(6) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

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PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 6. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 7. Section 814.3 is amended by adding paragraph (o) to read as follows:

§ 814.3 Definitions.

* * * * *

(o) *Newly acquired information* means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

■ 8. Section 814.39 is amended by revising paragraphs (d)(1) introductory text and (d)(2)(i) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

* * * * *

(2) * * *

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

* * * * *

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19572 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0424]

Special Local Regulation; U.S. Nationals Waterski Racing Championship; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the U.S. Nationals Waterski Racing Championship special local regulation on Mission Bay from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other vessels and users of the waterway. During the enforcement period, no person or vessel may enter the special local regulation without permission of the Captain of the Port.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008.

FOR FURTHER INFORMATION CONTACT: Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278–7233.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the U.S. Nationals Waterski Racing Championship in 33 CFR 100.1101 on October 10, 2008, from 8 a.m. to 7 p.m., October 11, 2008, from 8 a.m. to 7 p.m., and October 12, 2008, from 8 a.m. to 7 p.m.

Under the provisions of 33 CFR 100.1101, a vessel may not enter the regulated area, unless it receives permission from the COTP. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter in, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.1101(a) and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers. If the COTP or his designated representative determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 8, 2008.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. E8–19532 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2008–0769]

Oregon Symphony Celebration Fireworks Display, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the ''Oregon Symphony Celebration Fireworks Display safety zone on the Willamette River''; from 8:30 p.m. through 11:30 p.m. on August 28, 2008. This action is necessary to provide a safe display for the public and to keep them clear of the fall out area of the fireworks. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port Portland or his designated representative.

DATES: The regulations in 33 CFR 165.1315(a)(7) will be enforced from 8:30 p.m. through 11:30 p.m. on August 28, 2008.

FOR FURTHER INFORMATION CONTACT: BM2 Joshua Lehner, Sector Portland Waterways Management at (503) 247–4015.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the Oregon Symphony Celebration Fireworks Display in 33 CFR 165.1315(a)(7) on August 28, 2008 from 8:30 p.m. to 11:30 p.m.