PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014 and effective September 15, 2014, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways

V–6 [Amended]

From Oakland, CA; INT Oakland 039° and Sacramento, CA, 212°; Sacramento; Squaw Valley, CA; Mustang, NV; Lovelock, NV; Battle Mountain, NV; INT Battle Mountain 062° and Wells, NV, 256°; Wells; 5 miles, 40 miles, 98 MSL, 85 MSL, Lucin, UT; 43 miles, 85 MSL, Ogden, UT; 11 miles, 50 miles, 105 MSL, Fort Bridger, WY; Rock Springs, WY; 20 miles, 39 miles 95 MSL, Cherokee, WY; 39 miles, 27 miles 95 MSL, Medicine Bow, WY; INT Medicine Bow 106° and Sidney, NE., 291°; Sidney; North Platte, NE; Grand Island, NE; Omaha, NE; Des Moines, IA; Iowa City, IA; Davenport, IA; INT Davenport 087° and DuPage, IL, 255°; to DuPage. From INT Chicago Heights, IL, 358° and Gipper, MI, 271°; Gipper; INT Gipper 092° and Waterville, OH, 266°; to Waterville. From Dryer, OH; Youngstown, OH; Clarion, PA; Philipsburg, PA; Selingsgrove, PA; Allentown, PA; Solberg, NJ; INT Solberg 107° and Yardley, PA, 068°; radials; INT Yardley 068° and La Guardia, NY, 213°; to La Guardia. The airspace within R–4803, R–4813A, and R–4813B is excluded when active.

V–30 [Amended]

From Badger, WI; INT Badger 102° and Pullman, MI, 303°; Pullman; Litchfield, MI; to Waterville, OH. From Dryer, OH; Akron, OH; Clarion, PA; Philipsburg, PA; Selingsgrove, PA; East Texas, PA; INT East Texas 095° and Solberg, NJ, 264°; to Solberg.

V–65 [Removed]

V–126 [Amended]

From INT Peotone, IL, 053° and Knox, IN, 297°; INT Knox 297° and Goshen, IN, 270°; Goshen; to Waterville, OH. From Dryer, OH; Jefferson, OH; Erzie, PA; Bradford, PA; to Stonyfork, PA.
who also has addresses in Armenia, Greece, India, the U.A.E., and the U.K.

This final rule makes modifications to two existing entries on the Entity List to provide additional addresses and subordinates in those entries. This rule also removes three persons from the Entity List, as the result of a determination made by the End-User Review Committee (ERC).

DATES: Effective Date: This rule is effective September 18, 2014.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Fax: (202) 482-3911, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Entity List (Supplement No. 4 to Part 744) notifies the public about entities that have engaged in activities that could result in an increased risk of the diversion of exported, reexported or transferred (in-country) items to weapons of mass destruction (WMD) programs. Since its initial publication, grounds for inclusion on the Entity List have expanded to include activities sanctioned by the State Department and activities contrary to U.S. national security or foreign policy interests.

Certain exports, reexports, and transfers (in-country) to entities identified on the Entity List require licenses from BIS and are usually subject to a policy of denial. The availability of license exceptions in such transactions is very limited. The license review policy for each entity is identified in the license review policy column on the Entity List and the availability of license exceptions is noted in the Federal Register notices adding persons to the Entity List. BIS places entities on the Entity List based on certain sections of part 744 (Control Policy: End-User and End-Use Based) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add twenty-eight persons under thirty-four entries to the Entity List. These twenty-eight persons are being added on the basis of § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. There are thirty-four entries for twenty-eight persons because two persons are listed under multiple countries, resulting in six additional entries. The thirty-four entries added to the Entity List consist of one entry in Afghanistan, one entry in Armenia, one entry in Australia, one entry in China, two entries in Greece, five entries in Hong Kong, one entry in India, one entry in Ireland, nine entries in Pakistan, one entry in Singapore, ten entries in the U.A.E., and one entry in the U.K.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these twenty-eight persons to the Entity List. Under that paragraph, persons for whom there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such persons may be added to the Entity List. Paragraphs (b)(1) through (b)(5) of § 744.11 include an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States.

The twenty-eight persons being added have been determined by the ERC to be involved in activities that are contrary to the national security or foreign policy interests of the United States, including the activities described under paragraphs (b)(1), (b)(2) and (b)(5) of § 744.11.

The ERC determined that nine of the persons being added to the Entity List under the destinations of Australia (one addition), Hong Kong (one addition), Pakistan (six additions), and Singapore (one addition) have been involved in activities contrary to the national security and foreign policy interests of the United States. Specifically, the ERC determined to add Pakistan’s Advanced Engineering Research Organization (AERO) and entities working with AERO to the Entity List for their involvement in activities contrary to the national security and foreign policy interests of the United States as described in § 744.11(b)(5) of the EAR. These entities’ involvement in the procurement of sensitive U.S. technology in support of Pakistan’s development of its missile and strategic unmanned aerial vehicle (UAV) programs is in violation of § 744.3 of the EAR, which requires a license to export, reexport or transfer (in-country) any item subject to the EAR that the exporter, reexporter, or in-country transferor knows will be used in the design, development, production or use of rocket systems by a country listed in the EAR’s Country Group D:4 in Supplement No. 1 to part 740, in which Pakistan is included.

Since 2010, Pakistan’s AERO has used intermediaries and front companies to procure U.S.-origin items by disguising the end-uses and end-users of the items from U.S. exporters thereby circumventing BIS licensing requirements. The intermediaries used by AERO have included Beijing Lion International Trading Company (a.k.a., Wei Lai Xi Tong Ltd.); Ixiz Group Pte Ltd.; Future Systems Pvt. Ltd.; IKAN Engineering Services (a.k.a., IKAN Sourcing); Orion Eleven Pvt. Ltd.; Nazir and Sons International; LT Engineering and Trade Services (Pvt) Ltd. (LITE); and Vortex Electronics. AERO has procured items on behalf of Pakistan’s Air Weapons Complex, a Pakistani government entity responsible for Pakistan’s cruise missile and strategic UAV programs.

The ERC determined that four of the persons being added to the Entity List under the destination of Hong Kong have been involved in activities contrary to the national security and foreign policy interests of the United States. Specifically, the ERC made a determination to add Channel Rich Electronics Company Limited (Channel Rich) and Fortune Source Electronics Co. Ltd. (Fortune Source) and their employees, Sau Luen Chan (Chan) and Bako Cheung (Cheung), to the Entity List for their involvement in activities contrary to the national security and foreign policy interests of the United States. Specifically, the ERC determined to add Channel Rich Electronics Company Limited (Channel Rich) and Fortune Source Electronics Co. Ltd. (Fortune Source) and their employees, Sau Luen Chan (Chan) and Bako Cheung (Cheung), to the Entity List for their involvement in activities contrary to the national security and foreign policy interests of the United States as described in § 744.11(b)(5) of the EAR. Specifically, Cho-Man Wong (Wong), the owner of Channel Rich and Fortune Source, was placed on the Entity List along with Hang Tat Electronics (Hang Tat), a company owned by Wong, on October 12, 2011 for purchasing items subject to the EAR with the intention of reselling them to end-users in China without proper BIS authorization (see 76 FR 63184).

Subsequent to Hang Tat’s addition to the Entity List, Wong changed the name of Hang Tat to Channel Rich and then to Fortune Source to continue to receive U.S.-origin items subject to BIS licensing requirements. Chan and Cheung, the two employees, actively
informed supplier companies of the name changes.

The ERC made a determination to add Mohammad Jan Mangal Construction Company to the Entity List under the destination of Afghanistan for involvement in activities contrary to the national security and foreign policy interests of the United States as described under §744.11(b)(1) of the EAR. This entity has engaged in activities in support of persons designated by the Secretary of State as a Foreign Terrorist Organization (FTO). The persons designated as FTOs were so designated as a result of their activities against U.S. and coalition forces in Afghanistan contrary to the national security and foreign policy of the United States.

The ERC made a determination to add Rayyan Air Pvt Ltd., Veteran Avia LLC, Aerospace One, S.A., Agnee Sky Limited, Aeolus FZE, Aerospace Company FZE, Aircon Beibars FZE, and Aristeidis A. Pappas to the Entity List to prevent these entities from engaging in activities that are contrary to the national security and foreign policy interests of the United States as described under §744.11(b)(5) of the EAR. Specifically, these companies owned, operated, or controlled by Jaideep Mirchandani (Mirchandani) and his family members, Indira Mirchandani and Nitin Mirchandani, have been involved in activities in support of the Syrian regime. In addition, Mirchandani and certain other entities were attempting to export a U.S. aircraft that would be used to further support the Syrian regime.

