DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–344]

Schedules of Controlled Substances: Placement of FDA-Approved Products of Oral Solutions Containing Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(-)-delta-9-*trans*-tetrahydrocannabinol (delta-9-THC)] oral solution. Thereafter, the Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a scheduling recommendation that would result in Syndros (and other oral solutions containing dronabinol) being placed in schedule II of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing FDA-approved products of oral solutions containing dronabinol in schedule II of the CSA.

DATES: The effective date of this rulemaking is March 23, 2017. Interested persons may file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before April 24, 2017. 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 hearing pursuant to 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 24, 2017.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–344'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or 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 the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Acting Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–8953.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (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 all of 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 the 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, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, Notice of Appearance at Hearing, 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; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a) through (c), requests for a 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. Requests for a hearing and notices of participation must conform to the requirements of 21 CFR 1308.44(a) or (b), 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 of an opportunity for a hearing must conform to the requirements of 21 CFR 1308.44(c) 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 the hearing are 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 * * *.'' Requests for a hearing and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

Under the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), which was signed into law on November 25, 2015, DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the FDA. As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system, and that it appears that such drug has an abuse potential and (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of (1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation or (2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause therefor. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Background

Syndros is an oral solution that contains 5 mg of dronabinol (delta-9-THC) per mL of solution. Dronabinol is the generic name (International Nonproprietary Name, INN) for the (-) delta-9-trans isomer of tetrahydrocannabinol (THC), the primary psychoactive substance in marijuana. On June 1, 2015, Insys Therapeutics (Sponsor) submitted an NDA to the U.S. Food and Drug Administration (FDA) for Syndros, an oral formulation of dronabinol. The FDA accepted the NDA filing for Syndros on August 6, 2015 and approved the NDA on July 5, 2016. On December 28, 2016, the DEA received notification that HHS/FDA approved Syndros for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS), and for the treatment of nausea and vomiting resulting from cancer chemotherapy in patients who failed to respond to conventional anti-emetic therapies.

Determination To Schedule FDA-Approved Products Containing Dronabinol in an Oral Solution

On December 28, 2016, the HHS provided the DEA with a scientific and medical evaluation and scheduling recommendation related to dronabinol. Because DEA's authority to issue this interim final rule under subsection 811(j) is limited to drugs that are the subject of an approved NDA, and because the NDA was limited to an oral solution containing dronabinol, DEA's discussion here of the scheduling criteria is likewise limited to oral solutions containing dronabinol in FDA-approved drug products.[2] HHS's scientific and medical evaluation contained an eight-factor analysis of the abuse potential of FDA-approved products of oral solutions containing dronabinol and recommended that such products be placed in schedule II of the CSA.

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that FDA-approved dronabinol oral solutions met the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA.

Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule FDA-approved dronabinol oral solution as a schedule II controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its scheduling action. Please note that both the DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–344.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. *Its Actual or Relative Potential for Abuse:* Dronabinol is a generic name for the (-) delta-9-*trans* isomer of tetrahydrocannabinol (THC). THC is the primary psychoactive substance in marijuana. Dronabinol is the active pharmaceutical ingredient in Syndros. As stated by HHS, Marinol (synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule) was approved by the FDA for medical use on May 31, 1985 and placed in schedule II based on its accepted medical use and high abuse potential. On July 2, 1999, Marinol was rescheduled from schedule II to schedule III because of the findings of the DEA that the difficulty of separating dronabinol from the sesame oil formulation and the delayed onset of behavioral effects due to oral route administration supported a lower abuse potential of Marinol as compared to substances in Schedule II. 64 FR 35928.

According to HHS, although Syndros oral solution and Marinol capsules have

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

[2] To the extent HHS's submissions to DEA are outside the scope of this interim final rule (*i.e.,* those addressing dronabinol beyond that contained in an FDA-approved oral solution), they will not be addressed in this document.

the same pharmacology, these formulations differ in their physical and chemical properties. Both these formulations have abuse potential as demonstrated by their effects on subjective scores of ''Drug Liking'' in human abuse potential studies. HHS indicated that the formulation of Syndros (oral solution) is easier to abuse than Marinol because this liquid formulation can be manipulated to produce concentrated extracts of dronabinol for abuse by inhalation (smoking or vaping) or through other routes of administration. Because of the large amount of dronabinol in Syndros oral solution it has a greater potential for extraction than Marinol and thus has a greater abuse potential. Based on the data from in vitro studies conducted by the Sponsor, the large amount of dronabinol in the Syndros formulation, its pharmacokinetics upon oral administration, and its contribution to marijuana psychoactivity, HHS stated that the abuse potential of the dronabinol oral solution is similar to that of other THC containing products such as concentrates, infused edibles and drinks. Similar to these THC containing products, Syndros oral solution can be easily manipulated to other forms that can be easily abused through inhalation and oral routes of administration.

The 2014 and 2015 Monitoring the Future (MTF) [3] survey indicated that THC containing products are being taken orally, smoked, and vaporized using devices such as e-cigarettes. There is a lack of evidence pertaining to diversion of Syndros or Marinol from legitimate drug channels. Syndros is not yet available on the market. Marinol and generic forms that reference it, have low levels of abuse and diversion according to the HHS and DEA, and this is attributed to the formulation of dronabinol in sesame oil.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* Dronabinol, also known as THC, is the primary psychoactive substance in marijuana and is also the active pharmaceutical ingredient in Syndros and Marinol. Dronabinol binds to and activates the cannabinoid receptors (CB1 and CB2). HHS states that CB1 receptors activation underlie the psychotropic effects and many other pharmacological effects of dronabinol. Some behavioral and other effects of dronabinol in humans consist of dizziness, nausea, tachycardia, euphoria, enhanced sensory perception, heightened imagination, impaired judgment, emotional lability, and increased appetite. Dronabinol has been reported to be self-administered intravenously by squirrel monkeys and intracerebroventricularly by rats. Discriminative stimulus effects of dronabinol are specific to CB1 cannabinoids, and unique because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not generalize to dronabinol.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Dronabinol is the generic name for (-)delta-9-*trans*-tetrahydrocannabinol (THC) and is chemically known as (-)-(6a*R*-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[*b,d*]pyran-1-ol and has the chemical formula $C_{21}H_{30}O_2$. At room temperature (25 °C), dronabinol is a light-yellow oil and hardens upon refrigeration (4 °C) and is insoluble in water. The FDA-approved Syndros formulation consists of 5 mg dronabinol/mL of a 50 percent w/w alcoholic solution. Syndros will be marketed as 30 mL aliquots in clear, amber glass bottles and each bottle will contain 150 mg dronabinol.

In vitro manipulation studies with Syndros and Marinol (positive control) were conducted by the Sponsor. It was found that Syndros oral solution and Marinol capsules differ in their physiochemical properties. Specifically, Syndros, unlike Marinol, can be manipulated such that the dronabinol can be evaporated into residues that can be reconstituted for smoking or abused intravenously. According to HHS, Syndros contains a large amount of dronabinol (150 mg of dronabinol in 30 mL of solution) and would be an easily accessible source for abuse via the oral route.

4. *Its History and Current Pattern of Abuse:* There is a long history of abuse of THC in the United States. HHS noted that dronabinol in Marinol capsules is difficult to extract and therefore, cannot be used for smoking, vaping, or as an edible. The dronabinol in Syndros, however, is relatively easy to extract and concentrated forms can be used for smoking, vaping, or the sweetened alcoholic dronabinol in Syndros can be used as a substitute for THC in edibles. In the 2015 MTF survey, it was reported that teens were more likely to use e-cigarettes (vaping) than regular cigarettes (smoking). In this survey, 6.1 percent of 12th graders reported vaporizing marijuana or hash oil in their last e-cigarette. Additionally, in a recent analysis of marijuana users, 12 percent of users preferred vaping the drug over any other method and considered it a safer alternative to smoking. As a result, these data suggest that if dronabinol extracts or concentrates are available from dronabinol sources such as Syndros, a certain percent of the population are likely to vape these substances.

5. *The Scope, Duration, and Significance of Abuse:* As noted by HHS, information on the scope, duration, and significance of abuse of dronabinol was considered for both oral and inhalation routes. Data analyzed from the 2014 Summer Styles Survey, a national representative consumer panel survey of adult marijuana users aged 18 or older, showed that the majority of current marijuana users prefer smoking marijuana. In the same survey, it was reported that 16 percent of the current users consumed THC containing edibles or drinks. Individuals who preferred vaping (using a device to vaporize liquid THC) believed that vaping is ''healthier, better tasting'' and resulted in ''better effects'' associated with marijuana and THC.

6. *What, if any, Risk There is to the Public Health:* As stated by HHS, labeling on the Marinol packaging indicates that Central Nervous System (CNS) adverse reactions are dose-related and subject to patient variability. CNS adverse reactions are more likely to occur at higher doses of dronabinol. Following oral Marinol (dronabinol) doses of 0.4 mg/kg, CNS symptoms such as amnesia, confusion, delusions, depression, and hallucinations have been observed. According to HHS, it is assumed that Syndros oral solution will have similar adverse effects to Marinol. One concern with Syndros is that there is a large amount of dronabinol present in the product (150 mg dronabinol per bottle, 30 mL solution) that can easily be abused orally and may result in unintended overdoses.

Oral consumption of dronabinol, compared to inhaled THC, may result in psychoactive effects that are delayed and stronger with an increased risk of experiencing serious adverse events. When dronabinol (THC) is smoked, the drug rapidly reaches the brain and psychoactive effects are felt within minutes of inhalation, which allows the subject to control the dose more readily. Due to the absorption and metabolism by the liver following oral ingestion of dronabinol, it takes longer for an individual to feel the psychoactive effects. Therefore, the individual may underestimate the ingestion amount needed to feel the psychoactive effects

[3] MTF is a research program conducted at the University of Michigan's Institute for Social Research, under grants from NIDA. MTF tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades and high school graduates into adulthood by conducting national surveys.

which may potentially result in an overdose.

7. *Its Psychic or Physiological Dependence Liability:* As stated in labeling for Marinol and Syndros, psychological and physical dependence has been observed in healthy individuals following use of dronabinol. Abrupt discontinuation of dronabinol in individuals receiving 210 mg/day (25 times the recommended daily dose for the treatment of anorexia associated with weight loss in AIDS patients) for 12 to 16 days resulted in undesirable symptoms including insomnia, irritability, and restlessness at 12 hours after discontinuation. These symptoms worsened to include hot flashes, anorexia, sweating, rhinorrhea, loose stools, and hiccoughs at 24 hours after discontinuation of dronabinol.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Dronabinol oral solution is not an immediate precursor of any controlled substance.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS' recommendation, and its own eight-factor analysis, the DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of dronabinol oral solution. As such, the DEA hereby schedules FDA-approved products containing dronabinol oral solution as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular Schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1. FDA-approved products containing dronabinol in an oral solution have a high potential for abuse. The physicochemical properties of Syndros allow extraction of dronabinol for abuse through oral or inhalation (smoking or vaping) routes. Dronabinol is not easily extractable from Marinol. Oral abuse of dronabinol-containing products is associated with hallucinations, mood alterations, and paranoia. The 2015 MTF Survey reported that 6.1 percent of the 12th graders used e-cigarettes to vaporize marijuana or cannabinoid substances. Similarly, the 2014 Summer Styles Survey, 16 percent of current marijuana users indicated that they have consumed dronabinol containing edibles or drinks. These data collectively indicate FDA-approved oral solutions containing dronabinol have high potential for abuse.

2. FDA-approved products containing dronabinol in an oral solution have a currently accepted medical use in treatment in the United States. The FDA approved an oral solution containing dronabinol (Syndros) for the treatment of anorexia associated with weight loss in patients with AIDS, and for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

3. FDA-approved products containing dronabinol in an oral solution may lead to severe physical dependence. Following discontinuation of dronabinol at a dose 210 mg/day (25 times higher than the recommended daily dose for anorexia associated with weight loss in AIDS patients) for 12 to 16 consecutive days, withdrawal symptoms including irritability, insomnia, and restlessness were observed at 12 hours after discontinuation. These withdrawal symptoms worsened to include hot flashes, sweating, rhinorrhea, loose stools, hiccoughs, and anorexia at 24 hours after discontinuation of dronabinol. The withdrawal symptoms decreased gradually over the next 48 hours and patients reported having disturbed sleep for several weeks after discontinuation of dronabinol.

Based on these findings, the Acting Administrator of the DEA concludes that FDA-approved products containing dronabinol [(-)-delta-9-trans tetrahydrocannabinol (delta-9-THC)] in an oral solution warrant control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

Requirements for Handling FDA-Approved Products Containing Dronabinol in an Oral Solution.

