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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

General Hospital and Personal Use Devices

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 800 to 1299, revised as of April 1, 2006, on page 410, in § 880.5950, paragraph (b) is corrected to read as follows:

§ 880.5950 Umbilical occlusion device.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.
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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC") is amending the Iranian Transactions Regulations, 31 CFR part 560, to revoke the authorizations contained in § 560.516 with respect to Bank Saderat and to except Bank Saderat from the scope of § 560.405 and § 560.532(b). These amendments effectively prohibit all transactions directly or indirectly involving Bank Saderat. In addition, OFAC is making a technical amendment to paragraph (a)(1) of § 560.516.

DATES: *Effective Date:* September 8, 2006.

FOR FURTHER INFORMATION CONTACT:

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Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning the Office of Foreign Assets Control ("OFAC") 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 Iranian Transactions Regulations, 31 CFR part 560 (the "ITR"), implement a series of Executive orders, beginning with Executive Order 12957, issued on March 15, 1995, under the authority of the International Emergency Economic Powers Act (50 U.S.C. 1701-1706) ("IEEPA"). In that order, the President declared a national emergency with respect to the actions and policies of the Government of Iran, including its support for international terrorism, its efforts to undermine the Middle East peace process, and its efforts to acquire weapons of mass destruction and the means to deliver them. 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 this threat, and on August 19, 1997, the President issued Executive Order 13059 consolidating and clarifying the previous orders.

The Office of Foreign Assets Control ("OFAC") is amending the ITR to cut off Bank Saderat, one of the largest Iranian government-owned banks, from the U.S. financial system. Bank Saderat has been a significant facilitator of Hizballah's financial activities and has served as a conduit between the Government of Iran and Hizballah, Hamas, the Popular Front for the Liberation of Palestine-General Command, and Palestinian Islamic Jihad.

To cut off Bank Saderat from the U.S. financial system, OFAC is making three amendments to the ITR that effectively prohibit all transactions directly or indirectly involving Bank Saderat. OFAC is amending § 560.516, a general license authorizing payment and U.S. dollar clearing transactions involving Iran, to revoke its applicability to Bank Saderat. OFAC is also amending § 560.405, an interpretive section, and § 560.532(b), a statement of licensing policy, to exclude Bank Saderat from the scope of these provisions.

Section 560.516(a) authorizes U.S. depository institutions to process transfers of funds to or from Iran, or for the direct or indirect benefit of persons in Iran or the Government of Iran, if the transfer is covered in full by any of the following conditions and does not involve debiting or crediting an Iranian account: (1) The transfer is by order of a non-Iranian foreign bank from its own account in a domestic bank to an account held by a domestic bank for a second non-Iranian foreign bank; (2) the transfer arises from an underlying transaction that has been authorized by a specific or general license issued pursuant to the ITR; (3) the transfer arises from an underlying transaction that is not prohibited by the ITR; or (4) the transfer arises from an underlying transaction that is exempted from regulation pursuant to § 203(b) of IEEPA. Section 560.516(b) authorizes U.S. registered brokers or dealers in securities to process transfers of funds to or from Iran, or for the direct or indirect benefit of persons in Iran or the Government of Iran, if the transfer is covered in full by any of the conditions set forth in (2)-(4) above and does not involve debiting or crediting an Iranian account. The term *Iranian account* is defined in § 560.320 to mean an account of a person located in Iran or of the Government of Iran maintained on the books of either a U.S. depository institution or a U.S. registered broker or dealer in securities.

OFAC is adding a new paragraph (f) to § 560.516 to revoke the applicability to Bank Saderat of the general licenses in paragraphs (a) and (b) of § 560.516. Effective September 8, 2006, transactions directly or indirectly involving Bank Saderat are excluded from the scope of these authorizations. OFAC is also including an exception in this amendment to provide 90 days to wind down or complete performance of transactions involving Bank Saderat that are described in paragraphs (a)(2) through (4) or (b) of § 560.516 and that were entered into before September 8, 2006, except for specific licenses issued pursuant to § 560.532(b) that were being used before September 8, 2006 to obtain letters of credit issued by Bank Saderat, for which OFAC is providing a 180-day wind-down period.

Section 560.405 is an interpretive section providing that transactions ordinarily incident to licensed transactions and necessary to give them effect are also authorized, with certain exceptions. OFAC is adding a new exception to § 560.405 for transactions directly or indirectly involving Bank Saderat. Effective September 8, 2006, such transactions will not be authorized