IX. Paperwork Reduction Act of 1995

The Voluntary Malfunction Summary Reporting Program described in this Notice contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These provisions have been approved under OMB control number 0910–0437.

This document also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in part 4, subpart B, regarding postmarketing safety reporting for combination products have been approved under OMB control number 0910–0834; the collections of information in part 803, regarding medical device reporting, have been approved under OMB control number 0910–0437; the collections of information in 806, regarding corrections and removals, have been approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 810, regarding medical device recall authority, have been approved under OMB control number 0910–0432; the collections of information in part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 1002 through 1050, regarding radiological health, have been approved under OMB control number 0910–0025; the collections of information regarding the MedWatch: The Food and Drug Administration Medical Products Reporting Program have been approved under OMB control number 0910–0291; and the collections of information regarding the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)) have been approved under OMB control number 0910–0471.

X. References

The following references are on display in the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Medical Device User Fee Agreement IV Commitment Letter, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*
2. Food and Drug Administration, ''Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry,'' (October 19, 2000); available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072102.pdf.*
3. Food and Drug Administration, ''Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff,'' (November 8, 2016); available at *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf.*
4. Food and Drug Administration, ''Center for Devices and Radiological Health Appeals Processes; Guidance for Industry and Food and Drug Administration Staff,'' (May 17, 2013); available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf.*
5. Food and Drug Administration, ''International Medical Device Regulators Forum,'' available at *https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm.*
6. Appendix A, ''Case Examples of Summary Malfunction Reporting,'' available in Docket No. FDA–2017–N–6730.
7. Food and Drug Administration, ''Postmarketing Safety Reporting for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff,'' (March 2018); available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM601454.pdf.*
8. Food and Drug Administration, ''Compliance Policy for Combination Product Postmarketing Safety Reporting, Immediately in Effect Guidance for Industry and Food and Drug Administration Staff,'' available at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm601456.htm.*
9. Food and Drug Administration, Form FDA 3500A, available at *https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm048334.pdf.* 5.
10. Electronic Medical Device Reporting (eMDR) (manufacturers may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive), available at: *https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.*

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17770 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0775]

Drawbridge Operation Regulation; Columbia River, Portland, OR and Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Interstate 5 (I–5) Bridges across the Columbia River, mile 106.5, between Portland, Oregon, and Vancouver, Washington. The deviation is necessary to facilitate the presence of participants in the Hands Across the Bridge Project. This deviation allows the bridges to remain in the closed-to-navigation position during the event.

DATES: This deviation is effective from 11 a.m. to 2 p.m. on September 3, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0775 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Oregon Department of Transportation (bridge owner) requested a temporary deviation from the operating schedule for the I–5 Bridges, mile 106.5, across the Columbia River between Vancouver, WA, and Portland, OR, to facilitate safe passage of participants in the Hands Across the Bridge Project. The I–5 Bridges provides three designated navigation channels with vertical clearances ranging from 39 to 72 feet above Columbia River Datum 0.0 while the lift spans are in the closed-to-navigation position. The normal operating schedule for the I–5 Bridges is 33 CFR 117.869. The subject bridges need not open to marine vessels during

the deviation period from 11 a.m. to 2 p.m. on September 3, 2018. The bridge shall operate in accordance with 33 CFR 117.869 at all other times. Waterway usage on this part of the Columbia River includes vessels ranging from large commercial ships, tug and tow vessels to recreational pleasure craft.

Vessels able to pass under the bridges in the closed-to-navigation positions may do so at any time. Both bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 9, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–17801 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0676]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the Hawthorne Bridge crosses the Willamette River, mile 13.1, at Portland, OR. The deviation is necessary to accommodate a filming event for a movie. This modified deviation changes the period the bridge is authorized to remain in the closed-to-navigation position.

DATES: This modified deviation is effective from 6 p.m. on September 8, 2018, to 12:01 a.m. on September 9, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0676 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this modification, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: On July 19, 2018, we published a temporary deviation entitled ''Drawbridge Operation Regulation; Willamette River at Portland, OR'' in the **Federal Register** (83 FR 34041). That temporary deviation allowed the subject bridge to not open to marine vessels from 6 p.m. on September 1, 2018 to 12:01 a.m. on September 2, 2018. Multnomah County, the bridge owner, requested a modification of the current published deviation to the following times: 6 p.m. on September 8, 2018, to 12:01 a.m. on September 9, 2018. This change is due to scheduling issues with the filming crew for a movie.

The Hawthorne Bridge provides a vertical clearance of 49 feet in the closed-to-navigation position referenced to the vertical clearance above Columbia River Datum 0.0. The subject bridge operates per 33 CFR 117.897(c)(3)(v). Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard requested objections to this modification from local mariners via email. No objections were submitted to us. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 9, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–17800 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2017–0414; FRL–9971–37]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 27 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 27 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

DATES: This rule is effective on October 16, 2018. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on August 31, 2018.

Written adverse comments on one or more of these SNURs must be received on or before September 17, 2018 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse comments on one or more of these SNURs before September 17, 2018, EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID)