

radius of the Wichita Dwight D Eisenhower National Airport.

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Issued in Washington, DC, on January 8, 2026.

Alex W. Nelson,

Acting Manager, Rules and Regulations Group.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Chapter II

[Release Nos. 33-11399; 34-104555; IA-6936; IC-35865; File No. S7-2026-02]

List of Rules To Be Reviewed Pursuant to the Regulatory Flexibility Act

AGENCY: Securities and Exchange Commission.

ACTION: Publication of list of rules scheduled for review.

SUMMARY: The Securities and Exchange Commission (“Commission”) is publishing a list of rules to be reviewed pursuant to Section 610 of the Regulatory Flexibility Act. The list is published to provide the public with notice that these rules are scheduled for review by the agency and to invite public comment on whether the rules should be continued without change, or should be amended or rescinded to minimize any significant economic impact of the rules upon a substantial number of small entities.

DATES: Comments should be submitted by February 11, 2026.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/comments/s7-2026-02/list-of-rules-to-be-reviewed-pursuant-regulatory-flexibility-act#no-back>); or

- Send an email to rule-comments@sec.gov. Please include File Number S7-2026-02 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number S7-2026-02. This file number should be included on the subject line if email is used. To help the Commission process and review your

comments more efficiently, please use only one method of submission. The Commission will post all comments on the Commission’s website (<https://www.sec.gov/comments/s7-2026-02/list-of-rules-to-be-reviewed-pursuant-regulatory-flexibility-act#no-back>). Do not include personally identifiable information in submissions; you should submit only information that you wish to make available publicly. The Commission may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

FOR FURTHER INFORMATION CONTACT: Sandra Sojka, General Attorney, Office of the General Counsel, 202-551-4928.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act (“RFA”), codified at 5 U.S.C. 601 through 612, requires an agency to review its rules that have a significant economic impact upon a substantial number of small entities within 10 years of the publication of such rules as final rules. 5 U.S.C. 610(a). The purpose of the review is “to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of such small entities.” 5 U.S.C. 610(a). The RFA sets forth specific considerations that must be addressed in the review of each rule:

- The continued need for the rule;
- The nature of complaints or comments received concerning the rule from the public;
- The complexity of the rule;
- The extent to which the rule overlaps, duplicates or conflicts with other federal rules, and, to the extent feasible, with state and local governmental rules; and
- The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. 5 U.S.C. 610(b).

The list below includes rules adopted in 2016 that may have a significant economic impact on a substantial number of small entities (but excludes rules that have been substantially changed since adoption, rules that are minor amendments to previously adopted rules, and rules that are ministerial, procedural, or technical in nature).¹ Where the Commission has

¹ In addition, while the Commission adopted in 2016 a revised version of 17 CFR 240.13q-1 and an amendment to Form SD in Disclosure of Payments by Resource Extraction Issuers, June 27, 2016 (Release 34-78167), the revised rules were disapproved by a joint resolution of Congress pursuant to the Congressional Review Act on February 14, 2017. See H.R.J. Res. 41, 115th Cong.

previously made a determination of a rule’s impact on small businesses, the determination is noted on the list.

The Commission particularly solicits public comment on whether the rules listed below affect small businesses in new or different ways than when they were first adopted. The rules and forms listed below are scheduled for review by staff of the Commission.

Title: Changes to Exchange Act Registration Requirements To Implement Title V and Title VI of the JOBS Act.

Citation: 17 CFR 230.405, 17 CFR 240.3b-4, 17 CFR 240.12g-1, 17 CFR 240.12g-2, 17 CFR 240.12g-3, 17 CFR 240.12g-4, 17 CFR 240.12g5-1, 17 CFR 240.12h-3.

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77z-2, 77z-3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c-3, 78c-5, 78d, 78e, 78f, 78g, 78i, 78j, 78j-1, 78k, 78k-1, 78l, 78l-1, 78m, 78n, 78o, 78o-7 note, 78s, 78t, 78u-5, 78w, 78x, 78ll, 78ll(d), 78mm, 80a-8, 80a-20, 80a-23, 80a-24, 80a-28, 80a-29, 80a-30, and 80a-37, 80a-23, 80b-3, 80b-4, 80b-11, and Pub. L. 111-203, 939A, 124 Stat. 1376 (2010), Pub. L. 112-106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), Pub. L. 112-106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

Description: The Commission amended Rules 12g-1, 12g-2, 12g-3, 12g-4 and 12h-3 under the Securities and Exchange Act of 1934 (the “Exchange Act”) to reflect the higher thresholds for registration, termination of registration, and suspension of reporting that were set in the Jumpstart Our Business Startups Act (the “JOBS Act”) and Title LXXXV of the Fixing America’s Surface Transportation Act. In addition, the amendments revised the definition of “held of record” in Exchange Act Rule 12g5-1, in accordance with the JOBS Act, to exclude certain securities held by persons who received them pursuant to employee compensation plans and establish a non-exclusive safe harbor for determining whether securities are “held of record” for purposes of registration under Exchange Act Section 12(g).

Prior RFA Analysis: When the Commission adopted the amendments on May 3, 2016, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33-10075; 34-77757, available at: <https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10746.pdf>. The Commission solicited comment on the

(2017) (enacted). Accordingly, this rule has been omitted from the list of rules to be reviewed.

Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos 33–9693; 34–73876 (December 30, 2014), available at: <https://www.govinfo.gov/content/pkg/FR-2014-12-30/pdf/2014-30136.pdf>, and considered comments received at that time.

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Title: Form ADV and Investment Advisers Act Rules.

Citation: 17 CFR 275.202(a)(11)(G)–1, 17 CFR 275.203–1, 17 CFR 275.203A–5, 17 CFR 275.204–1, 17 CFR 275.204–2, 17 CFR 275.204–3, and 17 CFR 279.1.

Authority: 15 U.S.C. 80b–1, *et seq.*, 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

Description: The Commission adopted amendments to Form ADV that are designed to provide additional information regarding advisers, including information about their separately managed account business, incorporate a method for private fund adviser entities operating a single advisory business to register using a single Form ADV, and make clarifying, technical and other amendments to certain Form ADV items and instructions. The Commission also adopted amendments to the Investment Advisers Act of 1940 (“Advisers Act”) books and records rule and technical amendments to several Advisers Act rules to remove transition provisions that are no longer necessary.

Prior RFA Analysis: When the Commission adopted the amendments and forms on August 25, 2016, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. IA–4509, available at: <https://www.federalregister.gov/documents/2016/09/01/2016-20832/form-adv-and-investment-advisers-act-rules>. The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing release, Release No. IA–4091 (June 12, 2015), available at: <https://www.federalregister.gov/documents/2015/06/12/2015-12778/amendments-to-form-adv-and-investment-advisers-act-rules>, and considered comments received at that time.

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Title: Investment Company Reporting Modernization.

Citation: 17 CFR 200.800, 17 CFR 210.6–01, 17 CFR 210.6–03, 17 CFR 210.6–04, 17 CFR 210.6–05, 17 CFR 210.6–07, 17 CFR 210.6–10, 17 CFR 210.12–12, 17 CFR 210.12–12A, 17 CFR 210.12–12B, 17 CFR 210.12–12C, 17 CFR 210.12–13, 17 CFR 210.12–13A, 17

CFR 210.12–13B, 17 CFR 210.12–13C, 17 CFR 210.12–13D, 17 CFR 210.12–14, 17 CFR 232.105, 17 CFR 232.301, 17 CFR 232.401, 17 CFR 239.23, 17 CFR 240.10A–1, 17 CFR 240.12b–25, 17 CFR 240.13a–10, 17 CFR 240.13a–11, 17 CFR 240.13a–13, 17 CFR 240.13a–16, 17 CFR 240.15d–10, 17 CFR 240.15d–11, 17 CFR 240.15d–13, 17 CFR 240.15d–16, 17 CFR 249.322, 17 CFR 249.330, 17 CFR 249.332, 17 CFR 270.8b–16, 17 CFR 270.8b–33, 17 CFR 270.10f–3, 17 CFR 270.30a–1, 17 CFR 270.30a–2, 17 CFR 270.30a–3, 17 CFR 270.30a–4, 17 CFR 270.30b1–1, 17 CFR 270.30b1–2, 17 CFR 270.30b1–3, 17 CFR 270.30b1–5, 17 CFR 270.30b1–9, 17 CFR 270.30d–1, 17 CFR 239.15A, 17 CFR 274.11A, and 17 CFR 274.101.

