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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### 18 CFR Part 11

[Docket No. RM15-18-000, Order No. 815]

#### Commencement of Assessment of Annual Charges

AGENCY: Federal Energy Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Federal Energy Regulatory Commission (Commission) is revising its regulations to modify when the Commission will commence assessing annual charges to hydropower licensees and exemptees, other than state or municipal entities, with respect to licenses and exemptions authorizing unconstructed projects and new capacity. Specifically, the Commission will commence assessing annual charges on the date by which the licensee or exemptee is required to commence construction of an unconstructed project or new capacity, rather than on the date that project construction actually begins. The final rule provides administrative efficiency and promotes certainty among licensees, exemptees, and Commission staff as to when annual charges will commence.

**DATES:** *Effective:* December 21, 2015.

#### FOR FURTHER INFORMATION CONTACT:

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#### Order No. 815

*Final Rule*

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#### Order No. 815

*Final Rule*

(Issued October 15, 2015)

#### I. Background

1. On May 14, 2015, the Federal Energy Regulatory Commission (Commission) issued a Notice of Proposed Rulemaking (NOPR) proposing to revise its regulations governing the commencement of assessment of annual charges for non-municipal hydropower licensees and exemptees.<sup>1</sup> As explained in the NOPR, section 10(e)(1) of the Federal Power Act (FPA),<sup>2</sup> and section

3401 of the Omnibus Budget Reconciliation Act of 1986,<sup>3</sup> require the Commission to, among other things, collect annual charges from licensees in order to reimburse the United States for the costs of administering Part I of the FPA. The Commission assesses these annual charges against licensees and exemptees of projects with more than 1.5 megawatts (MW) of installed capacity under section 11.1 of its regulations.<sup>4</sup> 2. Currently, for exemptions and original licenses for unconstructed projects, the Commission begins assessing administrative annual charges on the date project construction starts.<sup>5</sup> For new capacity authorized by a

relicense<sup>6</sup> or an amendment of a license or exemption, the Commission begins assessing annual charges on the date that the construction to enable such capacity starts.<sup>7</sup> This final rule affects only projects with respect to which annual charges are assessed when project construction starts. It does not address state or municipal projects, projects with an installed capacity of 1.5 MW or less, or unconstructed projects without newly authorized capacity.<sup>8</sup>

<sup>1</sup> *Commencement of Assessment of Annual Charges*, 151 FERC ¶ 61,115 (2015). The NOPR was published in the **Federal Register** on May 22, 2015, 80 FR 29,562.

<sup>2</sup> 16 U.S.C. 803(e)(1) (2012).

<sup>3</sup> 42 U.S.C. 7178 (2012).

<sup>4</sup> 18 CFR 11.1 (2015).

<sup>5</sup> *Id.* (c)(5).

<sup>6</sup> We use the term “relicense” to refer to any new or subsequent license.

<sup>7</sup> 18 CFR 11.1(c)(5) (2015). We refer to the addition of capacity and a reduction of capacity (on occasion, capacity is reduced as a result of construction, in which case annual charges are lowered) as “new capacity.”

<sup>8</sup> Licensees and exemptees that are state or municipal entities are assessed annual charges

3. Original licenses for unconstructed projects require a licensee to start construction no later than two years from the effective date of the license, as required by section 13 of the FPA.<sup>9</sup> Generally, exemptions and operating projects where additional capacity is authorized similarly require that project construction<sup>10</sup> or construction of additional capacity<sup>11</sup> commence within two years of the order authorizing such construction.

4. In many instances, construction of authorized facilities does not begin by the set deadline. For original licenses, section 13 of the FPA provides that the Commission may grant an extension of the deadline for good cause shown, but only once and for no more than two additional years. These limitations of FPA section 13 do not apply to relicenses, exemptions, and amendments. From 2010 through 2014, the Commission granted extensions of the start-of-construction deadline (1) for original licenses and relicenses 17 times, or an average of 3.4 times per year; (2) for exemptions 2 times, or on average 0.4 times per year; and (3) for license amendments authorizing new capacity 6 times, or an average of 1.2 extensions per year.<sup>12</sup>

## II. Notice of Proposed Rulemaking (NOPR)

5. In the NOPR, the Commission proposed to revise section 11.1(c)(5) of its regulations regarding when it will commence assessing annual charges with respect to hydropower licenses, exemptions, and amendments authorizing unconstructed projects and new capacity. Specifically, the Commission proposed to commence assessing annual charges two years from the effective date of an order issuing a license, exemption, or an amendment authorizing additional capacity, rather

when project operation commences. 18 CFR 11.1(d)(6) (2015). As noted above, the Commission does not assess annual charges with respect to projects with installed capacity of less than or equal to 1.5 MW. 18 CFR 11.1(b) (2015). Constructed, operating projects where no new capacity is being authorized are assessed annual charges beginning on the effective date of the license or exemption. See 18 CFR 11.1(c)(5) (2015).

<sup>9</sup> See 16 U.S.C. 806 (2012).

<sup>10</sup> See 18 CFR 4.94(c) and 4.106(c) (2015) (including in exemptions standard Article 3 to allow the Commission to revoke an exemption if actual construction of the proposed generating facilities has not begun within two years).

<sup>11</sup> See e.g., *Northern States Power Co.*, 138 FERC ¶ 62,022, at ordering para. (E) (2012) (directing licensee to start construction of additional authorized capacity within two years).

<sup>12</sup> No extensions of the start-of-construction deadline were issued for exemption amendments during this period, however, exemptees rarely file amendment applications requesting authorization to increase exemption capacity.

than on the date project construction starts.

6. In support of the proposed rule, the Commission anticipated that the change would provide administrative efficiency and foster certainty among licensees, exemptees, and Commission staff as to when annual charges will commence. The NOPR explained that licensees and exemptees will no longer need to notify the Commission when project construction starts for the purpose of assessing annual charges and, in turn, the Commission will not have to contact the licensee or exemptee for that purpose.

7. While licensees and exemptees who begin construction expeditiously will benefit, the NOPR also acknowledged that the proposed change would adversely affect those licensees and exemptees that do not start construction within two years. The NOPR proposed that annual charges would be assessed two years from the effective date of an order issuing a license, exemption, or an amendment authorizing additional capacity, regardless of when actual construction commences. As noted above, on average, 5 (3.4 licenses + 0.4 exemptions + 1.2 license amendments) affected projects each year receive extensions of the start-of-construction deadline.<sup>13</sup>

8. The NOPR also acknowledged that licensees and exemptees of projects whose license or exemption is terminated for failure to timely commence construction also may be adversely affected. If a licensee fails to start construction within two years of its license's effective date or as extended by the Commission, the Commission must terminate the license pursuant to section 13 of the FPA.<sup>14</sup> Similarly, as noted above, standard exemption Article 3 states that the Commission may revoke an exemption if the exemptee fails to start construction within the time prescribed by the Commission. From 2010 through 2014, the Commission terminated one license, or an average of 0.2 licenses per year, and no exemptions. Therefore, in the NOPR, we estimated that annually 0.2 licenses would be assessed annual charges beginning two years after a licensee's effective date until the license is terminated for failure to construct.

9. In sum, the proposed rule estimated that, on average, 5.2 (5 extensions + 0.2 terminations) licensees and/or exemptees per year would begin paying

<sup>13</sup> In rare circumstances, the Commission may stay the effective date of a license, in which case the assessment of annual charges would also be stayed.

<sup>14</sup> 16 U.S.C. 806 (2012).

annual charges earlier than would be the case under the current regulations.

10. In response to the NOPR, the Commission received comments from two entities. On July 20, 2015, FFP New Hydro, LLC filed comments on behalf of its subsidiary project companies and together with its manager Rye Development, LLC (collectively, FFP New Hydro). On July 21, 2015, the National Hydropower Association (NHA) filed comments. The NOPR's proposal, the comments received, and the Commission's determination are discussed below.

