Rulemaking Requirements section above.

Based on the analysis provided above, the revisions in this rule would not impose a significant economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes in this rule and the corresponding reporting, recordkeeping, and other compliance requirements are discussed in the background section of the preamble of this document and, consequently, are not repeated here. To the extent that compliance with the changes in this rule would impose a burden on persons, including small businesses, BIS believes the burden will be minimal.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the revisions in this rule will have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these revisions to assess whether the alternatives would: (1) accomplish the stated objectives of this final rule (consistent with the objectives of the Section 232 exclusions process); and (2) minimize any significant economic impact of this final rule on small entities. BIS has determined that revisions detailed above are the least disruptive alternative for implementing changes to the Section 232 exclusions process.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and also considered whether an exemption for small businesses was practical under the circumstances (*i.e.,* within the context of the changes in this rule).

This final rule does not contain an exemption for small businesses from the Section 232 exclusions process changes because these controls are essential to U.S. national security and BIS' regulations apply to all parties. An exemption for small businesses would undermine the effectiveness of these revisions.

Conclusion

BIS has identified changes to the Section 232 exclusions process. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this FRFA addressing the impact that this final rule will have on small entities. BIS's assessment indicates that the amendments in this rule will not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this FRFA in accordance with the instructions provided in the **ADDRESSES** section of this final rule.

List of Subjects in 15 CFR Part 705

Administrative practice and procedure, Business and industry, Classified information, Confidential business information, Imports, Investigations, National defense.

For the reasons set forth in the preamble, part 705 of subchapter A of 15 CFR chapter VII is amended as follows:

PART 705—EFFECT OF IMPORTED ARTICLES ON THE NATIONAL SECURITY

■ 1. The authority citation for part 705 continues to read as follows:

Authority: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

■ 2. Supplement no. 2 to part 705 is amended by removing the entries for ''GAE.24.S: 7211296080;'' ''GAE.43.S: 7209900000;'' ''GAE.46.S: 7216330090;'' ''GAE.84.S: 7209270000;'' ''GAE.90.S: 7216100010;'' and ''GAE.93.S: 7208380015''.

■ 3. Supplement no. 3 to part 705 is amended by removing the entries for ''GAE.1.A: 7609000000;'' ''GAE.4.A: 7604210010;'' ''GAE.5.A: 7604291010;'' ''GAE.9.A: 7601209080;'' ''GAE.10.A: 7607116010;'' and ''GAE.13.A: 7604295090''.

Matthew S. Borman,

Principal Deputy Assistant Secretary for Export Administration.

[FR Doc. 2024–10725 Filed 5–17–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2018–N–3074]

Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order reclassifying the ultrasound cyclodestructive device, a postamendments class III device (product code LZR), into class II (special controls), subject to premarket notification. FDA is also establishing special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on valid scientific evidence. For this class II device, instead of a premarket approval application, manufacturers may submit a premarket notification, *i.e.,* a 510(k) submission, and obtain FDA clearance of the device before marketing it.

DATES: This order is effective June 20, 2024.

FOR FURTHER INFORMATION CONTACT: Claudine Krawczyk, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1238, Silver Spring, MD 20993, 301–796–6860, *claudine.krawczyk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls and general controls), and class III (premarket approval and general controls).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until (1) FDA reclassifies the device into class I or class II; or (2) 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 previously marketed devices by means of the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (part 807, subpart E (21 CFR part 807, subpart E)).

A postamendments device that has been initially classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act (21 U.S.C. 360c(f)(3)). Section 513(f)(3) provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)). Whether data before the Agency are old or new, the data to support reclassification under section 513(f)(3) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending premarket approval application (PMA) (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include the descriptions of methods of manufacture and product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the requirements under section 510(k) of the FD&C Act if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device type.

On September 25, 2018, FDA published a proposed order in the **Federal Register** to reclassify the ultrasound cyclodestructive device (product code LZR) (83 FR 48403, the ''proposed order''). The period for public comment on the proposed order closed on November 26, 2018. FDA received and has considered comments on the proposed order, as discussed in Section II of this document.

II. Comments on the Proposed Order and FDA Responses

A. Introduction

FDA received fewer than 10 public comments on the proposed order. These comments came from individual and anonymous commenters. The majority of the comments supported the proposed reclassification of ultrasound cyclodestructive devices.

We describe and respond to the comments in section II.B. The order of the comments and our response to them is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar.

B. Description of Comments and FDA Response

(Comment 1) The majority of commenters supported the proposed reclassification of ultrasound cyclodestructive devices. One commenter stated that decreasing the regulatory burden (through reclassification of the device from class III into class II) for ultrasound cyclodestructive devices will hopefully allow increased access of the devices for patients. The commenter further stated that having stricter manufacturing and regulatory controls during the initial years of device use (as a class III device) and then decreasing the controls should not result in an increase of known medical incidents. Another commenter stated that there is sufficient information to establish special controls which can provide a reasonable assurance of safety and effectiveness.

(Response 1) FDA agrees with the comments. Based on the available information (including valid scientific evidence), as discussed in the proposed order, and consideration of the comments received on the proposed order, FDA has determined that reclassification of ultrasound cyclodestructive devices into class II is appropriate because there is sufficient information to establish special controls for the device that, together with general controls, will provide for reasonable assurance of safety and effectiveness. The Agency believes that reclassification of ultrasound cyclodestructive devices under this final order will reduce the regulatory burden on manufacturers, while still providing reasonable assurance of safety and effectiveness. Specifically, reclassifying this type of device from class III into class II will reduce regulatory burdens on industry because instead of submission of a PMA, manufacturers may submit a less burdensome premarket notification (*i.e.,* a 510(k) submission) and obtain FDA clearance of the device before marketing it.

Additionally, FDA agrees that there is sufficient information to establish special controls and that the special controls required in this final order, along with general controls, provide a reasonable assurance of safety and effectiveness for these devices for their intended use. FDA has identified the probable risks to health in section V of the proposed order, and the Agency has determined, in finalizing the proposed order after considering the comments received, that the special controls in this final order will mitigate such risks to health.

(Comment 2) A commenter stated that ultrasound cyclodestructive devices should be reclassified into class II, similarly to devices indicated for use in conventional refractory glaucoma treatment modalities (*e.g.,* implantable aqueous shunts and valves, cyclocryotherapy, laser transcleral cyclophotocoagulation), all of which are regulated as class II devices subject to 510(k) requirements. The commenter stated that it also concurred with the definition of refractory glaucoma described in the proposed order and claimed that the definition is consistent with current medical practice for the management of the disease and with other device treatment modalities cleared by FDA (*e.g.,* implantable aqueous shunts).

(Response 2) This comment is supportive of the reclassification. The term ''refractory glaucoma'' in the proposed order refers to the intended use population for the device: ''patients who are refractory to or are poor candidates for laser or surgical treatment and fail to achieve target intraocular pressures on maximally tolerated drug therapy'' (83 FR 48403 at 48405, Section III, Device Description). Although we explained what we meant by ''refractory glaucoma'' in the preamble of the proposed order (as mentioned by the commenter), we did not include that clarification in the proposed codified text. Upon consideration of this comment, however, FDA believes clarifying in the codified text what we mean by

''refractory glaucoma'' would be helpful in reducing ambiguity in the codified text and reducing the potential for misunderstanding of the intended use population, which is specific to the population that was treated in the studies supporting the only PMA approved by FDA for a device within the device type being reclassified under this final order. Retaining the proposed codified language may incorrectly indicate that this classification applies to types of laser treatments for glaucoma that were developed after the approval of this PMA. Therefore, FDA is revising the device identification language in the codified text of the final order from ''. . . and that is intended for treatment of refractory glaucoma'' to ''. . . and that is intended for treatment of glaucoma patients who . . . are refractory to, or are poor candidates for, Argon laser trabeculoplasty or traditional filtering surgery and . . . had failures on maximally tolerated drug therapy.''

(Comment 3) A commenter requested clarification concerning the classification of certain conventional glaucoma treatment modalities mentioned at the end of section III of the proposed order; specifically, the commenter indicated that trabeculectomy and some incisional glaucoma surgeries do not involve a class II medical device and noted that class I manual ophthalmic instruments are used to perform some of these surgeries.

(Response 3) FDA notes that this final order only applies to ultrasound cyclodestructive devices. Nevertheless, to clarify, the commenter is correct in that the manual ophthalmic instruments (*e.g.,* trabeculotomes, cannulas, etc.) are class I devices, not subject to 510(k) requirements, and are indicated ''to aid or perform ophthalmic surgical procedures.'' However, FDA notes that these manual ophthalmic instruments regulated under 21 CFR 886.4350 are not indicated specifically to treat glaucoma patients.

(Comment 4) A commenter requested clarification on the device identification description in the proposed order. Specifically, the commenter stated that not all ultrasound cyclodestructive devices have been shown to create additional lesions in the trabecular meshwork and recommended that the device identification paragraph be revised accordingly.

(Response 4) FDA agrees that not all ultrasound cyclodestructive devices create lesions in the trabecular meshwork and that an edit to the device identification paragraph (a) of proposed § 886.5350 is appropriate. Specifically, FDA has modified the device identification paragraph (a) of § 886.5350 in the final order so that it reads: ''An ultrasound cyclodestructive device is a prescription device that reduces intraocular pressure by producing a series of lesions in the ciliary body *and/or* trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy . . .'' (italics added in this preamble discussion to highlight the change).

(Comment 5) A commenter requested the special controls in the proposed order to reference IEC 60601–2–62 *Medical electrical equipment—Part 2–62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment* since it is recognized by FDA and is relevant to the reclassification of these devices.

(Response 5) FDA acknowledges that IEC 60601–2–62 has been recognized by FDA (79 FR 38919, Jul. 9, 2014) and is relevant to ultrasound cyclodestructive devices.[1] This standard includes methods of thermal and mechanical safety analysis. FDA agrees that manufacturers may rely on this FDA-recognized standard to comply with some of the special controls identified in this final order. However, IEC–60601–2–62 is not the sole methodology for complying with some of the special controls identified in this final order. Therefore, no change has been made to reference IEC 60601–2–62 in the special controls.

(Comment 6) A commenter did not agree with the reclassification of ultrasound cyclodestructive devices from class III into class II due to the potential adverse events caused by the use of the device. Specifically, the commenter raised concerns related to the ultrasound cyclodestructive devices causing lesions, thermal damage of the ocular tissue, possible temperature elevation with use of the device causing corneoscleral lesions, intraocular inflammation, ciliary body hemorrhage, decreased visual acuity and worsening glaucoma.

(Response 6) The commenter raised important concerns regarding potential adverse effects secondary to the exposure to unsafe level of HIFU energy. The proposed order adequately discusses these and other risks to health associated with use of the device, including thermal injury, physical injury, post-treatment injury, electrical shock, electromagnetic interference, ocular irritation, and corneal infections. As stated in Response 1 and in section III of this document, based on the available information (including valid scientific evidence), as discussed in the proposed order, and considering the comments received on the proposed order, FDA has determined that reclassification of ultrasound cyclodestructive devices into class II is appropriate because there is sufficient information to establish special controls for the device, that together with general controls, will provide reasonable assurance of safety and effectiveness. For example, the special control under § 886.5350(b)(2)(i) of this final order requires, among other things, characterization of the total acoustic power radiated by the transducers, and § 886.5350(b)(2)(ii) requires characterization of the thermal and physical safety of the device. Any new device would have to show substantial equivalence to a legally marketed predicate device, which would include a comparison with respect to intended use and technology, and the supporting data submitted must demonstrate, among other things, that the device is as safe and effective as a legally marketed device. In addition, the special controls described in § 886.5350(b)(1) of this final order require clinical performance data to demonstrate an appropriate reduction in intraocular pressure in glaucoma patients who (1) are refractory to, or are poor candidates for, Argon laser trabeculoplasty or traditional filtering surgery and (2) have failures on maximally tolerated drug therapy. The submitted clinical performance data would also specifically need to include evaluation of all adverse events observed during clinical use, which would include not only adverse events observed when the device is in use but also during the post-treatment period, such as any ocular tissue thermal injuries, physical injuries, inflammation, etc. FDA has provided a minor revision to the proposed codified language to delete reference to an ''adequate safety profile'' in the special control to require more specifically ''an evaluation of all adverse events observed during clinical use.'' FDA has determined this change will establish the same reasonable assurance of safety and effectiveness for the device, while giving sponsors a more specific instruction on how to demonstrate the device's safety. Therefore, FDA believes that thermal damage, inflammation, and the other concerns identified by the commenter would be mitigated both by the comparison of the technological characteristics and performance of the

[1] See the current FDA database of Recognized Consensus Standards, available at *https:\\www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.*

device to a legally marketed predicate device and by device compliance with the special controls, including the clinical and non-clinical performance testing special controls established by this final order.

FDA, on its own initiative, has made non-substantive changes to the codified language to improve organization and clarity. For example, ''analysis/testing'' has been changed to ''analysis or testing'' to indicate that one or the other may be conducted as appropriate, and the special control for simulated use testing has been shifted out from under the non-clinical performance testing special control umbrella.

III. The Final Order

FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published on September 25, 2018, in the preamble to the proposed order (83 FR 48403).[2] FDA is issuing this final order to reclassify ultrasound cyclodestructive devices from class III into class II and to establish special controls by revising 21 CFR part 886. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, along with general controls, provide a reasonable assurance of the safety and effectiveness for ultrasound cyclodestructive devices.

FDA has determined that requiring 510(k) submission is necessary to reasonably assure the safety and effectiveness of the ultrasound cyclodestructive devices and, therefore, the Agency is not exempting this class II device from 510(k) submission requirements as provided under section 510(m) of the FD&C Act. Thus, under sections 510(k) and 513(f) and (i) of the FD&C Act, persons who intend to market this device type must submit a 510(k) notification containing information on the ultrasound cyclodestructive device that they intend to market and must obtain FDA clearance of the device prior to marketing it.

The device is assigned the generic name ultrasound cyclodestructive device, and it is identified as a prescription device that reduces intraocular pressure by producing a series of lesions in the ciliary body and/or trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy and that is intended for treatment of glaucoma in patients who (1) are refractory to, or are poor candidates for, Argon laser trabeculoplasty or traditional filtering surgery and (2) have failures on maximally tolerated drug therapy.

Under this final order, the ultrasound cyclodestructive device is a prescription use device under § 801.109 (21 CFR 801.109). 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 § 801.109 are met. The device would continue to be subject to the submission and device clearance requirements of sections 510(k) and 513 of the FD&C Act (21 U.S.C. 360(k) and 360c) and of part 807, subpart E.

IV. Analysis of Environmental Impact

We have 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.

V. Paperwork Reduction Act of 1995

This final administrative order refers to previously approved collections of information found in FDA regulations. 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 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

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

■ 2. Add § 886.5350 to read as follows:

§ 886.5350 Ultrasound cyclodestructive device.

(a) *Identification.* An ultrasound cyclodestructive device is a prescription device that reduces intraocular pressure by producing a series of lesions in the ciliary body and/or trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy and that is intended for treatment of glaucoma patients who:

(1) Are refractory to, or are poor candidates for, Argon laser trabeculoplasty or traditional filtering surgery; and

(2) Had failures on maximally tolerated drug therapy.

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

(1) The clinical performance data must demonstrate an appropriate reduction in intraocular pressure in glaucoma patients who:

(i) Are refractory to, or are poor candidates for, Argon laser trabeculoplasty or traditional filtering surgery; and

(ii) Had failures on maximally tolerated drug therapy, and an evaluation of all adverse events observed during clinical use.

(2) Non-clinical performance testing of device features and characteristics must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Ultrasound field characteristics, which must include the total acoustic power radiated by the transducer(s), the spatial distribution of the ultrasound field (including compressional and rarefactional pressure), and spatial-peak, temporal-average intensity; and

(ii) Thermal and physical safety characteristics of the device.

(3) Simulated use testing to validate that the device performs as intended under anticipated conditions of use, including eye movements and positioning error.

(4) Analysis or testing must demonstrate electrical safety in the appropriate use environment.

(5) Analysis or testing must demonstrate electromagnetic compatibility (EMC), including wireless coexistence (if applicable) in the appropriate use-environment.

(6) Software verification, validation, and hazard analysis must be performed commensurate with the level of concern of the device.

(7) The patient-contacting components must be demonstrated to be biocompatible.

[2] 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.

(8) Performance data must demonstrate sterility of all patient-contacting components labeled as sterile. If the device contains reusable eye-contact components, the validation tests must demonstrate adequate cleaning and reprocessing of these components.

(9) Labeling must include:

(i) A detailed description of the patient population for which the device is indicated for use, as well as warnings, and precautions regarding potential for device malfunction and use-error pertinent to use of the device.

(ii) A detailed summary of the clinical testing, including study outcomes and adverse events.

(iii) Information on how the device operates and the typical course of treatment.

(iv) Description of all main components of the device including HIFU generator, transducer(s), and controls. The labeling must include the technical specifications of the device including, but not limited to, treatment frequency, total acoustic power delivered by transducer, treatment duration, treatment zone, site targeting, power requirements, weight, and physical dimensions of the device.

(v) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

(vi) Safe-use conditions for electrical safety and electromagnetic compatibility.

Dated: May 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10895 Filed 5–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0368]

Special Local Regulations; Marine Events Within the Sector Columbia River Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations at various locations in the Sector Columbia River Captain of the Port Zone from May 31, 2024, to September 7, 2024. This action is necessary to provide for the safety of life and property on these navigable waters during marine events. During the enforcement periods, the operator of any vessel in the regulated area must comply with the directions from the Patrol Commander or any official patrol vessel.

DATES: The regulations in 33 CFR 100.1302 will be enforced for the regulated areas identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Carlie Gilligan, Waterways Management Division, Sector Columbia River, Coast Guard; telephone 503–240–9319, email *SCRWWM@USCG.MIL.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.1302 for the following events during the hours specified on the dates listed in the following table:

TABLE—DATES AND TIMES OF ENFORCEMENT OF 33 CFR 100.1302 SPECIAL LOCAL REGULATIONS AT VARIOUS LOCATIONS IN THE SECTOR COLUMBIA RIVER CAPTAIN OF THE PORT ZONE IN 2024

No.	Date	Event	Location
1	May 31, 2024, from 5:30 a.m. to 6:30 p.m.	Spring Testing Hydroplane races.	Kennewick, WA, Regulated area includes all navigable waters within the Columbia River in the vicinity of Columbia Park, commencing at the Interstate 395 Bridge and continuing upriver approximately 2.0 miles and terminating at the northern end of Wade Island.
2	June 8, 2024, through June 9, 2024, from 6:30 a.m. to 6:30 p.m.	Rose Fest Dragon Boat Races	Portland, OR. Regulated area includes all waters of the Willamette River shore to shore, bordered on the north by the Hawthorne Bridge, and on the south by the Marquam Bridge.
3	June 15, 2024, through June 16, 2024, from 7:30 a.m. to 6:30 p.m.	Richland Regatta	Richland, WA. Regulated area includes all navigable waters of the Columbia River in the vicinity of Howard Amon Park, between River Miles 337 and 338.
4	July 13, 2024, from 8:30 a.m. to 7:30 p.m.	The Big Float, group inner-tube float.	Portland, OR. Regulated area includes all navigable waters of the Willamette River, in Portland, Oregon, enclosed by the Hawthorne Bridge, the Marquam Bridge, and west of a line beginning at the Hawthorne Bridge at approximate location 45°30′50″ N.; 122°40′21″ W., and running south to the Marquam Bridge at approximate location 45°30′27″ N.; 122°40′11″ W.
5	July 26, 2024, through July 28, 2024, from 5:30 a.m. to 6:30 p.m.	Kennewick Hydroplane Races ..	Kennewick, WA. Regulated area includes all navigable waters within the Columbia River in the vicinity of Columbia Park, commencing at the Interstate 395 Bridge and continuing upriver approximately 2.0 miles and terminating at the northern end of Wade Island.
6	August 10, 2024, from 10:30 a.m. to 1:30 p.m.	Swim the Snake	Perry, WA. Regulated area includes all navigable waters, bank-to-bank of the Snake River, 500 yards upstream and 500 yards downstream from the Washington State Highway 261 Bridge at the approximate position of 46°35′23″ N.; 118°13′10″ W.
7	September 7, 2024, from 7:30 a.m. to 11:30 a.m.	Columbia Crossing Swim	Pasco, WA. Regulated area includes all navigable waters, bank-to-bank of the Columbia River in Pasco, Washington, between river mile 332 and river mile 335.