section 513(f)(2) of the act, is pending before the Food and Drug Administration, or

(ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.

* * * * *

**§ 807.87 [Amended]**

■ 3. Amend § 807.87 by removing the phrase ''(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0281)'' that appears after paragraph (m).

## PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 4. The authority citation for part 814 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

■ 5. In § 814.39, revise paragraph (b) to read as follows:

**§ 814.39 PMA supplements.**

* * * * *

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, *e.g.,* an editorial change in labeling which does not affect the safety or effectiveness of the device, or if the change is consistent with a predetermined change control plan (PCCP) approved under section 515C of the act.

* * * * *

Dated: March 11, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–05473 Filed 3–14–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1308

**[Docket No. DEA–1245]**

### Schedules of Controlled Substances: Placement of 2-Methyl AP–237 in Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final amendment; final order.

**SUMMARY:** With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one (commonly known as 2-methyl AP–237), including its optical and geometric isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle 2-methyl AP–237.

**DATES:** Effective April 15, 2024.

**FOR FURTHER INFORMATION CONTACT:** Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

**SUPPLEMENTARY INFORMATION:**

### Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

### Background

In a letter dated November 24, 2022, the Director-General of the World Health Organization recommended to the Secretary-General of the United Nations that 2-methyl AP–237 be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* 2-methyl AP–237 is similar to drugs such as isotonitazene) and has dependence and abuse potential. On May 17, 2023, the United States Government was informed by the Secretariat of the United Nations, by letter, that during its 66th session in March 2023, the Commission voted to place 2-methyl AP–237 in Schedule I of the Single Convention (CND Mar/66/1).

### 2-Methyl AP–237

2-Methyl AP–237 has a pharmacological profile similar to other classical opioids such as fentanyl (schedule II), morphine (schedule II) and heroin (schedule I), which act as mu-opioid receptor agonists. Because of the pharmacological similarities of 2-methyl AP–237 to the aforementioned opioids, 2-methyl AP–237 presents a high risk of abuse and has negatively affected users and communities. According to the DEA Toxicology Testing Program (DEA TOX) [1] and a recent publication,[2] the abuse of 2-methyl AP–237 has been associated with at least seven fatalities in the United States between February 2020 and July 2023. The identification of this substance in post-mortem cases is a serious concern to public safety.

In June 2019, 2-methyl AP–237 emerged on the United States illicit drug market as evidenced by its identification in drug seizures.[3] Law enforcement

[1] The DEA Toxicology Testing Program (DEA TOX) was initiated in response to the ongoing novel synthetic drug abuse epidemic. This program provides toxicology data on synthetic drugs from biological samples that may not be routinely identified, which are generated from drug overdose victims. Data queried on 8/7/2023.

[2] Fogarty, MF, Vandeputte, MM, Krotulski, AJ, Walton, SE, Stove, CP, and Logan, BK (2022). Toxicological and pharmacological characterization of novel cinnamylpiperazine synthetic opioids in humans and in vitro including 2-methyl AP–237 and AP–238. Archives of Toxicology 96:1701–1710.

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive

Continued

reports demonstrate that 2-methyl AP–237 is being illicitly distributed and abused. The illicit use and distribution of this substance is similar to that of heroin (schedule I) and prescription opioid analgesics. According to the National Forensic Laboratory Information System (NFLIS-Drug) database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State, and local forensic laboratories, there have been 92 reports of 2-methyl AP–237 in the United States since 2019 (data queried July 17, 2023).

DEA is not aware of any claims or any medical or scientific literature suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States. In addition, the Assistant Secretary for Health of the U.S. Department of Health and Human Services, by a letter to DEA dated December 22, 2022, stated that there are no investigational new drug applications or approved new drug applications for 2-methyl AP–237 in the United States; hence, there are no legitimate channels for this substance as a marketed drug product in the United States. Because 2-methyl AP–237 is not formulated or available for clinical use as an approved medicinal product, all current use of this substance by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such a drug.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that 2-methyl AP–237 has no currently accepted medical use in treatment in the United States [4] and is most appropriately placed in schedule I of the CSA. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule 2-methyl AP–237 pursuant to 21 U.S.C. 811(a).

## Conclusion

In order to meet the United States' obligations under the Single Convention and because 2-methyl AP–237 has no currently accepted medical use in treatment in the United States, the Administrator has determined that 2-methyl AP–237, including its optical and geometric isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, should be placed in schedule I of the CSA.

## Requirements for Handling

Upon the effective date of the final order contained in this document, 2-methyl AP–237 will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, 2-methyl AP–237 must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* 2-Methyl AP–237 must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* 2-Methyl AP–237 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling 2-methyl AP–237 must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of 2-methyl AP–237 must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture 2-methyl AP–237 in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle 2-methyl AP–237 must have an initial inventory of all stocks of controlled substances (including this substance) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 2-methyl AP–237) on hand every two years pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to 2-methyl AP–237 pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding 2-methyl AP–237 to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute 2-methyl AP–237 must comply with the order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 2-methyl AP–237 must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 2-methyl AP–237 not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV; 76 FR 77330, 77332, December 12, 2011. NFLIS data was queried on July 17, 2023. Reports to NFLIS-Drug are still pending for 2023.

