Agency	Law	Name/description	CFR citation	2022		2023	
				Min penalty (rounded to nearest dollar)	Max penalty (rounded to nearest dollar)	Min penalty (rounded to nearest dollar)	Max penalty (rounded to nearest dollar)
OWCP ...	Black Lung Benefits Act.	Failure to secure payment of benefits after 10th day of notice.	20 CFR 726.302(c)(4).	157	.....	169	
OWCP ...	Black Lung Benefits Act.	Failure to secure payment of benefits for repeat offenders.	20 CFR 726.302(c)(5).	468	.....	504	
OWCP ...	Black Lung Benefits Act.	Failure to secure payment of benefits	20 CFR 726.302(c)(5).	.....	$3,198	.....	$3,446.

[FR Doc. 2023–00271 Filed 1–12–23; 8:45 am]

BILLING CODE 4510–HL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2022–N–3240]

Medical Devices; Neurological Devices; Classification of the Digital Therapy Device To Reduce Sleep Disturbance for Psychiatric Conditions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the digital therapy device to reduce sleep disturbance for psychiatric conditions 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 digital therapy device to reduce sleep disturbance for psychiatric conditions' 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 13, 2023. The classification was applicable on November 6, 2020.

FOR FURTHER INFORMATION CONTACT: Patrick Antkowiak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4118, Silver Spring, MD 20993–0002, 240–402–3705, *Patrick.Antkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the digital therapy device to reduce sleep disturbance for psychiatric conditions 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 May 27, 2020, FDA received NightWare, Inc's request for De Novo classification of the NightWare Kit (Apple iPhone, Apple Watch, Apple iPhone Charging Cable, Apple Watch Charging Cable). 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 6, 2020, 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 882.5705.[1] We have named the generic type of device digital therapy device to reduce sleep disturbance for psychiatric conditions, and it is identified as a prescription device that is intended to provide stimulation using a general purpose computing platform to reduce sleep disturbance in patients who experience this symptom due to psychiatric conditions such as nightmare disorder or post-traumatic stress disorder.

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—DIGITAL THERAPY DEVICE TO REDUCE SLEEP DISTURBANCE FOR PSYCHIATRIC CONDITIONS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Ineffective treatment leading to worsening sleep	Clinical performance testing.
Ineffective treatment leading to worsening condition-specific symptoms	Clinical performance testing.
Device software failure leading to delayed access and treatment	Software verification, validation, and hazard analysis.
Improper device use leading to worsening sleep	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.

At the time of classification, digital therapy devices to reduce sleep disturbance for psychiatric conditions are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

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 parts 801, regarding labeling, have been approved under OMB control number 0910–0485.

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, 360l, 371.

■ 2. Add § 882.5705 to subpart F to read as follows:

§ 882.5705 Digital therapy device to reduce sleep disturbance for psychiatric conditions.

(a) Identification. A digital therapy device to reduce sleep disturbance for psychiatric conditions is a prescription device that is intended to provide stimulation using a general purpose computing platform to reduce sleep disturbance in patients who experience this symptom due to psychiatric conditions such as nightmare disorder or post-traumatic stress disorder.

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

(1) Clinical performance testing under the labeled conditions for use must evaluate the following:

(i) The ability of the device to provide therapy for patients with sleep disturbance due to psychiatric conditions, using a validated measure;

(ii) Worsening of any condition-specific symptoms using a validated measure for assessment of the particular condition; and

(iii) Increase in symptoms of disturbed sleep or sleepiness using a validated measure.

(2) Software must clearly describe all features and functions of the software implementing the digital therapy. Software verification, validation, and hazard analysis must also be provided.

[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.

(3) The labeling must include the following:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system and general purpose computing requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the digital therapy device is not intended for use as a stand-alone therapeutic device;

(iv) Patient and physician labeling must include a warning that the digital therapy device does not represent a substitution for the patient's medication; and

(v) Physician labeling must include a summary of the clinical performance testing conducted with the device.

Dated: January 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00497 Filed 1–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB–2021–0008; T.D. TTB–187; Re: Notice No. 205]

RIN 1513–AC61

Addition of Singani to the Standards of Identity for Distilled Spirits

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This final rule amends the Alcohol and Tobacco Tax and Trade Bureau regulations that set forth the standards of identity for distilled spirits to include ''Singani'' as a type of brandy that is a distinctive product of Bolivia. This amendment follows a joint petition submitted by the Plurinational State of Bolivia and Singani 63, Inc., and subsequent discussions with the Office of the United States Trade Representative.

DATES: This final rule is effective February 13, 2023.

FOR FURTHER INFORMATION CONTACT: Trevar D. Kolodny, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone 202–453–2226.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (the Secretary) to prescribe regulations relating to the labeling of containers of alcohol beverages that will prohibit consumer deception and provide the consumer with adequate information as to the identity and quality of the product contained therein.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). In addition, the Secretary has delegated certain administrative and enforcement authorities to TTB through Treasury Department Order 120–01.

The TTB regulations in 27 CFR part 5 implement those provisions of section 105(e) of the FAA Act as they pertain to distilled spirits.

Certificates of Label Approval

TTB's regulations at 27 CFR 5.24 prohibit the release of bottled distilled spirits from customs custody for consumption unless the person removing the distilled spirits has obtained and is in possession of a Certificate of Label Approval (COLA) covering the product. The bottles must bear labels identical to the labels appearing on the face of the certificate, or labels with changes authorized by TTB. The TTB regulations at 27 CFR 5.22 also generally prohibit the bottling or removal of distilled spirits from a distilled spirits plant unless the proprietor possesses a COLA covering the labels on the bottle.

Classes and Types of Spirits

The TTB regulations establish standards of identity for distilled spirits products and categorize these products according to various classes and types. See 27 CFR part 5, subpart I. As defined in 27 CFR 5.141(a), the term ''class'' refers to a general category of spirits. Subpart I sets out the various classes of distilled spirits, such as whisky, rum, gin, and brandy. As used in § 5.141(a), the term ''type'' refers to a subcategory within a class of spirits. For example, ''Cognac'' and ''Pisco'' are types of brandy, and ''Cachaça'' is a type of rum.

The TTB labeling regulations at 27 CFR 5.63(a)(2) require that the class, type, or other appropriate designation appear on the distilled spirits labels. If a class or type does not appear on the label, 27 CFR 5.156 and 5.166 require that such products be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, with a distinctive or fanciful name appearing in the same field of vision as a statement of composition.

Classification of Singani

''Singani'' is a term recognized by the Plurinational State of Bolivia (Bolivia) as a designation for an alcohol beverage product that is distilled from grape wine or grape pomace and produced in certain delimited parts of Bolivia. Under current TTB distilled spirits labeling regulations, Singani products are generally classified as brandies. TTB's regulations at 27 CFR 5.145(a) provide that ''brandy'' is a spirit distilled from the fermented juice, mash, or wine of fruit, or from the residue thereof. For this purpose, brandy must be distilled at less than 95 percent alcohol by volume (190° proof) and be bottled at not less than 40 percent alcohol by volume (80° proof). Under § 5.145(b), brandies generally must be labeled with their applicable type name as specified in the regulations, or, if the brandy does not conform to a specified type, must be labeled as ''brandy'' followed immediately by a truthful and adequate statement of composition.

Section 5.145(c) sets out the specific types of brandy and the standards for each type. As described by petitioners Singani 63, Inc. (Singani 63) and Bolivia, Singani may meet the criteria of several of these types of brandy, such as ''fruit brandy'' under § 5.145(c)(1) or ''pomace brandy'' (including ''grappa brandy'') under § 5.145(c)(9), depending on the amount of pomace used.

Section 5.145(c)(1) states that fruit brandy derived solely from grapes and stored for at least 2 years in oak containers must be designated as ''grape brandy'' or ''brandy.'' That regulation also generally requires that such grape brandy must be labeled as ''immature grape brandy'' or ''immature brandy'' if it has been stored in oak barrels for fewer than two years. However, this labeling requirement does not apply to other types of brandy derived from grapes specified in § 5.145(c). The Bolivian standards submitted by petitioners contain no minimum aging requirements, and petitioners' submissions suggest that, unlike many grape brandies, Singani is generally not aged in wood. Under current TTB regulations, a Singani product classified as a grape brandy under paragraph (c)(1) would need to be labeled as an immature brandy unless it was aged in oak barrels for at least two years.