Preliminarily, it should be noted that any form of dronabinol other than in an FDA-approved drug product remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations. However, for those who handle dronabinol oral solution exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule II regulatory requirements that apply as a result of this interim final rule:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) FDA-approved products containing dronabinol in an oral solution, or who desires to handle such products, must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles FDA-approved products containing dronabinol in an oral solution, and is not registered with the DEA, must submit an application for registration and may not continue to handle such products, unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Quota.* Only registered manufacturers are permitted to manufacture FDA-approved products containing dronabinol in an oral solution in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Upon obtaining a schedule II registration to handle FDA-approved products containing dronabinol in an oral solution, any person who does not desire or is not able to maintain such registration must surrender all quantities of such products, or may transfer all quantities of such products to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

4. *Security.* FDA-approved products containing dronabinol in an oral solution are subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of FDA-approved products containing dronabinol in an oral solution must take an inventory of such products on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle FDA-approved products containing dronabinol in an oral solution must take an initial inventory of all stocks of controlled

substances (including FDA-approved products containing dronabinol in an oral solution) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including FDA-approved products containing dronabinol in an oral solution) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for FDA-approved products containing dronabinol in an oral solution, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Orders for FDA-approved products containing dronabinol* in an oral solution. Every DEA registrant who distributes FDA-approved products containing dronabinol in an oral solution is required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing dronabinol in an oral solution may only be for the legitimate purposes authorized by the FDCA and CSA.

11. *Importation and Exportation.* All importation and exportation of FDA-approved products containing dronabinol in an oral solution must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving FDA-approved products containing dronabinol in an oral solution not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

As explained above, under 21 U.S.C. 811(j), where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA is required to issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause. Therefore, the standard notice-and-comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(j), this scheduling action is subject to formal rulemaking procedures performed ''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 procedures and 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, Civil Justice Reform

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

Executive Order 13132, Federalism

This 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 national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It 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

In accordance with 5 U.S.C. 603(a), ''[w]henever an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.'' As noted in the above discussion regarding applicability of the Administrative Procedure Act, the notice-and-comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* the DEA has determined 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 UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on

competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA amends 21 CFR part 1308 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, add paragraph (f)(2) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(f) * * *

(2) Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	(7365)

* * * * *

Dated: March 20, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–05809 Filed 3–22–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0100]

Drawbridge Operation Regulation; Des Allemands Bayou, Des Allemands, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Burlington Northern Santa Fe Railroad swing span drawbridge across Des Allemands Bayou, mile 14.0, at Des Allemands, St. Charles and Lafourche Parishes, Louisiana. The deviation is necessary to install two open-deck spans for increased reliability of bridge operations. This deviation allows the bridge to remain in the closed-to-navigation position for two (2) separate, two-day periods.

DATES: This deviation is effective from 6 a.m. on April 20, 2017 through 12 noon on April 28, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0100] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Giselle MacDonald, Bridge Management Specialist, Coast Guard; telephone 504–671–2128, email *Giselle.T.MacDonald@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Burlington Northern Santa Fe Railroad Company requested a temporary deviation from the operating schedule for the swing span drawbridge across Des Allemands Bayou, mile 14.0, at Des Allemands, St. Charles and Lafourche Parishes, Louisiana. The deviation was requested to install two open-deck spans, one on each side of the existing swing span, to increase the reliability of bridge opening and closing operations.

The draw currently operates under 33 CFR 117.440(b). The draw of the Burlington Northern Santa Fe Railroad Bridge, Mile 14.0, shall open on signal Monday through Friday from 7 a.m. to 3 p.m. At all other times the draw shall open on signal if at least 4 hours notice is given.

For purposes of this deviation, the bridge will remain closed to navigation for two separate dates, 30 hours each, from 6 a.m. April 20, 2017 through 12 noon, April 21, 2017 and from 6 a.m., April 27, 2017 through 12 noon, April 28, 2017. During this deviation, vessels will not be allowed to pass through the bridge. The bridge has a vertical clearance of 3 feet above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, fishing vessels and recreational craft.

The Coast Guard will inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 17, 2017.

Eric A. Washburn,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2017–05810 Filed 3–22–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP73

Release of VA Records Relating to HIV

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its medical regulations governing the release of VA medical records. Specifically, VA is eliminating the restriction on sharing a negative test result for the human immunodeficiency virus (HIV) with veterans' outside providers. HIV testing is a common practice today in healthcare and the stigma of testing that may have been seen in the 1980s when HIV was first discovered is no longer prevalent. Continuing to protect negative HIV tests causes delays and an unnecessary burden on veterans when VA tries to share electronic medical information with the veterans' outside providers through electronic health information exchanges. For this same reason, VA will also eliminate restrictions on negative test results of sickle cell anemia. This final rule eliminates the current barriers to electronic medical information exchange.

DATES: This final rule is effective April 24, 2017.