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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–SC–16–0107; SC17–985–1A FR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2017–2018 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Far West Spearmint Oil Administrative Committee (Committee) to revise the quantity of Class 3 (Native) spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which began on June 1, 2017. This rule increases the Native spearmint oil salable quantity and the allotment percentage. This rule also contains formatting changes to subpart references to bring the language into conformance with the Office of Federal Register requirements.

DATES: Effective February 6, 2018.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Marketing Specialist, or Gary D. Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: Barry.Broadbent@ams.usda.gov or GaryD.Olson@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence

Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Order No. 985 (7 CFR part 985), as amended, regulating the handling of spearmint oil produced in the Far West (Washington, Idaho, Oregon, and designated parts of Nevada and Utah). Part 985 (referred to as “the Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Committee locally administers the Marketing Order and is comprised of spearmint oil producers operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the provisions of the Order now in effect, salable quantities and allotment percentages may be established for classes of spearmint oil produced in the Far West. This rule increases the quantity of Native spearmint oil produced in the Far West that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which ends on May 31, 2018.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any

obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule revises the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year under the Order. The salable quantity and allotment percentage for Native spearmint oil was initially established at 1,075,051 pounds and 44 percent, respectively, in a final rule published May 25, 2017 (82 FR 24001). This rule increases the Native spearmint oil salable quantity from 1,075,051 pounds to 1,514,902 pounds and the allotment percentage from 44 percent to 62 percent.

Under the volume regulation provisions of the Order, the Committee meets each year to adopt a marketing policy for the ensuing year. When the Committee’s marketing policy considerations indicate a need for limiting the quantity of spearmint oil available to the market to establish or maintain orderly marketing conditions, the Committee submits a recommendation to the Secretary of Agriculture for volume regulation.

Volume regulation under the Order is effectuated through the establishment of a salable quantity and allotment percentage applicable to each class of spearmint oil handled in the production area during a marketing year. The salable quantity is the total quantity of each class of oil that handlers may purchase from, or handle on behalf of, producers during a given marketing year. The allotment percentage for each class of oil is derived by dividing the salable quantity by the total industry allotment base for that same class of oil. The total industry allotment base is the aggregate of all allotment base held individually by producers. Producer allotment base is the quantity of each class of spearmint oil that the Committee has determined is

representative of a producer's spearmint oil production. Each producer is allotted a pro rata share of the total salable quantity of each class of spearmint oil each marketing year. Each producer's annual allotment is determined by applying the allotment percentage to the producer's individual allotment base for each applicable class of spearmint oil.

The full Committee met on October 19, 2016, to consider its marketing policy for the 2017–2018 marketing year. At that meeting, the Committee determined that marketing conditions indicated a need for volume regulation of both classes of spearmint oil for the 2017–2018 marketing year. The Committee recommended salable quantities of 774,645 pounds and 1,075,051 pounds, and allotment percentages of 36 percent and 44 percent, respectively, for Scotch and Native spearmint oil. A proposed rule to that effect was published in the **Federal Register** on March 31, 2017 (82 FR 16001). Comments on the proposed rule were solicited from interested persons until May 1, 2017. No comments were received. Subsequently, a final rule establishing the salable quantities and allotment percentages for Scotch and Native spearmint oil for the 2017–2018 marketing year was published in the **Federal Register** on May 25, 2017 (82 FR 24001).

Pursuant to authority contained in §§ 985.50, 985.51, and 985.52, the full eight-member Committee met again on September 25, 2017, and October 25, 2017, to evaluate the current year's volume control regulation. At the meetings, the Committee assessed the current market conditions for spearmint oil in relation to the salable quantities and allotment percentages established for the 2017–2018 marketing year. The Committee considered a number of factors, including the current and projected supply, estimated future demand, production costs, and producer prices for all classes of spearmint oil. The Committee determined that the established salable quantity and allotment percentage in effect for Native spearmint oil for the 2017–2018 marketing year should be increased to take into account the unanticipated rise in market demand for that class of spearmint oil.

