

(2) Service information identified in this AD that is not incorporated by reference in this AD is available at the addresses specified in paragraphs (n)(5) and (n)(6) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on November 27, 2015.

(i) ALS Part 1, "Safe Life Airworthiness Limitation Items," Revision 01, dated September 5, 2013, of the Airbus Model A300 Airworthiness Limitations Section.

(ii) ALS Part 1, "Safe Life Airworthiness Limitation Items," Revision 01, dated September 5, 2013, of the Airbus Model A300-600 Airworthiness Limitations Section.

(iii) ALS Part 1, "Safe Life Airworthiness Limitation Items," Revision 01, dated September 5, 2013, of the Airbus Model A310 Airworthiness Limitations Section.

(4) The following service information was approved for IBR on October 27, 2009 (74 FR 48143, September 22, 2009).

(i) Section 05-10-00 of Chapter 05, "Service Life Limits and Maintenance Checks," of the Airbus A300 Aircraft Maintenance Manual (AMM), Revision 28, dated February 27, 1998.

(A) The AMM title page; the Record of Revisions, Effective Pages, and Table of Content pages; and Section 05-10-00; for Chapter 05 of Airbus A300 AMM are all dated February 27, 1998.

(B) The revision level of Chapter 05 of the Airbus A300 AMM is indicated only in the Record of Revisions section of Chapter 05.

(C) The List of Effective Pages (LOEP) for Chapter 05 of the Airbus A300 AMM contains the discrepancies identified in paragraphs (n)(4)(i)(C)(1) through (n)(4)(i)(C)(4) of this AD.

(1) The Transmittal Letter page, page 4 of the LOEP and Table of Contents sections, page 2 of Subsection 05-00-01, Subsection 05-10-00, and page 1 of Subsection 05-11-11, are not listed in the LOEP for Chapter 05 of the Airbus A300 AMM.

(2) The LOEP for Chapter 05 of the Airbus A300 AMM does not specify a date for the Record of Revisions page.

(3) The LOEP for Chapter 05 of the Airbus A300 AMM identifies three pages for Subsection 05-11-00, Configuration 5; however, only one page exists.

(4) The LOEP for Chapter 05 of the Airbus A300 AMM identifies three pages for Subsection 05-11-00, Configuration 9; however, those pages do not exist.

(ii) Airbus A300 Airworthiness Limitations Section, ALS Part 1, "Safe Life Airworthiness Limitations Items" dated September 6, 2007.

(iii) Airbus A300-600 Airworthiness Limitations Section, ALS Part 1, "Safe Life Airworthiness Limitations Items" dated December 21, 2006.

(iv) Airbus A310 Airworthiness Limitations Section, ALS Part 1, "Safe Life

Airworthiness Limitation Items" dated December 21, 2006.

(5) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>.

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on October 21, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 150911846-5846-01]

RIN 0694-AG74

Addition of Certain Persons and Modification of Certain Entries to the Entity List; and Removal of Certain Persons From the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by adding seven persons under ten entries to the Entity List. The seven persons who are added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. These persons will be listed on the Entity List under the destinations of China and Hong Kong.

This final rule also removes two persons from the Entity List. One entity requested removal from the Entity List in accordance with the procedure for requesting removal or modification of an Entity List entry. The End-User Review Committee (ERC) decided to remove this entity following a review of information provided in the removal request. The ERC decided to remove a

second person from the Entity List following a proposal submitted by an ERC member agency, in accordance with the procedure for requesting removal or modification of an Entity List entity.

Finally, this final rule modifies ten existing entries on the Entity List consisting of one entry under China and nine entries under Hong Kong to provide additional or modified addresses and/or aliases for these persons.

DATES: This rule is effective on November 12, 2015.

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) identifies entities and other persons reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The EAR imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to those listed. The "license review policy" for each listed entity or other person is identified in the License Review Policy column on the Entity List and the impact on the availability of license exceptions is described in the **Federal Register** notice adding entities or other persons to the Entity List. BIS places entities and other persons on the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The 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 seven persons under ten entries to the Entity List. These seven 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. The ten entries added to the Entity List consist of three entries in China and seven entries in Hong Kong. There are ten entries for the seven persons because three persons are listed in both China and Hong Kong, resulting in three additional entries.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these seven persons under ten entries 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. Pursuant to § 744.11 of the EAR, the ERC determined that the seven persons be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States.

