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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2005–N–0346] (formerly 2005N–0467)

Medical Devices; Radiology Devices; Reclassification of Bone Sonometers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of July 17, 2008 (73 FR 40967). The final rule reclassified bone sonometer devices from class III into class II, subject to special controls. The document contained an inadvertent error regarding the impact of the final rule on small businesses. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Domini Cassis, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2342.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–16354, appearing on page 40969 in the **Federal Register** of Thursday, July 17, 2008, there was an error regarding the impact of the final rule on small businesses. Specifically, language certifying that the final rule meets the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612) was inadvertently omitted during document preparation. Accordingly, the following correction is made:

1. On page 40969, in the middle column, under section ''VI. Analysis of Impacts,'' in the second full paragraph, the third sentence is revised to read: ''The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: August 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18792 Filed 8–13–08; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 6316]

RIN 1400–AC47

Amendment to the International Traffic in Arms Regulations: The United States Munitions List Category VIII

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the text of the International Traffic in Arms Regulations (ITAR), Part 121 to add language clarifying how the criteria of Section 17(c) of the Export Administration Act of 1979 (''EAA'') are implemented in accordance with the Department of State's obligations under the Arms Export Control Act (''AECA''), and restating the Department's longstanding policy and practice of implementing the criteria of this provision.

DATES: *Effective Date:* This rule is effective August 14, 2008.

FOR FURTHER INFORMATION CONTACT: Director Ann Ganzer, Office Defense Trade Controls Policy, Department of State, Telephone (202) 663–2792 or Fax (202) 261–8199; e-mail *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change, ITAR Part 121.

SUPPLEMENTARY INFORMATION: On April 11, 2008, the Department published a Notice of Proposed Rulemaking (NPRM) to add language clarifying how the criteria of Section 17(c) of the Export Administration Act of 1979 are implemented in accordance with the Arms Export Control Act by amending Category VIII *(b), (h), and the Note. Further background is provided with the NPRM at 73 FR 19778.

This rule reinstates the Section 17(c) reference in the ITAR to assist exporters in understanding the scope and application of the Section 17(c) criteria to parts and components for civil aircraft. It also clarifies that any part or component that (a) is standard equipment; (b) is covered by a civil aircraft type certificate (including amended type certificates and supplemental type certificates) issued by the Federal Aviation Administration for civil, non-military aircraft (this expressly excludes military aircraft certified as restricted and any type certification of Military Commercial Derivative Aircraft, defined by FAA Order 8110.101 effective date September 7, 2007 as ''civil aircraft procured or acquired by the military''); and (c) is an integral part of such civil aircraft, is subject to the jurisdiction of the Export Administrative Regulations (EAR). Where such part or component is not Significant Military Equipment (''SME''), no Commodity Jurisdiction (CJ) determination is required to determine whether the item meets these criteria for exclusion under the United States Munitions List (USML), unless doubt exists as to whether these criteria have been met. However, where the part or component is SME, a CJ determination is always required, except where a SME part or component was integral to civil aircraft prior to the effective date of this rule.

Additionally, this proposed rule adds language in a new Note after Category VIII(h) to provide guidelines concerning the parts or components meeting these criteria. The change to Category VIII*(b) also identifies and designates certain sensitive military items, heretofore controlled under Category VIII(h), as SME. Previous and current authorizations concerning the manufacturer of these items will not require notification in accordance with § 124.11, and will not require a ''Nontransfer and Use Certificate'' DSP–83, unless they are amended, modified, or renewed.

This requirement for a CJ determination by the Department of State helps ensure the U.S. Government is made aware of, and can reach an informed decision regarding, any sensitive military item proposed for standardization in the commercial aircraft industry before the item or technology is actually applied to a commercial aircraft program, whether such item is integral to the aircraft, and, if so, whether the development, production, and use of the technology