is not suitable for homologous use.

FDA agrees that under certain conditions it would be unnecessary to test blood used exclusively for autologous infusion for antibody to HIV because there is no risk of disease transmission to the donor/recipient through such infusion. In the proposed regulations, § 610.45(a) provided that human blood and blood components may be issued before the results of the test for antibody to HIV are available only in dire emergencies or as otherwise approved in writing by FDA. FDA has decided that the proposed regulation should be revised to allow as well for exceptions from the requirement to test each donation. Accordingly, FDA is amending § 610.45(a)(1) (proposed § 610.45(a)) in the final rule to provide that each donation of human blood or blood components intended for use in preparing a product shall be tested for antibody to HIV, except as otherwise approved in writing by FDA. The final regulations will continue to provide that, when the test is required, human blood and blood components may be issued before the results of the test for antibody to HIV are available only in dire emergencies or as otherwise approved by FDA.

The Director, Office of Biologics Research and Review intends to send a written memorandum to blood establishments setting forth the conditions for an exception to the HIV testing requirement for blood or blood components for autologous use only. Therefore, individual establishments need not write to the agency requesting specific exceptions from the HIV testing requirement for products for autologous use at this time. FDA emphasizes that it is the responsibility of each blood establishment to assure that its procedures regarding blood for autologous use protect the health of the patient and to assure that the blood or its components are not later accidentally or otherwise diverted for other uses. For example, blood establishments should take particular care to have adequate procedures to assure that plasma from blood intended for autologous use that does not meet FDA requirements is not separated, labeled, and sold for use in further manufacturing.

11. One comment requested that special provisions be made for cytapheresis products collected from persons who donate frequently. The comment noted that FDA's current policy concerning the collection of Platelets, Pheresis by automated apheresis methods provides for testing of donor blood for syphilis and hepatitis B surface antigen at the beginning of a 30-day period and to require more frequent testing for antibody to HIV would increase costs unnecessarily and delay delivery of the products to the patient.

FDA agrees with the comment. FDA is approving special programs of intensive plateletapheresis by which platelets are collected repeatedly from a single donor, such as a family member of the intended recipient, for transfusion into a single recipient. Platelets, Pheresis may be collected in this manner as often as every 48 hours for a period not to exceed 30 days. The donor's health is evaluated carefully at each visit; however, FDA requires that the donor's blood be tested for syphilis and hepatitis B surface antigen only at the beginning of the 30-day donation period. Likewise, FDA agrees that the donor's blood needs to be tested for antibody to HIV only at the beginning of the 30-day donation period. FDA believes this policy will eliminate unnecessary testing without jeopardizing the safety of the platelets administered to the recipient.

As discussed in comment 10, proposed § 610.45(a) is now being revised to allow for exceptions from the requirement to test each donation. As with the exception regarding products for autologous use only, the exception regarding single donor intensive plateletpheresis will be described in more detail in a memorandum from the Director, Office of Biologics Research and Review to blood establishments.

D. Product Labeling, Storage, and Restrictions on Use

12. One comment asked whether the requirements of current § 606.40(a)(4) would be fulfilled by storing blood that tests initially reactive for HIV antibody in the general quarantine area for untested blood until the completion of repeat testing. The comment agreed, however, that repeatably reactive units should be stored in a separate quarantine area reserved for biohazardous materials.

FDA finds that the storage conditions described in the comment, i.e., storage conditions in a general quarantine area for untested blood do not fulfill the requirements of current § 606.40(a)(4). Section 606.40(a)(4) requires that adequate space be available to provide for the quarantine storage of blood components in a designated location pending repetition of those tests that initially give questionable serological results. In compliance with § 606.40(a)(4), many small blood establishments designate a shelf or secondary storage container in a blood

storage refrigerator as being reserved for quarantine of blood and blood components with questionable test results. Blood with questionable test results must be isolated from untested blood at the time of labeling to assure that potentially hazardous units are not released inadvertently for transfusion when the testing of the other blood units is completed.

13. One comment on proposed § 610.45(a) asked that the regulations be amended to require that the labeling of blood and blood components indicate when testing for antibody to HIV has not been completed.

FDA agrees with the comment. In the **Federal Register** of August 30, 1985 (50 FR 35458), FDA issued a final rule revising the labeling requirements for blood and blood components intended for transfusion. The regulations became effective on September 2, 1986. Included in 21 CFR 606.121(h) is a requirement that the labels of blood or blood components shipped in an emergency, prior to the completion of testing, identify which required tests have been completed and which have not been completed before shipment. As provided in § 610.45(a)(1) (proposed § 610.45(a)), blood may be issued in a dire emergency before testing for antibody to HIV is completed. FDA is amending § 606.121(h) in this final rule to include reference to the test for antibody to HIV as one of the required tests for which the label of blood shipped in an emergency must identify the testing status.

14. Two comments asked that an exception be provided in § 610.45(c)(2) to permit the use in certain biological products of blood components known or suspected to be repeatably reactive for antibody to HIV. Specifically, the comments asked that the regulations provide for the use of such blood components in manufacturing Hepatitis B Vaccine or for manufacturing various in vitro diagnostic reagents derived from the plasma of persons with hemophilia A or B.

Under § 610.45(c)(1) of the proposed rule, blood and blood components testing repeatably reactive for antibody to HIV could be shipped or used, with limited exceptions, only for purposes and under conditions approved in writing by FDA. FDA continues to believe that this restriction on the use of such blood and blood components is necessary to assure that the agency can adequately monitor the handling, labeling, and use of these potentially hazardous materials. Accordingly, FDA does not believe that the regulations should be amended to specify the products for which repeatably reactive human blood source materials may be used in their manufacture. As provided in § 610.45(c)(1), manufacturers of products such as those mentioned in the comments may apply individually to FDA for permission to ship and use for manufacture blood and blood components that are repeatably reactive for antibody to HIV.

15. One comment by a manufacturer of blood derivatives asked whether plasma collected before the test for antibody to HIV became available (April 1985) could be used for the manufacture of albumin and immunoglobulin products. The comment expressed the belief that the manufacturing process renders these products safe for parenteral use. The comment estimated that it would take 4 years to completely dispose of all in-process lots of its products that are prepared from source materials that were not tested for antibody to HIV.

FDA advises that upon the effective date of this rule, untested plasma may not be used routinely for the manufacture of any product, including albumin and immunoglobulin products. Blood establishments have been testing blood and plasma for antibody to HIV since early 1985; therefore, supplies of untested plasma are largely depleted and supplies of tested plasma are adequate to meet routine needs. FDA recognizes that some untested plasma intended for special purposes, such as plasma containing a rare antibody that is used in the manufacture of in vitro diagnostic reagents, may still be stockpiled awaiting further manufacture. FDA also recognizes that untested plasma may be used safely in the manufacture of some biological products, provided the manufacturer takes appropriate precautions and the agency monitors the handling, labeling, and use of these potentially hazardous materials. As provided under § 610.45(a) of the final rule, a manufacturer may apply to FDA for permission to use untested plasma for further manufacture.

III. Economic, Environmental, and Paperwork Considerations

The agency has determined under 21 CFR 25.24(c)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency has examined the economic impact of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as specified in the Regulatory Flexibility Act (Pub. L. 96–354).

FDA concludes that a little over 2,000 establishments, about half of which are small businesses, will be affected by the final rule. FDA estimated that the final rule will require the performance of about 24 million serologic tests for HIV antibody each year: 14 million tests on units of blood and 10 million tests on units of Source Plasma. The nation's blood banks and plasmapheresis centers, large and small, are now performing the HIV antibody test voluntarily.

FDA cannot at this time quantify the benefits of the rule, which are related primarily to the decrease in the risk of transmitting AIDS by transfusion. Much of this benefit would take place even in the absence of these regulations, because the blood industry has instituted HIV antibody testing without the regulations. The main benefits of the regulations are to standardize industry practices, thereby providing a more complete and timely assurance of the continued safety of the nation's blood supply.

The anticipated costs are insufficient to warrant designation of this final rule as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291 or to require a regulatory flexibility analysis. Accordingly, under section 605(b) of the Regulatory Flexibility Act, the Commissioner of Food and Drugs certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch.

Sections 640.2(f) and 640.72(a)(2) of this final rule contain collection of information requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0227.

In addition, the final rule continues current collection of information requirements already submitted to OMB under section 3507 of the Paperwork Reduction Act (21 CFR 606.100 and 606.160, OMB control number 0910–0116).

List of Subjects

21 CFR Part 606

Blood, Laboratories.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Administrative Procedure Act, 21 CFR Parts 606, 610, and 640 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR Part 606 is revised to read as follows:

Authority: Secs. 201, 501, 502, 505, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended by 76 Stat. 780, 1052–1053 as amended, 1055–1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87–781 (21 U.S.C. 321, 351, 352, 355, 360 and note, 371), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 as amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)); 21 CFR 5.10 and 5.11.

2. In § 606.121 by revising paragraph (h) to read as follows:

§ 606.121 Container label.

* * * * *

(h) The following additional information shall appear on the label for blood or blood components shipped in an emergency, prior to completion of required tests, in accordance with § 640.2(f) of this chapter:

(1) The statement: "FOR EMERGENCY USE ONLY BY _____."

(2) Results of any tests prescribed under §§ 610.40, 610.45, and 640.5 (a), (b), or (c) of this chapter completed before shipment.

(3) Indication of any tests prescribed under §§ 610.40, 610.45, and 640.5 (a), (b), or (c) of this chapter and not completed before shipment.

* * * * *

3. In § 606.122 by revising paragraph (e) to read as follows:

§ 606.122 Instruction circular.

* * * * *

(e) Statements that the product was prepared from blood that was negative when tested for antibody to Human Immunodeficiency Virus (HIV) and nonreactive for hepatitis B surface antigen by FDA required tests and nonreactive when tested for syphilis by a serologic test for syphilis (STS).

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCT STANDARDS

4. The authority citation for 21 CFR Part 610 is revised to read as follows:

Authority: Secs. 201, 501, 502, 505, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended by 76 Stat. 780, 1052–1053 as amended, 1055–1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87–781 (21 U.S.C. 321, 351, 352, 355, 360 and note, 371), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 as amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)); 21 CFR 5.10 and 5.11.

5. By adding § 610.45, to read as follows:

§ 610.45 Human Immunodeficiency Virus (HIV) requirements.

(a) *Testing requirements.* (1) Each donation of human blood or blood components intended for use in preparing a product shall be tested for antibody to HIV by a test approved for such use by FDA, except as otherwise approved in writing by FDA. When the test for antibody to HIV is required, blood and blood products may be issued before the results of the test for antibody to HIV are available only in dire emergency situations or as otherwise approved in writing by FDA and, provided the test required by this paragraph is performed as soon as possible after issuance of the blood or blood product.

(2) Tests approved by FDA for the screening of blood and blood components for evidence of HIV may only be used in place of a test for antibody to HIV to satisfy the requirements of this section and related sections if so specified by FDA.

(b) *Testing responsibility.* The test for antibody to HIV shall be performed by the collection facility, by personnel of an establishment licensed to manufacture blood or blood derivatives under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or by a clinical laboratory which meets the standards of the Clinical Laboratory Improvement Act of 1967 (CLIA) (42 U.S.C. 263a), provided the establishment or clinical laboratory is qualified to perform the test.

(c) *Restrictions on use.* (1) Blood, plasma, or other blood components that are repeatably reactive to a test for antibody to HIV or that were collected from a donor whose blood is known to be repeatably reactive to a test for antibody to HIV, shall not be shipped or used to prepare any product, including products not subject to licensure; except that such blood and blood components shall be shipped or used only for purposes and under conditions specifically approved in writing by FDA.

(2) The restrictions on use contained in this paragraph shall not apply in the following cases:

(i) Blood and blood components testing repeatably reactive or from a donor whose blood is known to be repeatably reactive that are shown to be negative for evidence of HIV infection by a method or process approved for such use by FDA;

(ii) The distribution of blood, plasma, or serum samples, except when intended for use in the manufacture of a product;

(iii) The in-house use of blood and blood components for research purposes; or

(iv) The distribution of blood and blood components for research purposes, if not distributed by sale, barter, or exchange.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

6. The authority citation for 21 CFR Part 640 is revised to read as follows:

Authority: Secs. 201, 501, 502, 505, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 76 Stat. 794–795 as amended (21 U.S.C. 321, 351, 352, 355, 360, 371) and the Public Health Service Act (sec. 351, 361, 58 Stat. 702 as amended (42 U.S.C. 262, 264)) and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 702, 703, 704)); 21 CFR 5.10 and 5.11.

7. In § 640.2 by revising paragraph (f) and by adding a parenthetical statement at the end of the section, to read as follows:

§ 640.2 General requirements.

* * * * *

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in § 640.5, the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter, and a test for antibody to Human Immunodeficiency Virus (HIV) prescribed in § 610.45(a) of this chapter have been completed, where such issue is essential to allow time for transportation to ensure arrival of the blood by the time it is needed for transfusion: *Provided,* That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each container of such blood

bears the information required by § 606.121(h) of this chapter.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0227.)

8. In § 640.5 by adding paragraph (f), to read as follows:

§ 640.5 Testing the blood.

* * * * *

(f) *Test for antibody to HIV.* Whole Blood shall be tested for antibody to HIV as prescribed in § 610.45 of this chapter.

9. By revising § 640.14, to read as follows:

§ 640.14 Testing the blood.

Blood from which Red Blood Cells are prepared shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

10. In § 640.23 by revising paragraph (a), to read as follows:

§ 640.23 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Platelets shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

* * * * *

11. In § 640.33 by revising paragraph (a), to read as follows:

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

* * * * *

12. In § 640.53 by revising paragraph (a), to read as follows:

§ 640.53 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Cryoprecipitated AHF shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

* * * * *

13. By revising § 640.67, to read as follows:

§ 640.67 Laboratory tests.

(a) *Hepatitis B surface antigen.* Each unit of Source Plasma shall be nonreactive to a test for hepatitis B surface antigen as prescribed in §§ 610.40 and 610.41 of this chapter, except insofar as permitted in § 610.40(d) (2) and (3) of this chapter.

(b) *Antibody to HIV.* Each unit of Source Plasma shall be negative by a test for antibody to HIV as prescribed in § 610.45 of this chapter, except as provided in § 610.45(c) of this chapter.

14. In § 640.70 by adding paragraph (a)(11), to read as follows:

§ 640.70 Labeling.

(a) * * *

(11) The statement "Negative by a test for antibody to HIV", or equivalent statement.

* * * * *

15. In § 640.71 by adding paragraph (a)(4), to read as follows:

§ 640.71 Manufacturing responsibility.

(a) * * *

(4) A test for antibody to HIV.

* * * * *

16. In § 640.72 by revising paragraph (a)(2) and by adding a parenthetical statement at the end of the section, to read as follows:

§ 640.72 Records.

(a) * * *

(2) For each donor, a separate and complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., undertaken pursuant to §§ 640.63, 640.65, 640.66, and 640.67, except that negative test results for hepatitis B surface antigen, negative test results for antibody to HIV, and the volume or weight of plasma withdrawn from a donor need not be kept on the individual donor record: *Provided,* That such information is maintained on the premises of the plasmapheresis center where the donor's plasma has been collected.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0227.)

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary for Health and Human Services.

Dated: December 7, 1987.

[FR Doc. 88-60 Filed 1-4-88; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8171]

Income Taxes; Treatment of Salvage and Reinsurance Under Section 832 (b)

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the treatment of salvage and reinsurance in determining the paid and unpaid losses of property and casualty insurance companies. The text of the temporary regulations set forth in this document also serves as the text of the proposed regulations for the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register.** The temporary regulations are issued because the current treatment of salvage and reinsurance does not result in an accurate reflection of income for federal tax purposes. The regulations affect insurance companies taxable under section 831 (a). The Service will issue guidance making it clear that the principles of these regulations also apply to the treatment of salvage and reinsurance in determining a life insurance company's paid and unpaid losses on contracts other than life insurance contracts. See sections 811 (a), 807 (c), and 816 (c) of the Internal Revenue Code of 1986 and the regulations thereunder.

DATES: The regulations are effective as of January 1, 1988, and apply to taxable years beginning after December 31, 1987.

FOR FURTHER INFORMATION CONTACT: William L. Blagg of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Attention: CC:LR:T, (202) 566-3238 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Income Tax Regulations (26 CFR Part 1) to provide rules under section 832 (b)(5) of the Internal Revenue Code of 1986.

Explanation of Provisions

Under section 832 (b) the gross income of a property and casualty insurance company includes its underwriting income. Underwriting income means premiums earned on insurance contracts during the taxable year less losses incurred and expenses incurred. Section 832 (b) (5) provides that losses incurred are generally computed by deducting any increase in salvage and reinsurance recoverable from paid losses, and to that result adding any increase in unpaid losses. (The Tax Reform Act of 1986 provides for the discounting of unpaid losses to reflect the time value of money. The discounting of unpaid losses is expected to be the subject of another regulation project. That project is expected to address the proper treatment, under section 846 (g)(2), of salvage and reinsurance attributable to unpaid losses, where such amounts are not taken into account in determining the unpaid losses shown in the annual statement filed by the taxpayer, and

hence are not reflected in the taxpayer's "undiscounted unpaid losses," as defined in section 846 (b) (1)).

Although the statute clearly requires that paid losses be adjusted to take into account salvage recoverable (i.e., salvage not reduced to cash or cash equivalents), this adjustment generally has not been made. In 1947, the Internal Revenue Service promulgated regulations under section 832 that provided for the exclusion from salvage recoverable of an item if any state in which the taxpayer transacted business prohibited the taxpayer from reporting such an item for annual statement purposes. Several states have rules prohibiting the reporting of any salvage recoverable. These rules reflect the generally conservative nature of state reporting measures, which are designed primarily to ensure the solvency of insurance companies. After the 1947 regulations were issued, many insurance companies began transacting business in states that prohibited the reporting of salvage recoverable. There remained, however, certain regional companies which did not transact business in such states. These companies were required to take salvage recoverable into account. Despite this disparity in treatment, the exclusion of salvage recoverable was upheld in *Continental Insurance Co. v. United States*, 474 F.2d 661 (Ct. C1. 1973).

The exclusion of salvage recoverable, while consistent with state regulatory ends, does not result in an accurate reflection of income for federal tax purposes. Those purposes are best served by a close matching of income and expenses. The temporary regulations, therefore, amend § 1.832–4 (c) to require that paid losses be adjusted by all salvage recoverable attributable to such paid losses, regardless of how the salvage recoverable is reported for annual statement purposes.

Section 1.832–4 (b) of the regulations provides that the taxpayer must establish "that the part of the deduction for 'losses incurred' which represents unpaid losses at the close of the taxable year comprises only actual unpaid losses stated in amounts which, based upon the facts in each case and the company's experience with similar cases, can be said to represent a fair and reasonable estimate of the amount the company will be required to pay." The temporary regulations amend § 1.832–4 (b) of the regulations to clarify that, in making a "fair and reasonable estimate of the amount the company will be required to pay," estimated recoveries on account of salvage and reinsurance attributable to unpaid losses must be taken into account.

Thus, the temporary regulations provide that salvage and reinsurance recoverable attributable to paid losses must be taken into account under section 832 (b) (5) (A) (i) as an adjustment to paid losses. Estimated recoveries on account of salvage and reinsurance attributable to unpaid losses must be taken into account in calculating the reserve for unpaid losses under section 832 (b) (5) (A) (ii).