The ERC has determined that for the seven persons added, there is reasonable cause to believe, based on specific and articulable facts, that (Jack) Wang Wei, Sky Rise Technology Ltd., TiMi Technologies Co. Ltd., Caprice Group Ltd., Reekay Technology Limited, and 32 Group China Ltd. have made attempts to procure items, including U.S.-origin items, for activities contrary to the national security and foreign policy interests of the United States. Specifically, (Jack) Wang Wei has used these companies to supply U.S.-origin items to an Iranian party associated with the Iranian defense industry and to an Iranian party whose customers include companies designated by the Department of Treasury as Specially Designated Nationals.

Pursuant to § 744.11(b)(2) of the EAR, the ERC determined that the conduct of these seven 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 the seven persons this rule adds to the Entity List 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. 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 seven persons under ten entries to the Entity List:

China

(1) *Sky Rise Technology Ltd.*, a.k.a., the following one alias:

—Sky Rise Tech.

4-4-2301 Xinyi Jiayuan, Chongwenmen, Dongcheng, Beijing, China (See also addresses under Hong Kong);

(2) *TiMi Technologies Co., Ltd.*, a.k.a., the following two aliases:

—TiMi Technology Co. Ltd.; and
—TiMi Tech.

F/10, A-Tower, Nongke Building, 11/ Shu Guang Hua Yuan Zhong Lu, Haidian District, Beijing, China, 100097; and Nanshan Avenue, Nanshan District, 518054, Shenzhen, China (See also addresses under Hong Kong); and

(3) *Wang Wei*, a.k.a., the following one alias:

—Jack Wang.

4-4-2301 Xinyi Jiayuan, Chongwenmen, Dongcheng, Beijing, China; and F/10, A-Tower, Nongke Building, 11/Shu Guang Hua Yuan Zhong Lu, Haidian District, Beijing, China, 100097 (See also addresses under Hong Kong).

Hong Kong

(1) *32 Group China Ltd.*, Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; and Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong;

(2) *Caprice Group Ltd.*, Room 1119, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and Unit B1, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong; and Unit A, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong;

(3) *Kitronix Display*, Unit B1, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong;

(4) *Reekay Technology Ltd.*, a.k.a., the following one alias:

—Reekay Technology.

Suite 502, 5th Floor Arion Commercial Centre, No. 2-12 Queens Road West, Sheung Wan, Hong Kong;

(5) *Sky Rise Technology Ltd.*, a.k.a., the following one alias:

—Sky Rise Tech.

Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; and Room 1118, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong (See also address under China);

(6) *TiMi Technologies Co., Ltd.*, a.k.a., the following two aliases:

—TiMi Technology Co. Ltd.; and
—TiMi Tech.

Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and Room 1118, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and Unit A, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong; and Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong (See also addresses under China);

(7) *Wang Wei*, a.k.a., the following one alias:

—Jack Wang.

Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; and Room 1118, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong (See also addresses under China).

Removals From the Entity List

This rule implements a decision of the ERC to remove two persons, Weihai New Era Chemical Industrial Company Limited, located in China; and Able City Development Limited, located in Hong Kong, from the Entity List. This rule removes Weihai New Era Chemical Industrial Company Limited on the basis of a removal request submitted by this listed person pursuant to § 744.16 (Procedure for requesting removal or modification of an Entity List entity) of the EAR. Able City Development Limited is being removed pursuant to a proposal submitted by an End-User

Review Committee (ERC) member agency, in accordance with Supplement No. 5 to Part 744 of the EAR, as discussed below.

A. Removal pursuant to § 744.16.

Based upon a review of the information provided in a removal request made in accordance with § 744.16 of the EAR and further review conducted by the ERC, the ERC determined that the Weihai New Era Chemical Industrial Company Limited should be removed from the Entity List.

Weihai New Era Chemical Industrial Company Limited was added to the Entity List on May 1, 2014 (79 FR 24563) pursuant to § 744.11(b)(2) and (b)(5) of the EAR. The ERC's decision to remove Weihai New Era Chemical Industrial Company Limited from the Entity List was based on information provided by the company in its appeal request pursuant to § 744.16.

