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DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 774****The Commerce Control List***CFR Correction*

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2012, in supplement no. 1 to part 774, in Category 6, make the following corrections:

- 1. In 6A001:
 - A. On page 807, in the note following paragraph 6A001.a.1, add “equipment as follows” after “6A001.a.1 does not control”.
 - B. On page 807, in paragraph a.1.a.1.a, remove “20” and add “20” in its place.
 - C. On page 810, designating the notes following 6A001.b.2 as “Note 1” and “Note 2”.
 - D. On page 810, removing the note to 6A001.a.2 following the N.B. at the end of the section.
- 2. In 6A992, on page 826, in the table for “License Requirements”, remove the entry for RS and place it below the table as an indented paragraph.
- 3. In 6B108, on page 830, remove “Unit: r” and add “Unit: Number” in its place.
- 4. In 6C005, on page 831, add “License Requirements” above “Reason for Control”.
- 5. In 6D001, on page 831, remove “CIV: * * *” and add “CIV: N/A” in its place.
- 6. In 6D003:
 - A. On page 832, in “Reason for Control”, after “NS”, add “RS,”.
 - B. On page 833, remove paragraphs h.1.a and h.1.b.
- 7. In 6E001, on page 834, add “License Requirements” above “Reason for Control”.
- 8. In 6E002, on page 835, add “License Requirements” above “Reason for Control”.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 807**

[Docket No. FDA-2009-N-0114]

RIN 0910-AF88

Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect recent statutory amendments to the device registration and listing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Food and Drug Administration Amendments Act of 2007 (FDAAA), enacted on September 27, 2007, amended the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In addition, this final rule would facilitate FDA’s collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The final rule will update certain provisions in the regulations to improve the quality of registration and listing information available to FDA. FDA relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

DATES: This final rule is effective October 1, 2012.

FOR FURTHER INFORMATION CONTACT:

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I. Background

We originally published establishment registration regulations for medical devices in the **Federal Register** of September 3, 1976 (41 FR 37458) (proposed rule) and August 23, 1977 (42 FR 42520) (final rule), and device listing regulations in the **Federal Register** of September 30, 1977 (42 FR 52808) (proposed rule), and August 25, 1978 (43 FR 37990) (final rule).

These regulations called for establishment registration and device listing information to be submitted to the Center for Devices and Radiological Health (CDRH) on several paper forms: FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing. Once these forms were completed and submitted to FDA, FDA then forwarded them to a data entry contractor who entered the information into FDA’s device registration and listing database.

In June 2002, section 321 of the Bioterrorism Act (Pub. L. 107-188) amended section 510(i) of the FD&C Act (21 U.S.C. 360(i)) to require those foreign establishments who are required to register with FDA to do so by electronic means, and to include additional information identifying certain parties involved in the importation of the foreign establishment’s devices into the United States as part of their registration. Subsequently, in October 2002, section 207 of the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107-250) further amended section 510 of the FD&C Act by extending the requirement for electronic submission of registration information to include domestic firms as well as foreign firms. However, when adding these new electronic submission requirements, which appear in section 510(p) of the FD&C Act, Congress chose to delay their implementation so that FDA would have an opportunity to first put systems in place to accommodate the electronic receipt of registration information. This was accomplished by including a