BETTI, TX	FIX	(Lat. 29°57′54.97″ N, long. 098°03′23.98″ W)
MARCS, TX	FIX	(Lat. 29°53′52.04″ N, long. 097°51′40.70″ W)
SEEDS, TX	WP	(Lat. 29°39′31.94″ N, long. 097°14′58.66″ W)
LDRET, TX	WP	(Lat. 29°39′44.93″ N, long. 096°19′00.96″ W)
KEEDS, TX	WP	(Lat. 29°21′59.49″ N, long. 095°36′48.98″ W)
Scholes, TX (VUH)	VOR/DME	(Lat. 29°16′09.60″ N, long. 094°52′03.81″ W)
Sabine Pass, TX (SBI)	VOR/DME	(Lat. 29°41′12.19″ N, long. 094°02′16.72″ W)

* * * * *

Issued in Washington, DC, on October 28, 2022.

Mark E. Gauch,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–23852 Filed 11–3–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2020–N–2297]

Microbiology Devices; Reclassification of Human Immunodeficiency Virus Viral Load Monitoring Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order to reclassify human immunodeficiency virus (HIV) viral load monitoring tests, postamendments class III devices with the product code MZF, into class II (special controls), subject to premarket notification. Through this final order, FDA is also adding a new device classification regulation along with special controls that are necessary to provide a reasonable assurance of safety and effectiveness for this device type. The final order reclassifies this device type from class III (premarket approval) to class II (special controls) and will reduce the regulatory burdens associated with these devices because manufacturers will no longer be required to submit a premarket approval application (PMA) for this device type but can instead submit a less burdensome premarket notification (510(k)) and receive clearance before marketing their device.

DATES: This order is effective December 5, 2022.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Review, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 72, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (general controls and special controls), and class III (general controls and premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until: (1) FDA reclassifies the device into class I or class II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the

safety and effectiveness of the device for its intended use.

In the **Federal Register** of November 24, 2021 (86 FR 66982), FDA published a proposed order to reclassify HIV viral load monitoring tests from class III to class II (special controls), subject to premarket notification. The comment period on the proposed order closed on January 24, 2022.

II. Comments on the Proposed Order

In response to the November 24, 2021, proposed order, FDA received three comments (two comments from public health organizations and one comment from a device manufacturer) by the close of the comment period, each containing one or more comments on one or more issues. We describe and respond to the comments in this section of the document. The order of response to the commenters is purely for organizational purposes and does not signify the comment's value or importance nor the order in which the comments were received.

(Comment 1) All three commenters expressed general support for the proposed reclassification and proposed special controls.

(Response 1) We acknowledge and appreciate the supportive comments. In this final order, we are reclassifying HIV viral load monitoring tests into class II and establishing the special controls published in the proposed order (86 FR 66982) without modifications except for minor editorial changes. See Section III, below, for a summary of the final order.

(Comment 2) One commenter requested that FDA provide more detail regarding the application in various analytical studies of the proposed requirement under § 866.3958(b)(2)(iii) (21 CFR 866.3958(b)(2)(iii)) that ''[s]amples selected for use in analytical studies or used to prepare samples for use in analytical studies must be from subjects with clinically relevant genotypes circulating in the United States.''

(Response 2) FDA does not agree that additional detail is necessary to describe the requirement under § 866.3958(b)(2)(iii). The requirement to use or prepare samples from subjects with clinically relevant genotypes circulating in the United States is intended to ensure that the device will detect HIV genotypes that are of clinical concern at the time the device is cleared. How this requirement should be implemented for a particular analytical study would depend on other details regarding study design, the specific device at issue, and the currently circulating genotypes in the United States. Therefore, it is not practical to describe how this requirement would apply for all future analytical studies of HIV viral load monitoring tests in this final order. If the developer of an HIV viral load monitoring test seeks feedback about the design of an analytical study specific to the developer's device, such feedback can be provided through the Q-submission program.[1]

(Comment 3) One commenter addressed proposed § 866.3958(b)(2)(v) and agreed with the requirement that ''[s]amples tested to demonstrate analytical specificity must include appropriate numbers and types of samples from patients with underlying illness and infection. . . .'' With respect to the requirement under proposed § 866.3958(b)(2)(v) that samples tested to demonstrate analytical specificity ''include appropriate numbers and types of samples . . . from patients with potential interfering substances[,]'' the commenter suggested that there be an option to test the effect of specific interfering substances ''in accordance to *[sic]* CLSI EP07—Interference Testing in Clinical Chemistry; Ed 3. Approved Guideline.'' The commenter added that, ''[i]n this case both HIV–1 positive and HIV–1 negative specimens would be spiked with each potentially interfering substance (endogenous and exogenous) and tested in the investigational device.''

(Response 3) We agree with the comment that in some circumstances, a combination of clinical and spiked samples is appropriate based on the study goals and design, as discussed in EP07. The special control provision at § 866.3958(b)(2)(v) does not preclude this possibility. FDA believes that studies conducted to meet the requirements under § 866.3958(b)(2)(v) should use clinical samples to the extent possible because spiked samples may not mimic natural samples from individuals. We encourage device developers to consult the study designs and recommendations in the FDA recognized voluntary consensus standard EP07, Interference Testing in Clinical Chemistry, 3rd Ed. (see *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=37749*).

(Comment 4) One commenter requested that FDA clarify the meaning of ''production lots'' in § 866.3958(b)(2)(iv), which requires that device verification and validation include a ''[m]ultisite reproducibility study that includes the testing of three independent production lots.'' Specifically, the commenter asked if ''these [could] be premarket lots, which are equivalent to what would be commercialized''.

(Response 4) FDA believes the language in § 866.3958(b)(2)(iv) is sufficiently clear on this issue. The phrase ''three independent production lots'' means three lots of the finished device, where the lots are produced independently of each other. While the three independent lots may be produced in a premarket validation run, the devices must be manufactured by a process equivalent to that for the devices that will be commercialized.

(Comment 5) Two commenters recommended harmonizing reclassification of HIV viral load monitoring tests with the proposed reclassification of HIV diagnostic and supplemental tests and indicated that doing so could encourage development of or reduce barriers to marketing devices intended for use in both monitoring and diagnosis. Another comment recommended that FDA align the special controls for HIV tests with the requirements for HCV nucleic acid (NAT) tests in the final reclassification order ''Microbiology Devices; Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, To Be Renamed Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests'' (Docket No. FDA–2020–N–1088; April 2, 2020; 86 FR 66169).

(Response 5) Where appropriate, the special controls for HIV viral load monitoring tests in § 866.3958 are aligned with the special controls for HIV NAT diagnostic and/or supplemental tests in 21 CFR 866.3957, which were established in a final order published May 16, 2022 (Microbiology Devices: Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests, 87 FR 29661). However, although a test may use the same technology for two different intended uses, *e.g.,* use of NAT tests as an aid in diagnosis of HIV infection and for viral load monitoring, the risks of a false negative result from a diagnostic test are not identical to and are potentially greater than the risks of a false negative result of a viral load test. For example, an individual living with HIV whose viral load is being monitored

[1] FDA has issued guidance for submitters on the Q-submission program. See ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff'' dated January 6, 2021, available at *https://www.fda.gov/media/114034/download.*

is under the care of a healthcare provider. In this instance, the risk of an incorrect result may be mitigated by clinical oversight. However, an individual undergoing diagnostic testing may have no signs or symptoms of infection, and one risk of an incorrect result is that they may be lost to care altogether. FDA is committed to working with manufacturers seeking clearance of a device for both intended uses using a least-burdensome approach.[2]

With respect to the comment regarding alignment of special controls for HIV tests with those finalized for nucleic acid-based HCV ribonucleic acid (RNA) tests, we note that the special controls necessary to provide reasonable assurance of safety and effectiveness of an in vitro diagnostic device are based on, among other things, the specific analyte measured, the disease or condition for which the particular device is intended to be used in diagnosis, and the conditions of use. This means that the special controls may vary between devices that measure different analytes (*e.g.,* HIV and HCV) or with different conditions of use (*e.g.,* point of care versus lab-based) because the risks associated with each device are different. FDA has determined that the special controls identified in the proposed order are, together with general controls, sufficient to provide reasonable assurance of safety and effectiveness for HIV viral load monitoring tests. Therefore, FDA is finalizing those special controls in this order without making changes to align them further with those for nucleic acid-based HCV RNA tests.

To the extent the comment addresses alignment of special controls for HIV diagnostic and supplemental tests with those for nucleic acid-based HCV RNA tests, the comment is outside of the scope of this final order. For a discussion of comments received on FDA's proposed special controls for HIV NAT diagnostic and supplemental tests and HIV serological diagnostic and supplemental tests, please refer to the final order, ''Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests'' (Docket No. FDA–2019–N–5192; May 16, 2022; 87 FR 29661).

[2] See ''The Least Burdensome Provisions: Concepts and Principles; Guidance for Industry and Food and Drug Administration Staff'' (February 5, 2019), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

III. Final Order

Based on the information discussed in the preamble to the proposed order (86 FR 66982), the comments received on the proposed order, and FDA's experience over the years with this device type, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of HIV viral load monitoring tests. FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published in the preamble to the proposed order.

FDA is issuing this final order to reclassify HIV viral load monitoring tests from class III into class II and to establish special controls that will be codified at § 866.3958.[3] In this final order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act which, together with general controls, provide a reasonable assurance of the safety and effectiveness of HIV viral load monitoring tests. FDA is reclassifying these devices and establishing special controls as published in the proposed order (86 FR 66982) with minor editorial changes for clarity in § 866.3958(a), (b)(1)(iii), and (b)(2)(vii).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of HIV viral load monitoring tests. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market HIV viral load monitoring tests must submit and obtain clearance of a premarket notification and demonstrate compliance with the special controls in this final order, prior to marketing the device.

The devices that are the subject of this reclassification are assigned the generic name ''human immunodeficiency virus (HIV) viral load monitoring tests''. HIV viral load monitoring tests are identified as in vitro diagnostic prescription devices for the quantitation of the amount of HIV RNA in human body fluids. HIV viral load monitoring tests are intended for use in the clinical management of individuals living with HIV and are for professional use only. These devices are not intended for use as an aid in diagnosis or for screening donors of blood or blood products or human cells, tissues, or cellular and tissue-based products (HCT/Ps).

Under this final order, the HIV viral load monitoring tests are identified as prescription use only devices. As such, these prescription devices must satisfy prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)). A premarket notification submission for these devices will be required in the circumstances described in 21 CFR 807.81.

[3] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. This change was made in accordance with the Office of Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the *Document Drafting Handbook.*

IV. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. In accordance with section 513(f)(3) of the FD&C Act, we are codifying in this final order the classification of HIV viral load monitoring tests in the new § 866.3958, under which these devices are reclassified from class III to class II.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

This final order refers to previously approved FDA collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the

collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 866.3958 to subpart D to read as follows:

§ 866.3958 Human immunodeficiency virus (HIV) viral load monitoring test.

(a) *Identification.* A human immunodeficiency virus (HIV) viral load monitoring test is an in vitro diagnostic prescription device for the quantitation of the amount of HIV ribonucleic acid (RNA) in human body fluids. The test is intended for use in the clinical management of individuals living with HIV and is for professional use only. The test results are intended to be interpreted in conjunction with other relevant clinical and laboratory findings. The test is not intended to be used as an aid in diagnosis or for screening donors of blood or blood products or human cells, tissues, or cellular and tissue-based products (HCT/Ps).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The labeling must include:

(i) An intended use that states that the device is not intended for use as an aid in diagnosis or for use in screening donors of blood or blood products, or HCT/Ps.

