

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
21-Jul-16	MA	Beverly .....	Beverly Muni .....	6/8851	6/8/16	RNAV (GPS) RWY 16, Amdt 1C.
21-Jul-16	MA	Beverly .....	Beverly Muni .....	6/8853	6/8/16	RNAV (GPS) RWY 34, Orig-B.
21-Jul-16	SC	Mount Pleasant ..	Mt Pleasant Rgnl-Faison Field .....	6/9457	6/8/16	RNAV (GPS) RWY 35, Orig-B.
21-Jul-16	SC	Mount Pleasant ..	Mt Pleasant Rgnl-Faison Field .....	6/9459	6/8/16	VOR/DME-A, Amdt 1A.
21-Jul-16	SC	Mount Pleasant ..	Mt Pleasant Rgnl-Faison Field .....	6/9460	6/8/16	RNAV (GPS) RWY 17, Orig-B.

[FR Doc. 2016-15989 Filed 7-8-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Parts 730, 736, 738 and 746

[Docket No. 160622547-6547-01]

RIN 0694-AG99

### Updated Statements of Legal Authority for the Export Administration Regulations

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

**ACTION:** Final rule.

**SUMMARY:** This rule updates the Code of Federal Regulations (CFR) legal authority paragraphs in the Export Administration Regulations (EAR) to cite a Presidential notice extending an emergency declared pursuant to the International Emergency Economic Powers Act and also to remove one obsolete citation. This is a procedural rule that only updates authority paragraphs of the EAR to make them current and to avoid confusion. It does not alter any right, obligation or prohibition that applies to any person under the EAR.

**DATES:** The rule is effective July 11, 2016.

**FOR FURTHER INFORMATION CONTACT:** William Arvin, Regulatory Policy Division, Bureau of Industry and Security, Email [william.arvin@bis.doc.gov](mailto:william.arvin@bis.doc.gov), Telephone: (202) 482-2440.

#### SUPPLEMENTARY INFORMATION:

##### Background

The authority for parts 730, 736 and 746 of the EAR (15 CFR parts 730, 736 and 744) rests, in part, on Executive Order 13338 of May 11, 2004—Blocking Property of Certain Persons and Prohibiting the Export of Certain Goods to Syria (69 FR 26751, 3 CFR, 2004 Comp., p. 168) and on annual notices by the President continuing that emergency. This rule updates the authority paragraphs in 15 CFR parts 730, 736 and 746 to cite the Notice of

May 3, 2016, 81 FR 27293 (May 5, 2016), which continues that emergency.

This rule also removes the citation to 30 U.S.C. 185(s), 185(u), which imposed certain restrictions on exports of crude oil, from the authority paragraph of 15 CFR part 738 because, as a result of Division O, Title 1, Section 101, subsection (b) of Public Law 114-113, the EAR no longer imposes a license requirement on exports of crude oil.

This rule is purely procedural and makes no changes other than to revise CFR authority citations to make them current. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

#### Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223 and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701). 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). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor 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 does not involve any collection of information.

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

4. The Assistant Secretary for Export Administration finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. It clarifies information and is non-discretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice 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.

#### List of Subjects

##### 15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

##### 15 CFR Parts 736 and 738

Exports.

##### 15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 730, 736, 738 and 746 of the EAR (15 CFR parts 730-774) are amended as follows:

**PART 730—[AMENDED]**

- 1. The authority citation for part 730 is revised to read as follows:

**Authority:** 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; 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. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; 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; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015); Notice of January 20, 2016, 81 FR 3937 (January 22, 2016); Notice of May 3, 2016, 81 FR 27293 (May 5, 2016).

**PART 736—[AMENDED]**

- 2. The authority citation for part 736 is revised to read as follows:

**Authority:** 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015); Notice of May 3, 2016, 81 FR 27293 (May 5, 2016).

**PART 738—[AMENDED]**

- 3. The authority citation for part 738 is revised to read as follows:

**Authority:** 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

**PART 746—[AMENDED]**

- 4. The authority citation for part 746 is revised to read as follows:

**Authority:** 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. 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 August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of May 3, 2016, 81 FR 27293 (May 5, 2016).

Dated: July 6, 2016.

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

[FR Doc. 2016–16365 Filed 7–8–16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**21 CFR Part 882**

[Docket No. FDA–2016–N–1653]

**Medical Devices; Neurological Devices; Classification of the Thermal System for Insomnia**

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the thermal system for insomnia into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the thermal system for insomnia's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective July 11, 2016. The classification was applicable on May 13, 2016.

**FOR FURTHER INFORMATION CONTACT:** Leigh Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2656, Silver Spring, MD 20993–0002, 301–796–5613, [leigh.anderson@fda.hhs.gov](mailto:leigh.anderson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.