In accordance with § 744.16(c), the Deputy Assistant Secretary for Export Administration has sent written notification informing this person of the ERC's decision.

B. Other removal based on ERC decision.

This rule implements a decision of the ERC to remove one person located in Hong Kong, Able City Development Limited, from the Entity List. The ERC determined that this person no longer met the criteria for inclusion on the Entity List. Able City Development Limited was added to the Entity List on July 21, 2009 (74 FR 35797) pursuant to § 744.11(b) of the EAR. In accordance with the procedures outlined in Supplement No. 5 to part 744 of the EAR, any agency that participates in the ERC may make a proposal to add, modify or remove an entry from the Entity List by submitting that proposal to the chairman. For this removal, an ERC member agency proposed to the ERC to remove Able City Development Limited because a review of records indicated that the entity has dissolved. Because this entity does not exist, in accordance with § 744.16(c), the Deputy Assistant Secretary for Export Administration has not sent written notification informing this person of the ERC's decision.

This final rule implements the decision to remove the following two persons from the Entity List:

China

(1) *Weihai New Era Chemical Industrial Company Limited*, No. 985 Fenghua Shan Road, Yangting New Industrial District, Huancui District, Weihai, China.

Hong Kong

(1) *Able City Development Limited*, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong.

The removal of the two 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 two 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 these removals do 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. Additionally, as noted above, Able City Development Limited no longer exists so there should be no transactions involving this person.

Modifications to the Entity List

This final rule implements decisions of the ERC to modify ten existing entries on the Entity List. Under the destination of China, the ERC made a determination to add six additional addresses and eight additional aliases to the entry for China Electronics Technology Group Corporation 29 (CETC 29) Research Institute. Under the destination of Hong Kong, the ERC made a determination to make the following modifications to nine entries, as follows: add one additional address to the entry for Biznest, LTD; add one additional address to the entry for Giant Base Asia Limited; add one additional address to the entry for Jadeshine Engineering (HK) Co.; add one additional address to the entry for JLD Technology; add one additional address and two additional aliases to the entry for Kinglead Electronics Co., Ltd.; add one alias to the entry for PRC Lode Technology Company; add one additional address to

the entry for Serko Limited; add one additional address and one alias to the entry for Tex-Co Logistics Ltd.; and add one additional address and one alias to the entry for Yeraz, LTD.

This final rule makes the following modifications to ten entries on the Entity List:

China

(1) *China Electronics Technology Group Corporation 29 (CETC 29) Research Institute*, a.k.a., the following ten aliases:
 —CETC 29th Research Institute;
 —China Southwest Electronic Equipment Research Institute (SWIEE);
 —29 (SIWEI Co) Institute;
 —SIWI Electronics Corporation;
 —Chengdu SIWI Electronics Inc.;
 —Chengdu SIWEI Electronics Company;
 —Chengdu 29 Institute;
 —Si Wei Company 29th Institute;
 —SIWI Group; and
 —Southwest China Institute of Electronics.
 No. 496 West Yingkang Road, Chengdu, Sichuan Province 610036, China; and Box #429, #1 Waixichadianziheng Street, Chengdu, Sichuan Province 610036, China; and 5 Cheng Wen Road, Chengdu, China 610036; and No. 3 Research Department, Zhongdian, China; and No. 29 Institute, Waixi Chadi, Chengdu, China; and No. 81 BaiChao Road, XiPu Town, PiXian County, Chengdu, China; and Siwei Electron Mansion, Xiejiasi, Qingyang, Chengdu, China; and 1 Hengjie Chadianzi Western Suburb, Chengdu, China.

Hong Kong

(1) *Biznest, LTD*, Room 927 9/F Far East Consortium Building, 121 Des Voeux Road C, Central District, Hong Kong; and 4/F, Hong Kong Trade Centre, 161–167 Des Voeux Road, Central, Hong Kong;

(2) *Giant Base Asia Limited*, Room 2205, 22/F, Kowloon Building, 555 Nathan Road, Hong Kong; and Flat E, Block 1, 12/F, Superluck Industrial Centre, Tsuen Wan, New Territories, Hong Kong;

(3) *Jadeshine Engineering (HK) Co.*, Room 702, Boss Commercial Centre, Ferry Street 38, Kowloon, Hong Kong; and G/F BLK C 255 Sai Tau Wai DD 123 Lot 1307 Yuen Long, NT, Hong Kong;

(4) *JLD Technology*, Hong Kong Co., Ltd., Room 1237, Pacific Trade Centre, No. 2 Kai Hing Road, Kowloon Bay, Hong Kong; and Room 301–2, Hang Seng Wanchai Building, 3rd Floor, No. 200 Hennessy Road, Wanchai, Hong Kong;

(5) *Kinglead Electronics Co., Ltd.*, a.k.a., the following four aliases:

- Kinglead International Trading;
- Kinglead Trading;
- Kinglead International Trading Limited; *and*
- Phonide Electronics Limited.
Room 1041 Pacific Trade Center, No. 2 Kai Hing Road, Kowloon Bay, Hong Kong; *and* B5–3, 29/F, Legend Tower, 7 Shing Yip Street, Kwun Tong, Kowloon, Hong Kong (See alternate address under China);

(6) *PRC Lode Technology Company*, a.k.a., the following one alias:

- Lode International Limited.
Room 1019–1020 Nan Fung Centre, 264–298 Castle Peak Road, Tsuen Wan New Territories, Hong Kong; *and* Room 1522 Nan Fung Centre, 264–298 Castle Peak Road, Tsuen Wan New Territories, Hong Kong (See alternate addresses under China);

(7) *Serko Limited*, Room 704 7/F, Landwide Commercial Building, 118–120 Austin Rd, Tsim Sha Tsui, Hong Kong; *and* Room 1509, Unit A, 15th Floor, Mai Shun Industrial Building, No. 18–24 Kwai Cheong Road, New Territories, Hong Kong;

(8) *Tex-Co Logistics Ltd.*, a.k.a., the following one alias:

- Tex-Co Hongxin Logistics Limited.
GF Seapower Industrial Building 177, Hoi Bun Road, Kowloon, Hong Kong, *and* Room 2202, 22F, Causeway Bay Plaza 1, 489 Hennessey Road, Causeway Bay, Hong Kong, *and* Room B03, 6/F, Cheong Wah Factory Building, 39–41 Sheung Heung Road, Tokwawan, Kowloon, Hong Kong; *and* Room G, 6/F Winner Building, 36 Man Yue Street, Hung Hom, Kowloon; *and*

(9) *Yeraz, LTD*, a.k.a., the following one alias:

- Mikrocitcity HK Limited.
Room 927 9/F Far East Consortium Building, 121 Des Voeux Road C, Central District, Hong Kong; *and* Room 402–403, 4/F, Hong Kong Trade Centre, 161–167 Des Voeux Road, Central, Hong Kong.

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 November 12, 2015, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or

export or reexport without a license (NLR).

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 16129 (March 13, 2013) and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), 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, as amended by Executive Order 13637.

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 Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under 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. Sehra, Office of Management and Budget (OMB), by email to [\[Seehra@omb.eop.gov\]\(mailto:Seehra@omb.eop.gov\), or by fax to \(202\) 395–7285.](mailto:Jasmeet_K_</p>
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3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. For the seven persons under ten entries added to the Entity List in this final rule, and the ten existing entities whose entries on the Entity List are being modified to provide additional or modified addresses and/or aliases, 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 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 or modified 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. In addition, because these parties may receive notice of the U.S. Government's intention to place this entity 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.

For the two removals from the Entity List in this final rule, pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(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 two removals have been made within the established regulatory framework of the Entity List. One of the entities removed by this rule no longer exists. 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 to the other entity removed by this rule 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 the applicant already has received approval by the ERC pursuant to 15 CFR part 744, Supplement No. 5, as noted in 15 CFR 744.16(b).

The removal from the Entity List as a result of a removal request granted by the ERC or for other reasons 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, including 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 decisions to remove these two entities. In addition, the information included in the removal request 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, 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 553(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 two persons from the Entity List removes a requirement (the Entity-List-based license requirement and limitation on use of license exceptions) on these two persons being removed from the Entity List. The rule does not impose a requirement on any other person for these two 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 Subjects 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:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59

FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014); Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015).

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

- a. By adding under China, in alphabetical order, three Chinese entities;
- b. By revising under China, one Chinese entity, “China Electronics Technology Group Corporation 29 (CETC 29) Research Institute”;
- c. By removing under China, one Chinese entity, “Weihai New Era Chemical Industrial Company Limited, No. 985 Fenghua Shan Road, Yangting New Industrial District, Huancui District, Weihai, China.”;
- d. By adding under Hong Kong, in alphabetical order, seven Hong Kong entities;
- e. By revising under Hong Kong, nine Hong Kong entities, “Biznest, LTD”, “Giant Base Asia Limited”, “Jadeshine Engineering (HK) Co.”, “JLD Technology”, “Kinglead Electronics Co., Ltd.”, “PRC Lode Technology Company”, “Serko Limited”, “Tex-Co Logistics Ltd.”, “Yeraz, LTD”; and
- f. By removing under Hong Kong, one Hong Kong entity, “Able City Development Limited, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong.”

The additions and revisions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
* China, People's Republic of	* China Electronics Technology Group Corporation 29 (CETC 29) Research Institute, a.k.a., the following ten aliases: —CETC 29th Research Institute; —China Southwest Electronic Equipment Research Institute (SWIEE); —29 (SIWEI Co) Institute; —SIWI Electronics Corporation; —Chengdu SIWI Electronics Inc.; —Chengdu SIWEI Electronics Company; —Chengdu 29 Institute; —Si Wei Company 29th Institute; —SIWI Group; <i>and</i> —Southwest China Institute of Electronics No. 496 West Yingkang Road, Chengdu, Sichuan Province 610036, China; <i>and</i> Box #429, #1 Waixichadianziheng Street, Chengdu, Sichuan Province 610036, China; <i>and</i> 5 Cheng Wen Road, Chengdu, China 610036; <i>and</i> No.3 Research Department, Zhongdian, China; <i>and</i> No. 29 Institute, Waixi Chadi, Chengdu, China; <i>and</i> No.81 BaiChao Road, XiPu Town, PiXian County, Chengdu, China; <i>and</i> Siwei Electron Mansion, Xiejiasi, Qingyang, Chengdu, China; <i>and</i> 1 Hengjie Chadianzi Western Suburb, Chengdu, China.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial ...	* 79 FR 44680, 8/1/2014. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
*	* Sky Rise Technology Ltd., a.k.a., the following one alias: —Sky Rise Tech 4-4-2301 Xinyi Jiayuan, Chongwenmen, Dongcheng, Beijing, China (See also addresses under Hong Kong).	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial ...	* 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
*	* TiMi Technologies Co., Ltd., a.k.a., the following two aliases: —TiMi Technology Co. Ltd —TiMi Tech F/10, A-Tower, Nongke Building, 11/ Shu Guang Hua Yuan Zhong Lu, Haidian District, Beijing, China, 100097; <i>and</i> Nanhai Avenue, Nanshan District, 518054, Shenzhen, China (See also addresses under Hong Kong)	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial ...	* 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
*	* Wang Wei, a.k.a., the following one alias: —Jack Wang	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial ...	* 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.