[4] Although, as discussed above, there is no evidence suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (Mar 26,1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

**Regulatory Analyses**

*Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) and 14094 (Modernizing Regulatory Review)*

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), as amended by E.O. 14094, section 1(b), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

*Executive Order 12988, Civil Justice Reform*

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This action does not have federalism implications warranting the application of E.O. 13132. This action 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 action does not have tribal implications warranting the application of E.O. 13175. The action 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.

*Administrative Procedure Act*

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

*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 or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

*Paperwork Reduction Act of 1995*

This order would modify an existing collection of information requirement under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. Pursuant to section 3507(d) of the PRA of 1995 (44 U.S.C. 3507(d)), DEA is adding new reporting and recordkeeping requirements for 1117–0003. This order also involves existing collection 1117–0004, but would not modify the existing collection of information requirement under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

*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 and certifies that this action would 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 $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Congressional Review Act*

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

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(59) through (b)(103) as follows:

| Old paragraph | New paragraph |
|---|---|
| (b)(59) through (103) | (b)(60) through (104). |

■ b. Add new paragraph (b)(59).

The addition reads as follows:

**§ 1308.11 Schedule I.**

* * * * *

(b) * * *

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(59) 2-Methyl AP–237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one) ..... 9664

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**Signing Authority**

This document of the Drug Enforcement Administration was signed on March 8, 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**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2024–05543 Filed 3–14–24; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF STATE

### 22 CFR Part 126

**[Public Notice: 12306]**

**RIN 1400–AF80**

## International Traffic in Arms Regulations: Addition to List of Proscribed Countries

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the International Traffic in Arms Regulations (ITAR) to add Nicaragua in the list of countries for which it is the policy of the United States to deny licenses or other approvals for exports and imports of defense services and defense articles, except as otherwise provided.

**DATES:** The rule is effective on March 15, 2024.

**FOR FURTHER INFORMATION CONTACT:** Ms. Maria Tatarska, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (771) 205–7671; email *DDTCCustomerService@state.gov* ATTN: Regulatory Change, ITAR Section 126.1: Nicaragua.

**SUPPLEMENTARY INFORMATION:** Due to growing concerns regarding Nicaragua's continuing dismantling of democratic institutions, attacks on civil society, and increased security cooperation with Russia, to include support of Russia's full-scale invasion of Ukraine, the Under Secretary of State for Arms Control and International Security has determined that it is in the best interests of U.S. national security and foreign policy to restrict, with certain exceptions, the export and import of defense articles and defense services destined for or originating in Nicaragua. This policy reflects the U.S. government's opposition to the trade of arms with Nicaragua and its authoritarian government dominated by President Daniel Ortega Saavedra and his wife, Vice President Rosario Murillo Zambrana. Pursuant to this determination, the Department is adding Nicaragua to ITAR § 126.1 in paragraph (p). The policy of denial toward Nicaragua applies to licenses or other approvals for exports and imports of defense articles or defense services, except that a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Further, in accordance with ITAR § 129.7, no broker, as described in ITAR § 129.2, may engage in or make a proposal to engage in brokering activities subject to the ITAR that involve Nicaragua without obtaining the approval of the Directorate of Defense Trade Controls. Consistent with ITAR § 129.7(d), the Department of State will apply the same policy of denial to such requests.

### Regulatory Analysis and Notices

*Administrative Procedure Act*

This rulemaking is exempt from the rulemaking requirements of section 553 of the Administrative Procedure Act (APA) pursuant to 5 U.S.C. 553(a)(1) as a military or foreign affairs function of the United States.

*Regulatory Flexibility Act*

Since this rule is exempt from the notice-and-comment provisions of 5 U.S.C. 553, the rule does not require analysis under the Regulatory Flexibility Act.

*Unfunded Mandates Reform Act of 1995*

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*Congressional Review Act*

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

*Executive Orders 12372 and 13132*

This rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

*Executive Orders 12866, 13563, and 14094*

Executive Order 12866, as amended by Executive Orders 13563 and 14094, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). As a result of this change, certain exemptions to licensing requirements will not be available for exports, reexports, retransfers, and temporary imports destined for or originating in Nicaragua. However, a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Because the scope of this rule does not impose significant additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has been designated a ''significant regulatory action'' by the Office and Information and Regulatory Affairs under Executive Order 12866.

*Executive Order 12988*

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

*Executive Order 13175*

The Department of State determined that this rulemaking will not have Tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

*Paperwork Reduction Act*

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

### List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

For the reasons set forth above, title 22, chapter I, subchapter M, part 126 is amended as follows:

## PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for part 126 continues to read as follows:

**Authority:** 22 U.S.C. 287c, 2651a, 2752, 2753, 2776, 2778, 2779, 2779a, 2780, 2791, 2797; Sec. 1225, Pub. L. 108–375, 118 Stat. 2091; Sec. 7045, Pub. L. 112–74, 125 Stat.