Specifically, Rayyan Air and affiliated companies and enterprises owned, operated and/or controlled by Jaideep Mirchandani and members of his family have supported flights into Syria in support of the Assad regime. These flights transported large amounts of Russian currency to the Syrian Government. Additionally, the Mirchandani and their corporate officers/employees have engaged in transactions with individuals involved in weapons trafficking as well as individuals and companies named on the U.S. Treasury’s Specially Designated Nationals (SDNs) list, including Mahan Air of Iran and its affiliates. Persons designated as SDNs were so designated for supporting the terrorist activities of the Islamic Revolutionary Guard Corps-Qods Force.

The ERC made a determination to add Reza Ghoreishi to the Entity List under the destination of the U.A.E. on the basis of his involvement in activities contrary to the national security and foreign policy of the United States as described under §744.11(b)(2) of the EAR. Specifically, this person was involved in the attempted export of a lathe machine, an item used in the production of high grade steel or “bright steel,” an item used, among other things, in the manufacture of automobile and aircraft parts destined to Iran in violation of Department of the Treasury, Office of Foreign Assets Control regulations and the EAR.

The ERC made a determination to add Arif Mehboob Raja under the destination of Pakistan to the Entity List to prevent the export, reexport and transfer (in-country) of U.S.-origin items to unauthorized end users in Pakistan contrary to §744.11(a) and (b)(5) of the EAR. The ERC determined that Irum, as well as National Institute of Lasers and Optronics (NILOP) described below under the modifications to the Entity List, procured items, including U.S.-origin items, for, or on behalf of, Pakistan’s Atomic Energy Commission (PAEC), an entity on the Entity List, and its subordinate organization Pakistan Institute of Nuclear Science and Technology, which is included in PAEC’s entry on the Entity List.

Pursuant to §744.11(b)(1), (b)(2) and (b)(5) of the EAR, the ERC determined that the conduct of these twenty-eight persons raises sufficient concern that prior review of exports, reexports, or transfers (in-country) of items subject to the EAR involving these persons, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS’s ability to prevent violations of the EAR.

For twenty-seven of the twenty-eight persons recommended for addition on the basis of §744.11, the ERC specified a license requirement for all items subject to the EAR and a license review policy of presumption of denial. For Irum Mehboob Raja, the ERC specified a license requirement for all items subject to the EAR and a license review policy of case-by-case for all items listed on the CCL and a presumption of approval for EAR99 items, the same as the existing licensing policy for PAEC entities on the Entity List. The license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to any of the persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule.

This final rule adds the following twenty-eight persons under thirty-four entries to the Entity List:

**Afghanistan**

(1) Mohammad Jan Mangal Construction Company (MMCC), Kolola Pushata, Charahi Gul-e-Surkh, Kabul, Afghanistan; and Maidan Sahr, Hetefaq Market, Paktiya, Afghanistan.

**Armenia**

(1) Veteran Avia LLC, a.k.a., the following one alias:

—Veteran Airline, 64, Baghramyan Avenue, Apt 16, Yerevan 0033, Armenia; and 1 Eervand Kochari Street, Room 1, 375070 Yerevan, Armenia (See also addresses under Greece, India, Pakistan, U.A.E., and U.K.).

**Australia**

(1) Vortex Electronics, 125 Walker Street, Quakers Hill, NSW 2763, Australia.

**China**

(1) Beijing Lion Heart International Trading Company, a.k.a., the following one alias:

—Wei Lai Xi Tong Ltd. Suite number 1819, The International Center of Times, Number 101, Shoa Yao Ju BeiLi, Chaoyang District, Beijing, China (See also address under Hong Kong).

**Greece**

(1) Aerospace One, S.A., 4 Andrea Koumpi Str. Markopoulo19003 Attica, Greece; and

(2) Veteran Avia LLC, a.k.a., the following one alias:

—Veteran Airline, 24, A. Koumpi Street, Markopoulo 190 03, Attika, Greece (See also addresses under Armenia, India, Pakistan, U.A.E., and U.K.).

**Hong Kong**

(1) Bako Cheung,

—Unit 803, Fourseas Building, 208–212 Nathan Road, Kwloon, Hong Kong; and

—Room 803, Fourseas Bldg 208–212 Nathan Rd, Kwloon, Hong Kong.

