Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 135–773 and ANADA 200–421, and all supplements and amendments thereto, is hereby withdrawn, effective March 13, 2017.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03931 Filed 2–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2016–N–4661]

Gastroenterology-Urology Devices; Manual Gastroenterology-Urology Surgical Instruments and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the identification of manual gastroenterology-urology surgical instruments and accessories to reflect that the device does not include specialized surgical instrumentation for use with urogyencologic surgical mesh specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures (''specialized surgical instrumentation for use with urogynecologic surgical mesh''). These amendments are being made to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh.

DATES: This rule is effective March 1, 2017.

FOR FURTHER INFORMATION CONTACT: Sharon Andrews, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. G110, Silver Spring, MD 20993, 301–796–6529, *Sharon.Andrews@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is amending § 876.4730 (21 CFR 876.4730, Manual gastroenterology-urology surgical instrument and accessories), by adding language to the identification of the device to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is no longer regulated under § 876.4730.

In the **Federal Register** of November 23, 1983 (48 FR 53012), FDA issued a final rule classifying manual gastroenterology-urology surgical instrument and accessories into class I under § 876.4730 (48 FR 53012 at 53025). Certain specialized surgical instrumentation for use with urogynecologic surgical mesh was regulated as class I devices under that regulation. In the **Federal Register** of January 6, 2017 (82 FR 1598), FDA issued a final order reclassifying specialized surgical instrumentation for use with urogynecologic surgical mesh from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification. As a result of that final reclassification order, FDA is amending the identification at § 876.4730(a) to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is now regulated under 21 CFR 884.4910.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this rule only updates the identification of the device under § 876.4730 to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh (5 U.S.C. 553(b)(B)). In addition, FDA finds good cause for this amendment to become effective on the date of publication of this action. The Administrative Procedure Act allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendment to § 876.4730 does not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this amendment to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 876.4730 by revising paragraph (a) to read as follows:

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification.* A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop. A manual surgical instrument that is intended specifically for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures are classified under § 884.4910 of this chapter.

* * * * *

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03997 Filed 2–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–436]

Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places 10 synthetic

cathinones: 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone, bk-MBDB e); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone, bk-MBDP); 4-fluoro-*N*-methylcathinone (4-FMC, flephedrone); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); alpha-pyrrolidinobutiophenone (α-PBP) and their optical, positional, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This rule continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP.

DATES: *Effective date:* March 1, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, 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, and 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), chapter II.

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 ensuring an adequate supply is available 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 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.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes 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 * * *.'' 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 on the Attorney General's own motion, as delegated to the Administrator of the DEA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of the HHS and an evaluation of all relevant data by the DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP.

Background

On January 28, 2014, the DEA published a notice of intent to temporarily place 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); and alpha-pyrrolidinobutiophenone (α-PBP) into schedule I pursuant to the temporary scheduling provisions of the CSA. 79 FR 4429. On March 7, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these 10 synthetic cathinones into schedule I of the CSA. 79 FR 12938. That final order, effective on the date of publication, was based on findings by the DEA that the temporary scheduling of these 10 synthetic cathinones was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA requires that the temporary control of these substances expires two years from the issuance date of the scheduling order, or on or before March 6, 2016. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.* Accordingly, on March 4, 2016, the DEA extended the temporary scheduling of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP by one year, until March 3, 2017. 81 FR 11429. Also, on March 4, 2016, the DEA published a notice of proposed rulemaking (NPRM) to permanently control 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in schedule I of the CSA. 81 FR 11479. Specifically, the DEA proposed to add these 10 synthetic cathinones to 21 CFR 1308.11(d), hallucinogenic substances.

DEA and HHS Eight Factor Analyses

By letter dated March 2, 2016, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled ''Basis for the Recommendation to Control 4-

[1] As set forth 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 Department of Health and Human Services (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.

methyl-*N*-ethylcathinone (4-MEC), 4-methyl-pyrrolidinopropiophenone (4-MePPP), alpha-pyrrolidinopentiophenone (α-PVP), 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 2-(methylamino)-1-phenylpentan-1-one (pentedrone), 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 4-fluoro-*N*-methylcathinone (4-FMC), 3-fluoro-*N*-methylcathinone (3-FMC), 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone), alpha-pyrrolidinobutiophenone (α-PBP) and their Salts in Schedule I of the Controlled Substances Act (CSA).'' After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, α-PBP, and their salts be controlled in schedule I of the CSA. In response, the DEA conducted its own eightfactor analysis of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP. Both the DEA and HHS analyses are available in their entirety, under the tab ''Supporting Documents'' of the public docket of this action at *http://www.regulations.gov*, under FDMS Docket ID: DEA–2016–0004 (Docket No. DEA–436).[2]

Determination To Schedule 4-MEC, 4-MePPP, α-PVP, Butylone, Pentedrone, Pentylone, 4-FMC, 3-FMC, Naphyrone, and α-PBP

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled ''Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones into Schedule I,'' proposing to control 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, α-PBP, and their optical, positional and geometric isomers, salts and salts of isomers in schedule I of the CSA. 81 FR 11479, Mar. 4, 2016. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before April 4, 2016. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before April 4, 2016.

Comments Received

The DEA received two comments on the proposed rule to control 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in schedule I of the CSA. Both commenters were in opposition to the proposed scheduling of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in schedule I of the CSA, but the reasons for the opposition were different. The first commenter associated the scheduling of these substances with the ''War on Drugs,'' which according to the commenter ''has proven to be ineffective in past years in reducing the number of drug abuse victims in the United States.'' The second commenter questioned the findings considered by the DEA to control 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP. Both commenters offered alternative methods to address problems related to drug abuse instead of scheduling the 10 synthetic cathinones in schedule I of the CSA.

Opposition from First Commenter. The first commenter stated that he understood the DEA's reasons for proposing to schedule 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in schedule I of the CSA, but still opposed the control of these substances because, according to the commenter, it would neither reduce the number of drug users nor stop the production of illegal drugs. The commenter suggested that the DEA consider harm reduction solutions such as establishing drug clinics, finding jobs for prior offenders, and offering treatment and health care for drug users to address problems related to drug abuse.

DEA Response: Substances are controlled to protect the public health and safety. Pursuant to 21 U.S.C. 811(a), the CSA authorizes the DEA, under authority delegated by the Attorney General, to control any drug or other substance if it is found that the drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b). After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance's abuse potential, legitimate medical use, safety and dependence liability, the Assistant Secretary of the HHS recommended that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, α-PBP and their salts be controlled in schedule I of the CSA. The recommendations of the HHS to the DEA are binding on the DEA as to the scientific and medical matters. The DEA reviewed HHS's scientific and medical evaluations and all other relevant data on these substances and concurs with the HHS evaluations and findings. The current scientific, medical and other evidence on 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP warrant control of these substances and their optical, positional, and geometric isomers, salts and salts of isomers in schedule I of the CSA.

While the DEA appreciates the commenter's suggestions regarding the problems related to drug abuse, some of the suggested alternative solutions are outside the scope of the current scheduling action which pursuant to 21 U.S.C. 811 and 812 is to add drugs into one of the five schedules, remove drugs from the schedules, or transfer drugs within the schedules based on the drug's potential for abuse, medicinal value, harmfulness, and psychological or physical dependence. However, please note that in addition to law enforcement operations to reduce the supply of illicit controlled drugs, the DEA also recommends and supports non-enforcement programs such as the DEA 360 and the DEA Demand Reduction Section programs. The DEA 360 strategy involves community outreach activities such as the dissemination of drug information to increase the public's awareness about the dangers associated with drug use. The DEA's Community Outreach and Prevention Support Section supports initiatives to reduce the demand for drugs and gives assistance to community coalitions and drug prevention initiatives.

Some of the alternative methods suggested by the commenter to address the problems related to drug abuse that are outside of the scope of the DEA are, in fact, part of the initiatives of other federal institutions. For example, the Office of National Drug Control Policy (ONDCP), a component of the Executive Office of the President of the United States that coordinates drug-control activities and related funding across the Federal government including the DEA, incorporates community-based prevention programs, policies and systems to divert non-violent drug offenders into treatment instead of jail,

[2] Although the published notice of proposed rulemaking stated that the DEA 8-factor analysis had been placed into the docket on *http://www.regulations.gov*, DEA discovered in preparing this final rule that it had in fact not been posted. However, this document was available for review at the DEA. The DEA posted the cited analysis to *http://www.regulations.gov* upon discovery of the omission.

outreach programs as well as other drug control policies in its long term plans to reduce drug use and its consequences.

