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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]

BILLING CODE 0099–10–P

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

comment is impracticable, unnecessary, and contrary to the public interest. The temporary delay in the effective date until March 21, 2025, is necessary to give Agency officials the opportunity for further review and consideration of the new regulation, consistent with the memorandum described previously. Given the imminence of the effective date and the brief length of the extension of the effective date, seeking prior public comment on this temporary delay would have been impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of regulations.[1] FDA also believes that affected entities need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation process accordingly.

Dorothy A. Fink,

Acting Secretary.

[FR Doc. 2025–01840 Filed 1–24–25; 8:45 am]

BILLING CODE 4164–01–P

POSTAL SERVICE

39 CFR Parts 111 and 211

New Mailing Standards for Hazardous Materials Outer Packaging and Nonregulated Toxic Materials

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52 or Publication 52) by adding new section 131 to require specific outer packaging when mailing most hazardous materials (HAZMAT) or dangerous goods (DG), to remove quantity restrictions for nonregulated toxic materials, and to remove the telephone number requirement from the lithium battery mark.

DATES: Effective January 27, 2025. Applicable beginning January 19, 2025.

FOR FURTHER INFORMATION CONTACT: Dale Kennedy, (202) 268–6592, or Jennifer Cox, (202) 268–2108.

SUPPLEMENTARY INFORMATION: The Postal Service amends Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52 or Publication 52), with the provisions set forth herein. While not codified in title 39 of the Code of Federal Regulations (CFR), Publication 52 is a regulation of the Postal Service, and changes to it may be published in the **Federal Register**. 39 CFR 211.2(a)(2). Moreover, Publication 52 is incorporated by reference into *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) section 601.8.1, which is incorporated by reference, in turn, into the Code of Federal Regulations. 39 CFR 111.1 and 111.3. Publication 52 is publicly available, in a read-only format, via the Postal Explorer® website at *https://pe.usps.com.* In addition, links to Postal Explorer are provided on the landing page of *USPS.com,* the Postal Service's primary customer-facing website, and on *Postal Pro,* an online informational source available to postal customers.

Summary of New Measures

The Postal Service is the sole regulatory authority for the mail but aligns with regulations within 49 CFR in some instances. Per the regulations in 49 CFR 171.1(d)(7) the Postal Service is not subject to the regulations in the Hazardous Materials Regulations (HMR). Due to the increase of eCommerce shipping over the last several years, HAZMAT/Dangerous Goods (DG) incidents have increased significantly. Historic postal data from 2020 through 2022, showed a significant increase in HAZMAT/DG incidents, which prompted the Postal Service to implement new policies requiring mailers to present HAZMAT/DG separately from non-HAZMAT/DG and to include HAZMAT Service Type Codes (STC) and Extra Service Codes (ESC) when packages contain HAZMAT/DG. These requirements, at least in part, resulted in a 20% reduction of overall HAZMAT/DG incidents in 2023.

Except as otherwise specified below, the Postal Service will require mailers shipping HAZMAT or DG to utilize rigid outer packaging that meets a minimum edge crush test requirement of at least 32 or 200 lbs. burst test strength for packages weighing 20 pounds or less and at least 44 edge crush test or 275 lbs. burst test strength for packages weighing more than 20 pounds. By implementing these requirements, the capability of packages to withstand normal processing and handling from induction to delivery point will be increased, reducing the overall potential for HAZMAT or DG incidents.

Previously, the uses of padded and poly bags as outer packaging were permitted only when the mailpiece contained button cell batteries installed in the equipment/device they operate. This change will now allow mailers to use padded or poly bags as outer packaging for shipments containing lithium batteries installed in the new or manufacturer refurbished equipment/device they operate when placed within in a secondary container (*i.e.,* the manufacturer's box) that can withstand a 1.2-meter drop test, and only if they do not display and are not required to display HAZMAT text, marks or labels as provided in sections 349.221a6, 622.51f, and 622.52g of Publication 52.

The Postal Service will remove quantity restrictions for nonregulated liquid and solid toxic materials, for products such as pesticides, insecticides, and herbicides in section 346.232 of Publication 52, but any such items must be contained within outer packaging meeting the requirements of section 131 of Publication 52.

Lastly, the Postal Service will align with Pipeline and Hazardous Materials Safety Administration's (PHMSA) decision to remove the telephone number requirement from the lithium battery mark.[1] The Postal Service encourages mailers to switch to a mark that does not include a telephone number as soon as possible and be fully compliant by January 1, 2027.

This new rule reduces complexity and provides consistency for all customers. Therefore, the Postal Service believes this rule will provide a continued reduction in incidents and enhance the safety of our employees, our networks, and our transportation partners.

Response to Comments

In response to the proposed rule (88 FR 86868, December 15, 2023), the Postal Service received six formal responses to the proposed changes.

The comments received are as follows:

Comment: One commenter requested a 60-day extension to the public comment period.

Response: The Postal Service was unable to grant this request.

Comment: One commenter indicated they didn't believe outer packaging requirements should be based on the weight of hazardous materials, but instead on the total package weight and provided alternate language for new section 131.

Response: The Postal Service agrees with the alternate language and has incorporated it within new section 131.

Comment: One commenter indicated that the last sentence of proposed section 131 was very obtuse and may be misconstrued that it is applicable to

[1] In the event that this rule does not publish on or before January 27, 2025, good cause similarly exists to stay the effectiveness of the rule published December 26, 2024, and revise its effective date until March 21, 2025.

[1] *See* Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Hazardous Materials: Harmonization With International Standards, 89 FR 25434, 25490 (Apr. 10, 2024).