

processes in place to meet the requirements of section 582(g) of the FD&C Act, FDA recognizes that some technical and operational issues may not be fully resolved by November 27, 2023. The Agency believes the Enhanced Drug Distribution Security Compliance Policies can help trading partners address such issues by accommodating the additional time that may be needed to implement, troubleshoot, and mature their systems and processes. For additional information about enhanced drug distribution security please see the June 2021 draft guidance for industry entitled “Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act” (available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security-act>).

This guidance represents the current thinking of FDA on “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.¹

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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¹ The Office of the Federal Register has published this document under the category “Rules and Regulations” pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2023–0651]

Special Local Regulations; Portland Dragon Boat Races, Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Portland Dragon Boat Races from September 9 through 10, 2023, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Thirteenth Coast Guard District identifies the regulated area for this event on the Willamette River in Portland, OR. 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. Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the Captain of the Port, Sector Columbia River.

DATES: The regulations in 33 CFR 100.1302 will be enforced from 7:30 a.m. until 5:30 p.m., each day from September 9 through 10, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT 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 Portland Dragon Boat Races regulated area from 7:30 a.m. to 5:30 p.m. on September 9 and 10, 2023. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Thirteenth Coast Guard District, § 100.1302, specifies the location of the regulated area for the Portland Dragon Boat Races which encompasses portions of the Willamette River in Portland, OR. During the enforcement periods, as reflected in § 100.1302, vessels may not transit the regulated areas without approval from the Patrol Commander or an Official Patrol Vessel. Vessels permitted to transit must operate at a no wake speed,

in a manner which will not endanger participants or other crafts in the event.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: August 21, 2023.

J.W. Noggle,

Captain, U.S. Coast Guard, Captain of the Port Columbia River.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AR25

Presumptive Service Connection for Respiratory Conditions Due to Exposure to Fine Particulate Matter

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rulemaking adopts as final, with changes, an interim final rule that amended the Department of Veterans Affairs (VA) adjudication regulations governing presumptive service connection based on presumed exposures to fine particulate matter. The amendment was necessary to provide health care, services, and benefits to Gulf War Veterans who were exposed to fine particulate matter associated with deployment to the Southwest Asia theater of operations, as well as Afghanistan, Syria, Djibouti, and Uzbekistan. The amendment eased the evidentiary burden of Gulf War Veterans who file claims with VA for asthma, rhinitis, and sinusitis, to include rhinosinusitis.

DATES:

Effective date: This rule is effective October 31, 2023.

Applicability date: The provisions of this final rule shall apply to all applications for benefits that are received by VA on or after the effective date of this final rule or that are pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit on the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT: Jane Allen, Policy Analyst; Robert Parks, Chief, Part 3 Regulations Staff (211), Compensation Service (21C), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue