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CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1022

[Docket No. CFPB–2024–0023]

RIN 3170–AA54

Prohibition on Creditors and Consumer Reporting Agencies Concerning Medical Information (Regulation V)

Correction

In rule document 2024–30824, appearing on pages 3276–3374 in the issue of Tuesday, January 14, 2025, make the following correction:

On page 3276, in the first column, in the **DATES** section, ''March 17, 2024'' should read ''March 17, 2025''.

[FR Doc. C1–2024–30824 Filed 1–24–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2025, from the President, entitled ''Regulatory Freeze Pending Review,'' the effective date of the final rule, entitled ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use,'' (ACNU) is delayed until March 21, 2025.

DATES: The effective date for the final rule published December 26, 2024, (89 FR 105288), is delayed until March 21, 2025.

FOR FURTHER INFORMATION CONTACT: Myla Dellupac, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002, 301–837–7461.

SUPPLEMENTARY INFORMATION:

I. Electronic Access and Filing

A copy of the notice of proposed rulemaking (87 FR 38313, June 28, 2022), all comments received, the final rule (89 FR 105288, December 26, 2024), and all background material may be viewed online at *http://www.regulations.gov* using the docket number listed above. A copy of this document will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *http://www.ofr.gov* and the Government Publishing Office's website at *http://www.gpo.gov.*

II. Background

FDA published a final rule, titled ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use,'' in the **Federal Register** on December 26, 2024 (89 FR 105288). That rule was published with an effective date of January 27, 2025. On January 20, 2025, the President issued a memorandum titled, ''Regulatory Freeze Pending Review.'' With respect to rules that have been published in the **Federal Register**, but have not taken effect, the memorandum orders agencies consider postponing the rules' effective dates for 60 days from the date of the memorandum (*i.e.,* until March 21, 2025) for the purpose of reviewing any questions of fact, law, and policy the rules may raise.

In accordance with this direction, FDA has decided to delay the effective date of the final rule, ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use'' (89 FR 105288), until March 21, 2025. The final rule establishes requirements for a nonprescription drug product with an ACNU, including application, labeling, and postmarketing reporting requirements. In addition to applicable existing application requirements, the final rule establishes the specific requirements for a new drug application (NDA) or abbreviated new drug application (ANDA) for a nonprescription drug product with an ACNU. In circumstances where a prescription drug product is already approved, the rule requires an applicant to submit a separate application for the approval of a nonprescription drug product with an ACNU, rather than a supplement to the existing application for the approved prescription drug product. The final rule establishes specific labeling requirements, including the content and format of specific labeling statements. Additionally, the rule requires that an applicant submit a postmarketing report of an ACNU failure. The final rule clarifies that an ACNU constitutes a meaningful difference between a prescription drug product and a nonprescription drug product that makes the nonprescription drug product safe and effective for use without the supervision of a practitioner licensed by law to administer such drug; therefore, a prescription drug product and a nonprescription drug product with an ACNU with the same active ingredient may be simultaneously marketed even if they do not have meaningful differences other than the ACNU, such as different indications or strengths. The final rule specifies that FDA will refuse to approve an application for a nonprescription drug product with an ACNU if the application fails to meet applicable requirements. The final rule exempts a nonprescription drug product with an ACNU from the requirement to be labeled with adequate directions for use, provided that certain labeling conditions are met and the ACNU is implemented by the applicant as approved by FDA. Finally, the final rule explains certain circumstances in which a nonprescription drug product with an ACNU would be misbranded.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, FDA's implementation of this action without opportunity for public comment, effective immediately, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public