## III. Discussion

11. FFP New Hydro contends that the change contemplated by the NOPR would increase the cost of hydropower development and discourage investment in critical infrastructure, stating that developers often take two years following issuance of a license, exemption, or amendment to secure financing and often apply for extensions of time to commence construction.<sup>15</sup> In this vein, FFP New Hydro claims that the proposed change would discourage new hydropower development and is therefore contrary to the inherent goals of the Hydropower Regulatory Efficiency Act of 2013.<sup>16</sup> FFP New Hydro further asserts that developers, if faced with the prospect of being assessed annual charges before construction, will be forced to surrender their licenses more frequently.<sup>17</sup> For these reasons, FFP New Hydro advocates that the Commission continue to commence assessment of annual charges when project construction begins.<sup>18</sup>

12. NHA asserts that the proposed change would not further the administrative efficiency goals set forth in the NOPR, but would instead increase the administrative burden on Commission staff, licensees, and exemptees.<sup>19</sup> As an example of a new administrative burden that might result, NHA posits that the Commission would need to implement a procedure for issuing refunds for any payment of annual charges by a licensee or exemptee who ultimately fails to commence construction.<sup>20</sup> NHA further claims that the assessment of annual charges before project construction would negatively impact the hydropower industry and quell future investment in hydropower

<sup>15</sup> FFP New Hydro at 2.

<sup>16</sup> Pub. L. 113–23, 27 Stat. 493. *Id.* at 4–5.

<sup>17</sup> FFP New Hydro at 5.

<sup>18</sup> *Id.* at 6.

<sup>19</sup> NHA at 2–4.

<sup>20</sup> *Id.* at 4.

development, especially pumped storage projects.<sup>21</sup> Finally, NHA argues that the change would run counter to recent initiatives intended to stimulate and streamline hydropower development.<sup>22</sup>

13. NHA recommends that the Commission continue to commence assessment of annual charges on the date project construction begins.

Alternatively, NHA proposes that the Commission assess annual charges when project operation commences.

14. Both FFP New Hydro and NHA contend that the phase of project development that exists between issuance of a license, exemption, or amendment and the start of construction is a critical period. While the Commission recognizes the time constraints and financial obstacles faced by licensees and exemptees, the licensing and pre-construction phases also translate to a time-consuming and labor-intensive period for Commission staff.<sup>23</sup> During this time, the Commission's costs related to a particular project begin to accrue, but are passed along in the form of annual charges to the pool of non-municipal licensees and exemptees for operating projects that are already subject to assessment of annual charges.

15. In effect, the Commission's costs during the labor-intensive periods that surround issuance of a license, exemption, or amendment authorizing new capacity are shouldered by the existing pool of licensees and exemptees.<sup>24</sup> The change envisioned by the NOPR, as modified in this final rule, strives to strike a reasonable balance

that creates certainty for licensees and exemptees as to when assessment of annual charges will commence, promotes administrative efficiency for Commission staff by establishing a more clear point at which to begin assessing annual charges, and lessens the burden on the existing pool of licensees and exemptees currently bearing the burden of paying annual charges for the administration of all pre-construction projects. Moreover, this change will generate cost-saving benefits over the current regulations for licensees and exemptees who act expeditiously by commencing construction prior to the date triggering assessment of annual charges.

16. In its comments, NHA speculated that the proposed change would actually add new administrative burdens by requiring the Commission to create and implement a procedure to issue refunds for any payment of annual charges by a licensee or exemptee who ultimately fails to commence construction. This speculation is misguided. Because the assessment of annual charges will be contingent on the expiration of a set period of time rather than on whether the start of construction ultimately occurs, there is no need for the Commission to develop a program to handle refunds.

17. While no refunds will be offered, if a licensee or exemptee successfully demonstrates an inability to pay at the time assessment of annual charges commences, the availability of payment plans<sup>25</sup> may provide a measure of relief to certain licensees or exemptees assessed annual charges before construction, but who anticipate being able to settle their account once project financing is secured or generation begins.<sup>26</sup>

18. Both FFP New Hydro and NHA raised concerns that the effect of this

final rule might discourage hydropower development. NHA indicated that pumped storage projects would be particularly affected by the changes contemplated in the NOPR. In light of these concerns, the Commission has decided to set the commencement of assessment of annual charges to track the start-of-construction deadline for any license or exemption authorizing an unconstructed project that receives an extension of the start-of-construction deadline.<sup>27</sup> In other words, any license or exemption for an unconstructed project that receives an extension of the start-of-construction deadline will be assessed annual charges beginning at the expiration of the start-of-construction deadline, as extended by the Commission (*i.e.*, no longer than four years after the issuance date of the license or exemption authorizing an unconstructed project). A four-year period is consistent with the deadlines established by section 13 and, accordingly, will give developers a reasonable charge-free period in which to secure financing.

19. Similarly, for any license, exemption, or amendment authorizing additional capacity that receives an extension of the start-of-construction deadline, the Commission will begin assessing annual charges upon the expiration of the deadline to start construction as extended by the Commission. In light of the reasons discussed above, and those identified in the NOPR, the Commission has modified the NOPR's proposal to revise section 11.1(c)(5) of its regulations and will begin assessing annual charges on the date by which a licensee or exemptee is required to commence construction of an unconstructed project or new capacity, rather than on the date project construction actually begins. We believe that these modifications to the Final Rule substantially address the concerns raised in response to the NOPR, while also continuing to encourage hydropower development.

20. NHA has requested that the Commission not apply the revised regulations to all current licensees, exemptees, and applicants.<sup>28</sup> We grant the request in part. For any license, exemption, or amendment issued by the Commission prior to the effective date of this final rule, we agree that the assessment of annual charges should remain the start of construction. The revised regulations, however, will apply

<sup>21</sup> *Id.* at 4–7.

<sup>22</sup> *Id.* at 7–8 (referencing the Water Resources Reform and Development Act of 2014, Pub. L. 113–121, 128 Stat. 1193, the Hydropower Regulatory Efficiency Act of 2013, Pub. L. 113–23, 27 Stat. 493, and The President's Climate Action Plan, Executive Office of the President (June 25, 2013), available at: <https://www.whitehouse.gov/sites/default/files/image/president27climateactionplan.pdf>).

<sup>23</sup> The Commission's considerable involvement during the licensing and pre-construction phases of development is underscored by FFP New Hydro's statement that "they have filed hundreds of thousands of pages of documentation with the Commission, are in regular and constant communication with the Commission staff, and will continue to be so throughout the licensing, post-licensing, and construction stages." FFP New Hydro at 5.

<sup>24</sup> FFP New Hydro states that the assessment of annual charges historically has commenced at the start of construction. To the contrary, prior to 1995, annual charges were assessed from the date of issuance of the license, exemption, or amendment authorizing new capacity. 18 CFR 11.1 (1994). See *Charges and Fees for Hydroelectric Projects*, Order No. 576, 60 FR 15,040 (March 22, 1995), FERC Stats. & Regs. ¶ 31,016 (cross-referenced at 70 FERC ¶ 61,293) (1995) (amending section 11.1 of the regulations to defer annual charges until construction started).

<sup>25</sup> A payment plan request would be directed to, and ultimately coordinated by, the Commission's Office of the Executive Director, Revenue and Receivables Branch. The Commission's Chief Financial Officer would determine whether or not to grant a payment plan request.

<sup>26</sup> We note that the inability of a licensee or exemptee to pay annual charges may call into question that licensee or exemptee's ability to bring a hydropower project to fruition. For example, while the amount varies based on the type of project and its annual generation, the administrative annual charges amount for a 5-MW conventional project (with an annual energy output of zero), or a 5-MW exemption, might be expected to be in the area of \$8,000, an amount any financially-viable licensee should be able to pay. Although pumped storage projects and large, conventional projects are often responsible for paying much more substantial annual charge amounts, it is also the case that, if these projects are to be successfully developed, these licensees will need to have access to greater amounts of capital than do licensees of small projects.

<sup>27</sup> Even with an extension of the start-of-construction deadline, in no case would assessment of annual charges commence later than four years after the issuance of a license or exemption authorizing an unconstructed project.

<sup>28</sup> NHA at 9.

to any license, exemption, or amendment that is issued after the revised regulation's effective date. Thus, any application for a license, exemption, or amendment that is pending before the Commission when this final rule becomes effective will not be shielded from its effects. Based on the phase and complexity of the application process, an application could be before the Commission for several years before a determination is issued. Thus, using two separate standards, contingent on the date an application was filed, could potentially persist for several years, could lead to confusion, and would place an undue administrative burden on staff. Therefore, the revision to section 11.1(c)(5) of the Commission's regulations will apply to any applicable license, exemption, or amendment issued on or after the effective date of this final rule.

#### IV. Regulatory Requirements

##### A. Information Collection Statement

21. The Paperwork Reduction Act<sup>29</sup> requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB regulations require approval of certain information collection requirements contained in final rules published in the **Federal Register**.<sup>30</sup> The final rule discussed above does not impose or alter existing reporting or recordkeeping requirements on applicable entities as defined by the Paperwork Reduction Act.<sup>31</sup> Therefore, the Commission will submit this final rule to OMB for informational purposes only.

##### B. Environmental Analysis

22. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.<sup>32</sup> Commission actions concerning annual charges are categorically exempt from this requirement.<sup>33</sup>

##### C. Regulatory Flexibility Act

23. The Regulatory Flexibility Act of 1980 (RFA)<sup>34</sup> generally requires a description and analysis of proposed and final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule while minimizing any significant economic impact on a substantial number of small entities.<sup>35</sup> In the NOPR, we certified that the proposed regulation would not have a significant economic impact on a substantial number of small entities.

24. As explained in the NOPR, the Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.<sup>36</sup> The SBA revised its size standard for electric utilities (effective January 22, 2014) from a standard based on megawatt-hours to a standard based on the number of employees, including affiliates.<sup>37</sup> Under SBA's current size standards, a hydroelectric generator is small if, including its affiliates, it employs 500 or fewer people.<sup>38</sup> The Commission, however, currently does not require information regarding the number of individuals employed by hydroelectric generators to administer Part I of the FPA, and therefore, is unable to estimate the number of small entities using the new SBA definitions. Regardless, the Commission anticipates that this final rule will affect few small hydroelectric generators.

25. As noted earlier, this rulemaking will only affect non-state or municipal licensed projects with an installed capacity exceeding 1.5 MW that are unconstructed or have newly authorized capacity. From 2010 through 2014, the Commission issued on average 3.6 original licenses and 0.4 exemptions per year authorizing unconstructed projects to affected licensees and exemptees, and 1.6 relicenses and 5 license amendments per year authorizing new capacity. In the NOPR, we estimated that, in sum, on average a total of 10.6 licensees and exemptees may be affected by the proposed rule annually. 26. Of the 10.6 total entities, only those that do not start construction prior to the set deadline to commence construction (as may be extended) will be negatively affected by the acceleration of annual charges. Previously, the NOPR estimated that 5.2

licensees and/or exemptees per year may be negatively affected by the changes contemplated in the NOPR for failing to start construction within two years. However, based on the modifications reflected in the final rule,<sup>39</sup> we estimate that zero licensees and/or exemptees will be negatively affected by failing to start construction by the set deadline, as may be extended by the Commission.<sup>40</sup> Moreover, small entities that would otherwise start construction before the date by which they are required to commence construction of an unconstructed project or new capacity will benefit from the final rule as it delays the commencement of assessment of annual charges until the established deadline to start construction.

27. Accordingly, pursuant to section 605(b) of the RFA, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

##### D. Document Availability

28. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and print the contents of this document via the Internet through the Commission's Home Page (<http://www.ferc.gov>) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

29. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

30. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at [ferconlinesupport@ferc.gov](mailto:ferconlinesupport@ferc.gov), or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at [public.referenceroom@ferc.gov](mailto:public.referenceroom@ferc.gov).

<sup>39</sup> See *supra* paragraphs 18–19.

<sup>40</sup> Conceivably, a licensee or exemptee that has received an extension of the start-of-construction deadline might be responsible for paying annual charges that began to accrue four years after the issuance date of the license or exemption, but prior to termination of the license, or revocation of the exemption, for failure to commence construction. However, this would be rare.

<sup>29</sup> 44 U.S.C. 3501–3521 (2012).

<sup>30</sup> See 5 CFR 1320.12 (2015).

<sup>31</sup> 44 U.S.C. 3502(2)–(3) (2012).

<sup>32</sup> *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, 52 FR 47,897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

<sup>33</sup> See 18 CFR 380.4(a)(11) (2015).

<sup>34</sup> 5 U.S.C. 601–612 (2012).

<sup>35</sup> 5 U.S.C. 603(c) (2012).

<sup>36</sup> 13 CFR 121.101 (2015).

<sup>37</sup> SBA Final Rule on “Small Business Size Standards: Utilities,” 78 FR 77,343 (Dec. 23, 2013).

<sup>38</sup> 13 CFR 121.201, Sector 22, Utilities (2015).

**E. Effective Date and Congressional Notification**

31. This regulation is effective December 21, 2015. The Commission has determined, with concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a “major rule” as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996.<sup>41</sup> This rule is being submitted to the Senate, House, and Government Accountability Office.

**List of Subjects in 18 CFR Part 11**

Electric power, Reporting and recordkeeping requirements.

By the Commission.

Issued: October 15, 2015.

**Kimberly D. Bose,**  
*Secretary.*

In consideration of the foregoing, the Commission amends part 11, chapter I, title 18, *Code of Federal Regulations*, as follows:

**PART 11—ANNUAL CHARGES UNDER PART I OF THE FEDERAL POWER ACT**

■ 1. The authority citation for part 11 continues to read as follows:

**Authority:** 16 U.S.C. 792–828c; 42 U.S.C. 7101–7352.

■ 2. Revise § 11.1(c)(5) to read as follows:

**§ 11.1 Costs of administration.**

\* \* \* \* \*

(c) \* \* \*

(5) For unconstructed projects, the assessments begin on the date by which the licensee or exemptee is required to commence project construction, or as that deadline may be extended, but in no case longer than four years after the issuance date of the license or exemption. For constructed projects, the assessments begin on the effective date of the license or exemption, except for any new capacity authorized therein. The assessments for new authorized capacity at licensed or exempted projects begin on the date by which the licensee or exemptee is required to commence construction of the new capacity. In the event that assessments begin during a fiscal year, the charges will be prorated.

\* \* \* \* \*

[FR Doc. 2015–26726 Filed 10–20–15; 8:45 am]

**BILLING CODE 6717–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 870**

[Docket No. FDA–2015–N–3387]

**Medical Devices; Cardiovascular Devices; Classification of the Coronary Vascular Physiologic Simulation Software Device**

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the coronary vascular physiologic simulation software device 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 coronary vascular physiologic simulation software device’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 October 21, 2015. The classification was applicable on November 26, 2014.

**FOR FURTHER INFORMATION CONTACT:** Shawn Forrest, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1326, Silver Spring, MD 20993–0002, 301–796–5554.

**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 will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On November 6, 2013, HeartFlow, Inc. submitted a request for classification of the FFR<sub>CT</sub> v.1.4 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). 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

<sup>41</sup> 5 U.S.C. 804(2) (2012).