Opposition from Second Commenter. The second commenter also opposed the control of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in schedule I of the CSA, but for different reasons than the first commenter. The second commenter maintained that the three arguments the DEA relied on in its proposed rule for the scheduling of the 10 synthetic cathinones: (1) ''no medical or scientific use for these drugs;'' (2) ''there is a distinct public safety concern allowing these drugs to be sold;'' and (3) ''the use of this drug poses health concerns to those who use it,'' were illogical and based on faulty premises or speculative data. The commenter also stated that the number of reported cases (or law enforcement drug reports) involving these substances, especially if considered over the defined five year period (*i.e.,* January 2010 through December 2015), along with the population of the United States, is ''miniscule'' which indicates that these substances do not pose a large public safety concern. For example, the commenter provided information that estimated the U.S. population for 2015 to be 320 million, and considered this with the 20,090 total reported cases for all ten substances, as well as the 84 reported cases for naphyrone alone, over the defined five year period. Extrapolating this data further, the commenter estimated 4,018 reported cases annually for all ten substances (*i.e.,* 20,090 divided by 5 = 4,018), potentially impacting 0.000013 percent of the U.S. population (4,018 divided by 320 million = 0.000013 percent), and 17 reported cases annually for naphyrone alone (84 divided by 5 = 17). Furthermore, the commenter stated that there is no toxicology, efficacy, or safety data on these 10 synthetic cathinones in human beings indicating that these substances actually cause harm. The commenter also expressed concern that the proposed scheduling of the 10 synthetic cathinones would prohibit or significantly restrict the use of these substances in scientific and medical research, and that schedule I placement would put barriers in place for clinicians or researchers who might be interested in investigating the potential benefits of these substances in patients. In addition, this commenter believed that the proposed rule was unduly burdensome, leading to increased regulation and costs with ''little, if no impact'' on deterring abuse of these 10 synthetic cathinones. As an alternative to controlling these 10 synthetic cathinones, this commenter suggested ''placing restrictions on who can sell products with these compounds in them, and a restriction of the quantity that can be sold to any individual,'' and allowing States to regulate these substances.

DEA Response: Pursuant to 21 U.S.C. 811, the DEA considered the eight factors enumerated in 21 U.S.C. 811(c), the scientific and medical evaluations and scheduling recommendations from the HHS, and all other available data before making the required findings under 21 U.S.C. 812 to place these drugs into schedule I of the CSA. The DEA does not consider these finding to be illogical and based on faulty premises or speculative data. The summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in this scheduling action, was provided in the proposed rule. The information in these factors is from legitimate sources such as peer reviewed publications, national statistics (*e.g.,* seizure numbers, surveys), law enforcement communications, medical examiner reports, etc.

As of March 7, 2014, the date the final order to temporarily place the 10 synthetic cathinones into schedule I of the CSA was published and became effective, all persons handling the 10 synthetic cathinones were subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances. Based on a review of the DEA's records, each of the 43 registrations that have been identified to handle any of the 10 synthetic cathinones also handle other schedule I controlled substances. They have already established and implemented the systems and processes required to handle any of the 10 synthetic cathinones. Any additional cost to handle the one or more of the 10 synthetic cathinones is estimated to be minimal. Both the DEA and the HHS analyses have been made available in their entirety under ''Supporting Documents'' section of the public docket for this rule at *http://www.regulations.gov*, under FDMS Docket ID: DEA–2016–0004 (Docket No. DEA–436).[3]

As detailed in the HHS and DEA analyses and the HHS recommendation, studies indicate that the abuse potential and pharmacological effects of the 10 synthetic cathinones are similar to those of certain schedule I and II substances. Preclinical studies indicated that the 10 synthetic cathinones, like cocaine (schedule II), methamphetamine (schedule II), methcathinone (schedule I), and MDMA (schedule I) have pharmacological effects at monoamine transporters. Furthermore, behavioral effects of the 10 synthetic cathinones in animals were found to be similar to those of schedule I and II substances which have a high potential for abuse. In humans, the 10 synthetic cathinones are expected to produce subjective responses similar to methamphetamine and cocaine based on drug discrimination studies in rodents. Accordingly, published case reports demonstrate that some of the 10 synthetic cathinones produce pharmacological effects including adverse effects that are characteristic of substances like MDMA, methamphetamine, and cocaine that have a stimulant effect. However, there is no currently accepted medical use in treatment in the United States for any of the 10 synthetic cathinones. There are reports of emergency room admissions and deaths associated with the abuse of synthetic cathinones in general. Regarding the 10 synthetic cathinones, butylone, α-PVP, pentedrone, and pentylone have been implicated in the deaths of individuals. Consequently, the abuse of the 10 synthetic cathinones presents the possibility of death and potential safety hazards to the health of individuals.

Law enforcement data indicate that the 10 synthetic cathinones are being abused. Since 2010, law enforcement encounters of the 10 synthetic cathinones have increased and have been encountered in nearly every State (47 States as of December 2015). Regardless of the number of encounters of these 10 synthetic cathinones, evidence indicates that the abuse of the 10 synthetic cathinones is widespread. Thus, taking into consideration the harm that these substances can cause as demonstrated in case reports and other related information, the DEA believes that there is potential for widespread harm to the public health.

The DEA also considered all other relevant data including public comments regarding the proposed scheduling before controlling these drugs. After careful consideration of preclinical studies, case reports, law enforcement data and all other relevant data and in accordance with 21 U.S.C. 811(a) and (b) and considering the factors enumerated in 21 U.S.C. 811(c),

[3] Although the published notice of proposed rulemaking stated that the DEA 8-factor analysis had been placed into the docket on *http://www.regulations.gov*, DEA discovered in preparing this final rule that it had in fact not been posted. However, this document was available for review at the DEA. The DEA posted the cited analysis to *http://www.regulations.gov* upon discovery of the omission.

the DEA finds that the 10 synthetic cathinones have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision, thus supporting their placement in schedule I of the CSA.

The DEA does not agree that placement of these substances in schedule I of the CSA precludes scientific research from being conducted using these substances. Persons interested in using any of the 10 synthetic cathinones for research purposes can do so provided that they have a DEA schedule I researcher registration and meet all other statutory and regulatory criteria. This registration can be obtained by submitting an application for schedule I registration in accordance with 21 CFR 1301.11, 1301.13, 1301.18 and 1301.32.

As for the commenter's suggestion to allow States to regulate these substances, the DEA has no statutory authority under the CSA to require states to regulate these substances. With regard to the suggestion by the commenter to place ''restrictions on who can sell products with these compounds in them, and a restriction on the quantity that can be sold to any individual,'' the CSA and its implementing regulations do provide regulatory controls and administrative sanctions applicable to schedule I substances such as controls on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) schedule I substances.

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comment, the scientific and medical evaluations and accompanying recommendations of the HHS, and the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP. As such, the DEA is permanently scheduling 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for the HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP each have a high potential for abuse that is comparable to other schedule I and schedule II substances such as mephedrone, methylone, MDPV, methcathinone, MDMA, methamphetamine, and cocaine;

(2) 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); alpha-pyrrolidinobutiophenone (α-PBP) and their optical, positional, and geometric isomers, salts and salts of isomers, whenever the existence of salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP

4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are currently scheduled on a temporary basis in schedule I [4] and are therefore currently subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engaging in research, conducting instructional activities or chemical analysis, or possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, conducts instructional activities or chemical analysis with, or possesses) 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP, or who desires to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP 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.

2. *Security.* 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

5. *Inventory.* Every DEA registrant required to keep records and who possesses any quantity of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and/or α-PBP is required to maintain inventory of all stocks of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1317. Manufacturers and distributors must submit reports regarding 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and/or α-PBP to the Automation of Reports and Consolidated Orders System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33.

8. *Order Forms.* Every DEA registrant who distributes 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-

[4] 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 79 FR 12938, Mar. 7, 2014.

PBP must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP 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

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

In accordance with 21 U.S.C. 811(a), this final 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, 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 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

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On March 7, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these ten synthetic cathinones into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 12938. On March 4, 2016, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 81 FR 11429. The DEA estimates that all entities handling or planning to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP are currently registered to handle these substances. There are currently 43 registrants authorized to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally.[5] These 43 registrants represent 31 entities, of which 11 are small entities based on RFA definition of ''small entity'' and Small Business Administration size standards. Therefore, the DEA estimates that 11 small entities are affected by this rule.

