

Paragraph 6005 Class E Airspace Areas  
Extending Upward From 700 Feet or More  
Above the Surface of the Earth.

\* \* \* \* \*

#### ASO MS E5 Greenwood, MS [Amended]

Greenwood-Leflore Airport, MS  
(Lat. 33°29'36" N, long. 90°05'12" W)  
Sidon VORTAC

(Lat. 33°27'50" N, long. 90°16'38" W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of That That airspace That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Greenwood-Leflore Airport and within 1.2 miles each side of the Sidon VORTAC 079° radial, extending from the 6.9-mile radius to 2 miles each side of the VORTAC.

Issued in College Park, Georgia, on May 8, 2018.

**Debra L. Hogan,**

Acting Manager, Operations Support Group,  
Eastern Service Center, Air Traffic  
Organization.

[FR Doc. 2018-10389 Filed 5-16-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 744

[Docket No. 180214174-8174-01]

RIN 0694-AH54

#### Revisions to the Unverified List (UVL)

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

**ACTION:** Final rule.

**SUMMARY:** The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) by adding thirty-three (33) persons to the Unverified List ("UVL") and adding an additional address for one (1) person currently listed on the UVL. The thirty-three persons are being added to the UVL on the basis that BIS could not verify their *bona fides* because an end-use check could not be completed satisfactorily for reasons outside the U.S. Government's control. A new address is added for one person as BIS has determined that this person is receiving exports from the United States at an additional address.

**DATES:** This rule is effective May 17, 2018.

**FOR FURTHER INFORMATION CONTACT:** Kevin Kurland, Director, Office of Enforcement Analysis, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-4255 or by email at [UVLRequest@bis.doc.gov](mailto:UVLRequest@bis.doc.gov).

**SUPPLEMENTARY INFORMATION:**

#### Background

The Unverified List, found in Supplement No. 6 to Part 744 to the EAR, contains the names and addresses of foreign persons who are or have been parties to a transaction, as that term is described in § 748.5 of the EAR, involving the export, reexport, or transfer (in-country) of items subject to the EAR, and whose *bona fides* (i.e., legitimacy and reliability relating to the end use and end user of items subject to the EAR) BIS has been unable to verify through an end-use check. BIS may add persons to the UVL when BIS or federal officials acting on BIS's behalf have been unable to verify a foreign person's *bona fides* because an end-use check, such as a pre-license check (PLC) or a post-shipment verification (PSV), cannot be completed satisfactorily for such purposes for reasons outside the U.S. Government's control.

There are occasions where, for a number of reasons, end-use checks cannot be completed. These include reasons unrelated to the cooperation of the foreign party subject to the end-use check. For example, BIS sometimes initiates end-use checks and cannot find a foreign party at the address indicated on export documents, and cannot locate the party by telephone or email. Additionally, BIS sometimes is unable to conduct end-use checks when host government agencies do not respond to requests to conduct end-use checks, are prevented from scheduling such checks by a party to the transaction other than the foreign party that is the proposed subject of the end-use check, or refuse to schedule them in a timely manner. Under these circumstances, although BIS has an interest in informing the public of its inability to verify the foreign party's *bona fides*, there may not be sufficient information to add the foreign person at issue to the Entity List under § 744.11 of the EAR (Criteria for revising the Entity List). In such circumstances, BIS may add the foreign person to the UVL.

Furthermore, BIS sometimes conducts end-use checks but cannot verify the *bona fides* of a foreign party. For example, BIS may be unable to verify *bona fides* if during the conduct of an end-use check a recipient of items subject to the EAR is unable to produce those items for visual inspection or provide sufficient documentation or other evidence to confirm the disposition of those items. The inability of foreign persons subject to end-use checks to demonstrate their *bona fides* raises concerns about the suitability of such persons as participants in future exports, reexports, or transfers (in-

country) of items subject to the EAR and indicates a risk that such items may be diverted to prohibited end uses and/or end users. However, BIS may not have sufficient information to establish that such persons are involved in activities described in parts 744 or 746 of the EAR, preventing the placement of the persons on the Entity List. In such circumstances, the foreign persons may be added to the Unverified List.

As provided in § 740.2(a)(17) of the EAR, the use of license exceptions for exports, reexports, and transfers (in-country) involving a party or parties to the transaction who are listed on the UVL is suspended. Additionally, under § 744.15(b) of the EAR, there is a requirement for exporters, reexporters, and transferors to obtain (and keep a record of) a UVL statement from a party or parties to the transaction who are listed on the UVL before proceeding with exports, reexports, and transfers (in-country) to such persons, when the exports, reexports and transfers (in-country) are not subject to a license requirement.

Requests for removal of a UVL entry must be made in accordance with § 744.15(d) of the EAR. Decisions regarding the removal or modification of UVL listings will be made by the Deputy Assistant Secretary for Export Enforcement, based on a demonstration by the listed person of its *bona fides*.

