

(L) Fokker Drawing W69240, Sheet 004, Issue B, dated November 12, 2009.

(M) Fokker Drawing W69335, Sheet 001, dated November 12, 2009.

(N) Fokker Drawing W69405, Sheet 001, dated November 12, 2009.

(O) Fokker Drawing W69710, Sheet 004, Issue B, dated November 12, 2008.

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Issued in Renton, Washington, on March 27, 2014.

**Jeffrey E. Duven,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014-07326 Filed 4-4-14; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 556 and 558

[Docket No. FDA-2014-N-0002]

#### **Zoetis Inc., et al.; Withdrawal of Approval of New Animal Drug Applications for Combination Drug Medicated Feeds Containing an Arsenical Drug; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of withdrawal of approval; correction.

**SUMMARY:** The Food and Drug Administration (FDA) published a document in the **Federal Register** of February 27, 2014, concerning the voluntary withdrawal of approval of new animal drug applications (NADAs). The document contained an incorrect list of NADAs.

**DATES:** This correction is effective April 7, 2014.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary

Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, [George.haibel@fda.hhs.gov](mailto:George.haibel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2014-02616, appearing on page 10974 in the **Federal Register** of February 27, 2014, the following corrections are made:

On page 10974, in the third column, in the 2d line of the “SUMMARY” section remove “69” and add in its place “68”.

On page 10975, the first bulleted text “Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria has requested that FDA withdraw approval of the following 16 NADAs and 8 ANADAs” is corrected to read “Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria, has requested that FDA withdraw approval of the following 15 NADAs and 8 ANADAs”; and on the same page in the table, the entry “013-461 3-NITRO (roxarsone)/AMPROL Plus (amprolium and ethopabate).” is removed.

Dated: April 2, 2014.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2014-07702 Filed 4-4-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### 31 CFR Part 560

#### **Iranian Transactions and Sanctions Regulations**

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury’s Office of Foreign Assets Control (“OFAC”) is adopting a final rule amending the Iranian Transactions and Sanctions Regulations (“ITSR”) by expanding an existing general license that authorizes the exportation or reexportation of food to individuals and entities in Iran to include the broader category of agricultural commodities. The rule also clarifies and adds certain definitions in OFAC regulations. Finally, the rule adds a new general license that authorizes the exportation or reexportation of certain replacement parts for certain medical devices.

**DATES:** *Effective:* April 7, 2014.

**FOR FURTHER INFORMATION CONTACT:** Assistant Director for Licensing, tel.: 202/622-2480, Assistant Director for

Policy, tel.: 202/622-2746, Assistant Director for Regulatory Affairs, tel.: 202/622-4855, Assistant Director for Sanctions Compliance and Evaluation, tel.: 202/622-2490, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622-2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

**SUPPLEMENTARY INFORMATION:** OFAC is adopting a final rule amending the ITSR by expanding an existing general license that authorizes the exportation or reexportation of food to individuals and entities in Iran to include the broader category of agricultural commodities. Exports of certain specified items, as well as exports to certain persons, are excluded from the general license.

Additionally, OFAC is clarifying, for purposes of the general licenses in ITSR § 560.530, that the definitions of the terms agricultural commodities, medicine, and medical device include, in the case of items subject to the Export Administration Regulations, 15 CFR Part 730 *et seq.* (“EAR”), items that are designated as EAR99 and, in the case of items that are not subject to the EAR, items that would be designated as EAR99 if they were located in the United States.

Furthermore, this rule adds a definition of “covered person,” which, with respect to the exportation or reexportation of items subject to the EAR, is a U.S. person or a non-U.S. person, and for purposes of items not subject to the EAR, is a U.S. person, wherever located, or an entity owned or controlled by a U.S. person and established or maintained outside the United States (a “U.S.-owned or -controlled foreign entity”). This amendment clarifies that, for purposes of the exportation or reexportation of items that are not subject to the EAR, and consistent with 31 CFR 560.556, the general licenses set forth in § 560.530 apply to any U.S. person, wherever located, or any U.S.-owned or -controlled foreign entity.

Finally, OFAC is adding a new general license that authorizes the exportation or reexportation of replacement parts for certain medical devices to individuals and entities in Iran provided that the replacement parts are designated under the EAR as EAR99, or would be designated as EAR99 if they were located in the United States, and limited to a one-for-one export or reexport basis. This rule also updates the definition of “basic medical supplies” to exclude the word “basic” and make related conforming changes. Accordingly, the “List of Basic Medical

Supplies” published on the OFAC Web site and in the **Federal Register** will now be called the “List of Medical Supplies.”

#### Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC’s Web site ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)). Certain general information pertaining to OFAC’s sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622-0077.

#### Background

OFAC is adopting a final rule amending the ITSR, 31 CFR Part 560, by expanding the general license set forth in § 560.530(a)(2) that authorizes the exportation or reexportation of food to Iran to include the broader category of agricultural commodities. Exports of certain specified items, as well as exports to certain persons, are excluded from the general license. Additionally, OFAC is clarifying, for purposes of the general licenses in ITSR § 560.530, the definitions of the terms agricultural commodities, medicine, and medical device, as set forth in more detail below. Finally, OFAC is adding a new general license that authorizes the exportation or reexportation of replacement parts for certain medical devices to individuals and entities in Iran provided that the replacement parts are designated as EAR99, or would be designated as EAR99 if they were located in the United States, and further provided that the replacement parts are limited to a one-for-one export or reexport basis. Today’s amendments also update the definition of “basic medical supplies” to exclude the word “basic” and make related conforming changes. Accordingly, the “List of Basic Medical Supplies” published on the OFAC Web site and in the **Federal Register** will now be called the “List of Medical Supplies.”

The Trade Sanctions Reform and Export Enhancement Act of 2000, as amended (22 U.S.C. 7201 *et seq.*) (“TSRA”), provides that, with certain exceptions, the President may not impose a unilateral agricultural sanction or unilateral medical sanction against a foreign country or foreign entity unless, at least 60 days before imposing such a sanction, the President submits a report to Congress describing the proposed sanction and the reasons for it and Congress enacts a joint resolution approving the report. See 22 U.S.C. 7202. Section 906 of TSRA, however, requires in pertinent part that the export of agricultural commodities, medicine, or medical devices to the government of

a country that has been determined by the Secretary of State, pursuant to, *inter alia*, section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), to have repeatedly provided support for acts of international terrorism,<sup>1</sup> or to any entity in such a country, shall be made pursuant to one-year licenses issued by the United States Government, except that the requirements of such one-year licenses shall be no more restrictive than general licenses administered by the Department of the Treasury. See 22 U.S.C. 7205(a)(1). Section 906 also specifies that procedures be in place to deny licenses for exports of agricultural commodities, medicine, or medical devices to any entity within such country promoting international terrorism.

Moreover, as provided in section 221 of the USA PATRIOT Act (Pub. L. 107–56) (codified at 22 U.S.C. 7210), nothing in TSRA shall limit the application or scope of any law, including any Executive order or regulation promulgated pursuant to such law, establishing criminal or civil penalties for the unlawful export of any agricultural commodity, medicine, or medical device to a Foreign Terrorist Organization; a foreign organization, group, or person designated pursuant to Executive Orders 12947 or 13224 (sanctions on terrorists and certain supporters of terrorism); weapons of mass destruction or missile proliferators; or designated narcotics trafficking entities. In addition, TSRA itself provides in section 904(2) that the restrictions on the imposition of unilateral agricultural sanctions or unilateral medical sanctions shall not affect any authority or requirement to impose a sanction to the extent such sanction applies to any agricultural commodity, medicine, or medical device that is (A) controlled on the United States Munitions List (the “USML”), (B) controlled on any control list established under the Export Administration Act of 1979 or any successor statute, or (C) used to facilitate the design, development, or production of chemical or biological weapons, missiles, or weapons of mass destruction. See 22 U.S.C. 7203(2).

On October 12, 2011, OFAC adopted a final rule issuing a general license set forth in the ITSR § 560.530(a)(2) authorizing the exportation or reexportation of food (as defined in the general license), including bulk agricultural commodities listed in appendix B to the ITSR, to the

Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions (see 76 FR 63191). Separately, OFAC has routinely issued specific licenses authorizing the exportation or reexportation of agricultural commodities (other than food items as previously defined in ITSR section 560.530(a)(2)) to the Government of Iran, individuals or entities in Iran, or persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions. In addition, OFAC has continued to review its TSRA licensing procedures, particularly the procedures for licensing exports of agricultural commodities.

As a result of this review, OFAC today is further expanding the general license set forth at ITSR § 560.530(a)(2), which, prior to today’s amendment, authorized the exportation and reexportation of food (including bulk agricultural commodities listed on appendix B to the ITSR), to authorize the exportation or reexportation of the broader category of agricultural commodities, with certain specified exceptions, to the Government of Iran, to individuals or entities in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions. Activities authorized pursuant to ITSR § 560.530(a)(2), as amended today, are subject to the proviso that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to the general license are limited to, and consistent with, those authorized by ITSR § 560.532, and the further proviso that all such exports or reexports must be shipped within the 12-month period beginning on the date of the signing of the contract for export or reexport. All food items authorized by the general license prior to today’s amendment continue to be authorized under the general license, as amended. Each year, OFAC will determine whether to revoke this general license. Unless revoked, this general license will remain in effect.

OFAC has determined that the exportation or reexportation of a small number of specified agricultural commodities to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, as well as the exportation or reexportation of agricultural commodities to military or law enforcement purchasers or importers, continue to require the level of review

<sup>1</sup> The Secretary of State has made such a determination with respect to Iran.

afforded by specific licensing. As a result, the general license set forth at ITSR § 560.530(a)(2), as amended today, does not authorize the exportation or reexportation to Iran of castor beans, castor bean seeds, certified pathogen-free eggs (unfertilized or fertilized), dried egg albumin, live animals (excluding live cattle), embryos (excluding cattle embryos), Rosary/Jequirity peas, non-food-grade gelatin powder, peptones and their derivatives, super absorbent polymers, western red cedar, or all fertilizers. (See ITSR § 560.530(a)(2)(ii) for the exclusion of these items.) Similarly, the general license, as amended today, does not authorize the exportation or reexportation of agricultural commodities to military or law enforcement purchasers or importers. (See ITSR § 560.530(a)(2)(iii) for the exclusion of these persons.) The general license, as amended today, also does not authorize any transaction or dealing with a person whose property and interests in property are blocked under, or who is designated or otherwise subject to any sanction under, *inter alia*, the terrorism, proliferation of weapons of mass destruction, or narcotics trafficking programs administered by OFAC. (See ITSR § 560.530(d)(5).)

Additionally, OFAC is clarifying, for purposes of the general licenses in ITSR § 560.530, that the definitions of the terms agricultural commodities, medicine, and medical device include, in the case of items subject to the Export Administration Regulations, 15 CFR Part 730 *et seq.* ("EAR"), items that are designated as EAR99 and, in the case of items that are not subject to the EAR, items that would be designated as EAR99 if they were located in the United States. (See ITSR § 560.530(e).) For example, a company located in the United States may be authorized under the general license set forth at § 560.530(a)(2) to arrange for the export from a third country to Iran of agricultural commodities produced in the third country if those commodities would be designated as EAR99 if they were located in the United States.

Furthermore, this rule adds a definition of *covered person*, which, with respect to the exportation or reexportation of items subject to the EAR, is a U.S. person or a non-U.S. person, and for purposes of items not subject to the EAR, a U.S. person, wherever located, or an entity owned or controlled by a U.S. person and established or maintained outside the United States (a "U.S.-owned or -controlled foreign entity"). This amendment clarifies that, for purposes of the exportation or reexportation of

items that are not subject to the EAR, and consistent with 31 CFR 560.556, the general licenses set forth in § 560.530 apply to any U.S. person, wherever located, or any U.S.-owned or -controlled foreign entity. For example, a U.S.-owned or -controlled foreign entity may be authorized under the general license set forth at § 560.530(a)(2) to arrange for the reexport to Iran of EAR99 medicines, as well as the export to Iran of medicines not subject to the EAR (e.g., medicines produced outside the U.S. by a non-U.S. person with no controlled U.S. content) that would be designated as EAR99 if they were located in the United States.

The general licenses set forth at ITSR § 560.530(a)(2) through (4) do not authorize, and specific licenses are therefore still required for, the exportation or reexportation of the following to the Government of Iran (wherever located), to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and for the conduct of related transactions:

- the excluded agricultural commodities specified in ITSR § 560.530(a)(2)(ii);
- the excluded medicines specified in ITSR § 560.530(a)(3)(iii);
- medical devices other than medical supplies as defined in § 560.530(a)(3)(ii); or
- agricultural commodities, medicine, or medical supplies to military or law enforcement purchasers or importers.

In the course of continually reviewing its TSRA licensing procedures, OFAC also adopted a final rule on October 22, 2012, issuing a new general license set forth at ITSR § 560.530(a)(3) authorizing the exportation or reexportation to Iran of medicine and basic medical supplies (as defined in the general license and included in a List of Basic Medical Supplies posted to OFAC's Web site) (see 77 FR 64664). The definition of basic medical supplies as originally published on October 22, 2012, specifically excluded replacement parts. On July 25, 2013, OFAC updated the List of Basic Medical Supplies to include additional items. This update added to the list, among other items, certain EAR99-designated accessories, components, and optional equipment for use with medical devices included elsewhere on the list, which are distinct from replacement parts.

OFAC has now determined, however, that the export or reexport of replacement parts for certain medical devices should be authorized, provided that the replacement parts are designated as EAR99 or, in the case of

replacement parts that are not subject to the EAR, would be designated as EAR99 if they were located in the United States, and further provided that the replacement parts are limited to a one-for-one basis (*i.e.*, only one replacement part can be exported or reexported to replace a broken or non-operational component). Accordingly, OFAC today is issuing a new general license set forth at ITSR § 560.530(a)(4) authorizing the exportation or reexportation of replacement parts that are designated as EAR99, or that would be designated as EAR99 if they were located in the United States, for medical devices on a one-for-one basis and with certain exceptions, to the Government of Iran, to individuals or entities in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions. Each year, OFAC will determine whether to revoke this general license. Unless revoked, this general license will remain in effect.

#### Public Participation

Because the amendment of 31 CFR Part 560 involves a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, and the Administrative Procedure Act (5 U.S.C. 553), requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

#### Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR Part 501 (the "Reporting, Procedures and Penalties Regulations"). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

#### List of Subjects in 31 CFR Part 560

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Blocking of assets, Drugs, Exports, Food, Foreign trade, Humanitarian aid, Investments, Iran, Loans, Medical devices, Medicine, Penalties, Services, Specially designated nationals, Terrorism, Transportation, Weapons of mass destruction.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR Part 560 as follows:

## PART 560—IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS

- 1. The authority citation for part 560 is revised to read as follows:

**Authority:** 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa–9; 22 U.S.C. 7201–7211; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111–195, 124 Stat. 1312 (22 U.S.C. 8501–8551); Pub. L. 112–81, 125 Stat. 1298 (22 U.S.C. 8513a); Pub. L. 112–158, 126 Stat. 1214 (22 U.S.C. 8701–8795); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217; E.O. 13599, 77 FR 6659, February 8, 2012; E.O. 13622, 77 FR 45897, August 2, 2012; E.O. 13628, 77 FR 62139, October 12, 2012.

### Subpart D—Interpretations

- 2. Amend § 560.405 by revising the note to paragraph (e) to read as follows:

#### § 560.405 Transactions ordinarily incident to a licensed transaction authorized.

\* \* \* \* \*

**Note to Paragraph (e) of § 560.405:** See § 560.530(a)(2) through (4) for general licenses authorizing, with certain exceptions, the exportation or reexportation of agricultural commodities, medicine, medical supplies, and replacement parts for certain medical devices to the Government of Iran, individuals or entities in Iran, or persons in third countries purchasing specifically for resale to any of the foregoing. These general licenses also authorize the conduct of related transactions, including, but not limited to, financing and payment, provided that payment terms and financing are limited to, and consistent with, § 560.532, which sets forth payment terms for sales authorized by one of the general licenses set forth in paragraphs (a)(2) through (4) of § 560.530 or by a specific license issued pursuant to paragraph (a)(1) of the same section.

### Subpart E—Licenses, Authorizations and Statements of Licensing Policy

- 3. Amend § 560.530 by revising paragraphs (a), (b), (c) introductory text, (c)(4) and (5), adding paragraph (d)(6), revising paragraphs (e)(1)(i), (e)(1)(ii) introductory text, (e)(2) introductory text, and (e)(3), and adding paragraph (e)(4) to read as follows:

#### § 560.530 Commercial sales, exportation, and reexportation of agricultural commodities, medicine, and medical devices.

