service information related to this AD, contact Costruzioni Aeronautiche Tecnam Airworthiness Office, Via Maiorise–81043 Capua (CE) Italy; telephone: +39 0823 997538; fax: +39 0823 622899; email: *technical.support@tecnam.com;* Internet: *http://www.tecnam.com/Customer-Care/Service-Bulletins.aspx.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on October 22, 2014.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–25740 Filed 10–28–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Admininstration

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: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to remove naloxegol ((5α,6 α)-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. Naloxegol is currently a schedule II controlled substance because it can be derived from opium alkaloids. This action would remove 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: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before November 28, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)'', may file a request for hearing or waiver of participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48, or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before November 28, 2014.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–400'' on all correspondence, including any attachments.

- *Electronic comments:* The DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a comment tracking number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* an electronic format, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the DEA for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference. The DEA specifically solicits written comments regarding the DEA's economic analysis of the impact of these proposed changes. The DEA requests that commenters provide detailed descriptions in their comments of any expected economic impacts, especially to small entities. Commenters should provide empirical data to illustrate the nature and scope of such impact.

Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA) (5 U.S.C. 551–559). 21 CFR 1308.41–1308.45, and 21 CFR part 1316 subpart D. In accordance with 21 CFR 1308.44 (a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44 (a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing is restricted to ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.'' All requests for hearing and waivers of participation must be sent to the DEA using the address information above, on or before the date specified above.

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 part 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, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

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 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 would remove 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.

Proposed Determination To Decontrol Naloxegol

Pursuant to 21 U.S.C. 811(a), proceedings to issue, amend, or repeal scheduling actions may be initiated on the petition of any interested party. In accordance with 21 CFR 1308.43, 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. In accordance with 21 CFR 1308.43(c), the DEA accepted the petition for filing on October 1, 2012.

Pursuant to 21 U.S.C. 811(b), the DEA gathered the necessary data on naloxegol and on February 7, 2013, 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.

[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).

On August 8, 2014, the HHS provided to the DEA a scientific and medical evaluation document prepared by the FDA entitled ''Basis for the Recommendation to Decontrol Naloxegol and its Salts from Schedule II of the Controlled Substances Act.'' Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of naloxegol as a new drug, along with the HHS's recommendation to remove naloxegol from the schedules of the CSA.

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, and all other relevant data, and completed its own eight-factor review document on naloxegol pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by the HHS and DEA, and as considered by the DEA in this proposal to remove naloxegol from the schedules of the CSA. Please note that both the DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *http://www.regulations.gov* under docket number DEA–400.

1. The Drug's Actual or Relative Potential for Abuse

Naloxegol is a new molecular entity that has not been marketed in the United States or in any other country. As such, there is no information available regarding actual abuse of naloxegol. However, scientific studies show that naloxegol does not demonstrate a potential for abuse.

Naloxegol is a conjugation of polyethylene glycol (PEG) to naloxone. Naloxegol binds to mu, delta, and kappa opioid receptors and acts as an antagonist at these receptors. PEGylation of naloxone decreases the capacity of the substance to cross the blood-brain barrier, limiting the availability of naloxegol to peripheral opioid receptors (Diego et al., 2011; HHS review). Due to naloxegol being an antagonist at the three opioid receptors, mu, delta, and kappa, the HHS asserts that naloxegol does not have opioid agonist properties. Further, in abuse liability studies in animals, naloxegol did not produce responses seen with morphine administration. In clinical studies, the reports show that naloxegol does not produce euphoria or abuse potential related AEs. For example, the HHS stated that ''[n]aloxegol (30 to 1,000 mg/kg) produced less than 20% morphine-appropriate responding at any dose, which meets criteria for a 'no-drug' interoceptive cue.'' [3] Therefore, naloxegol does not demonstrate a potential for abuse.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

Binding studies showed that naloxegol does not bind significantly (>50% inhibition) to other molecular central nervous system (CNS) receptors, including dopamine, serotonin, glutamate, α-aminobutyric acid (GABA), sigma, acetylcholine, norepinephrine, cannabinoid, histamine, and monoamine transporters. Toxicological studies in rats and dogs did not produce behavioral signs of abuse potential, e.g. increased or decreased motor behavior, decreased body weight, or food intake. In two analgesia models in rodents, naloxegol did not produce any analgesic effects, demonstrating the lack of mu opioid receptor activation. Naloxegol was also tested in both analgesia models for its potency in reversing morphine-induced (subcutaneous or intravenous, 1–32 mg/kg) analgesia. Naloxegol did not fully reverse the analgesia produced by morphine, demonstrating that antagonistic actions of naloxegol were predominantly at the peripheral opioid receptor and not at the opioid receptors in the CNS. According to the HHS, oral naloxegol (12.5 and 25 mg/day) did precipitate opioid withdrawal in patients receiving opioids for pain management in the Phase 2/3 clinical trials. The incidence of withdrawal was low, the symptoms of opioid withdrawals occurred in patients taking naloxegol (2%) compared to placebo (<1%). It occurred with a higher incidence in patients receiving naloxegol (3%) at the higher dose (25 mg/day) than those receiving the 12.5 mg/day dose (1%). The HHS asserts that the withdrawal symptoms reported did not always meet the criteria of a clinically meaningful opioid withdrawal syndrome.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Naloxegol is known as (5α,6α)-17-allyl-6-((20-hydroxy-3,6,9,12,15,18-hexaoxaicos-1-yl)oxy)-4,5-epoxymorphinon-3,14-diol and also as alpha-6mPEG7–O-naloxol. The CAS number is 854601–70–0. The molecular formula of naloxegol is C34H53NO11 and the molecular weight is 651.8 g/mol. It is a white to off-white powder and is soluble in aqueous solvents over a pH range of 1 to 7.5. Naloxegol is synthesized in a five-step process from naloxone hydrochloride, an opioid antagonist derived from thebaine. Naloxegol (25 mg/day) is rapidly absorbed following oral administration in healthy volunteers. Maximum plasma concentrations were reached in 1.5 to 2 hours. The plasma half-life (t ½) is 7 to 9 hours, with a maximal plasma concentration (Cmax) of 45 ng/ml. In a drug distribution study in humans with radiolabeled naloxegol, the highest levels of radioactivity were in the liver and kidneys. The elimination t ½ of naloxegol is rapid, with majority being eliminated within 24-hours post-dose.

4. Its History and Current Pattern of Abuse

According to HHS, there has been no evidence of abuse-related signals from the human clinical trials. Naloxegol is a mu opioid antagonist, which as a class does not have abuse potential.

5. The Scope, Duration, and Significance of Abuse

There have been no reports of abuse of naloxegol. According to the National Forensic Laboratory Information System (NFLIS) [4] and the System to Retrieve Information from Drug Evidence (STRIDE),[5] there have been no reports of naloxegol seizures from 2010 to the present.

6. What, if Any, Risk There Is to the Public Health

According to the HHS, naloxegol is well-tolerated and safe at the therapeutic doses of 12.5 mg and 25 mg. Preclinical and clinical studies showed no evidence of potential for abuse of naloxegol and thus there is little public health risk from naloxegol.

[3] U.S. Food and Drug Administration, Department of Health and Human Services, *Basis for the Recommendation to Decontrol Naloxegol and Its Salts from Schedule II of the Controlled Substances Act* (2014), p. 6.

[4] The National Forensic Laboratory Information System (NFLIS) is a program of the DEA, Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 90% of an estimated 1.0 million distinct annual State and local drug analysis cases. 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* 76 FR 77330, 77332, Dec. 12, 2011.

[5] The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

7. Its Psychic or Physiological Dependence Liability

There were no symptoms of physical dependence in a naloxegol physical dependence liability study in rats. The HHS also mentioned that the lack of naloxegol self-administration by animals is consistent with a lack of psychic dependence liability.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

Naloxegol is not considered an immediate precursor of any controlled substance.

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all relevant data demonstrate that naloxegol does not possess abuse or dependence potential. Accordingly, the DEA finds that naloxegol does not meet the requirements for inclusion in any schedule, and should be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 and 15363

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform 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

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

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

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove naloxegol from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of naloxegol. Accordingly, it has the potential for some economic impact in the form of cost savings.

Naloxegol is a new molecular entity and is not currently available or marketed in any country. According to publicly available information reviewed by the DEA, naloxegol is anticipated to enjoy patent protection for an extended period of time before generic equivalents may be manufactured and marketed in the United States. Although the number of manufacturers of naloxegol may initially be limited, there is potential for numerous handlers in various business activities, e.g., distributors, hospitals/clinics, pharmacies, practitioners, etc.

If finalized, the proposed rule will affect all persons who would handle, or propose to handle, naloxegol. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates of new molecular entities, the DEA is unable to determine the number of entities and small entities which might handle naloxegol. However, the DEA estimates that all persons who would handle, or propose to handle naloxegol, are currently registered with the DEA to handle schedule II controlled substances. Therefore, the 1.5 million (1,469,418 as of September 2014) controlled substance registrations, representing approximately 426,714 entities, would be the maximum number of entities affected by this rule. The DEA estimates that 417,302 (97.8%) of 426,714 affected entities are ''small entities'' in accordance with the RFA and Small Business Administration size standards.

The DEA estimates all controlled substances registrants handle both controlled and non-controlled substances and these registrants are expected to continue to handle naloxegol if the proposed rule were finalized. Additionally, since prospective naloxegol handlers are likely to handle other schedule II controlled substances, the cost savings they would receive as a result of the de-control of naloxegol would be nominal. As naloxegol handlers continue to handle other scheduled II controlled substances, they will need to maintain their DEA registration and keep the same security and recordkeeping processes, equipment, and facilities in place and would experience only a nominal reduction in security, inventory, recordkeeping, and labeling costs.

While the DEA does not have a basis to estimate the number of affected entities, the DEA estimates that the maximum number of affected entities is 426,714 of which 417,302 are estimated to be small entities. Since the affected entities are expected to handle other schedule II controlled substances and maintain security and recordkeeping facilities and processes consistent with schedule II controlled substances handling requirements, the DEA estimates any economic impact (cost savings) will be nominal. Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 for inflation) in any one year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or

organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.12, amend the introductory text of paragraph (b)(1) by adding the word ''naloxegol,'' between ''nalmefene,'' and ''naloxone,'' to read as follows:

§ 1308.12 Schedule II.

(a) * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

* * * * *

Dated: October 23, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014–25685 Filed 10–28–14; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0696; FRL–9918–58–Region 9]

Revisions to the California State Implementation Plan, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by California for the Ventura County Air Pollution Control District (VCAPCD or ''the District'') portion of the California SIP. The submitted SIP revision contains the District's demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). We are proposing to approve the submitted SIP revision under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by November 28, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2014–0696, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, (415) 947–4122, *tong.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal

A. What document did the State submit?

Table 1 lists the document addressed by this proposal with the date that it was adopted by the local air agency and submitted by the California Air Resources Board.

TABLE 1—SUBMITTED DOCUMENT

Local agency	Document	Adopted	Submitted
VCAPCD	2014 Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision (''2014 RACT SIP'').	6/10/14	7/18/14