(2) All airplanes specified in paragraphs (c)(2)(i) through (xi) of this AD, type certificated in the restricted category.

(i) LeSEA Model C–130A airplanes (transferred from Central Air Services, Inc.), Type Certificate Data Sheet (TCDS) A34SO, Revision 1.

(ii) T.B.M., Inc., Model C–130A airplanes, TCDS A39CE, Revision 3.

(iii) Western International Aviation, Inc., Model C–130A airplanes, TCDS A33NM.

(iv) USDA Forest Service Model C–130A airplanes, TCDS A15NM, Revision 4.

(v) Snow Aviation International, Inc., Model C–130A airplanes, TCDS TQ3CH, Revision 1.

(vi) International Air Response (transferred from Rogers Helicopters, Inc., and Heavylift Helicopters Inc.) Model C–130A airplanes, TCDS A31NM, Revision 3.

(vii) Heavylift Helicopters, Inc., Model C–130B airplanes, TCDS A35NM, Revision 1.

(viii) Hawkins & Powers Aviation, Inc., Model HP–C–130A airplanes, TCDS A30NM, Revision 1.

(ix) Coulson Aviation (USA), Inc., Model EC–130Q and C–130H airplanes, TCDS T00019LA, Revision 4.

(x) Lockheed-Georgia Company Model 282–44A–05 (C–130B) airplanes, TCDS A5SO.

(xi) Surplus Model C–130A airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Unsafe Condition

This AD was prompted by reports of fatigue cracking of an upper lug of the engine truss mount, and by reports of cracks found prior to the initial inspection times required by AD 96–12–20. The FAA is issuing this AD to address such fatigue cracking. Fatigue cracking of a single engine truss mount upper lug could reduce the static strength of an engine mount to limit load, while cracking of both lugs can lead to separation of the engine, catastrophic structural damage, and loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Within 35 days after the effective date of this AD, do the inspections specified in paragraphs (g)(1) and (2) of this AD, using a method approved in accordance with the procedures specified in paragraph (i) of this AD. If any cracked or severed engine truss mount upper lug is found, the engine truss mount must be replaced before further flight, using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(1) Do a one-time detailed visual inspection for cracking of the No. 1 and No. 4 engine truss mount upper lugs, lower surfaces, at outer wing station (OWS) 162 and OWS 197; and for severed engine truss mount upper lugs; at a total of four locations: two locations per engine mount, one mount assembly at each OWS.

(2) Do a one-time borescope inspection for cracking of the No. 1 and No. 4 engine truss mount upper lug side surfaces, inboard and outboard, at OWS 162 and OWS 197; and for severed engine truss mount upper lugs; at a total of eight locations: two locations per engine truss mount lug, two lugs per engine, one mount assembly at each OWS.

Note 1 to paragraph (g): Guidance for accomplishing the inspections and replacement can be found in Lockheed Martin Aeronautics Company Alert Service Bulletin A382–57–103, dated October 19, 2023.

(h) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the inspections required by this AD can be performed, but special flight permits may not be issued to operate the airplane after a visual or borescope inspection has identified a cracked or severed lug, unless the operator contacts the Manager, East Certification Branch, FAA, for specific limitations that must be followed and complies with those limitations.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, East Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(j) Related Information

(1) For more information about this AD, contact Fred Caplan, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5507; email: *9-ASO-ATLACO-ADs@faa.gov*.

(2) For Lockheed Martin Aeronautics Company service information identified in this AD that is not incorporated by reference, contact Lockheed Martin Corporation/Lockheed Martin Aeronautics Company, Airworthiness Office, Dept. 6A0M, Zone 0252, Column P–58, 86 S Cobb Drive, Marietta, GA 30063; telephone 770–494–5444; fax 770–494–5445; email *ams.portal@lmco.com*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(k) Material Incorporated by Reference

None.

Issued on November 16, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–25762 Filed 11–17–23; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 231115–0270]

RIN 0694–AJ45

Additions to the Entity List

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

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding four entities under nine entries to the Entity List. These entities are listed under the destinations of Costa Rica (1), Ecuador (1), India (1) Panama (2), Spain (1), Russia (1), and Venezuela (2). These entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. Some entities are added under multiple entries, accounting for the difference in the totals.

DATES: This rule is effective November 17, 2023.

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) when 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 added the entity to the Entity List. The Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use Based) and 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.

Entity List Decisions

Additions to the Entity List

The ERC determined to add Aerofalcon S.L., under the destination of Spain; Novax Group S.A., under the destinations of Costa Rica, Ecuador, Panama, Venezuela, and Russia; and Zero Waste Global SA, under the destinations of Panama and Venezuela, to the Entity List. These entities are added to the Entity List pursuant to § 744.11 of the EAR for engaging in activities contrary to U.S. national security and foreign policy interests. Specifically, these entities were used by their principals to circumvent U.S. sanctions, supplying the representatives of Nicolás Maduro in Venezuela with U.S. origin aircraft parts. This circumvention was conducted by, among other efforts, concealing the true end user and end destination of the exports using misrepresentations and fraudulent documents, including the filing of false Electronic Export Information. These entities will be added with a license requirement for all items subject to the EAR and a license review policy of presumption of denial.

The ERC determined to add Si2 Microsystems Private Limited, under the destination of India, to the Entity List. This entity is added to the Entity List for providing support to Russia's military and/or defense industrial base. Specifically, this entity supplied Russian consignees connected to the Russian defense sector with U.S.-origin integrated circuits after March 1, 2023. These integrated circuits are classified under Harmonized Tariff System (HTS)-6 codes 854231, 854232, 854233, and/or 854239. These HTS–6 codes are identified under supplement no. 4 to part 746 (Russian and Belarusian Industry Sector Sanctions Pursuant to § 746.5(a)(1)(ii)). All U.S.-origin items classified under these HTS–6 codes have been controlled for export and reexport and transfer within Russia since September 15, 2022. Such U.S.-origin items require a license under § 746.5(a)(1)(ii) of the EAR when destined to Russia or Belarus.[1]

Therefore, the documented shipments by this entity to Russia of such U.S.-origin items are contrary to U.S. national security and foreign policy interests under § 744.11(b) of the EAR. This entity will be added with a license requirement for all items subject to the EAR and a license review policy of denial.

For the reasons described above, this final rule adds the following four entities, including aliases where appropriate, to the Entity List:

Costa Rica

- Novax Group S.A.

Ecuador

- Novax Group S.A.

India

- Si2 Microsystems Private Limited.

Panama

- Novax Group S.A.; *and*
- Zero Waste Global SA.

Spain

- Aerofalcon S.L.

Russia

- Novax Group S.A.

Venezuela

- Novax Group S.A.; *and*
- Zero Waste Global SA.

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 (in-country) 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 November 17, 2023, 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 December 18, 2023. Any such items not actually exported, reexported or transferred (in-country) before midnight, on December 18, 2023, 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 an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at *https://www.reginfo.gov/public/do/PRAMain.*

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 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

[1] On February 24, 2023 (88 FR 12150), BIS also expanded controls to include certain foreign-made items classified under the same HTS–6 codes destined to Russia, due to their demonstrated use in weapons found on the battlefield in Ukraine. Such foreign-made items are subject to the EAR and the license requirements of § 746.8(a)(2) when a reexport, export from abroad, or transfer (in-country) meets the destination scope of the Russia/Belarus/Temporarily occupied Crimea region of Ukraine FDP (Foreign Direct Product) rule described in § 734.9(f) of the EAR.

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—END-USE AND END-USER CONTROLS

■ 1. The authority citation for part 744 is revised 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 is amended:

■ a. Under COSTA RICA, by adding, in alphabetical order, an entry for ''Novax Group S.A.;''

■ b. Under ECUADOR, by adding, in alphabetical order, an entry for ''Novax Group S.A.;''

■ c. Under INDIA, by adding, in alphabetical order, an entry for ''Si2 Microsystems Private Limited.;''

■ d. Under PANAMA, by adding, in alphabetical order, entries for ''Novax Group S.A.;'' *and* ''Zero Waste Global SA;''

■ e. Under SPAIN, by adding, in alphabetical order, an entry for ''Aerofalcon S.L.;''

■ f. Under RUSSIA, by adding in alphabetical order, an entry for ''Novax Group S.A.;'' *and*

■ g. Under VENEZUELA, by adding in alphabetical order, entries for ''Novax Group S.A.,'' *and* ''Zero Waste Global SA.'' to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	* * *	*	* *	*
COSTA RICA	* *	*	*	*
	Novax Group S.A., Centro Corporative Lindora, Oficina Nro. 2–10, Pozos de Santa Ana, San Jose, 10903, Costa Rica. (See alternate addresses under Ecuador, Panama, Russia, and Venezuela).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
ECUADOR	* *	*	*	*
	Novax Group S.A., Avenida Joaquin Orrantia y Juan Tanca Marengo, Torres del Mall del Sol Piso 4, Torre B, Guayaquil, Ecuador. (See alternate addresses under Costa Rica, Panama, Russia, and Venezuela).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
INDIA	* *	*	*	*
	Si2 Microsystems Private Limited, 84, Deep Towers, EPIP Industrial Area, Whitefield, Bangalore, Karnataka, 560066, India; *and* #52/A, 1st Cross, 3rd Main KIADB Industrial Area, Hoskote, Bangalore, Karnataka, 562114, India; *and* 3796, 7th Main, Hal II Stage, Bangalore, Karnataka, 560008, India; *and* 493/3 Bramhalingeshwara Complex, Airport Road, Bangalore, Karnataka, 560008, India; *and* 177/2 Bannerghatta Road, Begur Hobli Bilekahalli Industrial Area, Bangalore, Karnataka, 560076, India.	For all items subject to the EAR (See § 744.11 of the EAR).	Policy of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
PANAMA	* *	*	*	*
	Novax Group S.A., Avenida Aquilino de la Guardia con Calle 47, Edificio Ocean Plaza, Piso 16, Oficina 8, Ciudad de Panama, Panama. (See alternate addresses under Costa Rica, Ecuador, Russia, and Venezuela).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
	Zero Waste Global S.A., 58 Street Obarrios Office One Building, Suite 1302, Panama City, Panama. (See alternate address under Venezuela).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
RUSSIA	* *	*	*	*
	Novax Group S.A., Koptevskaya Ulitsa 67, Moscow, 125239, Russia. (See alternate addresses under Costa Rica, Ecuador, Panama, and Venezuela).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
SPAIN	* *	*	*	*
	Aerofalcon S.L., Calle Ángel Cavero 28, Madrid, 28043, Spain.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	* *	*	*	*
VENEZUELA	* *	*	*	*

Country	Entity	License, requirement	License review policy	**Federal Register** citation
	Novax Group S.A., Caracas, Venezuela. (See alternate addresses under Costa Rica, Ecuador, Panama, and Russia).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
	Zero Waste Global S.A., Between Avenida Beethoven and Avenida Principal de Bello Monte, Edificio El Cigarral PH–A, Caracas, CP 1050, Venezuela. (See alternate address under Panama).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	88 FR [INSERT FR PAGE NUMBER AND 11/21/2023].
*	*	*	*	*	*

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–25684 Filed 11–17–23; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA–2009–N–0582]

RIN 0910–AG27

Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations concerning direct-to-consumer (DTC) advertisements (ads) for human prescription drugs presented in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads). Specifically, the final rule implements a requirement of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that in such DTC TV/radio ads, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner. As directed by FDAAA, FDA is establishing standards to determine whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and neutral manner.

DATES: This rule is effective May 20, 2024. The compliance date of this rule is November 20, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to human drug products: Suzanna Boyle, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1200, *CDER-OPDP-RPM@fda.hhs.gov.*

With regard to human biological products: Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

This final rule implements a statutory requirement that in human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads), the major statement relating to side effects and contraindications (major statement) (Ref. 1) must be presented in a clear, conspicuous, and neutral manner. (As used in this document, unless specifically stated otherwise, references to DTC ads and similar terms encompass ads for human prescription drugs only.) In enacting that requirement, Congress directed FDA to issue regulations establishing standards for determining whether a major statement is presented in a clear,