Country	Entity	License requirement	License review policy	Federal Register citation	
	Transeurope Bilişim Diş Ticaret Limited Şirketi, a.k.a., the following one alias: —Trans Europe Bilisim Dis Ticaret Ltd Sti. Kişla Mah. 37 Sk. Cengizhan Apt. No: 6 İç Kapi No. 102, Muratpasa/Antalya, Turkey.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER] 2/27/2024.	
	rapi No. 102, ividiatpasa/Aritalya, Turkey. *	*	* *	*	
	* * *	*	* *	*	
NITED ARAB EMIRATES.	* *	*	* *	*	
	Crynofist Aviation, a.k.a., the following two aliases: —Crynofist Aviation Fzco; and —Crynofist Design and Engineering Solutions Pvt Ltd. 9WB 159–SO–26, First Floor, 9WB, Dubai Airport Freezone, Dubai, United Arab Emirates. (See alternate address under India).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER] 2/27/2024.	
	Lucky Star General Trading LLC, Airport Cargo Village, Agents Building 2013, Dubai, Dubai, United Arab Emirates; and P.O. Box 62647, Dubai, United Arab Emirates; and Office 23, King of Sheikh Manea bin Khalifa Bin Saeed Al Maktoum, Ras Al Khor Industrial Area 1, P.O. Box 120300, Dubai, United Arab Emirates; and Office No 310, Rashid Almajid Bin Quraiban Building, Parcel 118–813, Naif, Deira, Dubai, United Arab Emirates.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER] 2/27/2024.	
	Marakish Express Cargo LLC, a.k.a., the following one alias: —MEC International. Warehouse #1205, Old Agents Building, Dubai Cargo Village, Dubai, United Arab Emirates; and P.O. Box 293004, Dubai, United Arab Emirates; and Shop No 2048, Department of Civil Aviation Building, Cargo Village, Deira, Dubai, United Arab Emirates.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER] 2/27/2024.	
	Payload Cargo LLC, a.k.a., the following one alias: —Payload Cargo LCC. Suite 212 E-Block Freight Gate 5, Dnata Building, Dubai, United Arab Emirates; and Suite 302, E Block, FG 5, Dubai Airport Free Zone, Dubai, United Arab Emirates; and P.O. Box 29300, Dubai, United Arab Emirates; and Suite 2026, Dubai Cargo Village, Dubai, United Arab Emirates.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER] 2/27/2024.	

³ For this entity, "items subject to the EAR" includes foreign-produced items that are subject to the EAR under § 734.9(g) of the EAR. See §§ 746.8 and 744.21 of the EAR for related license requirements, license review policy, and restrictions on license exceptions.

Alan F. Estevez,

Under Secretary of Commerce for Industry and Security.

[FR Doc. 2024-03969 Filed 2-23-24; 8:45 am]

BILLING CODE 3510-JT-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 240215-0049]

RIN 0694-AJ53

Additions of Entities, Revisions of Entries, and Removal of an Entity From the Entity List

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security is amending the Export Administration Regulations (EAR) by adding two entities under seven entries to the Entity List. These entities are listed under the destinations of Canada (1), the People's Republic of China (China) (1), India (1), Japan (1), Malaysia (1), Sweden (1), and the United Arab Emirates (UAE) (1). Some entities are added under multiple entries, accounting for the difference in the totals. This final rule also modifies two

existing entries on the Entity List under the destination of China. This final rule removes one entity under the destination of the UAE.

DATES: This rule is effective February 27, 2024.

FOR FURTHER INFORMATION CONTACT:

Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730-774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b). The EAR impose additional license requirements on, and limit the availability of, most license exceptions for exports, reexports, and transfers (in-country) where a listed entity is a party to the transaction. The license review policy for each listed entity 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 relevant Federal Register document that adds the entity to the Entity List. The Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) 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 makes all decisions to remove or modify an entry by unanimous vote.

Additions to the Entity List

The ERC determined to add Chengdu Beizhan Electronics Co. Ltd., to the Entity List under the destination of China for acquiring and attempting to acquire U.S.-origin items on behalf of the University of Electronic Science and Technology, an entity on the BIS Entity List. These activities are contrary to U.S. national security and foreign policy interests under § 744.11 of the EAR. This entity is added with a license requirement for all items subject to the EAR. The entity is added with a license review policy of a presumption of denial.

The ERC determined to add Sandvine Incorporated, under the destinations of Canada, India, Japan, Malaysia, Sweden, and the United Arab Emirates to the Entity List. This addition is being made based on information that Sandvine supplies deep packet inspection technology to the Government of Egypt, where it is used in mass web-monitoring and censorship to block news as well as target political actors and human rights activists. These activities are contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. These entities are added with a license requirement for all items subject to the EAR. They are added with a license review policy of a presumption of denial.

For the reasons described above, this final rule adds the following 2 entities under 7 entries to the Entity List and includes, where appropriate, aliases:

Canada

• Sandvine Incorporated.

China

• Chengdu Beizhan Electronics Co., Ltd.

India

• Sandvine Incorporated.

Japan

• Sandvine Incorporated.

Malaysia

Sandvine Incorporated.

Sweden

• Sandvine Incorporated.

United Arab Emirates

• Sandvine Incorporated.

Modifications to the Entity List

This final rule implements the decision of the ERC to modify two existing entries on the Entity List, both under the destination of China. The ERC determined to revise the entry for Beijing China Aviation Technology Co., Ltd., by adding an alias to the entry for a total of five aliases. In addition, the ERC determined to revise the entry for Rayscience Optoelectronics Innovation Co., Ltd., to add one alias and one additional address.

Removal From the Entity List

The ERC determined to remove Jazirah Aviation Club under the

destination of the UAE from the Entity List based on the review the ERC conducted in accordance with the procedures described in supplement no. 5 to part 744 of the EAR.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (incountry) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on February 27, 2024, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before March 28, 2024. Any such items not actually exported, reexported or transferred (incountry) before midnight, on March 28, 2024, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

- 1. 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 or 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 commodity classifications, and carries a burden estimate of 29.4 minutes for a manual or electronic submission for a total burden estimate of 33,133 hours. Total burden hours associated with the PRA and OMB control number 0694-0088 are not

expected to increase as a result of this rule.

- 3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.
- 4. Pursuant to § 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.
- 5. 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.

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—CONTROL POLICY: END-USER AND END-USE BASED

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

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 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. 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 November 8, 2022, 87 FR 68015, 3 CFR, 2022 Comp., p. 563; Notice of September 7, 2023, 88 FR 62439 (September 11, 2023).

- 2. Supplement No. 4 to part 744 is amended by:
- a. Under CANADA, adding an entry in alphabetical order for "Sandvine Incorporated;"
- b. Under CHINA, PEOPLE'S REPUBLIC OF:
- i. Revising the entry for "Beijing China Aviation Technology Co., Ltd.;" and

- ii. Adding an entry in alphabetical order for "Chengdu Beizhan Electronics Co., Ltd.;" and
- iii. Revising the entry for "Rayscience Optoelectronics Innovation Co., Ltd.;"
- c. Under INDIA, adding an entry in alphabetical order for "Sandvine Incorporated:"
- d. Under JAPAN, adding an entry in alphabetical order for "Sandvine Incorporated;"
- e. Under MALAYSIA, adding an entry in alphabetical order for "Sandvine Incorporated;"
- f. Under SWEDEN adding an entry in alphabetical order for "Sandvine Incorporated;"
- g. Under UNITED ARAB EMIRATES:
- i. Removing the entry for "Jazirah Aviation Club;" and
- ii. Adding an entry in alphabetical order for "Sandvine Incorporated."

The revisions and additions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation	
*	* *	*	* *	*	
CANADA	* *	*	* *	*	
	Sandvine Incorporated, a.k.a., the following one alias: —Sandvine Inc. 408 Albert St., Suite 201, Waterloo, Ontario, N2I 3V3, Canada. (See alternate addresses under India, Japan, Malaysia, Sweden, and the United Arab Emirates)	For all items subject to the EAR (See §744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER AND February 27, 2024.	
	* *	*	* *	*	
*	* *	*	* *	*	
	* *	*	* *	*	
CHINA, PEOPLE'S REPUBLIC OF.	Beijing China Aviation Technology Co., Ltd., a.k.a. the following five aliases: —BCAT Aviation; —B-CAT; —BEGAT, —Beijing Zhongxun Technology Co., Ltd.; and —Stratos. No. 18, Kaixuan Street, Liangxiang District, Fangshan District, Beijing, D3768, China; and No. 18, Cailida Road, Liang Tang Street, Liangxiang District, Fangshan District, Beijing, China; and Beijing Yizhuang Economic and Technological Development Zone No. 29 Council of Hai Second Road Zhongxing Science and Technology Park, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR 38741, 06/12/23. 89 FR [INSERT FR PAGE NUMBER February 27, 2024.	
	Chengdu Beizhan Electronics Co., Ltd., a.k.a, the following two aliases: —Chengdu Beizhang Electronics Co.; and —Chengdu North China Electronics Co., Ltd.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	89 FR [INSERT FR PAGE NUMBER February 27, 2024.	

Country	Entity	License requirement	License review policy	Federal Register citation
	Rm. 203, Yifu Building, University of Electronic Science and Technology of China, No. 4, Section 2 North Jianshe Road, Chengdu, 610054, China; and No. 923, Bin Fen/Bifen Holiday International, Building No 2, Baisi Street, Qing Yang District, Chengdu, 610054, China; and Room 906, Block B, Oaks Plaza, No. 666, Jincheng Avenue, High-tech Zone, Chengdu, 610054, China.	·		
	Rayscience Optoelectronics Innovation Co., Ltd., a.k.a., the following one alias: —Collective Enterprise Limited. 3rd Floor, Building 47, No. 2338, Duhui Road, Minhang District, Shanghai, China; and 5F, Building 21, Douhui Road 2338 Lane, Shanghai, China; and Ste. 306, Building 1, Shennan Road 59, Shanghai, China; and Unit 3A, 5F, Far East Consortium Building 21 Des Voeux Road Central HK01, Hong Kong; and Flat B 607, 6/F Jumbo Industrial Building, Hong Kong; and Room 2107, 21/F CCWU Building, 302—308 Hennessy Road, Wanchai, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	See § 744.3(d) of the EAR88 FR 13675, 3/6/23	89 FR [INSERT FR PAGE NUMBER February 27, 2024.
*	* *	*	* *	*
INDIA	* Sandvine Incorporated, a.k.a., the following one alias: —Sandvine Inc. Arliga Ecoworld, Building-1, Ground Floor, East Wing Devarabeesanahalli, Bellandur, Outer Ring Road, Bangalore, 560103, India. (See alternate addresses under Canada, Japan, Malaysia, Sweden, and	For all items subject to the EAR (See § 744.11 of the EAR).	* * Presumption of denial	* 89 FR [INSERT FR PAGE NUMBER February 27, 2024.
	the United Arab Emirates) * *	*	* *	*
*	* *	*	* *	*
JAPAN	* Sandvine Incorporated, a.k.a., the following one alias: —Sandvine Inc. 6F PO Higashi Shimbashi, 2–12–1 Higashi Shimbashi, Minato-ku, Tokyo, 105–0021, Japan. (See alternate addresses under Canada, India, Malaysia, Sweden, and the	For all items subject to the EAR (See § 744.11 of the EAR).	* Presumption of denial	* 89 FR [INSERT FR PAGE NUMBER February 27, 2024.
	United Arab Emirates) * *	*	* *	*
*	* *	*	* *	*
MALAYSIA	Sandvine Incorporated, a.k.a., the following one alias: —Sandvine Inc. E-13A-19, 20 & 21, Block E, Plaza Mont Kiara, Mont Kiara, Kualu Lumpur, 50480, Malaysia. (See alternate addresses under Canada, India, Japan, Sweden, and the United Arab Emirates)	For all items subject to the EAR (See § 744.11 of the EAR).	* Presumption of denial	* 89 FR [INSERT FR PAGE NUMBER February 27, 2024.
	* -	*		*
SWEDEN	* Sandvine Incorporated, a.k.a., the following one alias: —Sandvine Inc. Neptunigatan 1, 211 20, Malmo, Sweden and Svardfiskgatan 4, 432 40, Varberg, Sweden. (See alternate addresses under Canada, India, Japan, Malaysia, and the	For all items subject to the EAR (See § 744.11 of the EAR).	* * Presumption of denial	* 89 FR [INSERT FR PAGE NUMBER February 27, 2024.

Country	Entity		License requirement	License review policy		Federal Register citation	
		*	*	*	*	*	*
	*	*	*	*	*	*	*
JNITED ARAB EMIRATES.		*	*	*	*	*	*
	one alia —Sandvir Business floor, O Media (ternate			For all items subject to the EAR (See § 744.11 of the EAR).	Presumption	on of denial	89 FR [INSERT FR PAGE NUMBER February 27, 2024.
		*	*	*	*	*	*
	*	*	*	*	*	*	*

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024-03674 Filed 2-26-24; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2023-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications, Change of Sponsor, Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2023. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective February 27, 2024.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2023, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOIA Summaries) under the Freedom of Information Act (FOIA). These documents, along with marketing exclusivity and patent information, may be obtained at Animal Drugs @FDA: https://animaldrugsatfda. fda.gov/adafda/views/#/search.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Date of approval	File No.	Sponsor (drug labeler code)	Product name	Effect of the action	21 CFR section
October 11, 2023	141–572	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161 (051311).	AYRADIA (metronidazole) oral solution.	Original approval for the treatment of <i>Giardia duodenalis</i> infection in dogs.	520.1425
October 13, 2023	141–336	ECO LLC, 344 Nassau St., Princeton, NJ 08540 (066916).	AIVLOSIN (tylvalosin tartrate) Water Soluble Granules.	Supplemental approval adding fe- males intended for breeding to approved classes of swine.	520.2645
October 20, 2023	141–564	Pharmgate Inc., 1800 Sir Tyler Rd., Wilmington, NC 28405 (069254).	PENNCHLOR (chlortetracycline Type A medicated article) and RUMENSIN (monensin Type A medicated article).	Original approval for treatment of bacterial enteritis and pneumonia; and for increased rate of weight gain or prevention and control of coccidiosis in replacement beef and dairy heifers.	558.128
November 8, 2023	200–758	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland (086101).	Enrofloxacin Injectable Solution	Original approval for treatment and control of bovine respiratory disease (BRD) in beef cattle and non-lactating dairy cattle and swine respiratory disease (SRD) and control of colibacillosis in groups or pens of weaned pigs, as a generic copy of NADA 141–068.	522.812