provided, and an explanation of the device methodology. Additional information appropriate to the technology must be included such as design of primers and probes, rationale for the selected gene targets, specifications for amplicon size, and degree of nucleic acid sequence conservation.

(ii) For devices with assay calibrators, the design and composition of all primary, secondary, and subsequent quantitation standards used for calibration as well as their traceability to a standardized reference material that FDA has determined is appropriate (*e.g.,* a recognized consensus standard). In addition, analytical testing must be performed following the release of a new lot of the standard material that was used for device clearance or approval, or when there is a transition to a new calibration standard.

(iii) Documentation and characterization (*e.g.,* determination of the identity, supplier, purity, and stability) of all critical reagents (including nucleic acid sequences for primers and probes) and protocols for maintaining product integrity.

(iv) Risk analysis and management strategies demonstrating how risk control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on assay performance.

(v) Final release criteria to be used for manufactured assay lots with appropriate evidence that lots released at the extremes of the specification will meet the identified analytical and clinical performance characteristics as well as stability.

(vi) Stability studies for reagents must include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.

(vii) All stability protocols, including acceptance criteria.

(viii) Detailed documentation of analytical performance studies conducted as appropriate to the technology, specimen types tested, and intended use of the device, including limit of detection (LoD), linearity, precision, endogenous and exogenous interferences, cross-reactivity, carryover, matrix equivalency, sample and reagents stability, and as applicable, upper and lower limits of quantitation (ULoQ and LLoQ, respectively). Samples selected for use must be from subjects with clinically relevant circulating genotypes in the United States. Cross-reactivity studies must include samples from HBV nucleic acid negative subjects with other viral or non-viral causes of liver disease, including autoimmune hepatitis, alcoholic liver disease, chronic hepatitis C virus, primary biliary cirrhosis, and nonalcoholic steatohepatitis, when applicable. The effect of each identified nucleic-acid isolation and purification procedure on detection must be evaluated.

(ix) Analytical sensitivity of the assay that is the same or better than that of other cleared or approved assays.

(x) For devices with associated software or instrumentation, documentation must include a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, and hazard analysis and risk assessment activities, including an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(xi) Detailed documentation of performance from a clinical study with a design and number of clinical samples (appropriately statistically powered) that is appropriate for the intended use of the device as well as conducted in the appropriate settings by the intended users. The samples must include prospective (sequential) samples for each claimed specimen type and, as appropriate, additional characterized clinical samples. Samples must be sourced from geographically diverse areas.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18082 Filed 9–17–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1010

[Docket No. FDA–2018–N–3303]

Radiological Health Regulations; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is making technical amendments to its radiological health regulations to correct an error. On January 20, 2023, FDA published a final rule entitled ''Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products'' that inadvertently deleted certain existing regulatory text from the Code of Federal Regulations. This action corrects the error by restoring the inadvertently deleted regulatory text. This action is editorial in nature and is intended to ensure accuracy and clarity in FDA's regulations by restoring inadvertently deleted regulatory text.

DATES: This rule is effective September 18, 2025.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

On January 20, 2023, FDA published a final rule entitled ''Radiological Health Regulations: Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products'' (88 FR 3638, January 20, 2023). This rule amended § 1010.4(b) (21 CFR 1010.4(b)) to, among other things, permit manufacturers to submit applications for variances electronically and to remove the requirement for manufacturers to submit multiple paper copies of variance applications. FDA did not intend to make any other changes to § 1010.4(b). However, due to an error in FDA's amendatory instructions, FDA did not instruct the Office of the Federal Register to retain and renumber the prior content of § 1010.4(b)(1). As a result, the prior content of § 1010.4(b)(1)(i)–(xi), which listed the required elements of a variance application, was inadvertently deleted from the Code of Federal Regulations instead of retained and renumbered under § 1010.4(b)(2). This action corrects that error by restoring the inadvertently deleted regulatory text.

II. Description of the Technical Amendments

FDA is amending § 1010.4 by revising paragraph (b)(2) and adding paragraph

(b)(3) to restore the text that was inadvertently deleted from the Code of Federal Regulations. These amendments are editorial in nature and are intended to ensure accuracy and clarity in FDA's regulations.

III. Notice and Public Comment

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Under 5 U.S.C. 553(b)(B) of the APA, an agency may, for good cause, find (and incorporate the finding and a brief statement of reasons in the rules issued) that notice and public comment procedure on a rule is impracticable, unnecessary, or contrary to the public interest. FDA has determined that notice and public comment are unnecessary because these amendments only make technical changes to restore provisions that were never intended to be removed. Moreover, during the intervening period following the inadvertent deletion of the prior content of § 1010.4(b)(1)(i)–(xi), affected parties appear to have been operating under the assumption that the required elements of a variance application that were contained in the deleted provisions remained unchanged. For these reasons, FDA has determined that publishing a notice of proposed rulemaking and providing opportunity for public comments is unnecessary.

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because, as previously stated, FDA did not intend to delete the longstanding prior content of § 1010.4(b)(1), and affected parties appear to have been operating under the assumption that the required elements of a variance application that were contained in the deleted provisions remained unchanged during the intervening period. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1010 is amended as follows:

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

■ 1. The authority citation for part 1010 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

■ 2. In § 1010.4, revise paragraph (b)(2) and add paragraph (b)(3) to read as follows:

§ 1010.4 Variances.

* * * * *

(b) * * *

(2) The application for variance shall include the following information:

(i) A description of the product and its intended use.

(ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard.

(iv) A description of the advantages to be derived from such deviation.

(v) An explanation of how alternate or suitable means of radiation protection will be provided.

(vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.

(vii) In the case of prototype or experimental equipment, the proposed location of each unit.

(viii) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

(ix) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(x) [Reserved]

(xi) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in part 56 of this chapter, and is subject to the requirements for informed consent set forth in part 50 of this chapter, the investigation shall be conducted in compliance with such requirements.

(3) The application for amendment or extension of a variance shall include the following information:

(i) The variance number and expiration date.

(ii) The amendment or extension requested and basis for the amendment or extension.

(iii) A description of the effect of the amendment or extension on protection from radiation produced by the product.

(iv) An explanation of how alternate or suitable means of protection will be provided.

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Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18080 Filed 9–17–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1457]

Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places seven fentanyl-related substances, as identified in this final rule, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers in schedule I of the Controlled Substances Act. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these seven specific controlled substances will continue to apply as a result of this action.

DATES: Effective September 18, 2025.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this final rule, the Drug Enforcement Administration (DEA) permanently schedules the following seven controlled substances in schedule I of the Controlled Substances Act (CSA), including their isomers, esters, ethers, salts, and salts of isomers, esters, and