(ii) A detailed explanation of the principles of operation and procedures used for assay performance.

(iii) A detailed explanation of the interpretation of results and that recommended actions should be based on current clinical guidelines.

(iv) Limitations, which must be updated to reflect current clinical practice and patient management. The limitations must include, but are not limited to, statements that indicate:

(A) The matrices and sample types with which the device has been cleared and that use of this test with specimen types other than those specifically cleared for this device may cause inaccurate test results.

(B) Mutations in highly conserved regions may affect binding of primers and/or probes resulting in the under-quantitation of virus or failure to detect the presence of virus.

(C) All test results should be interpreted in conjunction with the individual's clinical presentation, history, and other laboratory results.

(2) Device verification and validation must include:

(i) Detailed device description, including the device components, ancillary reagents required but not provided, and an explanation of the device methodology. Additional information appropriate to the technology must be included, such as detailed information on the design of primers and probes.

(ii) For devices with assay calibrators, the design and nature of all primary, secondary, and subsequent quantitation standards used for calibration as well as their traceability to a reference material. 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 when there is a transition to a new calibration standard.

(iii) Detailed documentation of analytical performance studies conducted as appropriate to the technology, specimen types tested, and intended use of the device, including but not limited to, limit of blank, limit of detection, limit of quantitation, cutoff determination, precision, linearity, endogenous and exogenous interferences, cross-reactivity, carry-over, quality control, matrix equivalency, sample and reagent stability. Samples selected for use in analytical studies or used to prepare samples for use in analytical studies must be from subjects with clinically relevant genotypes circulating in the United States.

(iv) Multisite reproducibility study that includes the testing of three independent production lots.

(v) Analytical sensitivity of the device must demonstrate acceptable performance at current clinically relevant medical decision points. Samples tested to demonstrate analytical sensitivity must include appropriate numbers and types of samples, including real clinical samples near the lower limit of quantitation and any clinically relevant medical decision points. Analytical specificity of the device must demonstrate acceptable performance. Samples tested to demonstrate analytical specificity must include appropriate numbers and types of samples from patients with different underlying illnesses and infection and from patients with potential interfering substances.

(vi) Detailed documentation of performance from a multisite clinical study or a multisite analytical method comparison study.

(A) For devices evaluated in a multisite clinical study, the study must use specimens from individuals living with HIV being monitored for changes in viral load, and the test results must be compared to the clinical status of the patients.

(B) For tests evaluated in a multisite analytical method comparison study, the performance of the test must be compared to an FDA-cleared or approved comparator. The multisite method comparison study must include appropriate numbers and types of samples with analyte concentrations across the measuring range of the assay, representing clinically relevant genotypes. The multisite method comparison study design, including number of samples tested, must be sufficient to meet the following criteria:

(*1*) Agreement between the two tests across the measuring range of the assays must have an r2 of greater than or equal to 0.95.

(*2*) The bias between the test and comparator assay, as determined by difference plots, must be less than or equal to 0.5 log copies/mL.

(vii) Detailed documentation of a single-site analytical method comparison study between the device and an FDA-cleared or approved comparator if a multisite clinical study is performed under paragraph(b)(2)(vi) of this section. The analytical method comparison study must use appropriate numbers and types of samples with analyte concentrations across the measuring range of the assay, representing clinically relevant genotypes. The results must meet the criteria in paragraphs (b)(2)(vi)(B)(*1*) and (*2*) of this section.

(viii) Strategies for detection of new strains, types, subtypes, genotypes, and genetic mutations as they emerge.

(ix) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on test performance.

(x) Final release criteria to be used for manufactured device lots with an appropriate justification that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance

characteristics as well as the stability claims.

(xi) All stability protocols, including acceptance criteria.

(xii) Appropriate and acceptable procedure(s) for addressing complaints and other device information that determines when to submit a medical device report.

(xiii) Premarket notification submissions must include the information contained in paragraphs (b)(2)(i) through (xii) of this section.

Dated: October 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23868 Filed 11–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

[Docket No. USPC–2020–04]

RIN 1104–AA09

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is modifying a rule that permits it to reopen a case and rescind a parole date when the prisoner has committed a violation of institutional rules. This modification will permit findings by a Residential Reentry Center's Disciplinary Committee, as well as findings by the Disciplinary Hearing Officer, as conclusive evidence of misconduct for the United States Parole Commission to rescind an established parole date.

DATES: This regulation is effective November 4, 2022.

FOR FURTHER INFORMATION CONTACT: Helen H. Krapels, General Counsel, U.S. Parole Commission, 90 K Street NE, Third Floor, Washington, DC 20530, telephone (202) 346–7000. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: In 2021, the United States Parole Commission issued an interim rule revising 28 CFR 2.34(a) (86 FR 51271, September 15, 2021). The comment period expired on November 15, 2021, and the Parole Commission did not receive any comments on the change. On October 13, 2022, the Parole Commission voted to

After the U.S. Parole Commission has granted a prisoner a parole effective date, but before the prisoner has signed the parole certificate, if the prisoner violates the rules of the institution, the Parole Commission may reopen the case and schedule a rescission hearing. 28 CFR 2.34(a). At that hearing, the Parole Commission may consider the report of the Bureau of Prisons (''BOP'') Disciplinary Hearing Officer (''DHO'') following a disciplinary hearing, that a prisoner has violated disciplinary rules as ''conclusive evidence of institutional misconduct,'' and does not need to conduct a full hearing to consider witnesses and evidence. 28 CFR 2.34(c). The disciplinary hearing conducted by the DHO complies with the procedural due process requirements established by the Supreme Court in *Wolff* v. *McDonnell, i.e.,* the prisoner has notice of the alleged violations at least 24 hours in advance of hearing, a statement of factfinding, the right to call witnesses and present documentary evidence. Thus, the Parole Commission may rely on the findings and conclusions of the DHO to take action in response to the information.

For prisoners who are housed at a Residential Reentry Center (''RRC'') prior to their release and violate the rules, the in-person disciplinary hearing is conducted before the RRC's Center Disciplinary Committee (''CDC''). Under the BOP's Program Statement 7300.09, the CDC then refers its findings to the DHO for review, final action, and sanctions. Every court which has examined the procedures established by Program Statement 7300.09 has held that hearing procedures used by the CDC satisfy the procedural due process requirements established by the Supreme Court in *Wolff* v. *McDonnell.*

This rule permits the U.S. Parole Commission to rely on the CDC's findings to promote the smooth transition to the community or to return a prisoner who has demonstrated that he or she is not ready to be released to the community without requiring a second hearing by the DHO or a fully contested disciplinary hearing conducted by the U.S. Parole Commission.

The Parole Commission has added a phrase to clarify that parole may also be rescinded without a hearing for DC Code prisoners for up to 120 days. The interim rule only referenced the 90-day rescission of parole that pertains to US Code prisoners and the rule will apply correspondingly to US Code prisoner and DC Code prisoners under the Parole Commission's jurisdiction. The Parole Commission is publishing the revised rule at § 2.34(a) as a final rule without seeking public comment because this does not create a substantive change to parole decision-making.

Executive Orders 12866 and 13563

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulation Planning and Review,'' section 1(b), Principles of Regulation, and in accordance with Executive Order 13565, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation. The Commission has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications requiring a federalism assessment.

Regulatory Flexibility Act

This rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local, or tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

This rule is not a ''major rule'' as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 Subtitle E—Congressional Review Act, now codified at 5 U.S.C. 804(2). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability