

Employee means an “employee” as defined in 5 U.S.C. 2105 and an employee of the United States Postal Service or the Postal Regulatory Commission.

Political appointment means an appointment by the President without Senate confirmation (except those appointed under 5 CFR 213.3102(c)); an appointment to a position compensated under the Executive Schedule (5 U.S.C. 5312 through 5316); an appointment of a White House Fellow to be assigned as an assistant to a top-level Federal officer (5 CFR 213.3102(z)); a Schedule C appointment (5 CFR 213.3301, 213.3302); a noncareer, limited term, or limited emergency Senior Executive Service appointment (5 CFR part 317, subpart F); an appointee to serve in a political capacity under agency-specific authority; and a provisional political appointment.

§ 920.102 Positions covered by Fair Chance Act regulations.

(a) *Positions covered.* This part applies to all positions in the competitive service, excepted service, and Senior Executive Service in an agency.

(b) *Exempt positions.* For purposes of this part an exempt position is any position for which a hiring agency is required by statutory authority to make inquiries into an applicant’s criminal history prior to extending an offer of employment to the applicant.

Subpart B—Timing of Inquiries Regarding Criminal History

§ 920.201 Limitations on criminal history inquiries.

(a) *Applicability.* An employee of an agency may not request, in oral or written form (including through the Declaration for Federal Employment (Office of Personnel Management Optional Form 306) or any similar successor form, the USAJOBS internet website, or any other electronic means) that an applicant for an appointment to a position in the civil service disclose criminal history record information regarding the applicant before the appointing authority extends a conditional offer to the applicant. This includes the following points in the recruitment and hiring process:

(1) Initial application, through a job opportunity announcement on USAJOBS, or through any recruitment/public notification such as on the agency’s website/social media, etc.;

(2) After an agency receives an initial application through its back-end system, through shared service providers/recruiters/contractors, or orally or via

email and other forms of electronic notification; and

(3) Prior to, during, or after a job interview. This prohibition applies to agency personnel, including when they act through shared service providers, contractors (acting on behalf of the agency) involved in the agency’s recruitment and hiring process, or automated systems (specific to the agency or governmentwide).

(b) Exceptions for certain positions.

(1) The prohibition under paragraph (a) of this section shall not apply with respect to an applicant for an appointment to a position:

(i) Which is exempt in accordance with § 920.102(b);

(ii) That requires a determination of eligibility for access to classified information;

(iii) Has been designated as a sensitive position under the Position Designation System issued by OPM and the Office of Director of National Intelligence, which describes in greater detail agency requirements for designating positions that could bring about a material adverse effect on the national security;

(iv) Is a dual-status military technician position in which an applicant or employee is subject to a determination of eligibility for acceptance or retention in the armed forces, in connection with concurrent military membership; or

(v) Is a Federal law enforcement officer position meeting the definition in section 115(c) of title 18, U.S. Code.

(2) The prohibition under paragraph (a) of this section shall not apply with respect to an applicant for a political appointment.

(c) *Notification to applicants.* Each agency must publicize to applicants the prohibition described in paragraph (a) of this section in job opportunity announcements and on agency websites/portals for positions that do not require a posting on USAJOBS, such as excepted service positions, and in addition to information on where it has posted about its complaint intake process under as required by part 754 of this chapter.

§ 920.202 Violations.

(a) An agency employee may not request, orally or in writing, information about an applicant’s criminal history prior to making a conditional offer of employment to that applicant unless the position is exempted or excepted in accordance with § 920.201(b).

(b) A violation (or prohibited action) as defined in paragraph (a) of this section occurs when agency personnel, shared service providers, or contractors (acting on behalf of the agency) involved

in the agency’s recruitment and hiring process, either personally or through automated systems (specific to the agency or governmentwide), make oral or written requests prior to giving a conditional offer of employment—

(1) In a job opportunity announcement on USAJOBS or in any recruitment/public notification such as on the agency’s website or social media;

(2) In communications sent after an agency receives an initial application, through an agency’s talent acquisition system, shared service providers/recruiters/contractors, orally or in writing (including via email and other forms of electronic notification); or

(3) Prior to, during, or after a job interview or other applicant assessment.

(c) When a prohibited request, announcement, or communication is publicly posted or simultaneously distributed to multiple applicants, it constitutes a single violation.

(d) Any violation as defined in paragraph (a) of this section is subject to the complaint and penalty procedures in part 754 of this chapter.

[FR Doc. 2023–18242 Filed 8–31–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2019–D–4212]

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies, Revision 1; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies, Revision 1.” This revised guidance explains that FDA intends to extend for an additional year (from November 27, 2023, to November 27, 2024), the enforcement policies

described in the guidance entitled “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies,” published in the **Federal Register** on October 23, 2020 (the 2020 Compliance Policies). The 2020 Compliance Policies relate to provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA), requiring wholesale distributors to verify the product identifier prior to further distributing saleable returned product and requiring dispensers to verify the product identifier for suspect or illegitimate product in the dispenser’s possession or control.

DATES: The announcement of the guidance is published in the **Federal Register** on September 1, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-D-4212 for “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 23, 2020, FDA published the 2020 Compliance Policies. FDA is announcing the availability of a guidance for industry entitled “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies, Revision 1”, which extends the enforcement policies described in the 2020 Compliance Policies for an additional year, from November 27, 2023, until November 27, 2024. As described in this revised guidance, FDA does not intend to take enforcement action, prior to November 27, 2024, against wholesale distributors who do not verify the product identifier prior to further distributing saleable returned product, or against dispensers who do not verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser’s possession or control, as required under section 582 of the FD&C Act (21 U.S.C. 360eee-1), as added by the DSCSA (Title II of Pub. L. 113-54).

This revised guidance is being issued consistent with FDA’s good guidance practices regulations (21 CFR 10.115). FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). FDA made this determination because this guidance document provides information pertaining to statutory requirements that FDA had planned to begin enforcing as of November 27,

2023, for wholesale distributors to verify the product identifier prior to further distributing saleable returned product under section 582(c)(4)(D) of the FD&C Act and for dispensers to verify the product identifier, including the standardized numerical identifier, for suspect or illegitimate product in the dispenser's possession or control under section 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act. It is important that FDA provide this information before that date. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)).

Beginning November 27, 2019, wholesale distributors were required, under section 582(c)(4)(D) of the FD&C Act, to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product, prior to further distributing such returned product. In the **Federal Register** published September 24, 2019 (84 FR 50044), FDA issued a notice announcing the availability of the Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy guidance (2019 Compliance Policy), which described a 1-year enforcement policy with respect to this wholesale distributor requirement, until November 27, 2020. The Agency subsequently published the 2020 Compliance Policies, which extended the enforcement policy in the 2019 Compliance Policy with respect to this wholesale distributor requirement for 3 years, until November 27, 2023, and also included an enforcement policy until that same date with respect to the requirement for dispensers to verify the product identifier, including the standardized numerical identifier, for suspect or illegitimate product in the dispenser's possession or control.

Since the announcement of the 2020 Compliance Policies, FDA has received additional comments and feedback from wholesale distributors, as well as other trading partners and stakeholders, expressing concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors and the challenges stakeholders face with developing interoperable, electronic systems to enable such verification and achieve interoperability between networks. Specifically, comments received point out continuing challenges posed by the large volume of

saleable returned product, explaining that wholesale distributors still need more time to test verification systems using real-time volumes of saleable returned product with all trading partners involved, as opposed to using small-scale pilot test projects. Given all these concerns, FDA recognizes that some wholesale distributors may need additional time, beyond November 27, 2023, before they can begin verifying returned products prior to resale or other further distribution as required by section 582(c)(4)(D) of the FD&C Act in an efficient, secure, and timely manner. Additionally, section 582 of the FD&C Act requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement when engaging in transactions involving certain prescription drugs. Section 581(27)(E) of the FD&C Act (21 U.S.C. 360eee(27)(E)) requires that the transaction statement include a statement that the entity transferring ownership in a transaction had systems and processes in place to comply with verification requirements under section 582 of the FD&C Act. This revised guidance also explains that, prior to November 27, 2024, FDA does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D) of the FD&C Act. The guidance explains the scope of the compliance policy in further detail.

In addition to helping minimize possible disruptions in the distribution of certain prescription drugs in the United States, FDA believes that by extending the enforcement approach described in the 2020 Compliance Policies until November 27, 2024, wholesale distributors will be able to focus resources and efforts on the requirements for enhanced drug distribution security under section 582(g) of the FD&C Act (as described below). Thus, instead of developing separate processes or infrastructures solely for the saleable return verification requirement, wholesale distributors can incorporate the saleable return verification requirements into the enhanced verification required under section 582(g) of the FD&C Act.

Further, section 582 of the FD&C Act, as added by the DSCSA, also established the requirements that specify how dispensers must investigate suspect and illegitimate product. As part of the

investigation, section 582(d)(4)(A)(ii)(II) of the FD&C Act requires dispensers to verify the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than three, corresponds with the product identifier for such product in the dispenser's possession or control. Section 582(d)(4)(B)(iii) of the FD&C Act requires dispensers to verify product as described in section 582(d)(4)(A)(ii), which includes the section 582(d)(4)(A)(ii)(II) requirement, in response to a notification from FDA or a trading partner that the product is an illegitimate product.

In response to comments received from stakeholders regarding dispenser readiness to meet these requirements, and to minimize possible disruptions in the distribution of affected prescription drugs in the United States, this guidance also announces that FDA does not intend to take action before November 27, 2024, against dispensers who do not verify the product identifier of the statutorily designated proportion of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act, and that part of section 582(d)(4)(B)(iii) of the FD&C Act that requires dispensers to perform the same verification activities of section 582(d)(4)(A)(ii)(II) when responding to a notification of illegitimate product from FDA or another trading partner. FDA believes that the 1-year extension under this guidance of the applicable 2020 Compliance Policies will facilitate the ability of dispensers to ensure the systems and processes that are put into place to meet the enhanced drug distribution security requirements, which FDA will generally not enforce before November 27, 2024, will also fulfill the dispenser verification requirements under section 582(d)(4) of the FD&C Act.

In the "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies" (Enhanced Drug Distribution Security Compliance Policies) (88 FR 58498), FDA announced a 1-year enforcement policy with respect to the enhanced drug distribution security requirements set to take effect on November 27, 2023. FDA chose to adopt this enforcement policy until November 27, 2024, because FDA was aware that some stakeholders were facing challenges with implementing the section 582(g) requirements and needed additional time to comply with these requirements.

While FDA generally expects trading partners to have the systems and

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.

[FR Doc. 2023–18899 Filed 8–31–23; 8:45 am]

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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.

[FR Doc. 2023–18917 Filed 8–31–23; 8:45 am]

BILLING CODE 9110-04-P

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