A review of the 43 registrants indicates that all entities that currently handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP also handle other schedule I controlled substances, and have established and implemented (or currently maintain) the systems and processes required to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 11 affected small entities. Accordingly, the DEA has concluded that this rule will not have a significant economic impact on a substantial number of small entities.

[5] While analytical labs are required to obtain a registration for schedule I controlled substances, in order to handle any of the 10 synthetic cathinones, analytical labs are not required to identify the substances on their registration. Therefore, while every analytical lab that is authorized to handle schedule I controlled substances may handle any of the 10 synthetic cathinones, the DEA does not have a basis by which to estimate the number of analytical labs that actually handle the 10 synthetic cathinones. Since an analytical lab registered to handle schedule I controlled substances may manufacture or obtain any of the 10 synthetic cathinones without any modification to the analytical lab's registration, the DEA believes analytical labs' inventories of these substances are not significant and will have minimal impact on existing schedule I controlled substance storage space. Therefore, for the purposes of this analysis, the DEA assumes that no analytical lab is affected by this 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 and certifies 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 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 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, 21 CFR part 1308 is amended 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 § 1308.11:

■ a. Add paragraphs (d)(59) through (68);

■ b. Remove paragraphs (h)(1) through (10);

■ c. Redesignate paragraphs (h)(11) through (19) as (h)(1) through (9); and

■ d. Remove reserved paragraphs (h)(20) through (22).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(59) 4-methyl-*N*-ethylcathinone (4-MEC)	(1249)
(60) 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP)	(7498)
(61) *alpha*-pyrrolidinopentiophenone (α-PVP)	(7545)
(62) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone, bk-MBDB)	(7541)
(63) 2-(methylamino)-1-phenylpentan-1-one (pentedrone)	(1246)
(64) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone, bk-MBDP)	(7542)
(65) 4-fluoro-*N*-methylcathinone (4-FMC; flephedrone)	(1238)
(66) 3-fluoro-*N*-methylcathinone (3-FMC)	(1233)
(67) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone)	(1258)
(68) *alpha*-pyrrolidinobutiophenone (α-PBP)	(7546)

* * * * *

Dated: February 22, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–03974 Filed 2–28–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0055]

Drawbridge Operation Regulation; Cape Fear River, Wilmington, NC

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 Cape Fear Memorial Bridge which carries US 17 across the Cape Fear River, mile 26.8, at Wilmington, NC. The deviation is necessary to facilitate routine biennial maintenance and inspection of the lift span for the bridge. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 9 a.m. on March 7, 2017, through 4 p.m. on March 17, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0055] 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 Mr. Mickey Sanders, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6587, email *Mickey.D.Sanders2@uscg.mil*.

SUPPLEMENTARY INFORMATION: The North Carolina Department of Transportation, owner and operator of the Cape Fear Memorial Bridge that carries US 17 across the Cape Fear River, mile 26.8, at Wilmington, NC, has requested a temporary deviation from the current operating schedule to accommodate a routine biennial maintenance and inspection of the vertical lift span for the drawbridge. The bridge has a vertical clearance of 65 feet above mean high water (MHW) in the closed position and 135 feet above MHW in the open position.

The current operating schedule is set out in 33 CFR 117.822. Under this temporary deviation, the bridge will be maintained in the closed-to-navigation position for two separate four (4) day periods from 9 a.m. until 4 p.m. from March 7, 2017, through March 10, 2017, and from 9 a.m. until 4 p.m. from March 14, 2017, through March 17, 2017. During the closure periods, the bridge will open on signal if at least 3 hours notice is given. The bridge will open on signal at all other times.

The Cape Fear River is used by a variety of vessels including small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully considered the nature and volume of vessel traffic on the waterway in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed position may do so if at least 15 minutes notice is given. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by this temporary deviation.

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

Dated: February 23, 2017.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2017–03987 Filed 2–28–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2014–1037]

RIN 1625–AA00

Safety Zone: Eastport Breakwater Terminal, Eastport, Maine

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; change in effective period.

SUMMARY: The Coast Guard is extending the effective period of a safety zone in the vicinity of the Eastport Breakwater Terminal, Eastport, Maine. This safety zone was established on January 9, 2015 (80 FR 1344). This rule will extend the