

found in the AD docket at regulations.gov under Docket No. FAA-2024-0035.

(2) For more information about this AD, contact Doug Rudolph, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329-4059; email: doug.rudolph@faa.gov.

(j) 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 the AD specifies otherwise.

(i) GippsAero Service Bulletin SB-GA8-2005-23, Issue 8, dated October 11, 2023.

(ii) [Reserved]

(3) For service information contact GA8 Airvan (Pty) Ltd, PO Box 881, Morwell, Victoria 3840, Australia; phone: +61 03 5172 1200; website: gippsaero.com.au; email: TECHPUBS@gippsaero.com.au.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locationsoremailfr.inspection@nara.gov.

Issued on March 29, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024-09087 Filed 4-26-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA-2023-1836; Amdt. No. 91-371B]

RIN 2120-AL70

Inclusion of Additional Automatic Dependent Surveillance-Broadcast (ADS-B) Out Technical Standard Orders; Incorporation by Reference; Correction

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Direct final rule; correction.

SUMMARY: On October 17, 2023, the Federal Aviation Administration (FAA) published the subject direct final rule in the Federal Register, confirmed on November 29, 2023. In that direct final rule, the FAA redesignated two paragraphs in one section of the Code of

Federal Regulations but failed to amend cross-references to those paragraphs. This document corrects those errors.

DATES: This correction is effective April 29, 2024.

FOR FURTHER INFORMATION CONTACT: Juan Sebastian Yanguas, Airspace Rules & Regulations, AJV-P21, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267-8783; email Juan.S.Yanguas@faa.gov.

SUPPLEMENTARY INFORMATION: On October 17, 2023, the Federal Aviation Administration (FAA) published the direct final rule, Inclusion of Additional Automatic Dependent Surveillance-Broadcast (ADS-B) Out Technical Standard Orders; Incorporation by Reference, in the Federal Register.¹ In that direct final rule the FAA incorporated by reference two new Technical Standard Orders (TSOs), and three RTCA documents—TSO-C166c, TSO-C154d, section 2 of RTCA DO-260C, RTCA DO-260C Change 1, and section 2 of RTCA DO-282C into 14 CFR 91.225 and 91.227. The FAA responded to comments and confirmed the direct final rule on November 28, 2023.²

In the direct final rule, the FAA amended § 91.225 by redesignating paragraphs (h) and (i) as set out in the following redesignation table:

Table with 2 columns: Old paragraph, New paragraph. Row 1: paragraph (h) paragraph (i). Row 2: paragraph (i) paragraph (h).

While the FAA discussed the redesignation of paragraphs (h) and (i), it failed to revise cross-references to those paragraphs appearing elsewhere in § 91.225. This document corrects those errors.

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airports, Aviation safety, Incorporation by reference, Transportation.

Accordingly, 14 CFR part 91 is corrected by making the following correcting amendments:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506-46507, 47122, 47508, 47528-

¹ 88 FR 71468; FR Doc. 2023-22710.

² 88 FR 83022.

47531, 47534, Pub. L. 114-190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.225 by revising the introductory text of paragraphs (d) and (f) to read as follows:

§ 91.225 Automatic Dependent Surveillance-Broadcast (ADS-B) Out equipment and use.

* * * * *

(d) After January 1, 2020, except as prohibited in paragraph (h)(2) of this section or unless otherwise authorized by ATC, no person may operate an aircraft in the following airspace unless the aircraft has equipment installed that meets the requirements in paragraph (b) of this section:

* * * * *

(f) Except as prohibited in paragraph (h)(2) of this section, each person operating an aircraft equipped with ADS-B Out must operate this equipment in the transmit mode at all times unless—

* * * * *

Issued under the authority of 49 U.S.C. 106(f) in Washington, DC.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2024-08885 Filed 4-26-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 744, 746, and 762

[Docket No. 240423-0115]

RIN 0694-AJ59

Amendment to Existing Controls on Russia and Belarus Under the Export Administration Regulations (EAR) Adding New License Exception Medical Devices (MED); Corrections

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

ACTION: Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) makes changes to the Russia and Belarus sanctions under the Export Administration Regulations (EAR) to add a new license exception for EAR99 medical devices and related parts, components, accessories, and attachments for use in or with medical devices that are destined for both countries and the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. The purpose of this final rule is to authorize under a license

exception certain exports, reexports, and transfers (in-country) of “medical devices” that are being regularly approved and that advance U.S. national security and foreign policy interests. In addition, this final rule makes two corrections to the EAR related to Russia-related rules published in January, and March, 2024 by correcting an end-user control and adding a cross-reference correction.

DATES: This rule is effective on April 29, 2024.

FOR FURTHER INFORMATION CONTACT: For questions on this final rule, contact Mark Salinas, Senior Export Policy Analyst, Foreign Policy Division, Bureau of Industry and Security, Department of Commerce, Phone: 202–482–4252, Email: mark.salinas@bis.doc.gov.

For emails, include “License Exception MED” in the subject line.

SUPPLEMENTARY INFORMATION:

I. Background

A. Export Controls Implemented Against Russia and Belarus

In response to Russia’s February 2022 full-scale invasion of Ukraine, BIS imposed extensive sanctions on Russia under the EAR as part of the final rule, “Implementation of Sanctions Against Russia Under the Export Administration Regulations (EAR)” (the Russia Sanctions Rule) (87 FR 12226, March 3, 2022). To address Belarus’s complicity in the invasion, BIS imposed similar sanctions on Belarus under the EAR in a final rule, “Implementation of Sanctions Against Belarus” (“Belarus Sanctions Rule”) (87 FR 13048, March 6, 2022). During the last two years, BIS has published a number of additional final rules strengthening the export controls on Russia and Belarus, including measures undertaken in coordination with U.S. allies and partners. Most recently, in March 2024, BIS amended the EAR to strengthen export controls against Russia and other destinations by expanding controls on persons identified on the List of Specially Designated Nationals and Blocked Persons (SDN List) (March 21, 2024, 89 FR 20107). As corrected by this rule, as described below under section II.C.1, § 744.8 of the EAR imposes licensing restrictions on exports, reexports, and transfers (in-country) made in connection with persons designated as SDNs by the Department of the Treasury’s Office of Foreign Asset Controls pursuant to several Russia-related Executive Orders.

B. Overview of This Final Rule

In this final rule, BIS makes changes to the Russia and Belarus sanctions under the EAR to add a new license exception for “medical devices” under § 740.23 (Medical Devices (MED)). License Exception MED will authorize the export, reexport, or transfer (in country) of “medical devices” designated as EAR99 to or within Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. Items subject to the EAR that are not on the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR are designated as EAR99. License Exception MED will also authorize “parts,” “components,” “accessories,” and “attachments” designated as EAR99 that are exclusively for use in or with “medical devices” designated as EAR99. The purpose of this final rule is to create a new license exception that will authorize (subject to certain terms and conditions) certain exports, reexports, and transfers (in-country) that BIS generally has been approving under the licensing application review policies set forth in §§ 746.5, 746.6, and 746.10 of the EAR. New License Exception MED includes terms and conditions to ensure that only those exports, reexports, and transfers (in-country) that are in U.S. national security and foreign policy interests will be authorized.

This final rule also makes conforming changes to the EAR to reflect the addition of this new license exception.

Lastly, this final rule makes two corrections to the EAR, consisting of: one correction to an end-user control under the EAR that was impacted by the final rule, “Export Administration Regulations End-User Controls: Imposition of Restrictions on Certain Persons Identified on the List of Specially Designated Nationals and Blocked Persons (SDN List),” published March 21, 2024 (89 FR 20107); and a cross-reference correction to the final rule, “Implementation of Additional Sanctions Against Russia and Belarus Under the Export Administration Regulations (EAR) and Refinements to Existing Controls,” published January 25, 2024 (89 FR 4804).

The three sets of changes this final rule makes are described in section II as follows:

A. Addition of License Exception Medical Devices (MED);

B. Conforming changes to the EAR made in connection with the addition of License Exception MED; and

C. Correction to the March 21, 2024, final rule addressing EAR controls for certain Specially Designated Nationals

(SDNs) and correction to the January 25, 2024, Russia sanctions final rule.

II. Amendments to the EAR

A. Addition of License Exception Medical Devices (MED)

In part 740 (License Exceptions), this final rule adds a new license exception to the EAR under § 740.23 (Medical Devices (MED)).

1. Scope of License Exception MED

This final rule adds paragraph (a) (*Scope*) to specify that License Exception MED authorizes the export, reexport, or transfer (in country) of “medical devices” designated as EAR99 to Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. See the Supplement No. 3 to Part 774—Statements of Understanding under paragraph (a) (Statement of Understanding—medical equipment) for guidance on classifying medical equipment and the definition of “medical device” in § 772.1 of the EAR. Exporters, reexporters, or transferors that need assistance in classifying their items to determine whether they are designated as EAR99 may submit classification requests to BIS using the Simplified Network Application Process (SNAR-R) available on the BIS website at <https://www.bis.doc.gov>.

The second sentence of paragraph (a) specifies that License Exception MED is also available to authorize “parts,” “components,” “accessories,” and “attachments” designated as EAR99 that are exclusively for use in or with “medical devices” designated as EAR99. Due to the importance of “parts,” “components,” “accessories,” and “attachments” for the use of “medical devices,” these commodities are also included as part of this authorization. The criterion “exclusively for use in or with “medical devices” designated as EAR99” is intended to limit the types of “parts,” “components,” “accessories,” and “attachments” that may be exported, reexported, or transferred (in-country) under License Exception MED, to those which are necessary for replacement or maintenance in or with medical devices, which will also reduce the likelihood of diversion to industrial or military end uses. The last sentence of paragraph (a) specifies that License Exception MED authorizes transactions involving EAR99 designated items that would otherwise require a license pursuant to §§ 746.5, 746.6 or 746.10 of the EAR, provided the terms and conditions described in § 740.23 are met.

License Exception MED does not overcome any license requirements imposed under § 746.8 or any other EAR license requirement (*e.g.*, those specified under part 744) other than those specified under §§ 746.5, 746.6, or 746.10. Additionally, as with any EAR license exception, exports, reexports, or transfers (in-country) under License Exception MED may be restricted under § 740.2 (Restrictions on All License Exceptions).

2. Restrictions of License Exception MED

This final rule adds paragraph (b) (Restrictions) to specify that License Exception MED does not authorize the export, reexport, or transfer (in country) of any item that meets the restrictions under paragraph (b)(1), (2), or (3) of § 740.23. Paragraph (b)(1) specifies that License Exception MED is not available when a “proscribed person,” as defined in § 772.1, is a party to the transaction as described in § 748.5(c) through (f) of the EAR. This final rule also includes an illustrative list in a parenthetical phrase that provides some examples of “proscribed persons” (including but not limited to ‘military end users’ see §§ 744.17(e) and 744.21(g)) or in situations in which an entity on the Entity List in supplement no. 4 to part 744 or on the Military End-User (MEU) List) that are excluded from being parties to the transaction. License Exception MED may not be utilized to help support the Russian industrial base (in particular, the Russian medical device industry) or enable “proscribed persons” or entities to receive eligible items. Paragraph (b)(2) restricts any export, reexport, or transfers (in-country) destined to a “production” “facility,” as those terms are defined in § 772.1. For the same reason, this final rule under paragraph (b)(3) restricts any export, reexport, or transfer (in-country) destined to Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine when the exporter, reexporter, or transferor has “knowledge” that the items are intended to develop or produce items. This final rule also adds a Note 1 to paragraphs (b)(2) and (3), to specify that the assembly in a hospital or other health care “facility” of a finished “medical device” completely “produced” outside of Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine for the sole purpose of using that “medical device” at that facility is not considered a “production” activity for purposes of these two paragraphs.

3. Verification Procedures for License Exception MED

This final rule adds paragraph (c) (*Verification*) to impose a requirement on exporters, reexporters, and transferors to maintain a system of distribution that ensures that “medical devices” are not delivered to “proscribed persons” or entities engaged in the “production” of any product. Exporters, reexporters, and transferors are responsible for ensuring that the items being exported, reexported, or transferred (in-country) are not diverted contrary to the terms and conditions of License Exception MED. The paragraph (c) text specifies that the verification of the effectiveness of the distribution system may entail obtaining certain information from a consignee (*e.g.*, obtaining affirmations or other documentation from a consignee as part of an exporter, reexporter, or transferor’s compliance program) for ensuring that the use and disposition of “medical devices” received under License Exception MED meet the required terms and conditions.

This final rule under paragraph (c) also provides another illustrative example for how the verification of the effectiveness of the distribution system may be confirmed by the exporter, reexporter, or transferor by conducting periodic on-site spot checks. This final rule includes criteria in a parenthetical phrase that follows the phrase ‘or performing periodic on-site spot-checks’ to provide illustrative examples of the verification methods that may be adopted to ensure the effectiveness of the distribution system when an exporter, reexporter, or transferor decides to use conducting periodic on-site spot checks. Specifically, this final rule specifies in that parenthetical phrase that a verification system may include periodic on-site spot-checks in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine, by the exporter, reexporter, or transferor; an internationally accredited auditing firm; or by an internationally recognized non-governmental humanitarian organization.

4. Recordkeeping and Review of Records Under License Exception MED

This final rule under paragraph (d) (*Recordkeeping and review of records*), specifies that in addition to complying with the recordkeeping requirements in part 762 of the EAR, that exporters, reexporters, and transferors must maintain records of verification, as specified in paragraph (d), for 5 five years, and, upon request, these records

must be provided to BIS, or any other official of the United States designated by BIS, for review.

BIS estimates the new License Exception MED under § 740.23 will result in a reduction of 3,900 license applications being submitted to BIS annually.

B. Conforming Changes to the EAR for Addition of License Exception MED

In § 746.5 (Russian and Belarusian industry sector sanctions), this final rule revises paragraph (c)’s (License exceptions) introductory text, to add a reference to new paragraph (c)(8) (License Exception MED), an additional license exception that may overcome the license requirements set forth in this section. This final rule also adds paragraph (c)(8) (License Exception MED), including adding a cross reference to new § 740.23 of the EAR.

In § 746.6 (Temporarily occupied Crimea region of Ukraine and covered regions of Ukraine), this final rule adds a new paragraph (c)(7) (License Exception MED), including adding a cross reference to new § 740.23 of the EAR.

In § 746.10 (‘Luxury goods’ sanctions against Russia and Belarus and Russian and Belarusian oligarchs and malign actors), this final rule revises paragraph (c) (License Exceptions) introductory text to add a reference to new paragraph (c)(8) (License Exception MED) as an additional license exception that may overcome the license requirements in paragraph (a)(1) of this section. This final rule also adds paragraph (c)(8) (License Exception MED), including adding a cross reference to new § 740.23 of the EAR.

In § 762.2 (Records to be retained), this final rule revises paragraph (b) (Records retention references) to add a new paragraph (b)(55) (§ 740.23, License Exception MED) and makes two conforming changes by revising paragraph (b)(53) to remove the word “and” and revising paragraph (b)(54) to replace the period with a semi-colon to reflect the addition of new paragraph (b)(55).

C. Correction to March 24, 2024 Final Rule Imposing EAR Controls on Certain Persons Identified on the SDN List and Correction to January 25, 2024 Russia Sanctions Final Rule

1. Correction to March 24, 2024 Final Rule

This final rule makes a conforming change correction to § 744.11 to reflect the revisions made to § 744.8 in the March 24, 2024, final rule, “Export Administration Regulations End-User

Controls: Imposition of Restrictions on Certain Persons Identified on the List of Specially Designated Nationals and Blocked Persons (SDN List),” (89 FR 20107). Specifically, this final rule removes the fourth sentence of paragraph (b) introductory text that specified that § 744.11 “may not be used to place on the Entity List any party to which exports or reexports require a license pursuant to § 744.8, § 744.12, § 744.13, § 744.14, or § 744.18” because it is no longer needed or accurate. Sections 744.12 through 744.14 and 744.18 were reserved as of March 24, 2024. Note 2 to paragraph (a) of the revised § 744.8 provides guidance that the Entity List in supplement no. 4 to part 744 includes certain persons that have also been designated with certain identifiers on the SDN List. Note 2 includes a cross reference that directs persons to § 744.11 and supplement no. 4 to part 744 for requirements, including license review policies, for these entities, which take precedence over the requirements in § 744.8.

2. Correction to January 25, 2024 Russia Sanctions Final Rule

This final rule makes a cross-reference correction to § 746.10 to add a reference to paragraph (c)(7) to reflect that License Exception CCD is intended to be available to overcome the license requirements under § 746.10(a)(1) as described in the Background section of the January 25, 2024, final rule, “Implementation of Additional Sanctions Against Russia and Belarus Under the Export Administration Regulations (EAR) and Refinements to Existing Controls,” published January 25, 2024 (89 FR 4804), but the regulatory cross-reference was not updated to reflect paragraph (c)(3) was redesignated as paragraph (c)(7) in the January 25, 2024 final rule. This final rule corrects § 746.10(c) introductory text to make a needed cross-reference correction to specify that License Exception CCD is available.

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) (codified, as amended, at 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. To the extent it applies to certain activities that are the subject of this rule, the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) (codified, as amended, at

22 U.S.C. 7201–7211) also serves as authority for this rule.

Rulemaking Requirements

1. BIS has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094, which 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 (*e.g.*, potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). Pursuant to E.O. 12866, as amended, this final rule has not been determined to be a “significant regulatory action.”

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person 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 rule involves the following OMB-approved collections of information subject to the PRA:

- OMB Control Number 0694–0088, “Multi-Purpose Application,” which carries a burden hour estimate of 29.4 minutes for a manual or electronic submission;
- OMB Control Number 0694–0096 “Five Year Records Retention Period,” which carries a burden hour estimate of less than one minute; and
- OMB Control Number 0607–0152 “Automated Export System (AES) Program,” which carries a burden hour estimate of three minutes per electronic submission.

This rule changes the respondent burden for control number 0694–0088 by reducing the estimated number of submissions by 3,900, which is expected to reduce the current approved estimates, which will result in a reduction of 1,911 burden hours saved and cost savings to the public of \$72,618 under this collection. The respondent burden under controls numbers 0694–0096 and 0607–0152 are not anticipated to change as a result of this final rule.

Current information regarding all three collections of information—including all background materials—can be found at <https://www.reginfo.gov/public/do/PRAMain> by using the search function to enter either the title of the collection or the OMB Control Number.

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

4. Pursuant to section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).

5. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no Final Regulatory Flexibility Analysis is required and none has been prepared.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information, Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 740, 744, 746, and 762 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 740—LICENSE EXCEPTIONS

- 1. The authority citation for part 740 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. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

- 2. Part 740 is amended by adding § 740.23 to read as follows.

§ 740.23 MEDICAL DEVICES (MED).

(a) *Scope.* License Exception MED authorizes the export, reexport, or transfer (in country) of “medical devices” designated as EAR99 or within Russia, Belarus, the temporarily

occupied Crimea region of Ukraine, or the covered regions of Ukraine (as specified in § 746.6(a)(2) of the EAR). See Supplement no. 3 to part 774—Statements of Understanding under paragraph (a) (Statement of Understanding—medical equipment) for guidance on classifying medical equipment and the definition of “medical device” in § 772.1 of the EAR. License Exception MED also authorizes the export, reexport, or transfer (in country) to or within Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine of “parts,” “components,” “accessories,” and “attachments” designated as EAR99 that are exclusively for use in or with “medical devices” designated as EAR99. This license exception authorizes transactions involving items designated as EAR99 that would otherwise require a license pursuant to §§ 746.5, 746.6 or 746.10 of the EAR, subject to the terms and conditions described in this section. For “parts,” “components,” “accessories,” and “attachments” authorized under License Exception MED, such replacement “parts,” “components,” “accessories,” and “attachments” may only be exported, reexported, or transferred (in-country) if they also meet the additional requirements under paragraphs (a)(1) and (2) of this section:

(1) The “part,” “component,” “accessory,” or “attachment” is being exported, reexported, or transferred (in-country) solely to replace a broken or nonoperational “part,” “component,” “accessory,” or “attachment” for use in or with a “medical device” that falls within the scope of paragraph (a) of this section, or the export, reexport, or transfer (in-country) of such replacement “parts,” “components,” “accessories,” and “attachments” is necessary and ordinarily incident to the proper preventative maintenance of such a “medical device;” and

(2) The number of replacement “parts,” “components,” “accessories,” and “attachments” that are exported, reexported, transferred (in-country), and stored in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine does not exceed the number of corresponding operational “parts,” “components,” “accessories,” and “attachments” currently in use in or with the relevant medical devices in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine.

(b) *Restrictions.* This license exception does not authorize the export,

reexport, or transfer (in country) of any item:

(1) To a “proscribed person” (including but not limited to ‘military end users’ (see §§ 744.17(e) and 744.21(g)) or in situations in which an entity on the Entity List in supplement no. 4 to part 744 or on the Military End-User (MEU) List) is a party to the transaction as described in § 748.5(c) through (f) of the EAR;

(2) Destined to a “production” “facility;” or

(3) When you have “knowledge” that the item is intended to develop or produce items.

Note 1 to paragraphs (b)(2) and (3): The assembly in a hospital or other health care facility of a finished “medical device” completely “produced” outside of Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine” for the sole purpose of using that “medical device” at that facility is not considered a “production” activity for purposes of the restrictions under paragraphs (b)(2) and (3) of this section.

(c) *Verification.* Exporters, reexporters, and transferors must maintain a system of distribution that ensures that “medical devices” and “parts,” “components,” “accessories,” or “attachments” are not delivered to “proscribed persons” or entities engaged in the “production” of any product. Verification of the effectiveness of the distribution system may entail obtaining certain information from a consignee (e.g., obtaining affirmations or other documentation from a consignee, or performing periodic on-site spot-checks (e.g., conducting such verification by staff of the exporter, reexporter, or transferor; an internationally accredited auditing firm; or an internationally recognized non-governmental humanitarian organization in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine to conduct such verification).

(d) *Recordkeeping and review or inspection of records.* In addition to complying with the recordkeeping requirements in part 762 of the EAR, exporters, reexporters, and transferors must maintain records of verification, as specified in paragraph (c) of this section, for 5 years and, upon request, provide records to BIS, or any other official of the United States designated by BIS, for review or inspection.

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 3. 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 September 19, 2022, 87 FR 57569 (September 21, 2022); 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).

§ 744.11 [Amended]

■ 4. Section 744.11 is amended by removing the fourth sentence of paragraph (b) introductory text.

PART 746—EMBARGOS AND OTHER SPECIAL CONTROLS

■ 5. The authority citation for 15 CFR part 746 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. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 2151 note; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Presidential Determination 2007–7, 72 FR 1899, 3 CFR, 2006 Comp., p. 325; Notice of May 8, 2023, 88 FR 30211 (May 10, 2023).

■ 6. Section 746.5 is amended by revising paragraph (c) introductory text and adding paragraph (c)(8), to read as follows:

§ 746.5 Russian and Belarusian industry sector sanctions.

* * * * *

(c) *License exceptions.* No license exceptions may overcome the license requirements set forth in this section, except the license exceptions identified in paragraphs (c)(2), (7), and (8) of this section.

* * * * *

(8) License Exception MED (§ 740.23 of the EAR).

■ 7. Section 746.6 is amended by adding paragraph (c)(7), to read as follows:

§ 746.6 Temporarily occupied Crimea region of Ukraine and covered regions of Ukraine.

* * * * *

(c) * * *

(7) License Exception MED (§ 740.23 of the EAR).

* * * * *

■ 8. Section 746.10 is amended by revising paragraph (c) introductory text and adding paragraph (c)(8), to read as follows:

§ 746.10 ‘Luxury goods’ sanctions against Russia and Belarus and Russian and Belarusian oligarchs and malign actors.

* * * * *

(c) *License exceptions.* No license exceptions may overcome the license requirements in paragraph (a)(1) of this section except the license exceptions identified in paragraphs (c)(1) through (3), (c)(7) and (8) of this section.

* * * * *

(8) License Exception MED (§ 740.23 of the EAR).

PART 762—RECORDKEEPING

■ 9. The authority citation for 15 CFR part 746 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.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 10. Section 762.2 is amended by:

■ a. Revising paragraphs (b)(53) and (54), and

■ b. Adding paragraph (b)(55).

The revisions and addition read as follows:

§ 762.2 Records to be retained.

* * * * *

(b) * * *

(53) § 750.7(c)(2), Notification of name change by advisory opinion request;

(54) § 748.13, Certain Hong Kong import and export licenses; *and*

(55) § 740.23, License Exception MED.

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024–09076 Filed 4–25–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 161, 164, 184, and 186

[Docket No. FDA–2024–D–1669]

Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide; Availability

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

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide.” The small entity compliance guide (SECG) is intended to help small entities comply with our regulations after we revoked specific requirements pertaining to the use of partially hydrogenated oils in certain foods or as a direct or indirect food substance.

DATES: The announcement of the guidance is published in the **Federal Register** on April 29, 2024.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–D–1669 for “Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the SECG to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-