https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-meetings-medical-devices-advisory-committee.

*33. FDA Guidance, ''Public Availability of Advisory Committee Members' Financial Interest Information and Waivers,'' March 2014, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-availability-advisory-committee-members-financial-interest-information-and-waivers.*

List of Subjects in 21 CFR Part 882

Medical devices, Neurological 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, 360*l,* 371.

■ 2. Revise § 882.5800 to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a prescription device that applies electrical current that is not intended to induce a seizure to a patient's head to treat psychiatric conditions.

(b) *Classification.* (1) Class II (special controls) when intended to treat insomnia and/or anxiety. The special controls for this device are:

(i) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device to treat insomnia and/or anxiety.

(ii) Components of the device that come into human contact must be demonstrated to be biocompatible.

(iii) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC) in its intended use environment.

(iv) Appropriate software verification, validation, and hazard analysis must be performed.

(v) The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge, and energy, must be fully characterized and verified.

(vi) The labeling for the device must include the following:

(A) The intended use population and the intended use environment;

(B) A warning that patients should be monitored by their physician for signs of worsening;

(C) A warning that instructs patients on how to mitigate the risk of headaches, and what to do should a headache occur;

(D) A warning that instructs patients on how to mitigate the risk of dizziness, and what to do should dizziness occur;

(E) A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(F) Instructions for use that address where to place the electrodes, what stimulation parameters to use, and duration and frequency of treatment sessions. This information must be based on the results of clinical studies for the device;

(G) A detailed summary of the device technical parameters, including waveform, output mode, pulse duration, frequency, train delivery, and maximum charge and energy; and

(H) Information on validated methods for reprocessing any reusable components between uses.

(vii) Cranial electrotherapy stimulator devices marketed prior to the effective date of this reclassification must have an amendment submitted to the previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

(2) Class III (premarket approval) when intended to treat depression.

(c) Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 19, 2020, for any cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 19, 2020, been found to be substantially equivalent to any cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27295 Filed 12–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

[Docket No. USPC–2018–02]

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The United States Parole Commission is amending its rule allowing hearings by videoconference to include parole termination hearings.

DATES: This regulation is effective December 20, 2019.

FOR FURTHER INFORMATION CONTACT: Helen H. Krapels, General Counsel, U.S. Parole Commission, 90 K Street NE, Third Floor, Washington, DC 20530, telephone (202) 346–7030. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: Since early 2004, the United States Parole Commission has been conducting some parole proceedings by videoconference to cut down on delays in scheduling in-person hearings and conserve Commission resources. The Commission originally initiated the use of videoconference in parole release hearings as a pilot project in 2004 and then extended the use of videoconferencing to institutional revocation hearings in 2005, followed by probable cause hearings in 2007. Using videoconference for termination hearings is a natural progression in the use of this technology.

Conducted pursuant to 28 CFR 2.43(c) and 2.95(c), the primary objective of a termination hearing is to obtain information which assists the Commission in determining whether or not early termination of parole is appropriate. The subject is usually represented by an attorney, and the community supervision officer or the U.S. Probation officer provides a recommendation based on the subject's compliance with parole requirements. Given the limited purpose of the hearing, other witnesses are usually not present, and the hearing does not typically last long. The amendment will save travel time and expense, allowing the Commission to conduct termination hearings in a more expeditious manner.

In the interim rule with request for comments (83 FR 58500 (Nov. 20,

2018)), we encouraged the public to comment on our changes. We received written comments from the Public Defender Service for the District of Columbia (PDS) and one anonymous comment. We discuss those public comments below.

Public Comment From the Public Defender Service

PDS objects to amending § 2.25 to include parole termination hearings, and renews its prior objections to the use of videoconference for probable cause hearings. PDS's comments, both past and present, characterize videoconference as a barrier to due process which unjustifiably denies a subject the opportunity to appear in person before the Commission. The Commission does not agree with this proposition. Termination hearings are limited in scope. Unlike revocation hearings, when all facets of the case are explored, witnesses testify, and the status of the offender is finally determined, the purpose of a termination hearing is to obtain information regarding the parolee's conduct in the community. The liberty interest implicated in a revocation hearing is not implicated in a termination hearing. At a termination hearing, the subject does not face the possibility of a loss of freedom as a result of termination being denied. *See Henderson* v. *Sims,* 223 F.3d 267, 274 (4th Cir. 2000); *Little* v. *Thomas,* 719 F.2d 50, 52 (3d Cir. 1982). Further, there is no constitutional or statutory entitlement to early termination of parole supervision. *See Myers* v. *U.S. Parole Comm'n,* 813 F.2d 957, 960 (9th Cir. 1987). Thus, the fact that the parolee's appearance for the termination hearing will be by videoconference does not violate due process.

PDS recommends that termination hearings only be conducted by videoconference in circumstances where either distance or physical hardship renders the subject unable to appear in person. While the Commission agrees that videoconferencing may be appropriate in the circumstances described by PDS, the Commission does not agree that the rule should be so narrow. It is within the Commission's discretion to determine when conducting a termination hearing by videoconference is appropriate.

PDS also raises concerns about technological issues, stating that experiencing technical difficulties during a hearing would completely undermine the value of having a hearing at all. Over the years, the Commission's experience has been that the quality of the transmission has improved and the personal interactions among the hearing participants does not appreciably decline with the use of videoconferencing.

Anonymous Comment

The Commission also received an anonymous comment in support the use of videoconferencing for parole termination hearings. The comment, while acknowledging the issue of losing face-to-face contact, described the amendment as a logical practice that will increase the efficiency of the termination process.

Executive Orders 12866 and 13563

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulation Planning and Review,'' section 1(b), Principles of Regulation, and in accordance with Executive Order 13565, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation. The Commission has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications requiring a Federalism Assessment.

Regulatory Flexibility Act

The rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

The rule will not cause State, local, or tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

These rule is not a ''major rule'' as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 Subtitle E—Congressional Review Act, now codified at 5 U.S.C. 804(2). The rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability of United States-based companies to compete with foreign-based companies. Moreover, this is a rule of agency practice or procedure that does not substantially affect the rights or obligations of non-agency parties, and does not come within the meaning of the term ''rule'' as used in Section 804(3)(C), now codified at 5 U.S.C. 804(3)(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and Parole.

The Final Rule

■ Accordingly, the U. S. Parole Commission adopts the interim rule amending 28 CFR part 2, which was published at 83 FR 58500 on November 20, 2018, as final without change.

Patricia K. Cushwa,

Chairman (Acting), U.S. Parole Commission.

[FR Doc. 2019–27340 Filed 12–19–19; 8:45 am]

BILLING CODE 4410–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0945]

RIN 1625–AA08

Special Local Regulation; St. Thomas Lighted Boat Parade, St. Thomas, U.S. Virgin Island

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for the St. Thomas Lighted Boat Parade marine event. The special local regulation is for certain navigable waters of Crown Bay, Haulover Cay, and St. Thomas Harbor, St. Thomas, U.S. Virgin Islands. The special local regulation is necessary to ensure the safety of vessels, spectators, and public during the event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Juan or a designated representative.