At the September 25, 2017, meeting, the Committee recommended increasing the 2017–2018 marketing year Native spearmint oil salable quantity from 1,075,051 pounds to 1,221,696 pounds and the allotment percentage from 44 percent to 50 percent. The recommendation to increase the salable quantity and allotment percentage passed with a vote of seven members in

favor and one opposed. The member opposed to the recommendation favored increasing the Native spearmint oil salable quantity and allotment percentage for the 2017–2018 marketing year, but at an undetermined level lower than what was recommended.

At the October 25, 2017, meeting, the Committee met again to consider an additional increase to the 2017–2018 marketing year salable quantity and allotment percentage for Native spearmint oil. The Committee recommended further increasing the 2017–2018 marketing year Native spearmint oil salable quantity from 1,221,696 pounds to 1,514,902 pounds and the allotment percentage from 50 percent to 62 percent. The recommendation to further increase the salable quantity and allotment percentage passed with a unanimous vote.

This action makes additional amounts of Native spearmint oil available to the market by increasing the salable quantity and allotment percentage previously established under the Order for the 2017–2018 marketing year. This rule increases the Native spearmint oil salable quantity by 439,851 pounds, to 1,514,902 pounds, and raises the allotment percentage 18 percentage points, to 62 percent. Such additional oil will come from releasing Native spearmint oil held by producers in the reserve pool. As of May 31, 2017, the Committee records show that the reserve pool for Native spearmint oil contained 996,050 pounds of oil, an amount considered excessive relative to market conditions.

At both the September and October 2017 meetings, the Committee staff reported that demand for Native spearmint oil has been greater than previously anticipated. Committee records indicate that 2017–2018 marketing year sales to date (945,683 pounds) are tracking fairly closely to sales for the same period in the 2016–2017 marketing year (1,095,112 pounds). However, handlers reported to the Committee that an additional 345,446 pounds of Native spearmint oil are committed to be sold, which would leave a deficit of 216,078 pounds of oil (1,075,051 pounds salable quantity minus 945,683 pounds sold to date and 345,446 pounds committed) to supply the market until May 31, 2018. Another factor that contributed to the short supply was that only 143,011 pounds of salable product carried over from the 2016–2017 marketing year into the 2017–2018 marketing year, which was 46,809 pounds less than expected. The Committee initially estimated in October 2016 that the total available

supply of Native spearmint oil for the 2017–2018 marketing year would be 1,264,871 pounds, but that amount was reduced to 1,218,158 when the smaller carry-in quantity is accounted for.

The Committee initially estimated the trade demand for Native spearmint oil for the 2017–2018 marketing year to be 1,250,000. At the September 25, 2017, meeting, the Committee revised the expected trade demand for the 2017–2018 marketing year to be 1,338,820. At the October 25, 2017, meeting, the Committee further revised the expected trade demand for the 2017–2018 marketing year to 1,600,000 pounds. If realized, trade demand would be 381,842 pounds above the quantity of Native spearmint oil available under the volume control levels implemented in May 2017 (1,218,158 pounds available prior to this rule minus 1,600,000 pounds estimated demand equals a deficit of 381,842 pounds). Without increasing the salable quantity and allotment percentage, the market for Native spearmint oil may be shorted. The increased quantity of Native spearmint oil (439,851 pounds) that will be made available to the market as a result of this rulemaking will ensure that market demand is fully satisfied in the current year and that there would be approximately 20,171 pounds of Native spearmint oil salable inventory available to the market for the start of the 2018–2019 marketing year, which begins on June 1, 2018.

In making the recommendation to increase the salable quantity and allotment percentage of Native spearmint oil, the Committee considered all currently available information on the price, supply, and demand of Native spearmint oil. The Committee also considered reports and other information from handlers and producers in attendance at the meeting. Lastly, the Committee manager presented information and reports that were provided to the Committee staff by handlers and producers.

This rule increases the 2017–2018 marketing year Native spearmint oil salable quantity by 439,851 pounds, to a total of 1,514,902 pounds. However, the Committee expects that not all producers have Native spearmint oil held in reserve. As such, the Committee calculates that 37,796 pounds of the Native spearmint oil salable quantity will go unfulfilled. Therefore, the total supply of Native spearmint oil that the Committee anticipates actually being available to the market over the course of the 2017–2018 marketing year will be increased to 1,620,117 pounds (2017–2018 marketing year salable quantity plus salable carry-in of 143,011 pounds

from the 2016–2017 marketing year minus an unused allotment of 37,796 pounds due to lack of pool oil). Actual sales of Native spearmint oil for the 2016–2017 marketing year totaled 1,287,691 pounds. The 5-year average of Native spearmint oil sales is 1,309,793 pounds.

The Committee estimates that this action will result in 20,171 pounds of salable Native spearmint oil being carried into the 2018–2019 marketing year. While 20,171 pounds is a relatively low quantity of salable Native spearmint oil to end the marketing year, reserve pool oil could be released into the market under a future relaxation of the volume regulation should it be necessary to adequately supply the market prior to the beginning of the 2018–2019 marketing year. The Committee estimates that a total of 1,237,237 pounds of Native spearmint oil will be available from the reserve pool if needed.

As mentioned previously, when the original 2017–2018 marketing policy statement was drafted, handlers estimated the demand for Native spearmint oil for the 2017–2018 marketing year to be 1,250,000 pounds. The Committee's initial recommendation for the establishment of the Native spearmint oil salable quantity and allotment percentage for the 2017–2018 marketing year was based on that estimate. The Committee did not anticipate the increase in demand for Native spearmint oil that the market is currently experiencing and did not make allowances for it when the marketing policy was initially adopted.

At the September 25, 2017, meeting, the Committee revised its estimate of the current trade demand to 1,338,820 pounds, and further increased that estimate to 1,600,000 pounds at the October 25, 2017, meeting. The Committee now believes that the supply of Native spearmint oil available to the market under the initially established salable quantity and allotment percentage will be insufficient to satisfy the current level of demand for oil at reasonable price levels. The Committee further believes that the increase in the salable quantity and allotment percentage is vital to ensuring an adequate supply of Native spearmint oil is available to the market moving forward.

The Committee's stated intent in the use of the Order's volume control regulation is to keep adequate supplies available to meet market needs and to maintain orderly marketing conditions. With that in mind, the Committee developed its recommendation for increasing the Native spearmint oil

salable quantity and allotment percentage for the 2017–2018 marketing year based on the information discussed above, as well as the summary data outlined below.

(A) Initial estimated 2017–2018 Native Allotment Base—2,443,297 pounds. This is the allotment base estimate on which the original 2017–2018 salable quantity and allotment percentage was based.

(B) Revised 2017–2018 Native Allotment Base—2,443,391 pounds. This is 94 pounds more than the initial estimated allotment base of 2,443,297 pounds. The difference is the result of annual adjustments made to the allotment base according to the provisions of the Order.

(C) Initial 2017–2018 Native Allotment Percentage—44 percent. This was unanimously recommended by the Committee on October 19, 2016.

(D) Initial 2017–2018 Native Salable Quantity—1,075,051 pounds. This figure is 44 percent of the original estimated 2017–2018 allotment base of 2,443,297 pounds.

(E) Adjusted Initial 2017–2018 Native Salable Quantity—1,075,092 pounds. This figure reflects the salable quantity actually available at the beginning of the 2017–2018 marketing year. This quantity is derived by applying the initial 44-percent allotment percentage to the revised allotment base of 2,443,391.

(F) Revision to the 2017–2018 Native Salable Quantity and Allotment Percentage:

(1) Increase in the Native Allotment Percentage—18 percent. The Committee recommended an increase of six percentage points at its September 25, 2017, meeting, and a further 12 percentage points at its October 25, 2017, meeting for a total increase of 18 percentage points over the initial Native allotment percentage.

