

b. By revising the phrase "ECCNs 5A001.c and 5A994" to read "ECCNs 5A001.c and 5A991.c.1" in the introductory text of paragraph (c)(29); and

c. By revising the phrase "described in ECCN 1C994" to read "described in ECCN 1C006.d" in the heading of paragraph (c)(33).

**PART 744—[AMENDED]**

18. Section 744.8 is amended by revising paragraph (b) to read as follows:

**§ 744.8 Restrictions on certain exports to all countries for Libyan aircraft.**

\* \* \* \* \*

(b) *Scope of products subject to end-use prohibition for Libyan aircraft.* The general end-use prohibition in paragraph (a) of this section applies to items controlled by ECCNs 6A008, 6A108, 6A998, 7A001, 7A002, 7A003, 7A004, 7A006, 7A101, 7A102, 7A103, 7A104, 7A994, 9A001, 9A003, 9A018.a, 9A101, and 9A991.

\* \* \* \* \*

**PART 746—[AMENDED]**

**§ 746.4 [Amended]**

19. Section 746.4(c)(6) is amended by revising the phrase "ECCN 9A992" to read "ECCN 9A990.b".

20. Section 746.7 is amended by revising paragraph (a)(2)(ii) to read as follows:

**§ 746.7 Iran.**

\* \* \* \* \*

- (a) \* \* \*
- (2) \* \* \*

(ii) To reexport to Iran any of the items identified in paragraph (a)(2)(i) of this section, except for ECCNs 2A994; 3A992.a; 5A991.f; 5A992; 6A991; 6A998; 7A994; 8A992.d, .e, .f, and .g; 9A990.a and .b; and 9A991.d and .e. However, the export of these items from the United States to any destination with knowledge that they will be reexported, in whole or in part, to Iran, is prohibited without a license; or

\* \* \* \* \*

21. Section 746.8 is amended by revising paragraph (b)(1)(ii) to read as follows:

**§ 746.8 Rwanda.**

\* \* \* \* \*

- (b) \* \* \*
- (1) \* \* \*

(ii) Items described by any ECCN ending in "018", and items described by ECCNs 0A982; 0A984; 0A986; 0A988; 0B986; 1A005; 5A980; 6A002.a.1, a.2, a.3, and .c; 6A003.b.3 and b.4; 6E001; 6E002; and 9A991.a.

\* \* \* \* \*

**PART 748—[AMENDED]**

22. Supplement No. 2 to part 748 is amended by revising paragraphs (h)(1)(i)(G) and (h)(1)(ii)(H) to read as follows:

**Supplement No. 2 to Part 748—Unique License Application Requirements**

\* \* \* \* \*

- (h) \* \* \*
- (1) \* \* \*
- (i) \* \* \*

(G) Description of capabilities related to "real time processing" and receiving computer aided-design;

\* \* \* \* \*

- (ii) \* \* \*

(H) Slide motion test results.

\* \* \* \* \*

**PART 752—[AMENDED]**

**§ 752.3 [Amended]**

23. Section 752.3(a)(2) is amended by revising the phrase "1E001, 1E350, 1E391, 2B352," to read "1E001, 1E350, 1E351, 2B352,".

Dated: July 30, 1998.

**R. Roger Majak,**

*Assistant Secretary for Export Administration.*

[FR Doc. 98-21060 Filed 8-6-98; 8:45 am]

BILLING CODE 3510-33-P

**SECURITIES AND EXCHANGE COMMISSION**

**17 CFR Part 240 and 249**

[Release No. 34-40163A; File No. S7-8-98]

RIN 3235-AH42

**Year 2000 Readiness Reports To Be Made by Certain Transfer Agents Correction**

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Correction to final regulation.

**SUMMARY:** This document contains a correction to final regulation (Rule 17Ad-18), which was published Monday, July 13, 1998 (63 FR 37688). Rule 17Ad-18 requires certain transfer agents to file with the Commission two reports regarding their Year 2000 preparations.

**EFFECTIVE DATE:** The correction becomes effective August 7, 1998.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Mooney, Special Counsel, 202/942-4174, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW, Mail Stop 10-1, Washington, DC 20549.

**SUPPLEMENTARY INFORMATION:**

**Background**

New Rule 17Ad-18 requires certain transfer agents to file two reports regarding their Year 2000 preparations with the Commission on new Form TA-Y2K. The reports will increase transfer agent awareness of the specific steps they should be taking to prepare for the Year 2000; help coordinate industry testing and contingency planning; supplement the Commission's examination module for Year 2000 issues and identify potential Year 2000 compliance problems; and provide information regarding the securities industry's preparedness for the Year 2000.

**Need for Correction**

As published, Rule 17Ad-18 contains an error that may prove to be misleading and that needs to be corrected.

**Correction of Publication**

Accordingly, the publication on July 13, 1998, of Rule 17Ad-18, which was the subject of FR Doc. 98-18296, is corrected as follows:

**Appendix A—(Corrected)**

Appendix A. On page 37697, the first sentence of the first paragraph under the heading Part II is corrected by inserting the word "not" between the words "are" and "eligible."

Dated: August 3, 1998.

**Jonathan G. Katz,**  
*Secretary.*

[FR Doc. 98-21106 Filed 8-6-98; 8:45 am]

BILLING CODE 8010-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 806**

[Docket No. 98N-0439]

**Medical Devices; Reports of Corrections and Removals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations that govern reports of corrections and removals of medical devices to eliminate the requirement for distributors to make such reports. The amendments are being made to implement provisions of the Federal Food, Drug, and Cosmetic Act (the act),

as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is publishing these amendments in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

**DATES:** The regulation is effective December 21, 1998. Submit written comments on or before October 21, 1998. Submit written comments on the information collection provisions on or before October 6, 1998. If FDA receives no significant adverse comment within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends.

**ADDRESSES:** Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301-827-2970.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Changes Required by FDAMA*

FDAMA amended section 519(f) of the act (21 U.S.C. 360i(f)) to eliminate the requirement that distributors report corrections and removals. Section 519(f)(1) of the act previously required FDA to require device manufacturers, distributors, and importers to report promptly to FDA any correction or removal of a device undertaken: (1) To reduce a risk to health posed by the device; or (2) to remedy a violation of the act caused by a device which may present a risk to health. Section 519(f)(1) of the act also had required that manufacturers, distributors, and importers keep records of those corrections and removals that are not required to be reported to FDA. In accordance with the changes required by FDAMA, the reporting and recordkeeping requirements relating to corrections and removals have been eliminated for distributors. The requirements of the statute and FDA's implementing regulations remain unchanged for manufacturers and

importers. In addition, FDAMA did not change the remaining provisions of 519(f) of the act. Section 519(f)(2) of the act provides that no report of a correction or removal action under section 519(f)(1) of the act may be required if a report of the correction or removal is required and has been submitted to FDA under section 519(a), which prescribes rules for reporting and keeping records of certain significant device-related events. Section 519(f)(3) of the act states that the terms "correction" and "removal" do not include routine servicing.

*B. History of Part 806*

In the **Federal Register** of May 17, 1997 (62 FR 27183), FDA issued a final rule implementing the reports of corrections and removals provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101-629), which required device manufacturers, distributors, and importers to report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. These regulations were codified at part 806 (21 CFR part 806).

In the **Federal Register** of December 24, 1997 (63 FR 67274), FDA announced that it was staying the effective date of the information collection requirements of part 806 because the information collection requirements in the final rule had not yet received approval from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Following OMB's approval of the collection of information provisions for reports of corrections and removals (see the **Federal Register** February 17, 1998 (63 FR 7811)), FDA published a final rule in the **Federal Register** of April 16, 1998 (63 FR 18836) lifting the stay of effective date and the information collection requirements became effective May 18, 1998.

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105-115). Section 213 of FDAMA amended section 519(f) of the act by eliminating "distributors" from the reporting requirements of the reports of corrections and removals provisions of the act. FDAMA did not change the obligations of device manufacturers and importers, who continue to be required to comply with the existing reporting and recordkeeping provisions of the act for corrections and removals.

**II. Changes to Part 806—Medical Devices; Reports of Corrections and Removals**

Section 519(f)(1) of the act, as amended by section 213 of FDAMA, no longer requires "distributors" to report corrections and removals of medical devices. Accordingly, the following changes are being made to part 806 to implement the FDAMA provision:

1. Section 806.1 has been amended in paragraphs (a) and (b)(1) by changing the words "manufacturers and distributors, including importers," to "manufacturers and importers."

2. Section 806.2(f) has been amended by eliminating the definition of "distributor" that included a person who imports devices into the United States, and replacing that definition of distributor with a separate definition of "importer." For the purposes of this part, "importer" means any person who imports a device into the United States.

3. Section 806.10 has been revised in paragraphs (a), (b), (c), (c)(2), (c)(4), (d), and (e) to remove the word "distributor" each time it appears.

4. Section 806.20 has been amended in paragraphs (a) and (c) to remove the words "importer, or distributor" each time they appear and replace them with "or importer."

5. Section 806.30 is amended to remove the words "importer, or distributor" each time they appear and replace them with "or importer."

**III. Rulemaking Action**

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to an existing regulation, incorporating amendments to section 519(f) of the act made by FDAMA, and FDA anticipates no significant adverse comment. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend 21 CFR part 806. The companion proposed rule is substantively identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the comment period for the companion proposed rule. Any comments received under the companion proposed rule will be

considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule of 75 days after August 7, 1998. If the agency receives any significant adverse comment, FDA intends to withdraw this final rule by publication of a document in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment requesting that device manufacturers report corrections and removals under part 806 when a report is required and has already been submitted under 21 CFR part 803 will not be considered a significant adverse comment because it is outside the scope of the rule. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule using the agency's usual notice-and-comment procedures under the Administrative Procedure Act (5 U.S.C. 552 *et seq.*). If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends confirming that the direct final rule will go into effect on December 21, 1998.

#### IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

#### V. Analysis of Impacts

FDA has examined the impact of this direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule eliminates the reporting requirements for "distributors," as mandated by FDAMA, thereby reducing regulatory burdens. The agency certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local or tribal governments in the aggregate, or by the private sector, in any 1 year.

#### VI. Paperwork Reduction Act of 1995

The direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Medical Devices; Reports of Corrections and Removals.

*Description:* FDA is issuing this rule to amend the reporting and recordkeeping requirements for corrections and removals under part 806 to eliminate those requirements for distributors of medical devices. This amendment implements changes made by FDAMA to section 519(f) of the act. FDAMA did not amend section 519(f) with respect to manufacturers and importers. Manufacturers and importers continue to be subject to the requirements of part 806.

*Description of Respondents:* Business or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

<sup>1</sup> There are no operating and maintenance costs or capital costs associated with this information collection.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
806.20	440	1	440	10	4,400

<sup>1</sup> There are no operating and maintenance costs or capital costs associated with this information collection.

The information collection requirements in part 806 prior to this direct final rule have been approved by OMB and assigned control number 0910-0359. When preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under 21 CFR part 7 (the agency's recall provisions). During that period of time, no reports of corrections or removals were submitted by distributors. For that reason, FDA did not include distributors among the respondents estimated in the collection burden for the requirements previously approved by OMB. Because distributors were not included in that earlier estimate and because FDAMA now has eliminated requirements for distributor reporting, FDA has determined that estimates of the reporting burden for §§ 806.10 and 806.20 should remain the same.

As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection requirements of this direct final rule by October 6, 1998 to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a document in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a document in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**VII. Comments**

Interested persons may on or before October 21, 1998, submit written

comments regarding this rule to the Dockets Management Branch (address above). This comment period runs concurrently with the comment period for the companion proposed rule. 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 the brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

**List of Subjects in 21 CFR Part 806**

Corrections and removals, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 806 is amended as follows:

1. The part heading for part 806 is revised to read as follows:

**PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS**

2. The authority citation for 21 CFR part 806 continues to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

3. Section 806.1 is amended by revising paragraphs (a) and (b)(1) to read as follows:

**§ 806.1 Scope.**

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such

corrections and removals are required to be reported to FDA.

(b) \* \* \*

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

\* \* \* \* \*

4. Section 806.2 is amended by revising paragraph (f) to read as follows:

**§ 806.2 Definitions.**

\* \* \* \* \*

(f) "Importer" means, for the purposes of this part, any person who imports a device into the United States.

\* \* \* \* \*

5. Section 806.10 is amended by revising paragraphs (a) and (b), the introductory text of paragraph (c), paragraph (c)(2), and the last sentence of paragraph (c)(4); and in paragraphs (d) and (e) by removing the word "distributor," each time it appears to read as follows:

**§ 806.10 Reports of corrections and removals.**

(a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).

(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.

(c) The manufacturer or importer shall include the following information in the report:

\* \* \* \* \*

(2) The name, address, and telephone number of the manufacturer or importer,

and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.

\* \* \* \* \*

(4) \* \* \* A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.

\* \* \* \* \*

6. Section 806.20 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 806.20 Records of corrections and removals not required to be reported.**

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.

\* \* \* \* \*

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

7. Section 806.30 is revised to read as follows:

**§ 806.30 FDA access to records.**

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

Dated: July 9, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98-21091 Filed 8-6-98; 8:45 am]

BILLING CODE 4160-01-F

**UNITED STATES INFORMATION AGENCY**

**22 CFR Part 514**

**Exchange Visitor Program**

**AGENCY:** United States Information Agency.

**ACTION:** Statement of Policy.

**SUMMARY:** The Agency hereby announces its policy regarding requests for waiver of the two-year home country physical presence requirement set forth in Section 1182(e) of the Immigration and Nationality Act based upon the applicant's assertion that fulfillment of such requirement is not possible due to the loss of home country citizenship.

**EFFECTIVE DATE:** This policy statement is effective August 7, 1998.

**FOR FURTHER INFORMATION CONTACT:** Stanley S. Colvin, Assistant General Counsel, United States Information Agency, 301 4th Street, SW, Washington, DC 20547; telephone, (202) 619-6531.

**SUPPLEMENTARY INFORMATION:** The Director of the United States Information Agency is required by Section 1182(e) of the Immigration and Nationality Act to make recommendations to the Attorney General regarding the grant or denial of the two-year home country physical presence requirement imposed upon certain aliens who have entered the United States on a J visa or subsequently acquired such nonimmigrant status. Aliens who have received government funds, pursued graduate medical education or training, or who have participated in an activity involving skills identified of interest to the government of his or her home country are subject to the two-year home country physical presence requirement, viz., "until it is established that such person has resided and been physically present in the country of his nationality or his last residence for an aggregate of at least two years following departure from the United States." If subject, an alien must fulfill this requirement or have it waived before he or she is eligible to adjust to H, L, or legal permanent resident status.

Recommendations regarding the grant or denial of a waiver request are based upon a review of the unique program, policy, and foreign relations aspects presented by each individual request. Recently, the Agency has been approached and requested to recognize a theory that certain aliens subject to the return home requirement should be granted a waiver because their home country has revoked, by operation of law, their citizenship due to the acquisition of citizenship or legal permanent residence in another country. This theory suggests that the section 1182(e) requirement should be waived because the loss of citizenship has made it impossible for the alien to fulfill this requirement. Having

reviewed this matter at length, the Agency cannot adopt this theory as a matter of policy and will not recommend the grant of a waiver based solely upon the loss of home country citizenship. In many cases, other means of fulfillment, such as the utilization of a nonimmigrant visa for entry into the home country are available.

The Agency will review, on a case by case basis, those extraordinarily few instances where fulfillment of the Section 1182(e) requirement is impossible due to facts totally beyond the control of the waiver applicant and which were not the predictable consequences of action on the part of the applicant. Compelling and probative evidence of such impossibility of performance, furnished by the alien, is necessarily a prerequisite to Agency review. Such evidence may be, for example, proof of denial of a request for a nonimmigrant visa from the home country or denial of a request to restore home country citizenship.

**List of Subjects in 22 CFR Part 514**

Cultural exchange programs.

Dated: July 30, 1998.

**Les Jin,**

*General Counsel.*

[FR Doc. 98-21137 Filed 8-6-98; 8:45 am]

BILLING CODE 8230-01-M

**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 165**

[CGD01-98-102]

RIN 2115-AA97

**Safety Zone: Staten Island Fireworks, New York Harbor, Lower Bay**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Staten Island fireworks programs located in New York Harbor, Lower Bay. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of Lower Bay, New York Harbor.

**DATES:** This rule is effective July 21, 1998 through September 13, 1998. Compliance is required from 8:45 p.m. until 10:15 p.m. on the following dates: July 21, 1998; August 4, 1998; August 11, 1998; August 25, 1998; and September 12, 1998. If inclement weather causes cancellation of the fireworks display on September 12,