#### Changes to the EAR

##### Supplement No. 6 to Part 744 ("the Unverified List" or "UVL")

This rule adds thirty-three (33) persons to the UVL by amending Supplement No. 6 to Part 744 of the EAR to include their names and addresses. BIS adds these persons in accordance with the criteria for revising the UVL set forth in § 744.15(c) of the EAR. The new entries consist of eleven persons located in China, twelve in Russia, five in the United Arab Emirates, two in Canada, and one person located in each of the following countries: Estonia, Finland, and Pakistan. Each listing is grouped within the UVL by country with each party's name(s) listed in alphabetical order under the country; each entry includes available alias(es) and address(es), as well as the **Federal Register** citation and the date the person was added to the UVL. The UVL is included in the Consolidated Screening List, available at [www.export.gov](http://www.export.gov).

This rule also adds one additional address for one person currently listed on the UVL, Ling Ao Electronic Technology Co. Ltd, a.k.a. Voyage Technology (HK) Co., Ltd., a.k.a. Xuan

Qi Technology Co. Ltd., as BIS has determined that this person is receiving exports from the United States at an additional address.

#### *Savings Clause*

Shipments (1) removed from license exception eligibility or that are now subject to requirements in § 744.15 of the EAR as a result of this regulatory action; (2) eligible for export, reexport, or transfer (in-country) without a license before this regulatory action; and (3) on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on May 17, 2018, pursuant to actual orders, may proceed to that UVL listed person under the previous license exception eligibility or without a license so long as the items have been exported from the United States, reexported or transferred (in-country) before June 18, 2018. Any such items not actually exported, reexported or transferred (in-country) before midnight on June 18, 2018 are subject to the requirements in § 744.15 of the EAR in accordance with this regulation.

#### **Export Administration Act**

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 15, 2017, 82 FR 39005 (August 16, 2017) has continued the EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

#### **Rulemaking Requirements**

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866.

2. 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 to this rule, which is adding 33 persons to the UVL and adding a new address for one (1) other person currently listed on the UVL, because this regulation involves a military or foreign affairs function of the United States under 5 U.S.C. 553(a)(1). BIS implements this rule to protect U.S. national security or foreign policy interests by requiring a license or, where no license is required, a UVL statement for items being exported, reexported, or transferred (in country) involving a party or parties to the transaction who are listed on the UVL. If this rule were delayed to allow for notice and comment and a delay in effective date, the entities being added to the UVL by this action and the entity now receiving exports from the United States at an additional address would continue to be able to receive items without additional oversight by BIS and to conduct activities contrary to the national security or foreign policy interests of the United States. In addition, publishing a proposed rule would give these parties notice of the U.S. Government’s intention to place them on the UVL or amend their current entry on the UVL, and create an incentive for these persons to accelerate receiving items subject to the EAR in furtherance of activities contrary to the national security or foreign policy interests of the United States, and/or take steps to set up additional aliases, change addresses, and other measures to try to limit the impact of the listing 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. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

3. Notwithstanding any other provision of law, no person is required to respond to, nor is 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 the following control numbers: 0694–0088, 0694–0122, 0694–0134, and 0694–0137.

This rule slightly increases public burden in a collection of information approved by OMB under control number 0694–0088, which authorizes, among other things, export license applications. The removal of license exceptions for listed persons on the Unverified List will result in increased license applications being submitted to BIS by exporters. Total burden hours associated with the Paperwork Reduction Act and OMB control number 0694–0088 are expected to increase minimally, as the suspension of license exceptions will only affect transactions involving persons listed on the Unverified List and not all export transactions. Because license exceptions are restricted from use, this rule decreases public burden in a collection of information approved by OMB under control number 0694–0137 minimally, as this will only affect specific individual listed persons. The increased burden under 0694–0088 is reciprocal to the decrease of burden under 0694–0137, and results in no change of burden to the public. This rule also increases public burden in a collection of information under OMB control number 0694–0122, as a result of the exchange of UVL statements between private parties, and under OMB control number 0694–0134, as a result of appeals from persons listed on the UVL for removal of their listing. The total increase in burden hours associated with both of these collections is expected to be minimal, as they involve a limited number of persons listed on the UVL.

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

#### **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 through 774) is amended as follows:

#### **PART 744—[AMENDED]**

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

**Authority:** 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.

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 August 15, 2017, 82 FR 39005 (August 16, 2017); Notice of September 18, 2017, 82 FR 43825 (September 19, 2017); Notice of November 6, 2017, 82 FR 51971 (November 8, 2017); Notice of January 17, 2018, 83 FR 2731 (January 18, 2018).

■ 2. Supplement No. 6 to Part 744 is amended by:

- a. Adding two entries, in alphabetical order, for “Canada”;
- b. Adding eleven entries, in alphabetical order, under “China”;
- c. Adding one entry, in alphabetical order, under “Estonia”;
- d. Adding one entry, in alphabetical order, for “Finland”;
- e. Revising the entry for “Ling Ao Electronic Technology Co. Ltd., a.k.a. Voyage Technology (HK) Co., Ltd., a.k.a. Xuan Qi Technology Co. Ltd.” under “Hong Kong”;

- f. Adding one entry, in alphabetical order, for “Pakistan”;
- g. Adding twelve entries, in alphabetical order, under “Russia”;
- h. Adding five entries, in alphabetical order, under “United Arab Emirates”.

The additions and revisions read as follows:

**Supplement No. 6 to Part 744—  
Unverified List**

\* \* \* \* \*

Country	Listed person and address	Federal Register citation and date of publication
*	*	*
CANADA .....	Laval Electronics, 3073 Rue Edmond-Rostand, Laval, QC H7P, Canada.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Services GP Tek, a.k.a. Nouvelle Option, 1305 Rue Pise, Brossard, QC J4W 2P7, Canada; and 203-760 Rue Galt, Montreal, QC H4G 2P7, Canada; and 6271 Rue Beaulieu, Montreal, QC, H4E 3E9, Canada.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
CHINA .....	Changhe Aircraft Industries Group, No. 539, Chaoyang Road, Jingdezhen City, Jiangxi Province, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Dandong Center for Food Control, No. 31-1 Zhongyang Avenue, Dandong, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Institute of Geology, Chinese Academy of Geological Sciences, No. 26, Baiwanzhuang Street, Beijing, 100037, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Jiangxi Hongdu Aviation Ind. Group, The Nanchang National High & New Technology Development Zone, Jiangxi Province, Yaohu Nanchang, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Jiujiang Jinxin Nonferrous Metals Co, Ltd., Xunyang Chem. Bldg, Materials Factory, Xunyang District, Jiujiang City, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Liupanshui Normal University, 19 Minghu Road, Zhongshan District, Liupanshui, Guizhou, 553004, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Nanchang University, No. 999 Xuefu Avenue, Honggutan New District, Nanchang, 330031, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Shanxi Hemu Industrial Co., Ltd., Yongchang Rd, Xianyang HiTech Industries Development Zone, Shanxi, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Sino Superconductor Technology Company, a.k.a. Zongyi Superconductor Technologies Co. Ltd., a.k.a. SinoHTS, 505 Nantian Bldg, 10, Xixi Rd, Shangdi, Haidian, Beijing, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Xinjiang East Hope New Energy Company Ltd, Xinjiang East Eco. Development Zone, Xinjiang, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
	Yantai Salvage Bureau, No. 100 Zhifudao East Road, Zhifu District, Yantai, Shandong, 264012, China.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
ESTONIA .....	Simms Marine Group OU, Sergey Ivanov, Paavli str. 5/2, Tallinn, Estonia, 10412.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
FINLAND .....	Net Logistics JVM OY, a.k.a. Net Logistic JVM OY, Eskolantie 1, Helsinki, Finland 00720; and Merituulentie 486, Port Mussalo, Kotka, Finland 48310.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	*	*
HONG KONG ...		

Country	Listed person and address	Federal Register citation and date of publication
*	Ling Ao Electronic Technology Co. Ltd, a.k.a. Voyage Technology (HK) Co., Ltd. a.k.a. Xuan Qi Technology Co., Ltd., Room 17, 7/F, Metro Centre Phase 1, No. 32 Lam Hing St., Kowloon Bay, Kwun Tong, Hong Kong; and 15B, 15/F, Cheuk Nang Plaza, 250 Hennessy Road, Wanchai, Hong Kong; and Flat C, 11/F, Block No. 2, Camelpaint Bldg. 62 Hoi Yuen Street, Kwun Tong, Kowloon, Hong Kong; and Room C1–D, 6/F, Wing Hing Industrial Building 14 Hing Yip Street, Kwun Tong, Kowloon, Hong Kong; and Flat/Rm. A30, 9/F Silvercorp International Tower, 707–713 Nathan Road, Mongkok, Kowloon, Hong Kong; and Room, 912A, 9/F. Witty Commercial Building, 1A–1L Tung Choi Street, Mongkok, Kowloon, Hong Kong; and Unit A, 7/F, King Yip Factory Bldg., 59 King Yip Street, Kwun Tong, Kowloon, Hong Kong; and Unit D, 16/F, One Capital Place, 18 Luard Road, Wanchi, Hong Kong.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
PAKISTAN .....	Andleeb Associates, Sultan Complex, Abid Majeed Road, Rawalpindi, Pakistan.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
RUSSIA .....	Alliance EG Ltd., Leninsky Prospect 139, Office 310, St. Petersburg 198216, Russia. Eltech Ltd., 3A, pl. Konstitutsii, Saint Petersburg 196247, Russia. EFO Ltd., Politechnicheskaya Street 21, Saint Petersburg 192019, Russia and 15A Novolitovskaya Str., Office 441, Saint Petersburg, Russia. Intercom Ltd., Kalinina Street 13, Saint Petersburg 198099, Russia.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	MT Systems, Kalinina Street 13, Saint Petersburg 198099, Russia.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	Radiofizika OAO, D.10. Ul. Geroev Panfilovtsev, Moscow 125363, Russia. Romona Inc., Prospekt Mira 426, Yuzhno-Sakhalinsk 693004, Russia. FSUE Rosmorport Far Eastern Basin Branch, Nizhneportovaya Street 3, Primorskiy Territory, Vladivostok 690003, Russia. Sakhalin Energy Investment Company Ltd., Dzerzhinskogo Street 35, Yuzhno-Sakhalinsk 693020, Russia.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	SIC Dipaul, Bolshaya Monetnaya Street 16, Saint Petersburg 197101, Russia and 5B, Rentgena ul., 197101, Saint. Tavrida Microelectronics, Zelenaya Street 1, Dolgoprudnyy, Moscow 141700, Russia. VIP Technology Ltd., Bechtereva Street 3/2, Office 40, Saint Petersburg 192019, Russia.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.” 83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
UNITED ARAB EMIRATES.	Alsaroud General Trading, a.k.a. Alsaroud Ground Trading Company, a.k.a. Alsaroud General Trading LLC, Avenue 125, Street 2, Building 30/1, Industrial Area 17, Sharjah, UAE; and P.O. Box 35939, Sharjah, UAE; and 204 Shaikha Hind Bint Saqr Alqasemi Building, Near Etisalat Building, Almareja Street, Al Jubail, Sharjah, UAE.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	Chepstow FZE, Office No. 12, Y Block, P.O. Box 121227, Sharjah Airport International Free Zone, Sharjah, UAE.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”

Country	Listed person and address	Federal Register citation and date of publication
*	GenX Middle East FZE, a.k.a. GenX Systems LLC, #510–511 Le Solarium Building, Dubai Silicon Oasis, Dubai, UAE; and P.O. Box 121225, Office M07, Al Zahra, Khaleed Bin Al Waleed Road, Bur Dubai, Dubai, UAE.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	Roudah Al Hayat General Trading FZE, a.k.a. Rudha Al Hayat General Trading, a.k.a. JSB Logistics, 406 Al Rhakaimi Building, Deira, Dubai, UAE; and #3204 Aspect Tower D, Sheikh Zayed Road, Dubai, UAE; and #1506 Aspect Tower D, Sheikh Zayed Road, Dubai, UAE and 901 Regal Tower, Business Bay, Dubai, UAE and 402 Al Fahad Building, Damascus Street, Dubai, UAE.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”
*	TEM International FZC, Dubai Silicon Oasis Headquarters Building, 4th Floor C&D Wings, P.O. Box 341041, Dubai, UAE.	83 FR “[INSERT FEDERAL REGISTER PAGE NUMBER], May 17, 2018.”

Dated: May 12, 2018.

**Richard E. Ashooh,**  
Assistant Secretary for Export Administration.

[FR Doc. 2018–10528 Filed 5–16–18; 8:45 am]

BILLING CODE 3510–33–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 878**

[Docket No. FDA–2017–N–4919]

**Medical Devices; Exemption From Premarket Notification: Class II Devices; Surgical Apparel**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is publishing this final order to exempt certain surgical apparel from premarket notification requirements, subject to conditions and limitations. FDA is limiting the exemption to single-use, disposable respiratory protective devices (RPD) used in a healthcare setting and worn by healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These devices, commonly referred to as N95 filtering facepiece respirators (FFRs) and surgical N95 respirators (herein collectively referred to as N95s) are currently regulated by FDA under product code MSH. This exemption will decrease regulatory burden on the medical device

industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. All other class II devices classified under FDA’s surgical apparel classification regulation continue to be subject to premarket notification requirements. FDA is also amending the codified language for the surgical apparel devices classification regulation to reflect this final determination.

**DATES:** This order is effective May 17, 2018.

**FOR FURTHER INFORMATION CONTACT:** Aftin Ross, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301–796–5679, email: [Aftin.Ross@fda.hhs.gov](mailto:Aftin.Ross@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Statutory Background**

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807, subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under

paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** notice of its intent to exempt the device, or of the petition, and provide a 60-calendar day period for public comment. Within 120 days after the issuance of the notice, FDA shall publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

**II. Factors FDA May Consider for Exemption**

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions From Premarket Notification; Guidance for Industry and CDRH Staff” (“Class II 510(k) Exemption Guidance”) (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether a 510(k) is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3)