Country	Entity	License requirement	License review policy	Federal Register citation
	4-4-2301 Xinyi Jiayuan, Chongwenmen, Dongcheng, Beijing, China; and F/10, A-Tower, Nongke Building, 11/Shu Guang Hua Yuan Zhong Lu, Haidian District, Beijing, China, 100097 (See also addresses under Hong Kong)			
Hong Kong	32Group China Ltd., Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; and Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	Biznest, LTD, Room 927 9/F Far East Consortium Building, 121 Des Voeux Road C, Central District, Hong Kong; and 4/F, Hong Kong Trade Centre, 161-167 Des Voeux Road, Central, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	76 FR 44259, 7/25/11. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	Caprice Group Ltd., Room 1119, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; and Unit B1, G/F Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong; and Unit A, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	Giant Base Asia Limited, Room 2205, 22/F, Kowloon Building, 555 Nathan Road, Hong Kong; and Flat E, Block 1, 12/F, Superluck Industrial Centre, Tsuen Wan, New Territories, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	78 FR 18808, 03/28/13. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	Kitronix Display, Unit B1, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	Jadeshine Engineering (HK) Co., Room 702, Boss Commercial Centre, Ferry Street 38, Kowloon, Hong Kong; and G/F BLK C 255 Sai Tau Wai DD 123 Lot 1307 Yuen Long, NT, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	78 FR 18808, 03/28/13. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.
	JLD Technology, Hong Kong Co., Ltd., Room 1237, Pacific Trade Centre, No. 2 Kai Hing Road, Kowloon Bay, Hong Kong; and Room 301-2, Hang Seng Wanchai Building, 3rd Floor, No. 200 Hennessy Road, Wanchai, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial ...	79 FR 32441, 6/5/14. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.

Country	Entity	License requirement	License review policy	Federal Register citation
*	<p data-bbox="383 279 737 611">Kinglead Electronics Co., Ltd., a.k.a., the following four aliases: —Kinglead International Trading; —Kinglead Trading; —Kinglead International Trading Limited; <i>and</i> —Phonide Electronics Limited Room 1041 Pacific Trade Center, No. 2 Kai Hing Road, Kowloon Bay, Hong Kong; <i>and</i> B5-3, 29/F, Legend Tower, 7 Shing Yip Street, Kwun Tong, Kowloon, Hong Kong (See alternate address under China).</p>	<p data-bbox="756 279 984 348">For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 279 1247 296">Presumption of denial ...</p>	<p data-bbox="1268 279 1458 394">79 FR 32441, 6/5/14. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="383 667 737 926">PRC Lode Technology Company, a.k.a., the following one alias: —Lode International Limited. Room 1019–1020 Nan Fung Centre, 264–298 Castle Peak Road, Tsuen Wan New Territories, Hong Kong; <i>and</i> Room 1522 Nan Fung Centre, 264–298 Castle Peak Road, Tsuen Wan New Territories, Hong Kong (See alternate addresses under China).</p>	<p data-bbox="756 667 984 737">For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 667 1247 684">Presumption of denial ...</p>	<p data-bbox="1268 667 1495 762">79 FR 44680, 8/1/2014. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="383 982 737 1125">Reekay Technology Ltd., a.k.a., the following one alias: —Reekay Technology. Suite 502, 5th Floor Arion Commercial Centre, No. 2–12 Queens Road West, Sheung Wan, Hong Kong</p>	<p data-bbox="756 982 984 1052">For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 982 1247 999">Presumption of denial ...</p>	<p data-bbox="1268 982 1458 1052">80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="383 1182 737 1371">Serko Limited, Room 704 7/F, Landwide Commercial Building, 118–120 Austin Rd, Tsim Sha Tsui, Hong Kong; <i>and</i> Room 1509, Unit A, 15th Floor, Mai Shun Industrial Building, No. 18–24 Kwai Cheong Road, New Territories, Hong Kong.</p>	<p data-bbox="756 1182 984 1251">For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 1182 1247 1199">Presumption of denial ...</p>	<p data-bbox="1268 1182 1484 1276">77 FR 61249, 10/9/12. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="383 1428 737 1755">Sky Rise Technology Ltd., a.k.a., the following one alias: —Sky Rise Tech. Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; <i>and</i> Room 1118, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; <i>and</i> Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong (See also address under China).</p>	<p data-bbox="756 1428 984 1497">For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 1428 1247 1444">Presumption of denial ...</p>	<p data-bbox="1268 1428 1458 1497">80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>

