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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) was delayed until March 21, 2025. Additional time is needed for review; therefore, the delay is extended for an additional 60 days.

DATES: As of March 21, 2025, the effective date for the final rule published December 26, 2024, (89 FR 105288), is further delayed to a new effective date of May 27, 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 delayed the effective date of the final rule, ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use'' (89 FR 105288), until March 21, 2025. Given that more time is needed to review the rule, FDA is delaying the effective date an additional 60 days. 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 May 27, 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.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–04978 Filed 3–21–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 410

RIN 0970–AD16

Unaccompanied Children Program Foundational Rule; Update To Accord With Statutory Requirements

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period (IFR).

SUMMARY: ORR is amending a regulation so that it comports with the express language of the governing legislation. That regulation relates to key aspects of the placement, care, and services provided to unaccompanied alien children (UACs) referred to ORR, pursuant to ORR's responsibilities for coordinating and implementing the care and placement of UACs who are in Federal custody by reason of their immigration status under the Homeland Security Act of 2002 (HSA) and the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA).

DATES: This IFR is effective March 25, 2025. Comments on this IFR must be received on or before May 27, 2025.

ADDRESSES: You may send comments, identified by docket number ACF–2025–0003 and/or RIN 0970–AD16, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: UCPolicy-RegulatoryAffairs@acf.hhs.gov.* Include [docket number and/or RIN] in the subject line of the message.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' section of this document.

FOR FURTHER INFORMATION CONTACT: Toby Biswas, Director of Policy, Division of Unaccompanied Children Policy, Unaccompanied Children Bureau, Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services, Washington, DC, (202) 205–4440 or *UCPolicy-RegulatoryAffairs@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This interim final rule (IFR) removes a specific provision of the Code of Federal Regulations introduced by the April 30, 2024 ''Unaccompanied Children Program Foundational Rule'' (Foundational Rule) at 45 CFR 410.1201(b). This provision precludes ORR from ''shar[ing] any immigration status information relating to potential sponsors with any law enforcement or immigration enforcement related entity at any time.'' The regulatory provision conflicts with a federal statute, which provides, in part, as follows:

Notwithstanding any other provision of Federal, State, or local law, a Federal, State, or local government entity or official may not prohibit, or in any way restrict, any government entity or official from sending to, or receiving from, the Immigration and Naturalization Service information regarding the citizenship or immigration status, lawful or unlawful, of any individual.

8 U.S.C. 1373(a). Inasmuch as the regulation directly conflicts with federal law, it is ''not in accordance with law,'' 5 U.S.C. 706(2)(A), and is thus subject to invalidation. Accordingly, the information-sharing provision of the Foundational Rule must be removed.

II. Background and Scope of Regulatory Action

On April 30, 2024, ORR published the ''Unaccompanied Children Program Foundational Rule,'' which establishes regulations relating to key aspects of the placement, care, and services provided to unaccompanied alien children referred to the Office of Refugee Resettlement (ORR), pursuant to ORR's responsibilities for coordinating and implementing the care and placement of unaccompanied alien children who are in Federal custody by reason of their immigration status under the Homeland Security Act of 2002 (HSA) and the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA). Consistent with its statutory responsibilities, ORR must, among other things, conduct safety and suitability assessments of potential sponsors for the child. *See generally* 8 U.S.C. 1232(c)(3). As explained in the preamble to the Foundational Rule, in the process of vetting potential sponsors for unaccompanied alien children, the potential sponsor's immigration status is one factor that bears on the potential sponsor's suitability to care for the child. *See* 89 FR at 34442 (''To the extent ORR does collect information on the immigration status of a potential sponsor, it would be only for the purposes of evaluating the potential sponsor's ability to provide care for the child.''). And so ORR may collect information on the potential sponsor's immigration status, independent of a law enforcement or immigration enforcement purpose. *Id.*

In the Foundational Rule, ORR included a provision stating: ''ORR shall not disqualify potential sponsors based solely on their immigration status and shall not collect information on immigration status of potential sponsors for law enforcement or immigration enforcement related purposes. ORR shall not share any immigration status information relating to potential sponsors with any law enforcement or immigration enforcement related entity at any time.'' 45 CFR 410.1201(b). But this provision contravenes a federal statute: it contravenes existing statutory limitations on ORR's authority described at 8 U.S.C. 1373. And so, it must be excised from the Foundational Rule.

ORR's authority is limited by 8 U.S.C. 1373(a) and (b). Subsection (a) states: ''Notwithstanding any other provision of Federal, State, or local law, a Federal, State, or local government entity or official may not prohibit, or in any way restrict, any government entity or official from sending to, or receiving from, the Immigration and Naturalization Service information regarding the citizenship or immigration status, lawful or unlawful, of any individual.'' Subsection (b) states: ''Notwithstanding any other provision of Federal, State, or local law, no person or agency may prohibit, or in any way restrict, a Federal, State, or local government entity from doing any of the following with respect to information regarding the immigration status, lawful or unlawful, of any individual: (1) Sending such information to, or requesting or receiving such information

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