10. For calendar year 2022, the asset threshold was $2,336,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2021 had total assets of less than $2,336,000,000 on December 31, 2021, satisfied this criterion for purposes of any loan consummated in 2022 and for purposes of any loan consummated in 2023 for which the application was received before April 1, 2023.

11. For calendar year 2023, the asset threshold was $2,537,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2022 had total assets of less than $2,537,000,000 on December 31, 2022, satisfied this criterion for purposes of any loan consummated in 2023 and for purposes of any loan consummated in 2024 for which the application was received before April 1, 2024.

iv. The creditor and its affiliates do not maintain an escrow account for any mortgage transaction being serviced by the creditor or its affiliate at the time the transaction is consummated, except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Thus, the exemption applies, provided the other conditions of § 1026.35(b)(2)(iii) (or, if applicable, the conditions for the exemption in § 1026.35(b)(2)(vi)) are satisfied, even if the creditor previously maintained escrow accounts for mortgage loans, provided it no longer maintains any such accounts except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Once a creditor or its affiliate begins escrowing for loans currently serviced other than those addressed in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), however, the creditor and its affiliate become ineligible for the exemption in § 1026.35(b)(2)(iii) and (vi) on higher-priced mortgage loans they make while such escrowing continues. Thus, as long as a creditor (or its affiliate) services and maintains escrow accounts for any mortgage loans, other than as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), the creditor will not be eligible for the exemption for any higher-priced mortgage loan it may make. For purposes of § 1026.35(b)(2)(iii) and (vi), a creditor or its affiliate ''maintains'' an escrow account only if it services a mortgage loan for which an escrow account has been established at least through the due date of the second periodic payment under the terms of the legal obligation.

* * * * *

Paragraph 35(b)(2)(vi)(A).

1. The asset threshold in § 1026.35(b)(2)(vi)(A) will adjust automatically each year, based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. Unlike the asset threshold in § 1026.35(b)(2)(iii) and the other thresholds in § 1026.35(b)(2)(vi), affiliates are not considered in calculating compliance with this threshold. The Bureau will publish notice of the asset threshold each year by amending this comment. For calendar year 2024, the asset threshold is $11,835,000,000. A creditor that is an insured depository institution or insured credit union that during calendar year 2023 had assets of $11,835,000,000 or less on December 31, 2023, satisfies this criterion for purposes of any loan consummated in 2024 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2025 for which the application was received before April 1, 2025. For historical purposes:

1. For calendar year 2021, the asset threshold was $10,000,000,000. Creditors that had total assets of 10,000,000,000 or less on December 31, 2020, satisfied this criterion for purposes of any loan consummated in 2021 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2022 for which the application was received before April 1, 2022.

2. For calendar year 2022, the asset threshold was $10,473,000,000. Creditors that had total assets of $10,473,000,000 or less on December 31, 2021, satisfied this criterion for purposes of any loan consummated in 2022 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2023 for which the application was received before April 1, 2023.

3. For calendar year 2023, the asset threshold is $11,374,000,000. A creditor that is an insured depository institution or insured credit union that during calendar year 2022 had assets of $11,374,000,000 or less on December 31, 2022, satisfied this criterion for purposes of any loan consummated in 2023 and for purposes of any loan secured by a first lien on a principal dwelling of a consumer consummated in 2024 for which the application was received before April 1, 2024.

* * * * *

Brian Shearer,

Senior Advisor, Consumer Financial Protection Bureau.

[FR Doc. 2023–28076 Filed 12–20–23; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2023–2220; Airspace Docket No. 23–AWP–59]

RIN 2120–AA66

Amendment of Restricted Area R–2512 Holtville, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction; withdrawal.

SUMMARY: This action withdraws the final rule correction published in the **Federal Register** on December 6, 2023. That action incorrectly stated that the action would be incorporated by reference. The FAA has determined that withdrawal of the final rule correction is warranted since the action is not incorporated by reference.

DATES: As of date 0901 UTC, December 21, 2023, the final rule correction published December 6, 2023 (88 FR 84695), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** for Docket No. FAA–2023–2220 (88 FR 78636, November 16, 2023) that amended restricted area R–2512 in the vicinity of Holtville, CA. The section of 14 CFR part 73 to be amended by the final rule was inadvertently stated as § 73.22. The correct section of 14 CFR part 73 to be amended is § 73.25.

Subsequently, the FAA published a final rule correction in the **Federal Register** for Docket No. FAA–2023–2220 (88 FR 84695, December 6, 2023) that amended restricted area R–2512 in the vicinity of Holtville, CA, correcting the section of 14 CFR part 73 to be amended. That action incorrectly stated

that the action is incorporated by reference under 1 CFR part 51. As a result, the final rule correction is being withdrawn.

Lists of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Withdrawal

■ The FAA determined that the final rule correction published in the **Federal Register** on December 6, 2023 (88 FR 84695) contains incorrect references. Therefore, the FAA withdraws that final rule correction.

Issued in Washington, DC, on December 15, 2023.

Brian Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–28032 Filed 12–20–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 312, and 812

[Docket No. FDA–2018–N–2727]

RIN 0910–AH52

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The final rule permits an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

DATES: This rule is effective January 22, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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.

FOR FURTHER INFORMATION CONTACT: Lauren Milner, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5514, *lauren.milner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This final rule implements the statutory changes made to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Cures Act to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The rule will permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations.

B. Summary of the Major Provisions of the Final Rule

The final rule amends FDA's regulations to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that does not include or that alters certain informed consent elements, or to waive the requirement to obtain informed consent, for certain minimal risk clinical investigations. For an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the rule requires an IRB to find and document five criteria that are consistent with the revised rule entitled ''Federal Policy for the Protection of Human Subjects'' (the revised Common Rule (January 19, 2017)). FDA believes the amendment provides appropriate safeguards to protect the rights, safety, and welfare of the human subjects participating in such clinical investigations. We are also making conforming amendments to FDA's regulations.

C. Legal Authority

Sections 505(i)(4) and 520(g)(3) of the FD&C Act, as amended by the Cures Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act, serve as FDA's principal legal authority for this rule. In addition, the Cures Act directs the Secretary of the Department of Health and Human Services (HHS) to ''harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations,'' to the extent practicable and consistent with other statutory provisions.

D. Costs and Benefits

This rule will help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered.

We expect costs in the form of affected IRBs, as well as investigators and sponsors of clinical investigations, reading and learning the rule. We also expect costs in the form of drafting new