

**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]

**BILLING CODE 3510–33–P**

**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.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On October 17, 2014, Cerève Inc. submitted a request for classification of the Cerève Sleep System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are

insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 13, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.5700.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a thermal system for insomnia will need to comply with the special controls named in this final order.

The device is assigned the generic name thermal system for insomnia, and it is identified as a prescription device for use in patients with insomnia that is used to apply a specified temperature to the skin surface.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1:

TABLE 1—THERMAL SYSTEM FOR INSOMNIA RISKS AND MITIGATION MEASURES

| Identified risk                                       | Mitigation method   |
|---|---|
| Adverse skin reaction .....                           | Biocompatibility Assessment.<br>Labeling.   |
| Electromagnetic Interference with Other Devices ..... | Electromagnetic Compatibility Testing.<br>Labeling.   |
| Electrical Safety (e.g., shock) .....                 | Electrical Safety Testing.<br>Labeling.   |
| Thermal Injury .....                                  | Non-clinical Performance Testing.<br>Software Verification, Validation, and Hazard Analysis.<br>Labeling. |

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Thermal systems for insomnia devices are not safe to use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information

about the thermal system for insomnia they intend to market.

**II. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**III. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

**IV. Reference**

The following reference is on display in the Division of Dockets Management

(HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>.

1. DEN140032 De novo Request per 513(f)(2) from Cerève, Inc., dated October 17, 2014.

**List of Subjects in 21 CFR Part 882**

Medical devices.  
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

**PART 882—NEUROLOGICAL DEVICES**

- 1. The authority citation for part 882 continues to read as follows:  
**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.
- 2. Add § 882.5700 to subpart F to read as follows:

**§ 882.5700 Thermal system for insomnia.**

(a) *Identification.* A thermal system for insomnia is a prescription device for use in patients with insomnia that is

used to apply a specified temperature to the skin surface.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate electromagnetic compatibility and electrical safety.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Thermal performance of the device, including maintenance of the target temperature, must be evaluated under simulated use conditions.

(ii) Mechanical testing to demonstrate the device can withstand forces under anticipated use conditions.

(iii) Mechanical testing to demonstrate the device is resistant to leakage under anticipated use conditions.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Patient labeling must be provided to convey information regarding safe use of the device, including instructions for assembly.

Dated: July 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-16351 Filed 7-8-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### 29 CFR Part 2550

[Application No. D-11712; Prohibited Transaction Exemption 2016-01]

[ZRIIN 1210-ZA25]

#### Best Interest Contract Exemption; Correction

**AGENCY:** Employee Benefits Security Administration (EBSA), U.S. Department of Labor.

**ACTION:** Technical corrections.

**SUMMARY:** This document makes technical corrections to the Department of Labor's Best Interest Contract Exemption, which was published in the *Federal Register* on April 8, 2016. The Best Interest Contract Exemption allows certain persons that are fiduciaries under the Employee Retirement Income Security Act of 1974 (ERISA) or the

Internal Revenue Code (the Code), or both, by reason of providing investment advice, to receive compensation that may otherwise be prohibited. The corrections in this document fix typographical errors, make minor clarifications to provisions that might otherwise be confusing, and confirm insurers' broad eligibility to rely on the exemption, consistent with the exemption's clearly intended scope and the analysis and data relied upon in the Department's final regulatory impact analysis (RIA).

**DATES:** *Issuance date:* These technical corrections are issued July 11, 2016, without further action or notice.

*Applicability date:* The Best Interest Contract Exemption, as corrected herein, is applicable to transactions occurring on or after April 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Brian Shiker or Susan Wilker, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, (202) 693-8824 (this is not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The Best Interest Contract Exemption was granted pursuant to ERISA section 408(a) and Code section 4975(c)(2), and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637 (October 27, 2011)). It was adopted by the Department in connection with the publication of a final regulation defining who is a fiduciary of an employee benefit plan under ERISA as a result of giving investment advice to a plan or its participants or beneficiaries (Regulation).<sup>1</sup> The Regulation also applies to the definition of a "fiduciary" of a plan (including an IRA) under the Code.

The exemption provides relief from provisions of ERISA and the Code that generally prohibit fiduciaries with respect to employee benefit plans and individual retirement accounts (IRAs) from engaging in self-dealing and receiving compensation from third parties in connection with transactions involving the plans and IRAs. The exemption allows entities such as registered investment advisers, broker-dealers, banks and insurance companies (referred to in the exemption as Financial Institutions), and their employees, agents and representatives (referred to as Advisers), that are ERISA or Code fiduciaries by reason of the provision of investment advice, to receive compensation that may

otherwise give rise to prohibited transactions as a result of their advice to plan participants and beneficiaries, IRA owners and certain plan fiduciaries (including small plan sponsors). The exemption is subject to protective conditions to safeguard the interests of the plans, participants and beneficiaries and IRA owners.

The Best Interest Contract Exemption is broadly available for Advisers and Financial Institutions that make investment recommendations to retail "Retirement Investors," including plan participants and beneficiaries, IRA owners, and non-institutional fiduciaries (referred to in the exemption as "Retail Fiduciaries"). As a condition of receiving compensation that would otherwise be prohibited under ERISA and the Code, the exemption requires Financial Institutions to acknowledge their fiduciary status and the fiduciary status of their Advisers in writing. The Financial Institution and Advisers must adhere to enforceable standards of fiduciary conduct and fair dealing with respect to their advice. In the case of IRAs and non-ERISA plans, the exemption requires that the standards be set forth in an enforceable contract with the Retirement Investor; the exemption permits reliance on a negative consent process for existing contract holders. Under the exemption's terms, Financial Institutions are not required to enter into a contract with ERISA plan investors, but they must adhere to these same standards of fiduciary conduct, which the investors can effectively enforce pursuant to ERISA sections 502(a)(2) and (3). Likewise, "Level Fee" Fiduciaries that, with their Affiliates, receive only a Level Fee in connection with advisory or investment management services, do not have to enter into a contract with Retirement Investors, but they must provide a written statement of fiduciary status, adhere to standards of fiduciary conduct, and prepare a written documentation of the reasons for the recommendation.

##### Explanation of Corrections

This document makes technical corrections to the Best Interest Contract Exemption as described below. In addition, the document adds an identifier, Prohibited Transaction Exemption 2016-01, to the heading of the Best Interest Contract Exemption. For convenience, the text of the corrected exemption is reprinted in its entirety at the conclusion of this document. The preamble to the originally granted exemption provides a general overview of the exemption, at 81 FR 21002.

<sup>1</sup> 81 FR 20945 (April 8, 2016).