Authority: 15 U.S.C. 77c, 77d, 77f, 77g, 77h, 77j, 77s, 77s(a), 77z–2, 77z–3, 77aa(25), 77aa(26), 77nn(25), 77nn(26), 77eee, 77ggg, 77nnn, 77sss, 77ttt, 77sss(a), 78a *et seq.*, 78c, 78c(b), 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78n–1, 78o, 78o–1, 78o–4, 78o–7, 78o–7 note, 78o–10, 78o(d), 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78w(a), 78ll, 78mm, 80a–1 *et seq.*, 80a–2(a), 80a–3, 80a–6(c), 80a–8, 80a–9, 80a–10, 80a–13, 80a–20, 80a–23, 80a–24, 80a–26, 80a–29, 80a–30, 80a–31, 80a–34(d), 80a–37, 80a–37(a), 80a–39, 80b–3, 80b–4, 80b–11, 7201 *et seq.*, 7202, Sec. 7203, 7262, 8302, Sec. 71003, Sec. 84001; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 12 U.S.C. 5461 *et seq.*; 18 U.S.C. 1350; 44 U.S.C. 3506; 44 U.S.C. 3507; Public Law 111–203, 939A, 124 Stat. 1376 (2010); Sec. 953(b), Public Law 111–203, 124 Stat. 1904; Sec. 102(a)(3), Public Law 112–106, 126 Stat. 309 (2012); Sec. 107, Public Law 112–106, 126 Stat. 313 (2012); Public Law 112–106, sec. 503 and 602, 126 Stat. 326 (2012); Sec. 72001, Public Law 114–94, 129 Stat. 1312 (2015); and Sec. 71003 and Sec. 84001, Public Law 114–94, 129 Stat. 1312, unless otherwise noted.

Description: The Commission adopted new rules and forms as well as amendments to its rules and forms to modernize the reporting and disclosure of information by registered investment companies. The Commission adopted new Form N–PORT to require certain registered investment companies to report information about their monthly portfolio holdings to the Commission in a structured data format. In addition, the Commission adopted amendments to Regulation S–X to require standardized, enhanced disclosure about derivatives in investment company financial statements, as well as other amendments. The Commission adopted new Form N–CEN to require registered investment companies, other than face-

amount certificate companies, to annually report certain census-type information to the Commission in a structured data format. The Commission adopted amendments to Forms N–1A, N–3, and N–CSR to require certain disclosures regarding securities lending activities. Finally, the Commission rescinded Forms N–Q and N–SAR and amended certain other rules and forms.

Prior RFA Analysis: When the Commission adopted the amendments and forms on October 13, 2016, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33–10231; 34–79095; IC–32314, available at: <https://www.federalregister.gov/documents/2016/11/18/2016-25349/investment-company-reporting-modernization>. The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos. 33–9776; 34–75002; IC–31610 (June 12, 2015), available at: <https://www.federalregister.gov/documents/2015/06/12/2015-12779/investment-company-reporting-modernization>, and considered comments received at that time.

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Title: Investment Company Swing Pricing.

Citation: 17 CFR 210.6–02, 17 CFR 210.6–03, 17 CFR 270.22c–1, 17 CFR 270.31a–2, 17 CFR 274.11A, 17 CFR 274.101.

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77nn(25), 77nn(26), 78c, 78c(b), 78j–1, 78l, 78m, 78n, 78o(d), 78q, 78u–5, 78w, 78ll, 78mm, 80a–1 *et seq.*, 80a–8, 80a–20, 80a–24, 80a–26, 80a–29, 80a–30, 80a–31, 80a–34(d), 80a–37, 80a–37(a), 80a–39, 80b–3, 80b–11, 7202, 7262, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

Description: The Commission adopted amendments to rule 22c–1 under the Investment Company Act of 1940 to permit a registered open-end management investment company (“open-end fund” or “fund”) (except a money market fund or exchange-traded fund), under certain circumstances, to use “swing pricing,” the process of adjusting the fund’s net asset value (“NAV”) per share to effectively pass on the costs stemming from shareholder purchase or redemption activity to the shareholders associated with that activity. The Commission adopted amendments to rule 31a–2 to require funds to preserve certain records related to swing pricing. The Commission also adopted amendments to Form N–1A and Regulation S–X and a new item in Form N–CEN, all of which address a fund’s use of swing pricing.

Prior RFA Analysis: When the Commission adopted the amendments and forms on October 13, 2016, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33–10234; IC–32316, available at: <https://www.federalregister.gov/documents/2016/11/18/2016-25347/investment-company-swing-pricing>. The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos. 33–99932; IC–31835 (Oct. 15, 2015), available at: <https://www.federalregister.gov/documents/2015/10/15/2015-24507/open-end-fund-liquidity-risk-management-programs-swing-pricing-re-opening-of-comment-period-for>, and considered comments received at that time.