Country	Entity	License requirement	License review policy	Federal Register citation
*	<p data-bbox="386 279 737 323">* Tex-Co Logistics Ltd., a.k.a., the following one alias: —Tex-Co Hongxin Logistics Limited. GF Seapower Industrial Building 177, Hoi Bun Road, Kowloon, Hong Kong, <i>and</i> Room 2202, 22F, Causeway Bay Plaza 1, 489 Hennessey Road, Causeway Bay, Hong Kong, <i>and</i> Room B03, 6/F, Cheong Wah Factory Building, 39–41 Sheung Heung Road, Tokwawan, Kowloon, Hong Kong; <i>and</i> Room G, 6/F Winner Building, 36 Man Yue Street, Hung Hom, Kowloon.</p>	<p data-bbox="760 279 984 348">* For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 279 1247 302">* Presumption of denial ...</p>	<p data-bbox="1268 279 1459 396">* 75 FR 7358, 2/19/10. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
	<p data-bbox="386 638 737 730">* TiMi Technologies Co., Ltd., a.k.a., the following two aliases: —TiMi Technology Co. Ltd. —TiMi Tech. Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; <i>and</i> Room 1118, 11/F, Block B1, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; <i>and</i> Unit A, G/F, Pioneer Building, 213 Wai Yip St., Kwun Tong, Kowloon, Hong Kong; <i>and</i> Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong (See also addresses under China).</p>	<p data-bbox="760 638 984 707">* For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 638 1247 661">* Presumption of denial ...</p>	<p data-bbox="1268 638 1459 707">* 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="386 1098 737 1142">* Wang Wei, a.k.a., the following one alias: —Jack Wang. Room 1905, 19/F, Nam Wo Hong Bldg., 148 Wing Lok Street, Sheung Wang, Hong Kong; <i>and</i> Room 1118, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong; <i>and</i> Room 1119, 11/F, Block B, Yau Tong Industrial City, 17 Ko Fai Road, Yau Tong, Kowloon, Hong Kong (See also addresses under China).</p>	<p data-bbox="760 1098 984 1167">* For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 1098 1247 1121">* Presumption of denial ...</p>	<p data-bbox="1268 1098 1459 1167">* 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*	<p data-bbox="386 1486 737 1558">* Yeraz, LTD, a.k.a., the following one alias: —Mikrocity HK Limited. Room 927 9/F Far East Consortium Building, 121 Des Voeux Road C, Central District, Hong Kong; <i>and</i> Room 402–403, 4/F, Hong Kong Trade Centre, 161–167 Des Voeux Road, Central, Hong Kong.</p>	<p data-bbox="760 1486 984 1556">* For all items subject to the EAR. (See § 744.11 of the EAR).</p>	<p data-bbox="1011 1486 1247 1509">* Presumption of denial ...</p>	<p data-bbox="1268 1486 1484 1583">* 76 FR 44259, 7/25/11. 80 FR [INSERT FR PAGE NUMBER], 11/12/2015.</p>
*				

Dated: November 5, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015-28552 Filed 11-10-15; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-419F]

Schedules of Controlled Substances: Placement of Eluxadoline Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration places the substance 5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle eluxadoline.

DATES: *Effective date:* December 17, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,”

respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of controlled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *.” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated

¹ As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

at the request of the Assistant Secretary of the HHS and imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle eluxadoline.

Background

Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid), is a new molecular entity with central nervous system opioid properties. Eluxadoline has mixed mu opioid receptor (MOR) and kappa opioid receptor (KOR) agonist and delta opioid receptor (DOR) antagonist properties. The Food and Drug Administration (FDA) approved eluxadoline (brand name “VIBERZI”) as a prescription drug for the treatment of irritable bowel syndrome with diarrhea (IBS-D) on May 27, 2015.

DEA and HHS Eight Factor Analyses

On May 5, 2015, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled “Basis for the Recommendation to Place Eluxadoline in Schedule IV of the Controlled Substances Act.” After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that eluxadoline be controlled in schedule IV of the CSA. In response, the DEA completed its own eight-factor analysis of eluxadoline. Both the DEA and HHS analyses and other relevant documents are available in their entirety in the public docket of this rule (Docket Number DEA-419) at <http://www.regulations.gov> under “Supporting Documents.”²

Determination to Schedule Eluxadoline

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled “Schedules of Controlled Substances: Placement of Eluxadoline into Schedule

² Although the published notice of proposed rulemaking stated that such items had been placed into the docket on regulations.gov, the Administration discovered in preparing this final rule that the HHS analysis had in fact not been posted. However, that document was available for review at DEA. The DEA posted the cited analysis to regulations.gov upon discovery of the error.