46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

■ 6. Amend § 742.6 by revising paragraph (a)(4)(i) to read as follows:

§ 742.6 Regional stability.

(a) * * *

(4) * * *

(i) *License requirements applicable to most RS Column 2 items.* As indicated in the CCL and in RS Column 2 of the Commerce Country Chart (see Supplement No. 1 to part 738 of the EAR), a license is required to any destination except Australia, India, Japan, New Zealand, and countries in the North Atlantic Treaty Organization (NATO) for all items in ECCNs on the CCL that include RS Column 2 in the Country Chart column of the ''License Requirements'' section. A license continues to be required for items controlled under ECCNs 6A003.b.4.b and 9A515.e for RS Column 2 reasons when destined to India.

* * * * *

PART 758—[AMENDED]

■ 7. The authority citation for part 758 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 8. Amend § 758.1 by adding paragraph (b)(9) to read as follows:

§ 758.1 The Electronic Export Information (EEI) filing to the Automated Export System (AES).

* * * * *

(b) * * *

(9) For items that fall under ECCNs that list CC Column 1 and 3 and RS Column 2 (see Supplement No. 1 to part 738 of the EAR) as reasons for control and such items are for export, regardless of value, to India.

* * * * *

■ 9. Amend § 758.6 by adding paragraph (c) to read as follows:

§ 758.6 Destination control statements and other information furnished to consignees.

* * * * *

(c) *Additional requirement for items under ECCNs for which CC Column 1 or 3 or RS Column 2 are listed as reasons for control and are destined to India.* In addition to the DCS as required in paragraph (a) of this section, the following information must be printed on the invoice, bill of lading, air waybill, or other export control document that accompanies the shipment from its point of origin in the United States to the ultimate consignee or end-user in India: ''These items are classified under Export Control Classification Number(s) (ECCN(s)) [Fill-in the ECCNs for which CC 1 or 3 or RS 2 are listed as reasons for control] and destined to India. Authorization for reexport from India may be required from the U.S. Department of Commerce.''

Dated: January 20, 2015.

Eric L. Hirschhorn,

Under Secretary for Industry and Security.

[FR Doc. 2015–01273 Filed 1–22–15; 8:45 am]

BILLING CODE 3510–33–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC–2015–0002]

Notice of Determination Under the Drywall Safety Act of 2012

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of determination.

SUMMARY: The Consumer Product Safety Commission (CPSC, or Commission) is announcing that, pursuant to the requirements of the Drywall Safety Act of 2012 (DSA), the Commission has determined that: ASTM C1396–14a, ''Standard Specification for Gypsum Board,'' is a voluntary standard for drywall manufactured or imported for use in the United States that limits sulfur content to a level not associated with elevated rates of corrosion in the home; ASTM C1396–14a became effective less than two years after the enactment of the DSA; and ASTM C1396–14a was developed by Subcommittee C11.01 on Specifications and Test Methods for Gypsum Products of ASTM International. Based on these determinations, the sulfur content limit in ASTM C1396–14a shall be treated as a consumer product safety rule promulgated under the Consumer Product Safety Act (CPSA). Drywall manufactured or imported for use in the United States shall be subject to the general conformity certification (GCC) requirements of the CPSA.

DATES: This action becomes effective on July 22, 2015.

FOR FURTHER INFORMATION CONTACT: Rohit Khanna, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987–2508; email *rkhanna@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CPSC began investigating drywall in 2009, after reports from homeowners that they were seeing corrosion of metal items inside their homes. According to homeowners' reports, the items primarily involved were electrical fixtures, appliances, plumbing, and air conditioner coils. CPSC used the term ''problem drywall'' to refer to drywall associated with elevated rates of metal corrosion. After CPSC's initial investigations, CPSC joined with the U.S. Department of Housing and Urban Development (HUD), the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Environmental Protection Agency (EPA) to form the Federal Interagency Task Force on Problem Drywall (Task Force).

In the course of this investigation, samples of problem drywall were analyzed for chemical content and emissions. CPSC staff analysis of chemical content and emissions from problem drywall determined that certain brands of drywall produced around the year 2006 contain elevated levels of elemental sulfur (octahedral sulfur, S_8) and have elevated emission factors for hydrogen sulfide (H_2S) and other reactive sulfur gases known to corrode materials containing copper and silver. CPSC staff's analysis of the technical data also determined that the presence of elemental sulfur in excess of 10 ppm in drywall is associated with elevated emission factors for hydrogen sulfide (H_2S) and other reactive sulfur gases that are known to cause accelerated corrosion of copper and silver in homes.

CPSC staff and HUD relied on the results of this analysis to develop guidance materials to help homeowners identify homes with problem drywall and to correct the problem by removing and replacing the problem drywall and certain other components of the home. These guidance documents are available on CPSC's Web site.[1]

II. The Drywall Safety Act of 2012

On January 14, 2013, the President signed the Drywall Safety Act of 2012 (DSA) into law. Pub. L. 112–266, 126 Stat. 2437 (2013). The DSA established

[1] Identification Guidance for Homes with Corrosion from Problem Drywall as of March 18, 2011, by the U.S. Consumer Product Safety Commission and the U.S. Department of Housing and Urban Development *http://www.cpsc.gov//PageFiles/115328/IDguidance031811.pdf.* Remediation Guidance for Homes with Corrosion from Problem Drywall as of March 15, 2013, by the U.S. Consumer Product Safety Commission and the U.S. Department of Housing and Urban Development *http://www.cpsc.gov//Global/Safety%20Education/Safety-Information-Centers/Drywall/remediation031513.pdf.*

several requirements related to problem drywall.

The Drywall Labeling Requirement. The DSA states that 180 days after the date of enactment of the DSA, the gypsum board labeling provisions of standard ASTM C1264–11 [2] must be treated as a rule promulgated by CPSC under section 14(c) of the CPSA. ASTM uses the more technical term ''gypsum board'' to refer to the class of products that CPSC refers to as ''drywall.'' The labeling provisions in ASTM C1264–11 are currently in effect as a CPSC mandatory standard. The DSA provides a process for revision of the CPSC standard if ASTM revises the labeling provisions in the ASTM standard and notifies the Commission of the revision. To date, although ASTM has revised some provisions in ASTM C1264–11, ASTM has not revised the labeling provisions.

Revision of Remediation Guidance for Drywall Disposal Required. The DSA requires the CPSC to revise CPSC's guidance entitled ''Remediation Guidance for Homes with Corrosion from Problem Drywall'' to specify that problem drywall removed from homes pursuant to the guidance should not be reused or used as a component in the production of new drywall. CPSC revised the Remediation Guidance as directed when CPSC published a new Remediation Guidance on the CPSC Web site on March 15, 2013.

Sulfur Content Standard Requirement. The DSA requires CPSC to promulgate a final rule pertaining to drywall manufactured or imported for use in the United States within two years of the date of enactment of the DSA. The rule must limit sulfur content ''to a level not associated with elevated rates of corrosion in the home.'' As discussed below, the rulemaking requirement does not apply if the Commission makes certain determinations regarding an ASTM voluntary standard and publishes the determinations in the **Federal Register**. With this document, the Commission makes the necessary determinations.

III. Standard for Sulfur Content in Drywall

A. Determination

Section 4(a) of the DSA requires the Commission to promulgate a final rule limiting sulfur content in drywall manufactured or imported for use in the United States ''to a level not associated with elevated rates of corrosion in the home.'' The rulemaking requirement does not apply if the Commission determines that:

(a) A voluntary standard pertaining to drywall manufactured or imported for use in the United States limits sulfur content to a level not associated with elevated rates of corrosion in the home;

(b) The voluntary standard is in effect within two years of enactment the DSA; and

(c) The voluntary standard is developed by ASTM International's Subcommittee C11.01 on Specifications and Test Methods for Gypsum Products. *Id.* 4(c).

If the Commission makes such determinations, the sulfur content limit in the voluntary standard pertaining to drywall manufactured or imported for use in the United States ''shall be treated as a consumer product safety rule under section 9 of the Consumer Product Safety Act.'' *Id.* 4(d).

The Commission determines that the sulfur limit stated in section 4.7 of ASTM C1396–14a, *Standard Specification for Gypsum Board,* meets the requirements of section 4(c) of the DSA. CPSC staff worked with the relevant ASTM Subcommittee (ASTM Subcommittee C11.01 on Specifications and Test Methods for Gypsum Products) to develop a test method for elemental sulfur in gypsum products. The test method is stated in ASTM Standard C471M, Test Methods for Chemical Analysis of Gypsum and Gypsum Products (Metric). ASTM Subcommittee C11.01 then worked with CPSC staff to develop a requirement stated in section 4.7 of ASTM C1396–14a limiting the sulfur content of gypsum board. That provision requires that gypsum board must contain not greater than 10 ppm of orthorhombic cylooctasulfur (*i.e.,* elemental sulfur or ''S_8'') when tested in accordance with the test methods for Determination of S_8 in Gypsum Panel Products by Liquid Extraction for Analysis by Liquid or Gas Chromatography in sections 55–65 of ASTM C471M.

In accordance with section 4(c) of the DSA, ASTM C1396–14a is a voluntary standard pertaining to drywall manufactured or imported for use in the United States stating that gypsum board (drywall) ''shall contain not greater than 10 ppm of orthorhombic cyclooctasulfur (S_8).'' As discussed in the staff's briefing memorandum,[3] this limit on sulfur content is consistent with CPSC staff's numerous corrosion studies, which showed an association between high levels of elemental sulfur (S_8) in drywall and corrosion in the home, but no association between sulfur levels that did not exceed 10 ppm and elevated corrosion.

ASTM C1396–14a was published and became effective October 14, 2014, less than two years after enactment of the DSA. Finally, ASTM C1396–14a was developed by Subcommittee C11.01 on Specifications and Test Methods for Gypsum Products of ASTM International.

Based on these determinations the Commission finds that the requirements of section 4(c) of the DSA have been met. Accordingly, the sulfur content limit requirement stated in section 4.7 of ASTM C1396–14a is a consumer product safety rule under the CPSA.

B. Effective Date and Certification

DSA section 4(d) provides that if the Commission determines that a voluntary standard meets the requirements of section 4(c) of the DSA, the sulfur content limit stated in the voluntary standard shall be treated as a consumer product safety rule beginning on the later of:

- 180 days after publication of the Commission's determination; or
- the effective date stated in the voluntary standard.

ASTM C1396–14a took effect when the standard was published on October 14, 2014. Therefore, the sulfur content limit stated in ASTM C1396–14a shall be treated as a consumer product safety rule effective 180 days after publication of this determination in the **Federal Register**.

Section 14(a)(1) of the CPSA requires that every manufacturer of a product that is subject to a consumer product safety rule and is imported into or distributed in the United States must certify that the product complies with all applicable CPSC rules, rules, bans, standards, or regulations. 15 U.S.C. 2063(a)(1). As a product subject to a consumer product safety rule, drywall imported into or distributed in the United States will be subject to the certification requirements of section 14(a)(1) of the CPSA (15 U.S.C. 2063(a)(1)) and the Commission's certification regulations at 16 CFR part 1110 once the voluntary standard sulfur limit requirement is in effect as a consumer product safety standard. Drywall manufactured or imported on or after the effective date must comply

[2] Standard Specification for Sampling, Inspection, Rejection, Certification, Packaging, Marking, Shipping, Handling, and Storage of Gypsum Panel Products.

[3] Drywall Safety Act of 2012; Briefing Memorandum for Draft Federal Register Notice, Sulfur Content in Drywall Standard *http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2015/Drywall-Safety-Act-FR-Notice-Sulfur-Content-in-Drywall-Standard.pdf.*

with the sulfur content limits of ASTM C1396–14a and must be accompanied by a general certification of compliance (GCC).

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2015–01051 Filed 1–22–15; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–400]

Schedules of Controlled Substances: Removal of Naloxegol From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration removes naloxegol ((5α,6α)-17-allyl-6-((20-hydroxy-3,6,9,12,15,18-hexaoxaicos-1-yl)oxy)-4,5-epoxymorphinon-3,14-diol) and its salts from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, naloxegol 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 naloxegol.

DATES: *Effective Date:* January 23, 2015.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, but they are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. 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. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR 1308. 21 U.S.C. 812(a).

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 DEA. 28 CFR 0.100.

The 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 by a petition from the drug sponsor to remove naloxegol 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 naloxegol.

Background

Naloxegol, or PEG-naloxol, is a new molecular entity and is a polyethylene glycolyated (PEGylated) derivative of naloxone. Its chemical names are (5α,6α)-17-allyl-6-((20-hydroxy-3,6,9,12,15,18-hexaoxaicos-1-yl)oxy)-4,5-epoxymorphinon-3,14-diol or alpha-6mPEG7-O-naloxol. Naloxegol is an antagonist predominantly of peripheral mu opioid receptors. The Food and Drug Administration (FDA) approved naloxegol for marketing on September 16, 2014, under the brand name Movantik™.[2] It is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Gastrointestinal adverse events (AEs) effects are commonly experienced by chronic users of opioid analgesics. Opioids delay gastric emptying and intestinal transport, which over time leads to debilitating constipation. OIC is caused by activation of the mu opioid receptor in the GI tract.

DEA and HHS Eight Factor Analyses

The DEA received a petition from the drug sponsor dated March 22, 2012, requesting that the DEA amend 21 CFR 1308.12(b)(1) to exclude naloxegol as a schedule II controlled substance. The petitioner stated that naloxegol is a mu opioid receptor antagonist without mu opioid agonist or partial agonist properties. The DEA accepted the petition for filing on October 1, 2012.

On February 7, 2013 the DEA forwarded to the HHS the data with the sponsor's petition along with a request for a scientific and medical evaluation and the HHS's recommendation as to whether or not naloxegol should be removed from the list of controlled substances. According to the HHS, the sponsor submitted a New Drug Application (NDA) for naloxegol on September 16, 2013. Based on the NDA, the HHS summarized that naloxegol is an antagonist of peripheral opioid receptors for the treatment of OIC.

On August 8, 2014, the HHS provided to the DEA a scientific and medical evaluation document prepared by the FDA entitled ''Basis for the

[1] As discussed in a memorandum of understanding entered into by 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 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/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails* (last accessed Sept. 26, 2014).