(2) Revised 2017–2018 Native Allotment Percentage—62 percent. This number was derived by adding the increase of 18 percentage points to the initially established 2017–2018 allotment percentage of 44 percent.

(3) Revised 2017–2018 Native Salable Quantity—1,514,902 pounds. This amount is 62 percent of the revised 2017–2018 allotment base of 2,443,391 pounds.

(4) Computed Increase in the 2017–2018 Native Salable Quantity as a Result of the Revision—439,851 pounds. This figure represents 18 percent of the 2017–2018 revised allotment base.

(5) Expected Actual Increase in the Native Spearmint Oil Available to the Market for the 2017–2018 Marketing Year—402,055 pounds. This amount is

based on the Committee's estimation of Native spearmint oil that is actually held by producers in the reserve pool that may enter the market as a result of this action. The Committee estimates that approximately 37,796 pounds of the computed increase will go unfulfilled due to producers who do not have sufficient Native spearmint oil in reserve to utilize their full allotted salable quantity.

Scotch spearmint oil is also regulated by the Order. As mentioned previously, a salable quantity and allotment percentage for Scotch spearmint oil was established in a final rule published in the **Federal Register** on May 25, 2017 (82 FR 24001). At the September 25, 2017, meeting, the Committee considered the current production, inventory, and marketing conditions for Scotch spearmint oil. After receiving reports from the Committee staff and comments from the industry, the consensus of the Committee was that the previously established salable quantity and allotment percentage for Scotch spearmint oil was appropriate for the current market conditions. As such, the Committee took no further action with regards to Scotch spearmint oil for the 2017–2018 marketing year.

This rule relaxes the regulation of Native spearmint oil and allows producers to meet market demand while improving producer returns. In conjunction with the issuance of the proposed rule, the Committee's revised marketing policy statement for the 2017–2018 marketing year has been reviewed by USDA. The Committee's marketing policy statement, a requirement whenever the Committee recommends implementing volume regulations or recommends revisions to existing volume regulations, meets the intent of § 985.50. During its discussion of revisions to the 2017–2018 salable quantities and allotment percentages, the Committee considered: (1) The estimated quantity of salable oil of each class held by producers and handlers; (2) the estimated demand for each class of oil; (3) the estimated production of each class of oil; (4) the total of allotment bases of each class of oil for the current marketing year and the estimated total of allotment bases of each class for the ensuing marketing year; (5) the quantity of reserve oil, by class, in storage; (6) producer prices of oil, including prices for each class of oil; and (7) general market conditions for each class of oil, including whether the estimated season average price to producers is likely to exceed parity. Conformity with USDA's "Guidelines for Fruit, Vegetable, and Specialty Crop

Marketing Orders” has also been reviewed and confirmed.

The increase in the Native spearmint oil salable quantity and allotment percentage will account for the anticipated market needs for that class of oil. In determining anticipated market needs, the Committee considered changes and trends in historical sales, production, and demand.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are eight spearmint oil handlers subject to regulation under the Order, and approximately 41 producers of Scotch spearmint oil and approximately 94 producers of Native spearmint oil in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$7,500,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000 (13 CFR 121.201).

Based on the SBA’s definition of small entities, the Committee estimates that only two of the eight handlers regulated by the Order could be considered small entities. Most of the handlers are large corporations involved in the international trading of essential oils and the products of essential oils. In addition, the Committee estimates that 12 of the 39 Scotch spearmint oil producers and 31 of the 94 Native spearmint oil producers could be classified as small entities under the SBA definition. Thus, the majority of handlers and producers of Far West spearmint oil may not be classified as small entities.

The use of volume control regulation allows the spearmint oil industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. Without volume control regulation, the supply and price of spearmint oil would likely fluctuate

widely. Periods of oversupply could result in low producer prices and a large volume of oil stored and carried over to future crop years. Periods of undersupply could lead to excessive price spikes and drive end users to source flavoring needs from other markets, potentially causing long-term economic damage to the domestic spearmint oil industry. The Order’s volume control provisions have been successfully implemented in the domestic spearmint oil industry since 1980 and provide benefits for producers, handlers, manufacturers, and consumers.

