IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

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 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 890.5420 to subpart F to read as follows:

§ 890.5420 Electroencephalography (EEG)-driven upper extremity powered exerciser.

(a) *Identification.* An EEG-driven upper extremity powered exerciser is a non-invasive prescription device intended for rehabilitation by driving movement or exercise of an impaired upper extremity in response to the detection of purpose oriented electrical activity produced by the patient's brain.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must capture any adverse events observed during clinical use and must demonstrate that the EEG signal can be translated into intended motion.

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

(3) Performance data must demonstrate the electromagnetic compatibility, electrical safety, battery safety, and wireless compatibility of the device.

(4) The device components that contact the patient must be demonstrated to be biocompatible.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

(6) Labeling must include:

(i) Instructions on fitting the device to the patient;

(ii) Information on how the device operates and the typical sensations experienced during treatment; and

(iii) Reprocessing instructions.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00007 Filed 1–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2022–N–3184]

Medical Devices; Physical Medicine Devices; Classification of the Virtual Reality Behavioral Therapy Device for Pain Relief

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

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the virtual reality behavioral therapy device for pain relief into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the virtual reality behavioral therapy device for pain relief's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 6, 2023. The classification was applicable on November 16, 2021.

FOR FURTHER INFORMATION CONTACT: Kaitlin Olsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4212, Silver Spring, MD 20993–0002, 240–402–9983, *Kaitlin.Olsen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the virtual reality behavioral therapy device for pain relief as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After

receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 30, 2021, FDA received AppliedVR Inc.'s request for De Novo classification of the EaseVRx. 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.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 16, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 890.5800.[1] We have named the generic type of device virtual reality behavioral therapy device for pain relief, and it is identified as a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display that utilizes a software program containing the behavioral therapy content.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—VIRTUAL REALITY BEHAVIORAL THERAPY DEVICE FOR PAIN RELIEF RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Electric shock or burn or interference with other devices	Electromagnetic compatibility testing, and Electrical, mechanical, and thermal safety testing.
Nausea and motion sickness	Clinical performance testing, and Labeling.
Discomfort	Clinical performance testing, and Labeling.
Ineffective treatment	Clinical performance testing, Software verification, validation, and hazard analysis, and Labeling.
Use error or improper device use leading to a delay in treatment	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 890.5800 to subpart F to read as follows:

§ 890.5800 Virtual reality behavioral therapy device for pain relief.

(a) *Identification.* A virtual reality behavioral therapy device for pain relief is a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display that utilizes a software program containing the behavioral therapy content.

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

(1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.

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

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

(4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(5) Labeling must include the following:

(i) A warning regarding the risk of nausea and motion sickness;

(ii) A warning regarding the risk of discomfort from the device; and

(iii) A summary of the clinical testing with the device.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00014 Filed 1–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 36 and 42

RIN 2900–AR79

Federal Civil Penalties Inflation Adjustment Act Amendments

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations to adjust for inflation the amount of civil monetary penalties that are within VA's jurisdiction. These adjustments comply with the requirement in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, to make annual adjustments to the penalties.

DATES: This rule is effective January 6, 2023.

FOR FURTHER INFORMATION CONTACT: Stephanie Li, Chief, Regulations Team, Loan Guaranty Service (26), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–8862. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act) (Pub. L. 114–74, sec. 701, 129 Stat. 584, 599–600), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, sec. 5, 104 Stat. 890, 891–892), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The amended statute, codified in a note following 28 U.S.C. 2461, requires agencies to publish annual adjustments for inflation, based on the percentage change between the Consumer Price Index (defined in the statute as the Consumer Price Index for all-urban consumers (CPI–U) published by the Department of Labor) for the month of October preceding the date of the adjustment and the prior year's October CPI–U. 28 U.S.C. 2461 note, secs. 4(a) and (b) and 5(b)(1). This rule implements the 2023 calendar year inflation adjustment amounts.

Under 38 U.S.C. 3710(g)(4)(B), VA is authorized to levy civil monetary penalties against private lenders that originate VA-guaranteed loans if a lender falsely certifies that they have complied with certain credit information and loan processing standards, as set forth by chapter 37, title 38 U.S.C. and part 36, title 38 CFR. Under section 3710(g)(4)(B), any lender who knowingly and willfully makes such a false certification shall be liable to the United States Government for a civil penalty equal to two times the amount of the Secretary's loss on the loan involved or to another appropriate amount, not to exceed $10,000, whichever is greater. VA implemented the penalty amount in 38 CFR 36.4340(k)(1)(i) and (k)(3). On December 15, 2022, the Office of Management and Budget (OMB) issued Circular M–23–05. This circular reflects that the October 2021 CPI–U was 276.589 and the October 2022 CPI–U was 298.012, resulting in an inflation adjustment multiplier of 1.07745. Accordingly, the calendar year 2023 inflation revision imposes an adjustment from $25,076 to $27,018.

Under 31 U.S.C. 3802, VA can impose monetary penalties against any person who makes, presents, or submits a claim or written statement to VA that the person knows or has reason to know is false, fictitious, or fraudulent, or who engages in other covered conduct. The statute permits, in addition to any other remedy that may be prescribed by law, a civil penalty of not more than $5,000 for each claim. 31 U.S.C. 3802(a)(1) and (2). VA implemented the penalty amount in 38 CFR 42.3(a)(1)(iv) and (b)(1)(ii). As previously noted, OMB Circular M–23–05 reflects an inflation adjustment multiplier of 1.07745. Therefore, the calendar year 2023 inflation revision imposes an adjustment from $12,537 to $13,508.

Accordingly, VA is revising 38 CFR 36.4340(k)(1)(i) and (3) and 38 CFR 42.3(a)(1)(iv) and (b)(1)(ii) to reflect the 2023 inflationary adjustments for civil monetary penalties assessed or enforced by VA.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to dispense with the opportunity for prior notice and public comment and to publish this rule with an immediate effective date. The statute requires agencies to make annual adjustments for inflation to the allowed amounts of civil monetary penalties ''notwithstanding section 553 of title 5, United States Code.'' 28 U.S.C. 2461 note, sec. 4(a) and (b). The penalty adjustments, and the methodology used to determine the adjustments, are set by the terms of the statute. VA has no discretion to make changes in those areas. Therefore, an opportunity for prior notice and public comment and a delayed effective date are unnecessary.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of