

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

**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,

**UNITED STATES INFORMATION AGENCY**

**22 CFR Part 514**

**Exchange Visitor Program**

**AGENCY:** United States Information Agency.