

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Global Pharmaceutical Corp.” and by alphabetically adding an entry for “IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544”; and in the table in paragraph (c)(2) in the entry for “000115” by removing the sponsor name and address and by adding their place “IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.

Dated: April 24, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00-10932 Filed 5-2-00; 8:45 am]

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DEPARTMENT OF THE TREASURY**Office of Foreign Assets Control****31 CFR Part 560****Iranian Transactions Regulations: Licensing of Imports of, and Dealings in, Certain Iranian-Origin Foodstuffs and Carpets**

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: The Treasury Department is amending the Iranian Transactions Regulations to add general licenses authorizing the importation into the United States of, and dealings in, certain Iranian-origin foodstuffs and carpets and related transactions.

EFFECTIVE DATE: April 28, 2000.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing (tel.:

202/622-2480), Barbara C. Hammerle, Deputy Chief Counsel (tel.: 202/622-2410), Office of Foreign Assets Control, U.S. Treasury Department, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:**Electronic and Facsimile Availability**

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Background

On March 17, 2000, Secretary of State Madeleine K. Albright announced that economic sanctions against Iran would be eased to allow Americans to purchase and import carpets and food products such as dried fruits, nuts, and caviar from Iran. To implement this policy, the Treasury Department’s Office of Foreign Assets Control (“OFAC”) is amending the Iranian Transactions Regulations, 31 CFR part 560 (the “Regulations”), to authorize, by general license, the importation into the United States of, and dealings in, certain Iranian-origin foodstuffs and carpets and related transactions.

Section 560.534(a) of this final rule authorizes the importation into the United States of Iranian-origin foodstuffs intended for human consumption that are classified under chapters 2-23 of the Harmonized Tariff Schedule of the United States (“HTS”). Items that are classified in chapters 2-23 of the HTS that are not foodstuffs intended for human consumption are not authorized for importation into the United States by this section. This final rule also authorizes the importation into the United States of Iranian-origin carpets and other textile floor coverings and carpets used as wall hangings that are classified under chapter 57 or heading 9706.00.0060 of the HTS. Items that are classified under heading 9706.00.0060 (“Antiques of an age

exceeding one hundred years/Other”) that are not carpets and other textile floor coverings or carpets used as wall hangings are not authorized for importation into the United States by this section.

Section 560.534(b) of this rule authorizes U.S. persons, wherever located, to engage in transactions or dealings in such Iranian-origin foodstuffs and carpets, provided that such transactions or dealings do not involve a prohibited exportation to Iran or the Government of Iran. Section 560.534(c) sets forth the effect of this rule on open and closed enforcement actions initiated by the U.S. Government prior to the effective date of this final rule.

Transactions ordinarily incident to the transactions authorized in § 560.534 and necessary to give effect thereto also are authorized as set forth in § 560.405. Section 560.405 is amended to exclude from the scope of permitted incidental transactions letter of credit services relating to transactions authorized in § 560.534. See § 560.405(e). Those letter of credit services that are authorized are set forth separately in § 560.535. Forms of financing other than letters of credit are permitted as incidental transactions as set forth in § 560.405, provided that such forms of financing do not involve a debit or credit to an account of a person in Iran or of the Government of Iran maintained on the books of a U.S. depository institution. See § 560.534(d). Brokering services relating to transactions authorized by this final rule also are authorized. See § 560.535(c). Examples of transactions permitted under this final rule are set forth in §§ 560.534(e) and 560.535(e).

Technical changes are made to § 560.405, to clarify that loading of licensed cargo in Iran is a permitted incidental transaction, and to § 560.524, to clarify that the importation into the United States of qualifying household goods and personal effects is permitted regardless of the time elapsed since the importer’s arrival in the United States from Iran.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act (5 U.S.C. 553) (the “APA”) 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 and Procedures Regulations"). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information were previously approved by the Office of Management and Budget ("OMB") 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, Carpets and rugs, Drugs, Exports, Foods, Foreign trade, Imports, Information, Investments, Iran, Loans, Medical devices, Penalties, Reporting and recordkeeping requirements, Services, Specially designated nationals, Terrorism, Transportation.