In addition, the temporary regulations address the adjustments that must be made if the temporary regulations require an insurance company to change its method of accounting for salvage and reinsurance. The temporary regulations provide that the fresh start of section 1023 (e) of the Tax Reform Act of 1986 is not applicable to such a change in accounting method.

Finally, the temporary regulations make explicit that the term "salvage" includes subrogation claims. The temporary regulations do not thereby change the law concerning the meaning of salvage (as illustrated by *Continental Insurance Co. v. United States*, 474 F.2d 661 (Ct. C1. 1973)), and no inference should be drawn with respect to any section of the Internal Revenue Code or the regulations thereunder that any change is intended.

Special Analyses

The Commissioner of Internal Revenue has determined that the temporary rule is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required. A general notice of proposed rulemaking is not required by 5 U.S.C. 553 for temporary regulations. Accordingly, these temporary regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these temporary regulations is William L. Blagg of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, on matters of both substance and style.

List of Subjects in 26 CFR 1.801–1 Through 1.832–6

Income taxes, Insurance companies.

Amendments to the Regulations

For the reasons set out in the preamble, Title 26, Chapter 1, Subchapter A, Part 1 of the Code of Federal Regulations is amended as set forth below:

PART 1—[AMENDED]

Paragraph 1. The authority for Part 1 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 2. Section 1.832–4 is redesignated as § 1.832–4T and amended by revising the heading, adding a new sentence at the end of paragraph (a)(5), revising paragraphs (b) and (c), and adding paragraphs (d) and (e) to read as follows:

§ 1.832-4T Gross income (temporary).

(a) * * *

(5) * * * See paragraph (b) of this section for rules relating to the treatment of salvage and reinsurance in determining unpaid losses.

(b) Every insurance company to which this section applies must be prepared to establish to the satisfaction of the district director that the part of the deduction for "losses incurred" which represents unpaid losses at the close of the taxable year comprises only actual unpaid losses stated in amounts which, based upon the facts in each case and the company's experience with similiar cases, represent a fair and reasonable estimate of the amount the company will be required to pay. Estimated recoveries on account of salvage and reinsurance attributable to unpaid losses must be taken into account in the computation of unpaid losses. The amounts of such expected recoveries should be estimated based upon the facts in each case and the company's experience with similar cases. Amounts included in, or added to, the estimates of unpaid losses which, in the opinion of the district director, are in excess of the actual liability determined as provided in the preceding sentences will be disallowed as a deduction. The district director may require any such insurance company to submit such detailed information with respect to its actual experience as is deemed necessary to establish the reasonableness of the deduction for "losses incurred."

(c) That part of the deduction for "losses incurred" which represents an adjustment to losses paid for salvage and reinsurance recoverable shall include all salvage in course of liquidation, and all reinsurance in process of collection not otherwise taken into account as a reduction of losses paid, outstanding at the end of the taxable year. Salvage in course of liquidation includes all property (other than cash or cash equivalents), real or

personal, tangible or intangible. Such salvage in course of liquidation shall be taken into account to the extent of the value thereof at the end of the taxable year as determined from a fair and reasonable estimate based upon either the facts in each case or the company's experience with similar cases. Cash or cash equivalents received during the taxable year with respect to items of salvage or reinsurance shall reduce losses paid during such taxable year. For purposes of this section the term "salvage" includes subrogation claims.

(d)(1) The treatment of salvage and reinsurance is a method of accounting. Every insurance company to which this section applies that did not treat salvage and reinsurance as provided in this section for the last taxable year beginning before January 1, 1988, must change its method of accounting with respect to salvage and reinsurance in the first taxable year beginning after December 31, 1987. The change in method of accounting will result in a section 481(a) adjustment. The fresh start provision of section 1023(e) of the Tax Reform Act of 1986 does not apply to the change in method of accounting required by this paragraph (d)(1).

(2) In the case of any insurance company required by paragraph (d)(1) of this section to change its method of accounting for any taxable year, such change shall be treated as initiated by the taxpayer and made with the consent of the Commissioner.

(3) Any insurance company required to change its method of accounting under paragraph (d)(1) of this section shall take the required adjustment into account as provided in applicable administrative procedures.

(e) This section is effective for taxable years beginning after December 31, 1987. In computing unpaid losses for taxable years beginning before January 1, 1988, an insurance company to which this section applies is not required to take into account estimated recoveries on account of salvage attributable to unpaid losses. In addition, in computing paid losses for such taxable years, an insurance company to which this section applies is not required to take into account salvage recoverable if during such taxable years the inclusion of such salvage was prohibited by the laws of a state in which the company transacted business.

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason it is impracticable to issue this Treasury decision with notice and public procedure under section (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

Lawrence B. Gibbs,

Commissioner of Internal Revenue.

Approved: December 22, 1987.

Donaldson Chapoton,

Assistant Secretary of the Treasury.

[FR Doc. 87-30193 Filed 12-30-87; 1:51 pm]

BILLING CODE 4830-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD7-87-37]

Drawbridge Operation Regulations; Okeechobee Waterway, Florida

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of Martin County, the Coast Guard is changing regulations governing the Evans Crary drawbridge in Martin County by permitting the number of openings to be limited during certain periods. This change is being made because of complaints about highway traffic delays. This action will accommodate the current needs of vehicular traffic and still provide for reasonable needs of navigation.

EFFECTIVE DATE: These regulations become effective on February 4, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Walt Paskowsky, telephone (305) 536-4103.

SUPPLEMENTARY INFORMATION: On October 2, 1987, the Coast Guard published proposed rule (52 FR 36961) concerning this amendment. The Commander, Seventh Coast Guard District, also published the proposal as a Public Notice dated October 16, 1987. In each notice, interested persons were given until November 16, 1987, to submit comments.

Drafting Information

The drafters of these regulations are Mr. Walt Paskowsky, Bridge Administration Specialist, project officer, and Lieutenant Commander S.T. Fuger, Jr., project attorney.

Discussion of Comments

The Coast Guard's notice of proposed rulemaking solicited comments on a proposal to change the operating regulations of the Evans Crary bridge and the Roosevelt bridge. Over 100 comments were received concerning the proposed rule change for the Roosevelt bridge and that matter is being witheld for further study. 60 of these comments were generally in support of the proposed regulations for both bridges including 2 petitions with 61 signatures. Many commenters complained about vessels which request openings merely to clear outriggers and antennae. The requirement to lower these appurtenances is contained in 33 CFR 117.11. Several commenters asked that signs stating the bridge opening times be placed along both the waterway and the highway. Waterway signs are addressed by 33 CFR 117.55. Posting of highway signs is not within the Coast Guard's jurisdiction, but the suggestion will be passed to the Florida Department of Transportation. One commentor expressed concern for movement of emergency vehicles when the bridge is open for navigation. This is addressed in 33 CFR 117.31. Some commenters suggested that a limit be placed on the number of vessels allowed to pass through an open bridge to avoid extended openings. This is not considered a safe navigational practice. 33 CFR 117.9 addresses unnecessary delays in the opening and closure of the draw. Several commenters asked that the regulations be implemented year-round. Available highway traffic and bridge opening data do not support the need for year-round regulations. No objections were received from navigation interests; however 1 commenter stated the regulations should be temporary, contingent on replacement of the drawbridge by a high level fixed bridge within 2 years. The Coast Guard offers no comment on this proposal since replacement of the bridge goes beyond the scope of these regulations. After careful consideration of all comments, the Coast Guard has determined the final rule for the Evans Crary bridge will be unchanged from the proposed rule published on October 2, 1987.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979).

The economic impact has been found to be so minimal that a full regulatory evaluation is unnecessary. We conclude this because the regulations exempt tugs with tows. Since the economic impact of these regulations is expected to be minimal, the Coast Guard certifies that they will not have a significant