of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND
MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:


2. Section 866.3305 is revised to read as follows:

§ 866.3305 Herpes simplex virus
serological assays.

(a) Identification. Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.

(b) Classification. (1) Class II (special controls). The device is classified as class II (special controls) if the herpes simplex virus serological assay is type 1 and/or 2. The special control for the device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.” For availability of the guidance document, see § 866.1(e).

(2) Class III (premarket approval). The device is classified as class III if the herpes simplex virus serological assay is a type other than type 1 and/or 2.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established for the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 866.3.


Linda S. Kahan,
Deputy Director, Center for Devices and Radiological Health.

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subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 126
Arms and munitions, Exports.
Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PRACTICES
1. The authority citation for part 126 continues to read as follows:

2. Section 126.1 is amended by revising paragraph (a) and adding paragraph (l) to read as follows:

§ 126.1 Prohibited exports and sales to certain countries.
(a) General. It is the policy of the United States to deny licenses and other approvals for exports and imports of defense articles and defense services, destined for or originating in certain countries. This policy applies to Belarus, Cuba, Iran, North Korea, Syria, and Venezuela. This policy also applies to countries with respect to which the United States maintains an arms embargo (e.g., Burma, China, Liberia, Somalia, and Sudan) or whenever an export would not otherwise be in furtherance of world peace and the security and foreign policy of the United States. Information regarding certain other embargoes appears elsewhere in this section. Comprehensive arms embargoes are normally the subject of a State Department notice published in the Federal Register. The exemptions provided in the regulations in this subchapter, except § 123.17 of this subchapter, do not apply with respect to articles originating in or for export to any proscribed countries, areas, or persons in this § 126.1.

* * * * *

(l) Vietnam. It is the policy of the United States to deny licenses, other approvals, exports or imports of defense articles and defense services destined for or originating in Vietnam except, on a case-by-case basis, for:
(1) Non-lethal defense articles and defense services, and
(2) Non-lethal, safety-of-use defense articles (e.g., cartridge actuated devices, propellant actuated devices and technical manuals for military aircraft for purposes of enhancing the safety of the aircraft crew) for lethal end-items.

For non-lethal defense end-items, no distinction will be made between Vietnam’s existing and new inventory.


Stephen D. Mull,
Acting Assistant Secretary for Political-Military Affairs, Department of State.

BILLING CODE 4710–25–P

DEPARTMENT OF THE TREASURY
Office of Foreign Assets Control
31 CFR Parts 538 and 560
Sudanese Sanctions Regulations; Iranian Transactions Regulations
AGENCY: Office of Foreign Assets Control, Treasury.
ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury is amending the Sudanese Sanctions Regulations, 31 CFR part 538, and the Iranian Transactions Regulations, 31 CFR part 560, to authorize the exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, of any goods or technology to a third-country government, or to its contractors or agents, for shipment to, respectively, Sudan or Iran via a diplomatic pouch.

DATES: Effective Date: April 3, 2007.


SUPPLEMENTARY INFORMATION:
Electronic and Facsimile Availability
This document and additional information concerning the Office of Foreign Assets Control are available from OFAC’s Web site (http://www.treas.gov/ofac) or via facsimile through a 24-hour fax-on-demand service, tel.: (202) 622–0077.

Background
The Sudanese Sanctions Regulations, 31 CFR part 538 (the “SSR”), were promulgated to implement Executive Order 13067 of November 3, 1997 (“E.O. 13067”), in which the President declared a national emergency with respect to the policies and actions of the Government of Sudan. To deal with that emergency, E.O. 13067 imposed comprehensive trade sanctions with respect to Sudan and blocked all property and interests in property of the Government of Sudan in the United States or within the possession or control of United States persons. Subsequently, the President issued Executive Order 13412 of October 13, 2006 (“E.O. 13412”), to take additional steps with respect to the emergency declared in E.O. 13067. While it exempted specific areas of Sudan from certain prohibitions in E.O. 13067, E.O. 13412 continued the blocking of the Government of Sudan’s property and interests in property and imposed a prohibition on transactions relating to Sudan’s petroleum or petrochemical industries. E.O. 13412 also removed the regional government of Southern Sudan from the definition of the Government of Sudan.

Existing § 538.516 of the SSR authorizes all transactions in connection with the importation into the United States from Sudan, or the exportation from the United States to Sudan, of diplomatic pouches and their contents. OFAC is amending this general license to expand the scope of authorized transactions relating to the importation and exportation of diplomatic pouches and their contents. Specifically, OFAC is revising § 538.516 of the SSR by redesignating the original section as § 538.516(a) and by adding a new paragraph (b). New § 538.516(b) authorizes the exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, of any goods or technology to a third-country government, or to its contractors or agents, for shipment to Sudan via a diplomatic pouch. In addition, § 538.516(b) clarifies that, to the extent necessary, the shipment by a third-country government to Sudan of U.S.-origin goods or technology in a diplomatic pouch is authorized.

The Iranian Transactions Regulations, 31 CFR part 560 (the “ITR”), implement a series of Executive orders, beginning with Executive Order 12957 of March 15, 1995, in which the President declared a national emergency with respect to the actions and policies of the Government of Iran. To deal with that threat, Executive Order 12957 imposed prohibitions on certain transactions with respect to the development of Iranian petroleum resources. On May 6, 1995, the President issued Executive Order 12959 imposing comprehensive trade sanctions to further respond to the threat, and on August 19, 1997, the President issued Executive Order 13059