(2) Beijing Lion Heart International Trading Company, a.k.a., the following one alias:

—Wei Lai Xi Tong Ltd. Room 1318–20, 13F, Hollywood Plaza, 610 Nathan Road, Mongkok Kwoloon, Hong Kong (See also address under China);

(3) Channel Rich Electronics Company Limited,

—Unit 803, Fourseas Building, 208–212 Nathan Road, Kwloon, Hong Kong; and
—Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong;
(4) Fortune Source Electronics Co. Ltd., Unit A, 7/F Capri Building, 130 Austin Road, KLN, Hong Kong; and Unit A7/F Capri Building, 130 Austin Road, KLN, Hong Kong; and Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and
(5) Sau Luen Chan, Room 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.

India

(1) Veteran Avia LLC, a.k.a., the following one alias:
—Veteran Airline. A–107, Lajpat Nagar—1 New Delhi 110024, India; and Room No. 34 Import Cargo, IGI Airport Terminal—II, New Delhi 110037, India; and 25B, Camac Street 3E, Camac Court Kolkata, 700016, India; and Ali’s Chamber #202, 2nd Floor Sahar Cargo Complex Andheri East Mumbai, 400099, India (See also addresses under Armenia, Greece, India, Pakistan, U.A.E., and U.K.).

Ireland

(1) Agneet Sky Limited, 12, Fitzwilliam Place Dublin, 2 Ireland.

Pakistan

(1) Advanced Engineering Research Organization (AERO), Lub Thatoo Hazara Road, The Taxila district, Rawalpindi, Pakistan;
(2) Future Systems Pvt. Ltd., 10 Main Double Road F11/3, Islamabad, Pakistan;
(3) IKAN Engineering Services, a.k.a., the following one alias:
—IKAN Sourcing. 34–KM Shamki Valley Road, Westridge Rawalpindi, Pakistan;
(4) Irum Mehboob Raja, Pakistan Institute of Nuclear Science and Technology (PINSTECH), Nilore, Rawalpindi, Pakistan;
(5) Lt Engineering and Trade Services (Pvt) Ltd. (LTE), Lub Thatoo, Abbotabad Road, Hasan Abdal, Pakistan; and 30 Nazimud din Road, F–10/4, Islamabad, Pakistan;
(6) Nazir and Sons International, 2nd Floor, Pracha Plaza, Near Municipal Committee Office Road, Taxila, Pakistan;
(7) Orion Eleven Pvt. Ltd., Street 11 Valley Road, Westridge Rawalpindi, Pakistan;
(8) Ruyyan Air Pvt Ltd., House No 614, Street No 58 1–8/2 Islamabad, Pakistan; and Office No 456, K Street No 57 1–8/3 Islamabad, Pakistan; and
(9) Veteran Avia LLC, a.k.a., the following one alias:
—Veteran Airline. Room No. 1, ALC Building, PIA Cargo Complex Jip. Karachi, Pakistan (See also addresses under Armenia, Greece, India, U.A.E., and U.K.).

Singapore

(1) Isix Group Pte Ltd., Number 26 Defu Lane 9, Singapore 539267; and 50 Bukit Batok Street, 23 #07–08 Midview Building, Singapore 659578.

United Arab Emirates

(1) Aeolus FZE, a.k.a., the following one alias:
—Aeolus Air Group. Sharjah Airport Saif Zone, P.O. Box 120435 Sharjah, U.A.E.;
(2) Aerospace Company FZE, a.k.a., the following one alias:
—Aerospace Consortium. 18, Fujairah Free Zone, P.O. Box 1729, Fujairah, U.A.E.; and Fujairah Free Zone, P.O. Box 7168, Fujairah, U.A.E.;
(3) Aircon Beibars FZE, Plot of Land L4–03, 04, 05, 06, P.O. Box 121095, Sharjah, U.A.E.;
(5) Group Sky One, a.k.a., the following one alias:
—Sky One FZE. Q4 76, Sharjah Airport Free Zone, Sharjah, U.A.E.; and Executive Desk, Q1–05, 030/C, P.O. Box 122849, Sharjah, U.A.E.;
(6) Indira Mirchandani, Town House 1033 Uptown Miranda, Miranda, Algeria Street, Dubai, U.A.E.;
(7) Jaideep Mirchandani, a.k.a., the following one alias:
(8) Nitin Mirchandani, a.k.a., the following one alias:
—Nithin Merchandani. H2601 Group Sky One, a.k.a., the following one alias:
—Power Plant Workshops, P.O. Box 1114, Islamabad; and Technology, which is included in Pakistan Atomic Energy Commission (PAEC), is listed under Pakistan.

This final rule makes the following modifications to two persons on the Entity List:

Hong Kong

(1) Cho-Man Wong, Room 2608, Technology Plaza 29–35 Sha Tsui Road Tsuen Wan, Hong Kong; and Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.

Pakistan

(1) Pakistan Atomic Energy Commission (PAEC), a.k.a., the following one alias:
—Power Plant Workshops, P.O. Box 1114, Islamabad; and the following four subordinate entities:
—National Development Complex (NDC), a.k.a., the following two aliases:
—National Development Centre; and
—National Defense Complex. Fateh Jang, Punjab, Rawalpindi, Pakistan; and P.O. Box 2216, Islamabad, Pakistan;
—Pakistan Institute for Nuclear Science and Technology (PINSTECH), Nilore, Islamabad;
—Nuclear reactors (including power plants), fuel reprocessing and
enrichment facilities, all uranium processing, conversion and enrichment facilities, heavy water production facilities and any collocated ammonia plants; and
—National Institute of Lasers and Optronics (NILOP), a.k.a., the following one alias:
—National Institute of Lasers.
Lethrar Road, Islamabad, 45650, Pakistan; and
Lethrar Road, Nilore, 45650, Islamabad, Pakistan; and
Hetrat Road, Nilore, 45650, Islamabad, Pakistan; and
House #453 St., #16 Sector, Islamabad, Pakistan.

Removal From the Entity List
This rule implements a decision of the ERC to remove three persons, Bruce Lam, Creative Electronics and United Sources Industrial Enterprises, all located in Hong Kong, from the Entity List. The three persons removed were determined to no longer meet the criteria for listing on the Entity List.

United Sources Industrial Enterprises was added to General Order No. 3 in Supplement No. 1 to part 736 of the EAR on June 8, 2007, due to its involvement in transactions involving Mayrow General Trading ("Mayrow") (72 FR 31716) and was subsequently added to the Entity List when the entities identified in General Order No. 3 were added to the Entity List on September 22, 2008 (73 FR 54499). Bruce Lam and Creative Electronics were also added to the Entity List on September 22, 2008 (73 FR 54499) for the same reasons that United Sources Industrial Enterprises was added to the Entity List. These entities have reached agreements with BIS that include measures protecting U.S. national security and foreign policy interests. In light of the content of these agreements, the ERC deemed it no longer necessary to impose licensing requirements pursuant to § 744.11 on the three entities.

This final rule implements the decision to remove the following three persons located in Hong Kong from the Entity List:

Hong Kong
(1) Bruce Lam, 11/F Excelsior Bldg., 68–76, Sha Tsui Rd., Tsuen Wan, New Territories, Hong Kong;
(2) Creative Electronics, Room 2202c, 22/F, Nan Fung Centre, 264–298 Castle Peak Road, Hong Kong and G/F 1 J Kong Chuk Street Shamshuiipo, Kowloon, Hong Kong; and
(3) United Sources Industrial Enterprises, 11/F, Excelsior Building, 68–76 Sha Tsui Road, Hong Kong.

The removal of the three entities referenced above, which was approved by the ERC, eliminates the existing license requirements in Supplement No. 4 to part 744 for exports, reexports and transfers (in-country) to these entities. However, the removal of these entities from the Entity List does not relieve persons of other obligations under part 744 of the EAR or under other parts of the EAR. Neither the removal of an entity from the Entity List nor the removal of Entity List-based license requirements relieves persons of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that, "you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR." Additionally this removal does not relieve persons of their obligation to apply for export, reexport or in-country transfer licenses required by other provisions of the EAR. BIS strongly urges the use of Supplement No. 3 to part 732 of the EAR, "BIS’s ‘Know Your Customer’ Guidance and Red Flags," when persons are involved in transactions that are subject to the EAR.

Savings Clause
Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on September 18, 2014, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination, subject to the EAR.

Export Administration Act
Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 1429 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 49650 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements
1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.
2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid OMB control number 0694–0088. Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to Jasmeet K. Seehra@omb.eop.gov, or by fax to (202) 395–7285.
3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.
4. For the twenty-eight persons added under thirty-four entries to the Entity List in this final rule and the modifications to the existing entries on the Entity List, the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (See 5 U.S.C. 553(a)(1)). BIS implements this rule to protect U.S. national security or foreign policy interests by preventing items from being exported, reexported, or transferred (in-country) to the persons being added to or the entries being modified on the Entity List. If this rule were delayed to allow for notice
and comment and a delay in effective date, then entities being added to the Entity List by this action would continue to be able to receive items without a license and to conduct activities contrary to the national security or foreign policy interests of the United States. For the entities whose entries on the Entity List are being modified, allowing for notice and comment and a delay in the effective date would allow for continued transactions involving an additional address for a person already listed on the Entity List or for the continued procurement of items for an entity on the Entity List. In addition, because these parties may receive notice of the U.S. Government’s intention to place these entities on the Entity List if a proposed rule is published, doing so would create an incentive for these persons to either accelerate receiving items subject to the EAR to conduct activities that are contrary to the national security or foreign policy interests of the United States, or to take steps to set up additional aliases, change addresses, and other measures to try to limit the impact of the listing on the Entity List once a final rule was published. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

5. For the three removals from the Entity List in this final rule, pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because it would be contrary to the public interest. In determining whether to grant removal requests from the Entity List, a committee of U.S. Government agencies (the End-user Review Committee (ERC)) evaluates information about and commitments made by listed persons requesting removal from the Entity List, the nature and terms of which are set forth in 15 CFR part 744, Supplement No. 5, as noted in 15 CFR 744.16(b). The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (72 FR 31005 (June 5, 2007) (proposed rule), and 73 FR 49311 (August 21, 2008) (final rule)). These three removals have been made within the established regulatory framework of the Entity List. If the rule were to be delayed to allow for public comment, U.S. exporters may face unnecessary economic losses as they turn away potential sales because the customer remained a listed person on the Entity List even after the ERC approved the removal pursuant to the rule published at 73 FR 49311 on August 21, 2008. By publishing without prior notice and comment, BIS allows the applicant to receive U.S. exports immediately since these three applicants already have received approval by the ERC pursuant to 15 CFR part 744, Supplement No. 5, as noted in 15 CFR 744.16(b).

The removals from the Entity List granted by the ERC involve interagency deliberation and result from review of public and non-public sources, including sensitive law enforcement information and classified information, and the measurement of such information against the Entity List removal criteria. This information is extensively reviewed according to the criteria for evaluating removal requests from the Entity List, as set out in 15 CFR part 744, Supplement No. 5 and 15 CFR 744.16(b). For reasons of national security, BIS is not at liberty to provide to the public detailed information on which the ERC relied to make the decision to remove these entities. In addition, the information included in the removal requests is information exchanged between the applicant and the ERC, which by law (section 12(c) of the Export Administration Act), BIS is restricted from sharing with the public. Moreover, the removal requests from the Entity List contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such removal requests.

Section 533(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the Federal Register. BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(1) because this rule is a substantive rule which relieves a restriction. This rule’s removal of three persons from the Entity List removes a requirement (the Entity-List-based license requirement and limitation on use of license exceptions) on these three persons being removed from the Entity List. The rule does not impose a requirement on any other person for these three removals from the Entity List.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are not applicable. As a result, no final regulatory flexibility analysis is required and none has been prepared.

List of Subject in 15 CFR Part 744
Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:


2. Supplement No. 4 to part 744 is amended:

a. By adding under Afghanistan, in alphabetical order, one Afghan entity;

b. By adding under Armenia, in alphabetical order, one Armenian entity;

c. By adding in alphabetical order the destination of Australia under the Country Column, and one Australian entity;

d. By adding under China, People’s Republic of, in alphabetical order, one Chinese entity;

e. By adding under Greece, in alphabetical order, two Greek entities;
f. By adding under Hong Kong, in alphabetical order, five Hong Kong entities;
g. By revising under Hong Kong, the Hong Kong entity, “Cho-Man Wong”; h. By removing under Hong Kong, three Hong entities, “Bruce Lam, 11/F Excelsior Bldg., 68–76, Sha Tsui Rd., Tsuen Wan, New Territories, Hong Kong,” “Creative Electronics, Room 2202c, 22/F, Nan Fung Centre, 264–298 Castle Peak Road, Hong Kong and G/F
The additions and revisions read as follows:

**SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST**

<table>
<thead>
<tr>
<th>Country</th>
<th>Entity</th>
<th>License requirement</th>
<th>License review policy</th>
<th>Federal Register citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFGHANISTAN</td>
<td>Mohammad Jan Mangal Construction Company (MMCC), Kolola Pushta, Charahi Gul-e-Surkh, Kabul, Afghanistan; and Maidan Sahr, Hetefaq Market, Paktiya, Afghanistan.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>ARMENIA</td>
<td>Veteran Avia LLC, a.k.a., the following one alias: Veteran Airline. 64, Baghramyam Avenue, Apt 16, Yerevan 0033, Armenia; and 1 Eervand Kochari Street Room 1, 375070 Yerevan, Armenia (See also addresses under Greece, India, Pakistan, U.A.E., and U.K.).</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>Vortex Electronics, 125 Walker Street, Quakers Hill, NSW 2763, Australia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>CHINA, PEOPLE’S REPUBLIC OF</td>
<td>Beijing Lion Heart International Trading Company, a.k.a., the following one alias: Wei Lai Xi Tong Ltd. Suite number 1819, The International Center of Times, Number 101, Shoa Yao Ju BeiLi, Chaoyang District, Beijing, China (See also address under Hong Kong).</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
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### SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

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<th>Country</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Veteran Avia LLC, a.k.a., the following one alias:</strong> Veteran Airline. 24, A. Koumbi Street, Markopoulo 190 03, Attika, Greece (See also addresses under Armenia, India, Pakistan, U.A.E., and U.K.).</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<tr>
<td><strong>HONG KONG</strong></td>
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<tr>
<td></td>
<td>Bako Cheung, Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Beijing Lion Heart International Trading Company, a.k.a., the following one alias: Wei Lai Xi Tong Ltd. Room 1318–20, 13F, Hollywood Plaza, 610 Nathan Road, Mongkok Kowloon, Hong Kong (See also address under China).</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Channel Rich Electronics Company Limited, Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Cho-Man Wong, Room 2608, Technology Plaza 29–35 Sha Tsui Road Tsuen Wan, Hong Kong; and Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>76 FR 63184, 10/12/11. 79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Fortune Source Electronics Co. Ltd., Unit A, 7/F Capri Building, 130 Austin Road, KLN, Hong Kong; and Unit A7/F Capri Building, 130 Austin Road, KLN, Hong Kong; and Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<td></td>
<td>Sau Luen Chan, Unit 803, Fourseas Building, 208–212 Nathan Road, Kowloon, Hong Kong; and Room 803, Fourseas Bldg 208–212 Nathan Rd, Kowloon, Hong Kong.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<tr>
<td><strong>INDIA</strong></td>
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<td>Country</td>
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<td>Veteran Avia LLC, a.k.a., the following one alias:</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>— Veteran Airline. A–107, Lajpat Nagar—I New Delhi 110024, India; and Room No. 34 Import Cargo, IGI Airport Terminal—II, New Delhi 110037, India; and 25B, Camac Street 3E, Camac Court Kolkata, 700016, India; and Ali’s Chamber #202, 2nd Floor Sahar Cargo Complex Andheri East Mumbai, 400099, India (See also addresses under Armenia, Greece, Pakistan, U.A.E., and U.K.).</td>
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<td></td>
<td>IRELAND</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<td>Agneet Sky Limited, 12, Fitzwilliam Place Dublin, 2 Ireland.</td>
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<td>PAKISTAN</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<tr>
<td></td>
<td>Advanced Engineering Research Organization (AERO), Lub Thatoon Hazara Road, The Taxi district, Rawalpindi, Pakistan.</td>
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<td></td>
<td>stan. IKAN Engineering Services, a.k.a., the following one alias:</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>— IKAN Sourcing. 34–KM Shamki Bhattan Sultan Road, Lahore, Pakistan; and Plot 7, I–11/3 Markaz, Islamabad, Pakistan.</td>
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<td></td>
<td>Irum Mehoob Raja, Pakistan Institute of Nuclear Science and Technology (PINSTECH), Nilore, Islamabad, Pakistan.</td>
<td>For all items subject to the EAR.</td>
<td>Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items.</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>LT Engineering and Trade Services (Pvt) Ltd. (LTE), Lub Thatoon, Abbotabad Road, Hasan Abdal, Pakistan; and 30 Nazimud din Road, F–10/4, Islamabad, Pakistan.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Nazir and Sons International, 2nd Floor, Pracha Plaza, Near Municipal Committee Office Road, Taxila, Pakistan.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>Orion Eleven Pvt. Ltd., Street 11 Valley Road, Westridge Rawalpindi, Pakistan.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
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<tbody>
<tr>
<td><strong>Pakistan</strong></td>
<td>Atomic Energy Commission (PAEC), a.k.a., the following one alias:</td>
<td>For all items subject to the EAR.</td>
<td>Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items.</td>
<td>63 FR 64322, 11/19/98. 65 FR 14444, 03/17/00. 66 FR 50090, 10/01/01. 77 FR 58006, 9/19/12. 79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td></td>
<td>—Power Plant Workshops, P.O. Box 1114, Islamabad; and the following four subordinate entities:</td>
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<td>—National Development Complex (NDC), a.k.a., the following two aliases:</td>
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<td>—National Development Centre; and</td>
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<td></td>
<td>—National Defense Complex.</td>
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<td>Fateh Jang, Punjab, Rawalpindi, Pakistan; and P.O. Box 2216, Islamabad, Pakistan;</td>
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<td>—Pakistan Institute for Nuclear Science and Technology (PINSTECH), Nilore, Islamabad;</td>
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<td></td>
<td>—Nuclear reactors (including power plants), fuel reprocessing and enrichment facilities, all uranium processing, conversion and enrichment facilities, heavy water production facilities and any collocated ammonia plants; and</td>
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<td>—National Institute of Lasers and Optronics (NILOP), a.k.a., the following one alias:</td>
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<td>—National Institute of Lasers.</td>
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<td>Lethrar Road, Islamabad, 45650, Pakistan; and Lethrar Road, Nilore, 45650, Islamabad, Pakistan; and Hetrat Road, Nilore, 45650, Islamabad, Pakistan; and House #453 St., #16 Sector, Islamabad, Pakistan.</td>
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</tr>
<tr>
<td><strong>Rayyan Air Pvt Ltd., House No 614 Street No 58 I–8/2 Islamabad, Pakistan; and Office No 456, K Street No 57 I–8/3 Islamabad, Pakistan.</strong></td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<tr>
<td><strong>Veteran Avia LLC, a.k.a., the following one alias:</strong></td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<tr>
<td></td>
<td>—Veteran Airline.</td>
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<tr>
<td></td>
<td>Room No. 1, ALC Building, PIA Cargo Complex Jiap, Karachi, Pakistan (See also addresses under Armenia, Greece, India, U.A.E., and U.K.).</td>
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<tr>
<td><strong>SINGAPORE</strong></td>
<td></td>
<td></td>
<td></td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td><strong>Izix Group Pte Ltd., Number 26 Defu Lane 9, Singapore 539267; and 50 Bukit Batok Street, 23 #07–08 Midview Building, Singapore 659578.</strong></td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
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<td><strong>UNITED ARAB EMIRATES</strong></td>
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<tbody>
<tr>
<td>Aeolus FZE, a.k.a., the following one alias: —Aeolus Air Group. Sharjah Airport Saif Zone, P.O. Box 120435 Sharjah, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Aerospace Company FZE, a.k.a., the following one alias: —Aerospace Consortium. 18, Fujairah Free Zone, P.O. Box 1729, Fujairah, U.A.E.; and Fujairah Free Zone, P.O. Box 7168, Fujairah, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Aircon Beibars FZE, Plot of Land L4—03, 04, 05, 06, P.O. Box 121095, Sharjah, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Group Sky One, a.k.a., the following one alias: —Sky One FZE. Q4 76, Sharjah Airport Free Zone, Sharjah, U.A.E., and Executive Desk, Q1–05, 030/C, P.O. Box 122849, Sharjah, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Indira Mirchandani, Town House 1033 Uptown Mirdif, Mirdif, Algeria Street, Dubai, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Nitin Mirchandani, a.k.a., the following one alias: —Nithin Merchandani. H2601 Executive Towers, Business Bay, Dubai, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
<tr>
<td>Reza Ghoreishi, P.O. Box 61342, Jebel Ali, U.A.E.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR).</td>
<td>Presumption of denial ......</td>
<td>79 FR [INSERT FR PAGE NUMBER] 09/18/14.</td>
</tr>
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</table>
SUMMARY: The Food and Drug Administration (FDA) is classifying tryptase test system devices into class II (special controls). The Agency is classifying the device into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 20, 2014. The classification was applicable February 15, 2012.

FOR FURTHER INFORMATION CONTACT: Elizabeth Stafford, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5608, Silver Spring, MD 20993–0002, 301–796–6184.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low–moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.