For the reasons set forth in the preamble, 31 CFR part 560 is amended as set forth below:

PART 560—IRANIAN TRANSACTIONS REGULATIONS

1. The authority citation for part 560 continues to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2332d; 22 U.S.C. 2349aa-9; 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); 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.

Subpart D—Interpretations

2. Section 560.405 is amended by revising paragraph (b), removing the word "and" at the end of paragraph (c), revising paragraph (d), and adding paragraph (e), to read as follows:

§ 560.405 Transactions incidental to a licensed transaction authorized.

* * * * *

(b) Provision of any transportation services to or from Iran not explicitly authorized in or pursuant to this part other than loading or discharging licensed or exempt cargo there;

* * * * *

(d) Financing of licensed sales for exportation or reexportation of agricultural commodities or products, medicine or medical equipment to Iran or the Government of Iran (see § 560.532); and

(e) Letter of credit services relating to transactions authorized in § 560.534. See § 560.535(a).

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

3. Section 560.524 is amended by adding a sentence to the end of paragraph (b) to read as follows:

§ 560.524 Household goods and personal effects.

* * * * *

(b) * * * For purposes of this paragraph, household and personal effects include all articles meeting the criteria stated in this paragraph regardless of the time elapsed since the importer's arrival in the United States from Iran.

4. Section 560.534 is added to subpart E to read as follows:

§ 560.534 Importation into the United States of, and dealings in, certain foodstuffs and carpets authorized.

(a) The importation into the United States, from Iran or a third country, of the following goods of Iranian-origin is authorized:

(1) Foodstuffs intended for human consumption that are classified under chapters 2-23 of the Harmonized Tariff Schedule of the United States;

(2) Carpets and other textile floor coverings and carpets used as wall hangings that are classified under chapter 57 or heading 9706.00.0060 of the Harmonized Tariff Schedule of the United States.

(b) United States persons, wherever located, are authorized to engage in transactions or dealings in or related to the categories of Iranian-origin goods described in paragraph (a) of this section, provided that the transaction or dealing does not involve or relate to goods, technology, or services for exportation, reexportation, sale, or supply, directly or indirectly, to Iran or the Government of Iran, other than services described in § 560.405 ("Transactions incidental to a licensed transaction authorized").

(c) This section does not affect any open enforcement action initiated by the U.S. Government prior to April 28, 2000, or any seizure, forfeiture, penalty, or liquidated damages case that is considered closed in accordance with Customs or other agency regulations. This section also does not authorize the importation into the United States of goods that are under seizure or detention by U.S. Customs officials pursuant to Customs laws or other applicable provisions of law, until any applicable penalties, charges, duties, or other conditions are satisfied. This

section does not authorize importation into the United States of goods for which forfeiture proceedings have commenced or of goods that have been forfeited to the U.S. Government, other than through Customs disposition by selling at auction.

(d) Iranian accounts. Nothing in this section authorizes a debit or credit to an account of a person located in Iran or of the Government of Iran maintained on the books of a U.S. depository institution.

(e) Examples. The following are examples of transactions permitted under this section:

(1) A United States person living abroad is permitted to purchase or sell an Iranian-origin carpet, as long as the sale is not to Iran or the Government of Iran.

(2) A United States person may process a documentary collection relating to the importation into the United States of Iranian-origin pistachios, but payment under the documentary collection may not involve the crediting of an account of a person located in Iran or of the Government of Iran maintained on the books of a U.S. depository institution.

5. Section 560.535 is added to subpart E to read as follows:

§ 560.535 Letters of credit and brokering services relating to certain foodstuffs and carpets.

(a) Purchases from Iran or the Government of Iran. United

States depository institutions are authorized to issue letters of credit in favor of a beneficiary in Iran or the Government of Iran to pay for purchases from Iran or the Government of Iran of the categories of Iranian-origin goods described in § 560.534(a), provided that such letters of credit are not advised, negotiated, paid, or confirmed by the Government of Iran.

