

make this rulemaking effective upon publication in the **Federal Register**.¹

III. Paperwork Reduction Act

The Commission may not conduct or sponsor, and a respondent is not required to respond to, a collection of information contained in a rulemaking unless the information collection displays a currently valid control number issued by the Office of Management and Budget (“OMB”) pursuant to the Paperwork Reduction Act.² This rulemaking contains no collection of information for which the Commission is obligated to obtain a control number from OMB.

List of Subjects in 17 CFR Part 38

Commodity futures, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 38 as follows:

PART 38—DESIGNATED CONTRACT MARKETS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6c, 6d, 6e, 6f, 6g, 6i, 6j, 6k, 6l, 6m, 6n, 7, 7a–2, 7b, 7b–1, 7b–3, 8, 9, 15, and 21, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376.

■ 2. In § 38.1051, add paragraph (n)(3) to read as follows:

§ 38.1051 General requirements.

* * * * *

(n) * * *

(3) *Delegation of authority.* The Commission hereby delegates, until it orders otherwise, to the Director of the Division of Market Oversight or such other employee or employees as the Director may designate from time to time, the authority to provide each designated contract market with its percentage of the total annual trading volume of all designated contract markets regulated by the Commission, as set forth in paragraph (n)(2) of this section. The Director of the Division of Market Oversight may submit to the Commission for its consideration any matter that has been delegated pursuant to this section. Nothing in this section prohibits the Commission, at its election, from exercising the authority delegated in this section.

Issued in Washington, DC, on September 26, 2017, by the Commission.

Christopher J. Kirkpatrick,
Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Commission Delegated Authority Provisions for Designated Contract Markets’ System Safeguards Requirements—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Bowen, Quintenz, and Behnam voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2017–20924 Filed 9–28–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–10413; 34–81592; 39–2518; IC–32818]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the “Commission”) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (“EDGAR”) Filer Manual and related rules to reflect updates to the EDGAR system. The EDGAR system is scheduled to be upgraded on September 11, 2017.

DATES: Effective September 29, 2017, except that amendatory instruction 4 to § 232.301 is effective June 1, 2018. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of September 29, 2017.

FOR FURTHER INFORMATION CONTACT: In the Division of Investment Management, for questions concerning Forms N–PORT and N–CEN, contact Heather Fernandez at (202) 551–6708; in the Division of Corporation Finance, for questions concerning Forms S–1, S–3, S–4, S–8, S–11, F–1, F–3, F–4, 8–K, 10, 10–K, 10–Q, 20–F, and 40–F, contact Heather Mackintosh at (202) 551–8111; in the Office of Financial Management, for questions about negative account balances, contact Andrew Grimaldi at (202) 551–7304.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I and Volume II. The Filer Manual describes the technical

formatting requirements for the preparation and submission of electronic filings through the EDGAR system.¹ It also describes the requirements for filing using EDGARLink Online and the Online Forms/XML Web site.

The revisions to the Filer Manual reflect changes within Volume I, entitled EDGAR Filer Manual, Volume I: “General Information,” Version 29 (September 2017), and Volume II, entitled EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 43 (September 2017). The updated manual will be incorporated by reference into the Code of Federal Regulations.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.² Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.³

The EDGAR system will be upgraded to Release 17.3 on September 11, 2017, and will introduce the following changes:

In Release No. 33–10231 (October 13, 2016) [81 FR 81870], the Commission adopted changes to the reporting requirements for investment companies. Among the changes was the adoption of Form N–PORT, which requires investment companies to report information about portfolio holdings monthly in a structured format. EDGAR Release 17.3 will provide a pilot program whereby filers may submit TEST versions of the following form types:

- Public Monthly Portfolio Investments Report on Form N–PORT (NPORT–P).
- Amended Public Monthly Portfolio Investments Report on Form N–PORT (NPORT–P/A).
- Non-Public Monthly Portfolio Investments Report on Form N–PORT (NPORT–NP).
- Amended Non-Public Monthly Portfolio Investments Report on Form N–PORT (NPORT–NP/A).

¹ We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on July 17, 2017. See Release No. 33–10385 (July 6, 2017) [82 FR 35062].

² See Rule 301 of Regulation S–T (17 CFR 232.301).

³ See Release No. 33–10385 in which we implemented revisions to reflect EDGAR Release 17.2. For additional history of EDGAR Filer Manual revisions, please see the citations therein.

¹ 5 U.S.C. 553(d).

² 44 U.S.C. 3501 *et seq.*

- Portfolio Holdings Exhibit to Form N-PORT (NPORT-EX).
- Amended Portfolio Holdings Exhibit to Form N-PORT (NPORT-EX/A).

In Release No. 33-10231 the Commission also adopted new Form N-CEN, which will require investment companies, other than face amount certificate companies, to provide an annual report of census-type information in a structured format. EDGAR Release 17.3 will permit investment companies to submit TEST versions of the following form types:

- Annual Report for Registered Investment Companies (N-CEN).
- Amendment to Annual Report for Registered Investment Companies (N-CEN/A).
- EDGAR Release 17.3 will also introduce two additional submission form types:
 - Notice under Exchange Act Rule 12b-25 of the inability to timely file Form N-CEN (NT-NCEN).
 - Amendment to Notice under Exchange Act Rule 12b-25 of the inability to timely file Form N-CEN (NT-NCEN/A).

EDGAR will only accept TEST submissions of form types NPORT-P, NPORT-P/A, NPORT-NP, NPORT-NP/A, NPORT-EX, NPORT-EX/A, N-CEN, and N-CEN/A from September 11, 2017, through December 31, 2017, and then again from March 1, 2018 until May 31, 2018. Beginning June 1, 2018, EDGAR will accept both TEST and LIVE submissions of form types NPORT-P, NPORT-P/A, NPORT-NP, NPORT-NP/A, NPORT-EX, NPORT-EX/A, N-CEN, and N-CEN/A. The EDGAR Filer Manual will be revised to provide instructions for making TEST N-PORT and N-CEN filings. Corresponding changes will be made to Chapter 8 (Preparing and Transmitting Online Submissions) of the EDGAR Filer Manual, Volume II: "EDGAR Filing."

In Release No. 33-10332 (March 31, 2017) [82 FR 17545] the Commission made rule and form changes to effectuate inflation adjustments and other technical amendments required under Titles I & III of the JOBS Act. Among the technical changes was the revision to Commission forms so that registrants can designate whether they are an Emerging Growth Company and whether they have elected not to use the extended transition period for complying with any new or revised financial accounting standards.

Updates are being made in EDGAR Release 17.3 so that the same disclosures can be provided for any co-registrants. The following EDGARLink Online submission form types will be

revised to reflect the two fields for each co-registrant: S-1, S-1/A, S-3, S-3/A, S-4, S-4/A, S-8, S-11, S-11/A, F-1, F-1/A, F-3, F-3/A, F-4, F-4/A, 10-12B, 10-12B/A, 10-12G, 10-12G/A, 8-K, 8-K/A, 8-K12B, 8-K12B/A, 8-K12G3, 8-K12G3/A, 8-K15D5, 8-K15D5/A, 10-Q, 10-Q/A, 10-QT, 10-QT/A, 10-K, 10-K/A, 10-KT, 10-KT/A, 20-F, 20-F/A, 20FR12B, 20FR12B/A, 20FR12G, 20FR12G/A, 40-F, 40-F/A, 40FR12B, 40FR12B/A, 40FR12G, and 40FR12G/A. Corresponding changes will be made to Chapter 7 (Preparing and Transmitting EDGARLink Online Submissions) of the EDGAR Filer Manual, Volume II: "EDGAR Filing."

The "Balance Information" and "Account Activity Statement" screen of the EDGAR Filing Web site will be updated with the following text: "A negative balance amount indicates that money is owed to the SEC and the account is past due. For more information on making filing fee payments, see <https://www.sec.gov/paymentoptions>." Corresponding changes will be made to Chapter 5 (Maintenance of Company Data) of the EDGAR Filer Manual Volume I: "General Information."

Along with the adoption of the Filer Manual, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual will be available for Web site viewing and printing; the address for the Filer Manual is <https://www.sec.gov/info/edgar/edmanuals.htm>. You may also obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m.

Since the Filer Manual and the corresponding rule changes relate solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act ("APA").⁴ It follows that the requirements of the Regulatory Flexibility Act⁵ do not apply.

The effective date for the updated Filer Manual and the rule amendments is September 29, 2017. In accordance with the APA,⁶ we find that there is good cause to establish an effective date

less than 30 days after publication of these rules. The EDGAR system upgrade to Release 17.3 is scheduled to become available on September 11, 2017. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with these system upgrades.

Statutory Basis

We are adopting the amendments to Regulation S-T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,⁷ Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,⁸ Section 319 of the Trust Indenture Act of 1939,⁹ and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.¹⁰

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S-T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

- 1. The authority citation for part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a-6(c), 80a-8, 80a-29, 80a-30, 80a-37, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

- 2. The amendment to § 232.301 published November 18, 2016 (81 FR 82019) is withdrawn.

- 3. Effective September 29, 2017, § 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: "General Information," Version 29 (September 2017). The requirements for filing on EDGAR are set forth in the updated

⁷ 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

⁸ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w, and 78ll.

⁹ 15 U.S.C. 77sss.

¹⁰ 15 U.S.C. 80a-8, 80a-29, 80a-30, and 80a-37.

⁴ 5 U.S.C. 553(b)(A).

⁵ 5 U.S.C. 601-612.

⁶ 5 U.S.C. 553(d)(3).

EDGAR Filer Manual, Volume II: "EDGAR Filing," Version 43 (September 2017). Additional provisions applicable to Form N-SAR filers are set forth in the EDGAR Filer Manual, Volume III: "N-SAR Supplement," Version 6 (January 2017). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is <https://www.sec.gov/info/edgar/edmanuals.htm>. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

§ 232.301 [Amended]

■ 4. Effective June 1, 2018, amend § 232.301 by removing the fourth sentence.

By the Commission.

Dated: September 13, 2017.

Brent J. Fields,
Secretary.

[FR Doc. 2017-20654 Filed 9-28-17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-468]

Schedules of Controlled Substances: Removal of Naldemedine From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration removes the substance naldemedine (4*R*,4*aS*,7*aR*,12*bS*)-3-(cyclopropylmethyl)-4*a*,7,9-trihydroxy-*N*-(2-(3-phenyl-1,2,4-oxadiazol-5-yl)propan-2-yl)-2,3,4,4*a*,5,7*a*-hexahydro-1*H*-4,12-methanobenzofuro[3,2-

e]isoquinoline-6-carboxamide) including its salts from the schedules of the Controlled Substances Act. Prior to the effective date of this rule, naldemedine was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle naldemedine.

DATES: The effective date of this rule is September 29, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, "remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule." The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary of the Department of Health and Human Services (HHS)¹, or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated at the request of the Acting Assistant Secretary for Health of the HHS and by a petition by the drug sponsor to DEA to remove naldemedine from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary of the HHS and an evaluation

of all relevant data by the DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle naldemedine.

Background

Naldemedine, known chemically as (4*R*,4*aS*,7*aR*,12*bS*)-3-(cyclopropylmethyl)-4*a*,7,9-trihydroxy-*N*-(2-(3-phenyl-1,2,4-oxadiazol-5-yl)propan-2-yl)-2,3,4,4*a*,5,7*a*-hexahydro-1*H*-4,12-methanobenzofuro[3,2-*e*]isoquinoline-6-carboxamide, is an opium alkaloid derivative. Naldemedine is a high-affinity antagonist at the mu, kappa, and delta opioid receptors. On March 23, 2016, a new drug application (NDA) was submitted by Shionogi Inc. (Sponsor) to the Food and Drug Administration (FDA) for approval of naldemedine for the treatment of opioid induced constipation in patients with chronic non-cancer pain. The FDA approved naldemedine for marketing on March 23, 2017, under the trade name Symproic® (0.2 mg tablets).² Naldemedine is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Opioid-induced constipation is caused by an activation of mu-opioid receptors in the gastrointestinal tract. Naldemedine, a peripheral acting mu-opioid antagonist, can prevent OIC.

DEA and HHS Eight Factor Analyses

On June 8, 2016, the DEA received a petition from the drug sponsor requesting that the DEA amend 21 CFR 1308.12(b)(1) to exclude naldemedine as a schedule II substance from the Controlled Substances Act (CSA). The petitioner stated that naldemedine is a potent peripherally acting mu-opioid receptor antagonist. In accordance with 21 CFR 1308.43(c), the DEA accepted the petition for filing on August 5, 2016.

On March 22, 2017, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled "Basis for the Recommendation to Decontrol Naldemedine and its Salts from the Controlled Substances Act." After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that naldemedine

¹ As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

² http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/208854Orig1s000ltr.pdf (last accessed 04/13/2017).