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Title: Investment Company Liquidity Risk Management Programs.

Citation: 17 CFR 270.22e–4, 17 CFR 270.30b1–10, 17 CFR 274.11A, 17 CFR 274.101, 17 CFR 274.150, 17 CFR 274.223.

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a–1 *et seq.*, 80a–8, 80a–24, 80a–26, 80a–29, 80a–34(d), 80a–37, 80a–39, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

Description: The Commission adopted new rules, a new form, and amendments to a rule and forms designed to promote effective liquidity risk management throughout the open-end investment company industry, thereby reducing the risk that funds will be unable to meet their redemption obligations and mitigating dilution of the interests of fund shareholders. The amendments also sought to enhance disclosure regarding fund liquidity and redemption practices. The Commission adopted new rule 22e–4, requiring each registered open-end management investment company, including open-end exchange-traded funds (“ETFs”) but not including money market funds, to establish a liquidity risk management program. Rule 22e–4 also requires principal underwriters and depositors of unit investment trusts (“UITs”) to engage in a limited liquidity review. The Commission also adopted amendments to Form N–1A regarding the disclosure of fund policies concerning the redemption of fund shares. The Commission also adopted new rule 30b1–10 and Form N–LIQUID (subsequently re-titled to Form N–RN) to generally require a fund to confidentially notify the Commission when the fund’s level of illiquid investments that are assets exceeds 15%

of its net assets or when its highly liquid investments that are assets fall below its minimum for more than a specified period of time. The Commission also adopted certain sections of Forms N–PORT and N–CEN to require disclosure of certain information regarding the liquidity of a fund’s holdings and the fund’s liquidity risk management practices.

Prior RFA Analysis: When the Commission adopted the amendments and forms on October 13, 2016, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33–10233; IC–32315, available at: <https://www.federalregister.gov/documents/2016/11/18/2016-25348/investment-company-liquidity-risk-management-programs>. The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos. Nos. 33–9922; IC–31835; (October 15, 2015), available at: <https://www.federalregister.gov/documents/2015/10/15/2015-24507/open-end-fund-liquidity-risk-management-programs-swing-pricing-re-opening-of-comment-period-for>, and considered comments received at that time.

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Title: Exemptions To Facilitate Intrastate and Regional Securities Offerings.

Citation: 17 CFR 200.30–1, 17 CFR 230.147, 17 CFR 230.147A, 17 CFR 230.501, 17 CFR 230.502, 17 CFR 230.503, 17 CFR 230.504, 17 CFR 230.505, 17 CFR 230.507, 17 CFR 230.508, 17 CFR 239.500, 17 CFR 240.15g–9, 17 CFR 249.308, 17 CFR 270.17j–1, 17 CFR 275.204A–1.

Authority: 15 U.S.C. 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77o, 77r, 77s, 77z–2, 77z–3, 77sss, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78a *et seq.*, 78c, 78c–3, 78c–5, 78d, 78d–1, 78d–2, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78n–1, 78o, 78o(d), 78o–4, 78o–7 note, 78o–10, 78p, 78q, 78q–1, 78s, 78t, 78u–5, 78w, 78w(a), 78x, 78ll, 78ll(d), 78mm, 80a–1 *et seq.*, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–20, 80a–23, 80a–24, 80a–26, 80a–28, 80a–29, 80a–30, 80a–34(d), 80a–37, 80a–39, 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, 80b–11, 7201 *et seq.*, 7202, 7211 *et seq.*, and Sec. 8302; Sec. 71003, and Sec. 84001; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3), 12 U.S.C. 5461 *et seq.*, 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376, (2010); Sec. 953(b), Public Law 111–203, 124 Stat. 1904; Sec. 102(a)(3), Public Law 112–106, 126 Stat. 309 (2012); Sec.

107, Public Law 112–106, 126 Stat. 313 (2012); Public Law 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012); Sec. 72001, Public Law 114–94, 129 Stat. 1312 (2015); Sec. 71003 and Sec. 84001, Pub. L. 114–94, 129 Stat. 1312; and Sec. 72001, Public Law 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

Description: The Commission adopted amendments to modernize Rule 147 under the Securities Act of 1933, which provides a safe harbor for compliance with the Section 3(a)(11) exemption from registration for intrastate securities offerings. The Commission also established a new intrastate offering exemption under the Securities Act, designated Rule 147A, similar to amended Rule 147, but with no restriction on offers and allows issuers to be incorporated or organized outside of the state in which the intrastate offering is conducted provided certain conditions are met. The amendments to Rule 147 and new Rule 147A are designed to facilitate capital formation, including through offerings relying upon intrastate crowdfunding provisions under state securities laws, while maintaining appropriate investor protections and providing state securities regulators with the flexibility to add additional investor protections they deem appropriate for offerings within their state.

The Commission also adopted amendments to Rule 504 of Regulation D under the Securities Act to facilitate issuers’ capital raising efforts and provide additional investor protections. The amendments to rule 504 are designed to increase the aggregate amount of securities that may be offered and sold in any twelve-month period from \$1 million to \$5 million and disqualify certain bad actors from participation in Rule 504 offerings. In light of these amendments to Rule 504, the Commission also repealed Rule 505.

Prior RFA Analysis: When the Commission adopted the amendments and forms on October 26, 2016, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33–10238; 34–79161, available at: <https://www.federalregister.gov/documents/2016/11/21/2016-26348/exemptions-to-facilitate-intrastate-and-regional-securities-offerings>. The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos. 33–9973; 34–76319 (Nov. 10, 2015), available at: <https://www.federalregister.gov/documents/2015/11/10/2015-28219/exemptions-to-facilitate-intrastate-and-regional>

securities-offerings, and considered comments received at that time.

By the Commission.

Dated: January 7, 2026.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2026-00315 Filed 1-9-26; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1337]

Schedules of Controlled Substances: Placement of N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene 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 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino metonitazene or metonitazepyne) and 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino protonitazene or protonitazepyne), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, in schedule I under the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1961 Single Convention on Narcotic Drugs. This action imposes permanent 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 handle *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene.

DATES: Effective February 11, 2026.

ADDRESSES: 8701 Morrisette Drive, Springfield, Virginia 22152.

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 United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 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 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, 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 she 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.¹

Background

On November 21, 2024, the Director-General of the World Health Organization recommended to the Secretary-General that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene be placed in Schedule I of the Single Convention, as these substances have pharmacological effects similar to other opioid drugs that are controlled in Schedule I of the Single Convention. On June 9, 2025, the Secretariat of the United Nations informed the United States government, by letter, that the Commission voted to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in Schedule I of the Single Convention during its 68th session on March 12, 2025 (CND Mar 68/2 and 68/1).

On August 15, 2025, DEA issued a temporary scheduling order, placing *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene temporarily in schedule I of the CSA.² That order for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene (codified at

21 CFR 1308.11(h)(77) and (78)) was based on the Administrator’s finding that the temporary scheduling of these substances was necessary to avoid an imminent hazard to public safety.³

N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene

Benzimidazole-opioids, commonly referred to as “nitazenes,” emerged on the recreational drug market in 2019. This class of substances shares a similar pharmacological profile with fentanyl, morphine, and other mu-opioid receptor agonists. In 2023, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene emerged on the illicit opioid drug market. The abuse of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene has been associated with adverse events to include their identification in toxicology cases in the United States. Several substances belonging to the benzimidazole-opioid drug class have been controlled in the United States, and as a class of drug in China, Canada, and the United Kingdom.

Law enforcement reports demonstrate that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are being illicitly distributed and abused. According to the National Forensic Laboratory Information System (NFLIS-Drug)⁴ database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been 284 reports for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene between January 2022 and August 2025 (query date: August 13, 2025). Specifically, there have been 253 encounters of *N*-pyrrolidino protonitazene from 22 States and 31 encounters of *N*-pyrrolidino metonitazene from 10 States. Benzimidazole-opioids have been identified in counterfeit prescription tablets in the United States. A report from the Expert Committee on Drug Dependence Critical Review on *N*-pyrrolidino protonitazene indicate this

³ *Id.*

⁴ NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1 million distinct annual federal, state, and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data are not direct evidence of abuse, these 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 (Dec. 12, 2011).

¹ 28 CFR 0.100.

² *Schedules of Controlled Substances: Temporary Placement of N-pyrrolidino metonitazene and N-pyrrolidino protonitazene in Schedule I*, 90 FR 39314 (August 15, 2025).