(b) Transactions or dealings in Iranian-origin goods other than purchases from Iran or the Government of Iran. United States depository institutions are authorized to issue, advise, negotiate, pay, or confirm letters of credit to pay for transactions in or related to the categories of Iranian-origin goods described in § 560.534(a), other than purchases from Iran or the Government of Iran, provided that such letters of credit are not issued, advised, negotiated, paid, or confirmed by the Government of Iran.

(c) Brokering. United States persons, wherever located, are authorized to act as brokers for the purchase or sale of the categories of Iranian-origin goods described in § 560.534(a), provided that the goods are not for exportation,

reexportation, sale, or supply, directly or indirectly, to Iran or the Government of Iran.

(d) *Iranian accounts.* Nothing in this section authorizes a debit or credit to an account of a person located in Iran or of the Government of Iran maintained on the books of a U.S. depository institution.

(e) Examples. The following are examples of transactions permitted under this section:

(1) A United States depository institution may issue a letter of credit in favor of a person in Iran to finance the importation into the United States of Iranian-origin caviar; the letter of credit may be confirmed by a third-country bank that is not included within the definition of the term Government of Iran.

(2) A United States depository institution may advise or confirm a letter of credit issued by a third-country bank that is not included within the definition of the term Government of Iran to finance the purchase from a third country of Iranian-origin carpets by a U.S. person or third-country national.

(3) A United States person may broker the sale of Iranian-origin carpets from Iran to a third-country national located outside Iran.

(4) A bank that is owned or controlled by the Government of Iran may forward letter of credit documents, strictly on a documentary collection basis, either directly to a United States depository institution or to a third country bank that is not included within the definition of the term Government of Iran and that is party to a letter of credit issued by a United States depository institution. The Iranian bank may not, however, send the documents on an "approval" basis, since it is not and cannot be party to the letter of credit.

Note to § 560.535: See §§ 560.304 and 560.313 for information relating to individuals and entities that are included within the definition of the term Government of Iran. Some entities meeting this definition are listed in appendix A to this part. See also § 560.516 for information relating to authorized transfers to Iran by U.S. depository institutions relating to licensed transactions.

Dated: April 26, 2000.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: April 27, 2000.

Elisabeth A. Bresee,

*Assistant Secretary (Enforcement),
Department of the Treasury.*

[FR Doc. 00-11009 Filed 4-28-00; 2:25 pm]

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DEPARTMENT OF TRANSPORTATION

33 CFR Part 100

[CGD07-00-035]

RIN 2115-AE47

Special Local Regulations: South Carolina Aquarium Grand Opening Fireworks Display, Charleston Harbor, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary Special Local Regulations are being adopted for the: South Carolina Aquarium Grand Opening fireworks display. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations become effective at 8:30 p.m. and terminate at 10 p.m. EDT on May 20, 2000.

FOR FURTHER INFORMATION CONTACT: Lt. Simone Brisco at (843) 724-7628.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and making these regulations effective less than 30 days after the **Federal Register** publication. Publishing an NPRM and delaying the effective date would be contrary to national safety interests since immediate action is needed to minimize potential danger to the public as there will be numerous spectator craft in the area, the event date is scheduled for May 20, 2000, and the permit request was only recently received.

Background and Purpose

These regulations are required to provide for the safety of life on navigable waters because of the inherent danger of the storage and launching of fireworks in the vicinity of spectator craft in Charleston Harbor, Charleston, SC. These regulations prohibit non-participating vessels from entering the area surrounding the two fireworks barges.

Regulatory Evaluation

This proposal is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that order. It is not "significant" under the

regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. The regulated area will only be in effect for approximately 1½ hours.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic effect upon a substantial number of small entities. "Small entities" include small business, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities as the regulations will only be in effect for 1½ hours in a limited area and the event will be highly publicized.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-221), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).