(a)(1) *One-year license requirement.*  
(i) The exportation or reexportation of agricultural commodities, medicine, and medical devices that are not covered by the general licenses in paragraphs (a)(2) through (4) of this section (as set forth in paragraph (a)(1)(ii) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, shall only be made pursuant to a one-year specific license issued by the Office of Foreign Assets Control (“OFAC”) for contracts entered into during the one year period of the license and shipped within the 12-month period beginning on the date of the signing of the contract. No specific license will be granted for the exportation or reexportation of the items set forth in paragraph (a)(1)(ii) of this section to any entity or individual in Iran promoting international terrorism, to any individual or entity designated pursuant to Executive Order 12947 (60 FR 5079, 3 CFR, 1995 Comp., p. 356), Executive Order 13224 (66 FR 49079, 3 CFR, 2001 Comp., p. 786), or Public Law 104–132, to any narcotics trafficking entity designated pursuant to Executive Order 12978 of October 21, 1995 (60 FR 54579, 3 CFR, 1995 Comp., p. 415) or the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1901–1908), or to any foreign organization, group, or persons subject to any restriction for its or their involvement in weapons of mass destruction or missile proliferation. Executory contracts entered into pursuant to paragraph (b)(2) of this section prior to the issuance of a one-year license described in this paragraph shall be deemed to have been signed on the date of issuance of that one-year license (and, therefore, the exporter is authorized to make shipments under that contract within the 12-month period beginning on the date of issuance of the one-year license).  
(ii) For the purposes of this part, “agricultural commodities, medicine, and medical devices that are not covered by the general licenses in paragraphs (a)(2) through (4) of this section” are:

- (A) The excluded agricultural commodities specified in paragraph (a)(2)(ii) of this section;  
(B) The excluded medicines specified in paragraph (a)(3)(iii) of this section;  
(C) Medical devices (as defined in paragraph (e)(3) of this section) other than medical supplies (as defined in paragraph (a)(3)(ii) of this section); and

(D) Agricultural commodities (as defined in paragraph (e)(1) of this section), medicine (as defined in paragraph (e)(2) of this section), and medical supplies (as defined in paragraph (a)(3)(ii) of this section) to military or law enforcement purchasers or importers.

(2)(i) *General license for the exportation or reexportation of agricultural commodities.* Except as provided in paragraphs (a)(2)(ii) and (iii) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) of agricultural commodities (as defined in paragraph (e)(1) of this section) (including bulk agricultural commodities listed in appendix B to this part) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions, including, but not limited to, the making of shipping and cargo inspection arrangements, the obtaining of insurance, the arrangement of financing and payment, shipping of the goods, receipt of payment, and the entry into contracts (including executory contracts), are hereby authorized, provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532 of this part; and further provided that all such exports and reexports are shipped within the 12-month period beginning on the date of the signing of the contract for export or reexport.

(ii) *Excluded agricultural commodities.* Paragraph (a)(2)(i) of this section does not authorize the exportation or reexportation of the following items: castor beans, castor bean seeds, certified pathogen-free eggs (unfertilized or fertilized), dried egg albumin, live animals (excluding live cattle), embryos (excluding cattle embryos), Rosary/Jequirity peas, non-food-grade gelatin powder, peptones and their derivatives, super absorbent polymers, western red cedar, or all fertilizers.

(iii) *Excluded persons.* Paragraph (a)(2)(i) of this section does not authorize the exportation or reexportation of agricultural commodities to military or law enforcement purchasers or importers.

**Note to Paragraph (a)(2) of § 560.530:** Consistent with section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7205), each year OFAC will determine whether to revoke this general

license. Unless revoked, the general license will remain in effect.

(3)(i) *General license for the exportation or reexportation of medicine and medical supplies.* Except as provided in paragraphs (a)(3)(iii) and (iv) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) of medicine (as defined in paragraph (e)(2) of this section) and medical supplies (as defined in paragraph (a)(3)(ii) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions, including, but not limited to, the making of shipping and cargo inspection arrangements, the obtaining of insurance, the arrangement of financing and payment, shipping of the goods, receipt of payment, and the entry into contracts (including executory contracts), are hereby authorized, provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532 of this part; and further provided that all such exports or reexports are shipped within the 12-month period beginning on the date of the signing of the contract for export or reexport.

(ii) *Definition of medical supplies.* For purposes of this general license, the term *medical supplies* means those medical devices, as defined in paragraph (e)(3) of this section, that are included on the List of Medical Supplies on OFAC's Web site ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)) on the Iran Sanctions page.

**Note to Paragraph (a)(3)(ii) of § 560.530:** The List of Medical Supplies is maintained on OFAC's Web site ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)) on the Iran Sanctions page. The list also will be published in the **Federal Register**, as will any changes to the list. The List of Medical Supplies contains those medical devices for which OFAC previously did not require an Official Commodity Classification of EAR99 issued by the Department of Commerce's Bureau of Industry and Security to be submitted with a specific license application and which are now generally licensed.

(iii) *Excluded medicines.* Paragraph (a)(3)(i) of this section does not authorize the exportation or reexportation of the following medicines: non-NSAID analgesics, cholinergics, anticholinergics, opioids, narcotics, benzodiazepenes, and bioactive peptides.

(iv) *Excluded persons.* Paragraph (a)(3)(i) of this section does not

authorize the exportation or reexportation of medicine or medical supplies to military or law enforcement purchasers or importers.

**Note to Paragraph (a)(3) of § 560.530:** Consistent with section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7205), each year, OFAC will determine whether to revoke this general license. Unless revoked, the general license will remain in effect.

(4) *General license for the exportation or reexportation of replacement parts for certain medical devices.* (i) The exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) of replacement parts for medical devices (as defined in paragraph (e)(3) of this section) exported or reexported pursuant to paragraphs (a)(1) or (a)(3)(i) of this section to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions, including, but not limited to, the making of shipping and cargo inspection arrangements, the obtaining of insurance, the arrangement of financing and payment, shipping of the goods, receipt of payment, and the entry into contracts (including executory contracts), are hereby authorized, provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532 of this part; provided that such replacement parts are designated as EAR99, or, in the case of replacement parts that are not subject to the Export Administration Regulations, 15 CFR parts 730 *et seq.* ("EAR"), would be designated as EAR99 if they were located in the United States; and further provided that such replacement parts are limited to a one-for-one export or reexport basis (*i.e.*, only one replacement part can be exported or reexported to replace a broken or non-operational component).

(ii) *Excluded persons.* Paragraph (a)(4)(i) of this section does not authorize the exportation or reexportation of replacement parts for medical devices to military or law enforcement purchasers or importers.

**Note to Paragraph (a)(4) of § 560.530:** Consistent with section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7205), each year, OFAC will determine whether to revoke this general license. Unless revoked, the general license will remain in effect.

(b) *General license for arrangement of exportation and reexportation of*

*covered products that require a specific license.* (1) With respect to sales authorized pursuant to paragraph (a)(1)(i) of this section, the making of shipping arrangements, cargo inspections, obtaining of insurance, and arrangement of financing (consistent with § 560.532) for the exportation or reexportation of agricultural commodities, medicine, and medical devices that are not covered by the general licenses in paragraphs (a)(2) through (4) of this section (as set forth in paragraph (a)(1)(ii) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, are authorized.

(2) Entry into executory contracts (including executory pro forma invoices, agreements in principle, or executory offers capable of acceptance such as bids in response to public tenders) for the exportation or reexportation of agricultural commodities, medicine, and medical devices that are not covered by the general licenses in paragraphs (a)(2) through (4) of this section (as set forth in paragraph (a)(1)(ii) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, is authorized, provided that the performance of an executory contract is expressly made contingent upon the prior issuance of a one-year specific license described in paragraph (a)(1)(i) of this section.

(c) *Instructions for obtaining one-year licenses.* In order to obtain the one-year specific license described in paragraph (a)(1)(i) of this section, the exporter must provide to OFAC:

\* \* \* \* \*

(4) A description of all items to be exported or reexported pursuant to the requested one-year license, including a statement that the items are designated as EAR99, or would be designated as EAR99 if they were located in the United States, and, if necessary, documentation sufficient to verify that the items to be exported or reexported are designated as EAR99, or would be designated as EAR99 if they were located in the United States, and do not fall within any of the limitations contained in paragraph (d) of this section; and

(5) For items subject to the EAR, an Official Commodity Classification of EAR99 issued by the Department of Commerce's Bureau of Industry and Security ("BIS"), certifying that the product is designated as EAR99, is

required to be submitted to OFAC with the request for a license authorizing the exportation or reexportation of all fertilizers, live horses, western red cedar, or medical devices other than medical supplies (as defined in § 560.530(a)(3)(ii)). See 15 CFR 745.3 for instructions for obtaining an Official Commodity Classification of EAR99 from BIS.

(d) \* \* \*

(6) Nothing in this section or in any general or specific license set forth in or issued pursuant to paragraph (a) of this section authorizes the exportation or reexportation of any agricultural commodity, medicine, or medical device that is not designated as EAR99 or, in the case of any agricultural commodity, medicine, or medical device not subject to the EAR, would not be designated as EAR99 if it were located in the United States.

