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FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), we are giving notice that we have filed a color additive petition (CAP 4C0328), submitted by Exponent, Inc., on behalf of Sensient Colors, LLC., 1150 Connecticut Ave. NW, Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in § 73.69 (21 CFR 73.69) *Listing of Color Additives Exempt from Certification: Butterfly pea flower extract* to expand the safe use of butterfly pea flower extract to include ready-to-eat cereals, crackers and snack mixes, and chips at levels consistent with good manufacturing practice.

The petitioner claims that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner states that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: February 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-1043]

RIN 1117-AB82

Conforming Amendment Regarding the Veterinary Medicine Mobility Act of 2014

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: The Veterinary Medicine Mobility Act of 2014 (VMMA), which became law on August 1, 2014, amended the Controlled Substances Act to address separate registration requirements for veterinarians. The VMMA allows a veterinarian to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the veterinarian's registered principal place of business or professional practice without obtaining a separate registration, subject to certain limitations. The Drug Enforcement Administration is amending its regulations to codify the VMMA. This rule merely conforms DEA regulations to statutory amendments of the Controlled Substances Act that have already taken effect and makes no substantive change to existing legal requirements.

DATES: This final rule is effective on February 8, 2024.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, as amended.¹ The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research,

and industrial needs of the United States. DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to 1399.

On August 1, 2014, the President signed the Veterinary Medicine Mobility Act of 2014 (VMMA) into law as Public Law 113-143.² The VMMA amended section 302(e) of the CSA to address separate registration requirements for veterinarians. Specifically, the VMMA redesignated 21 U.S.C. 822(e) as 21 U.S.C. 822(e)(1) and added a new paragraph, 21 U.S.C. 822(e)(2). The newly added 21 U.S.C. 822(e)(2) provides that ". . . a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice." In this final rule, DEA is amending its regulations to conform to the change to the CSA made by the VMMA.

Regulatory Analysis

Administrative Procedure Act

Under the Administrative Procedure Act (APA),³ agencies generally offer interested parties the opportunity to comment on proposed regulations before they become effective. However, an agency may find good cause to exempt a rule from certain provisions of the APA, including those requiring the publication of a prior notice of proposed rulemaking and the opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds there is good cause within the meaning of the APA to issue this amendment as a final rule without opportunity for public comment and with an immediate effective date because such comment is unnecessary.

This final rule amends DEA regulations simply to incorporate the provisions of the VMMA. The legal requirements articulated in this final rule are already in effect by virtue of the VMMA. This rule merely incorporates the statutory provision into DEA regulations.

DEA is publishing this as a final rule because notice of proposed rulemaking and solicitation of public comment is

² Public Law 113-143, 128 Stat. 1750 (2014).

³ 5 U.S.C. 553.

¹ 21 U.S.C. 801-971.

unnecessary.⁴ Because the statutory change at issue has been in effect since August 1, 2014, DEA finds good cause exists to make this rule effective immediately upon publication.⁵ Therefore, DEA is issuing this amendment as a final rule, effective upon publication in the **Federal Register**.

Executive Orders 12866, 13563, and 14094 (Regulatory Review)

DEA has determined that this rulemaking is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review. Accordingly, this final rule has not been submitted to the Office of Management and Budget (“OMB”) for review. This final rule has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation; Executive Order 13563, “Improving Regulation and Regulatory Review,” section 1(b), General Principles of Regulation; and Executive Order 14094, “Modernizing Regulatory Review.”

As stated above, this final rule amends DEA regulations only to the extent necessary to be consistent with current Federal law, as modified by the VMMA. DEA has no discretion with respect to this amendment. The legal requirements in this final rule have been in effect since 2014, when the VMMA became law. DEA anticipates all affected persons are operating in accordance with the VMMA and this codification will have no economic impact.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As explained above, DEA determined that there is good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule. In any event, as explained above, this rule is a conforming amendment that makes no change in the status quo.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action will not result in any Federal mandate that may result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This final rule does not involve a collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–21. This final rule would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

Congressional Review Act

This is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 29, 2024, by Administrator Anne Milgram. That document with the

original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

For the reasons stated above, 21 CFR part 1301 is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. In § 1301.12, add paragraph (c) to read as follows:

§ 1301.12 Separate registrations for separate locations

* * * * *

(c) As provided in 21 U.S.C. 822(e)(2), a registrant who is a veterinarian may transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant’s registered principal place of business or professional practice without obtaining a separate registration so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

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⁴ See 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). “[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.” *Gray Panthers Advocacy Comm. v. Sullivan*, 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also *Komjathy v. Nat’l Transp. Safety Bd.*, 832 F.2d 1294, 1296 (D.C. Cir. 1987) (per curiam) (notice-and-comment procedures are not required when a rule “does no more than repeat, virtually verbatim, the statutory grant of authority”).

⁵ See 5 U.S.C. 553(d).