This final rule increases the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2017–2018 marketing year, which ends May 31, 2018. The 2017–2018 Native spearmint oil salable quantity was initially established at 1,075,051 pounds and the allotment percentage initially set at 44 percent. This final rule increases the Native spearmint oil salable quantity to 1,514,902 pounds and the allotment percentage to 62 percent.

Based on the information and projections available at the September 25, 2017, and October 25, 2017, meetings, the Committee considered several alternatives to this increase. The Committee considered leaving the salable quantity and allotment percentage unchanged, and also considered other potential levels of increase. The Committee reached its recommendation to increase the salable quantity and allotment percentage for Native spearmint oil after careful consideration of all available information and input from all interested industry participants, and believes that the levels recommended will achieve the desired objectives. Without this increase, the Committee believes the industry will not be able to satisfactorily meet market demand.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order’s information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 (Generic Specialty Crops). No changes are necessary in those requirements as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule relaxes the volume regulation requirements established under the Order. Accordingly, this action will not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil handlers. As with all Federal marketing order programs, reports and forms are

periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, the Committee’s meeting was widely publicized throughout the Far West spearmint oil industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. The September 25, 2017, and October 25, 2017, meetings were public and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on December 1, 2017 (82 FR 56922). Copies of the rule were mailed or sent via facsimile to all Committee members and Far West spearmint oil handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 15-day comment period ending December 18, 2017, was provided to allow interested persons to respond to the proposal.

Ten comments were received from nine commenters in response to the proposed rule. All ten comments were in support of the proposed increase in the salable quantity and allotment percentage. Two of the comments, in addition to supporting the action, also voiced strong interest in USDA effectuating this increase as soon as possible. Accordingly, no changes will be made to the rule as proposed, based on the comments received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because an increase in the Native spearmint oil salable quantity relieves a restriction on the amount of Native spearmint available to the

market. There is pent up demand for additional Far West Native spearmint oil that will not be available under the volume regulation provisions of the Order until this final rule is effective. Handlers want to take advantage of the relaxation of the limitation on the salable quantity of oil as soon as possible, as delay will likely result in the loss of marketing opportunities, in both the short and long term. Native spearmint oil demand that cannot be satisfied from spearmint oil from the Far West production area may be fulfilled from other U.S. production areas or imported product. The loss of immediate business resulting from a delayed implementation of this rule could result in customers entering into long term contracts with other Native spearmint oil providers. There is therefore a risk that delayed implementation of this rule would have a negative impact on Far West spearmint oil handlers' sales in future marketing years.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

- 1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

[Subpart Redesignated as Subpart A]

- 2. Redesignate “Subpart-Order Regulating Handling” as “Subpart A-Order Regulating Handling”.

[Subpart Redesignated as Subpart B and Amended]

- 3. Redesignate “Subpart-Administrative Rules and Regulations” as subpart B and revise the heading to read as follows:

Subpart B—Administrative Requirements

- 4. In § 985.236, revise paragraph (b) to read as follows:

§ 985.236 Salable quantities and allotment percentages—2017–2018 marketing year.

* * * * *

(b) Class 3 (Native) oil—a salable quantity of 1,514,902 pounds and an allotment percentage of 62 percent.

Dated: January 31, 2018.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2018–02264 Filed 2–2–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2018–N–0371]

Medical Devices; Neurological Devices; Classification of the Percutaneous Nerve Stimulator for Substance Use Disorders

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the percutaneous nerve stimulator for substance use disorders 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 percutaneous nerve stimulator for substance use disorders' 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, in part by reducing regulatory burdens.

DATES: This order is effective February 5, 2018. The classification was applicable on November 15, 2017.

FOR FURTHER INFORMATION CONTACT: Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2684, Silver Spring, MD 20993–0002, 301–796–6285, Eric.Franca@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the percutaneous nerve stimulator for substance use disorders 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 reducing regulatory burdens 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall classify the device by written order within 120 days. The classification will be according to