(e) \* \* \*

(1) \* \* \*

(i) In the case of products subject to the EAR, 15 CFR part 774, products that are designated as EAR99, and, in the case of products not subject to the EAR, products that would be designated as EAR99 under the EAR if they were located in the United States, in each case that fall within the term “agricultural commodity” as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) In the case of products subject to the EAR, products that are designated as EAR99, and in the case of products not subject to the EAR, products that would be designated as EAR99 if they were located in the United States, in each case that are intended for ultimate use in Iran as:

\* \* \* \* \*

(2) *Medicine*. For the purposes of this part, *medicine* is an item that falls within the definition of the term “drug” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and that, in the case of an item subject to the EAR, is designated as EAR99 or, in the case of an item not subject to the EAR, that would be designated as EAR99, if it were located in the United States.

\* \* \* \* \*

(3) *Medical device*. For the purposes of this part, a *medical device* is an item that falls within the definition of “device” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and that, in the case of an item subject to the EAR, is designated as EAR99, or in the case of an item not subject to the EAR, that would be designated as EAR99 if it were located in the United States.

(4) *Covered person*. For purposes of this part, a *covered person* is, with respect to the exportation or reexportation of items subject to the EAR, a U.S. person or a non-U.S. person, and for purposes of items not subject to the EAR, a U.S. person, wherever located, or an entity owned or controlled by a U.S. person and established or maintained outside the United States.

\* \* \* \* \*

■ 4. Amend § 560.533 by revising paragraphs (a) and (b) to read as follows:

**§ 560.533 Brokering sales of agricultural commodities, medicine, and medical devices.**

(a) *General license for brokering sales by U.S. persons*. United States persons are authorized to provide brokerage services on behalf of U.S. persons for the sale and exportation or reexportation by U.S. persons of agricultural commodities, medicine, and medical devices, provided that the sale and exportation or reexportation is authorized, as applicable, by a one-year specific license issued pursuant to paragraph (a)(1)(i) of § 560.530 or by one of the general licenses set forth in paragraphs (a)(2), (a)(3), and (a)(4) of § 560.530.

(b) *Specific licensing for brokering sales by non-U.S. persons of agricultural commodities*. Specific licenses may be issued on a case-by-case basis to permit U.S. persons to provide brokerage services on behalf of non-U.S., non-Iranian persons for the sale and exportation or reexportation of agricultural commodities to the Government of Iran, entities in Iran, or individuals in Iran. Specific licenses issued pursuant to this section will authorize the brokering only of sales that are to purchasers permitted pursuant to § 560.530.

**Note To Paragraph (b) of § 560.533:**

Requests for specific licenses to provide brokerage services under this paragraph must include all of the information described in § 560.530(c).

\* \* \* \* \*

Dated: March 31, 2014.

**Adam J. Szubin,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2014-07572 Filed 4-4-14; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket No. USCG-2014-0113]

**Special Local Regulation; Annual Marine Events on the Colorado River, Between Davis Dam (Bullhead City, Arizona) and Headgate Dam (Parker, Arizona) Within the San Diego Captain of the Port Zone**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the 2014 Lake Havasu Desert Storm marine event special local regulations on April 26, 2014. This annual marine event occurs on the navigable waters of the Colorado River in Lake Havasu, Arizona. This action is necessary to provide for the safety of the participants, crew, spectators, safety vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

**DATES:** This rule is effective from 8 a.m. to 2 p.m. April 26, 2014. If the event is delayed by inclement weather, these regulations will also be enforced on April 27, 2014, from 8 a.m. to 2 p.m.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or email Lieutenant Commander John Bannon, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619-278-7261, email [John.E.Bannon@uscg.mil](mailto:John.E.Bannon@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the Special Local Regulations in Lake Havasu for the 2014 Desert Storm Shootout in 33 CFR 100.1102, Table 1, Item 4 from 8 a.m. to 2 p.m. on April 26, 2014. If the event is delayed by inclement weather, these regulations will also be enforced on April 27, 2014, from 8 a.m. to 2 p.m.

Under provisions of 33 CFR 100.1102, persons and vessels are prohibited from entering into, transiting through, or anchoring within the regulated area, unless authorized by the Coast Guard Captain of the Port or his designated representative. Persons or vessels desiring to enter into or pass through the special local regulations may request permission from the Captain of the Port or a designated representative. If