

reservations systems to comply with the new rule is a complex undertaking. Indeed, in response to such concerns, we extended the effective date of this rule for 90 days, from October 24, 2011, to its present date of January 24, 2012. (76 FR 45181, July 28, 2011) We can appreciate that any errors that might occur the first day the new system is implemented would have a greater impact on carriers or ticket agents selling air transportation if that day happens to be their busiest business day. We are concerned that, similarly, any such problems may have a more wide-ranging negative effect on consumers, as well. For this reason, and because we agree that a two-day delay in the start of the new rule will not significantly affect consumers, we find that grant of American's petition is in the public interest. In order to avoid confusion over airfares advertised using various media, which include Web sites, email, print, television, and radio, this short two-day extension will apply to all fare advertisements.

The Direct Final Rule Procedure

On January 30, 2004, OST published a final rule adopting direct final rulemaking procedures intended to expedite the rulemaking process for noncontroversial rules. By using direct final rulemaking, OST can reduce the time necessary to develop, review, clear and publish a rule to which no adverse public comment is anticipated by eliminating the need to publish separate proposed and final rules (69 FR 4455).

OST anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, if no adverse or negative comment or written notice of intent to submit such a comment is received, OST will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If OST does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This final rule is not a significant regulatory action under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures. Accordingly, this final rule has not been reviewed by the Office of Management and Budget (OMB).

B. Regulatory Flexibility Act

Pursuant to section 605 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), DOT certifies that this final rule does not have a significant impact on a substantial number of small entities. The final rule does not impose any duties or obligations on small entities.

C. Executive Order 13132 (Federalism)

This Final Rule does not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

D. Executive Order 13084

This Final Rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 ("Consultation and Coordination with Indian Tribal Governments"). Because the rule does not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget

(OMB) for each collection of information it conducts, sponsors, or requires through regulations. DOT has determined that there is no new information collection requirements associated with this final rule.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this Final Rule.

Issued this 13th day of December 2011, in Washington, DC.

Susan Kurland,

Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2011-32336 Filed 12-15-11; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 111202715-1724-01]

RIN 0694-AF46

Addition of Certain Persons to the Entity List; and Implementation of Entity List Annual Review Changes

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by adding two persons to the Entity List. The 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 United Arab Emirates (U.A.E.).

This rule also amends the Entity List on the basis of the annual review of the Entity List conducted by the End-User Review Committee (ERC). The ERC conducts the annual review to determine if any entries on the Entity List should be removed or modified.

This rule removes two persons located in Singapore and two persons located in Taiwan on the basis of the annual review, and revises the entry concerning one person located in Malaysia to add an alternate address.

The Entity List provides notice to the public that certain exports, reexports, and transfers (in-country) to entities identified on the Entity List require a license from the Bureau of Industry and Security (BIS) and that availability of

license exceptions in such transactions is limited.

DATES: *Effective Date:* This rule is effective December 16, 2011.

FOR FURTHER INFORMATION CONTACT:

Karen Nies-Vogel, 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) provides notice to the public that certain exports, reexports, and transfers (in-country) to entities identified on the Entity List require a license from the Bureau of Industry and Security and that the availability of license exceptions in such transactions is limited. Entities are placed on the Entity List on the basis of certain sections of part 744 (Control Policy: End-User and End-Use Based) of the EAR.

The ERC, composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, when 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 two persons to the Entity List on the basis of Section 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 two entries added to the Entity List consist of two persons located in the U.A.E.

The ERC reviewed Section 744.11(b) (Criteria for revising the Entity List) in making the determination to add the two persons located in the U.A.E. to the Entity List. Under that paragraph, persons for which there is reasonable cause to believe, based on specific and articulable facts, that the persons 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 pursuant to Section 744.11. Paragraphs (b)(1)–(b)(5) of Section 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 two persons in the U.A.E. being added to the Entity List under this rule have been determined by the ERC to be involved in activities that could be contrary to the national security or foreign policy interests of the United States. Specifically, BIS's Office of Export Enforcement is investigating the presence of Blue Coat internet filtering devices in Syria and has developed evidence regarding the parties involved in the transfer of these devices to Syria. Waseem Jawad, using the company name Infotec, a.k.a., Info Tech, ordered multiple Blue Coat SG9000–20 Proxy devices in December 2010 from a Blue Coat authorized distributor in the U.A.E. That authorized distributor in turn placed an order for the devices with Blue Coat. A December 2010 email notification identified the end-user of the Blue Coat products for this order as the Ministry of Communication (National Telecom), Al Fadi Street, Baghdad, Iraq. In February 2011, the devices were shipped from the United States to the United Arab Emirates, and ownership was transferred to Waseem Jawad, Info Tech, RAKFTZ, U.A.E. Approximately three days later, the devices departed the U.A.E. for delivery to Syria. Several of these devices have been identified by serial number as the devices being used by the Syrian Telecommunications Establishment in Damascus, Syria. The investigation is ongoing and additional parties related to these transactions may be added to the Entity List in the future.

For the two persons added to the Entity List, the ERC specified a license requirement for all items subject to the EAR and established a license application review policy of a presumption of denial. The license requirement applies to any transaction in which items are to be exported, reexported, or transferred (in-country) to such 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 those persons being added to the Entity List.

This final rule adds the following two persons under two entries to the Entity List:

United Arab Emirates

- (1) *Infotec*, a.k.a., Info Tech., Ras Al Khaimah Free Trade Zone (RAKFTZ), U.A.E.; and
- (2) *Waseem Jawad*, Ras Al Khaimah Free Trade Zone (RAKFTZ), U.A.E.; and P.O. Box: 25123, Dubai U.A.E.

Annual Review of the Entity List

This rule also amends the Entity List on the basis of the annual review of the Entity List conducted by the ERC, in accordance with the procedures outlined in Supplement No. 5 to part 744 (Procedures for End-User Review Committee Entity List Decisions). The changes from the annual review of the Entity List that are approved by the ERC are implemented in stages as the ERC completes its review of entities listed under different destinations on the Entity List. This rule implements the results of the annual review for entities located in Malaysia, Singapore, and Taiwan.

A. Removals From the Entity List

This rule removes four entities from the Entity List, which consists of two entities from Singapore and two entities from Taiwan. Specifically, this rule implements the decision of the ERC to remove two entities, Strive Components and Synoptics Imaging Systems Pte Ltd., located in Singapore, and two entities, Christine Sun and In-Tech Company, a.k.a., In-Tech Telecom, located in Taiwan, from the Entity List on the basis of the annual review of the Entity List, as follows:

Singapore

- (1) *Strive Components*, Block 10 Toa Payoh Industrial Park Lor 8 #01–1221, Singapore, 319062; and
- (2) *Synoptics Imaging Systems Pte Ltd.*, 12 Lor Bakar Batu #06–09, Singapore, 348745.

Taiwan

- (1) *Christine Sun*, 7th Floor, Number 17, Zhonghua Rd., Sec 2, Xinzhuang City, Taipei, Taiwan; and
- (2) *In-Tech Company, a.k.a., In-Tech Telecom*, Number 15, Lane 347, Jhongheng Road, Sinji Huang City, Taipei, Taiwan, and 7th Floor, Number 17, Zhonghua Rd., Sec 2, Xinzhuang City, Taipei, Taiwan.

The removal of the above-referenced four entities from the Entity List eliminates the existing license requirements in Supplement No. 4 to part 744 for exports, reexports and transfers (in-country) to the four entities. However, the removal of these four 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 section 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.

B. Modifications to the Entity List

On the basis of a decision made by the ERC during the annual review, this rule amends one entry currently on the Entity List under Malaysia by adding an alternate address, as follows:

Malaysia

(1) *VTE Industrial Automation SDN BHD*, 97C, Jalan Kenari 23, Puchong Jaya, Puchong, Selangor, Malaysia; and 45-02, Jalan Kenari 19A, Puchong Jaya, 47100 Malaysia.

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 on dock for loading, on lighter, laden aboard an exporting or reexporting carrier, or en route aboard a carrier to a port of export or reexport, on December 16, 2011, 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) so long as they are exported or reexported before January 3, 2012. Any such items not actually exported or reexported before midnight, on January 3, 2012, require a license in accordance with the EAR.

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 extended by the Notice of August 12, 2011, 76 FR 50661 (August 16, 2011), 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 Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by the OMB under control numbers 0694-0088, “Multi-Purpose Application,” which carries a burden hour 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. 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 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 these entities on the Entity List once a final rule was published it 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 and/or to take steps to set up additional aliases, change addresses, and take other steps 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.

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:

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 January 13, 2011, 76 FR 3009, January 18, 2011; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70391 (November 9, 2011).

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

■ (a) By revising under Malaysia, in alphabetical order, one Malaysian entity;

■ (b) By removing under Singapore, the two Singaporean entities: “Strive Components, Block 10 Toa Payoh Industrial Park Lor 8 #01-1221, Singapore, 319062” and “Synoptics Imaging Systems Pte Ltd., 12 Lor Bakar Batu #06-09, Singapore, 348745”;

■ (c) By removing under Taiwan, the two Taiwanese entities: “Christine Sun,

7th Floor, Number 17, Zhonghua Rd., Sec 2, Xinzhuang City, Taipei, Taiwan” and “In-Tech Company, a.k.a., In-Tech Telecom, Number 15, Lane 347, Jhongjheng Road, Sinji Huang City,

Taipei, Taiwan, and 7th Floor, Number 17, Zhonghua Rd., Sec 2, Xinzhuang City, Taipei, Taiwan”; and

■ (d) By adding under United Arab Emirates, in alphabetical order, two U.A.E. entities:

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
Malaysia				
	VTE Industrial Automation SDN BHD, 97C, Jalan Kenari 23, Puchong Jaya, Puchong, Selangor, Malaysia; and 45-02, Jalan Kenari 19A, Puchong Jaya, 47100 Malaysia.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	73 FR 54503, 9/22/08. 76 FR [INSERT FR PAGE NUMBER] 12/16/11.
United Arab Emirates				
	Infotec, a.k.a., Info Tech, Ras Al Khaimah Free Trade Zone (RAKFTZ), U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	76 FR [INSERT FR PAGE NUMBER] 12/16/11.
	Waseem Jawad, Ras Al Khaimah Free Trade Zone (RAKFTZ), U.A.E.; and P.O. Box: 25123, Dubai U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	76 FR [INSERT FR PAGE NUMBER] 12/16/11.

Dated: December 12, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011-32341 Filed 12-15-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Estriol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of estriol tablets for the control of estrogen-

responsive urinary incontinence in ovariectomized female dogs.

DATES: This rule is effective December 16, 2011.

FOR FURTHER INFORMATION CONTACT: Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8322, email: lisa.troutman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 556 Morris Ave., Summit, NJ 07901, filed NADA 141-325 that provides for the veterinary prescription use of INCURIN (estriol) Tablets for the control of estrogen-responsive urinary incontinence in ovariectomized female dogs. The NADA is approved as of July 24, 2011, and the regulations are amended in 21 CFR part 520 to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows: