Costs of Compliance

We estimate that this proposed AD will affect 18 products of U.S. registry. We also estimate that it would take about 2.5 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $3,825, or $212.50 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes and domestic business jet transport airplanes to the Director of the Policy and Innovation Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Pilatus Aircraft Limited: Docket No. FAA–2017–1079; Product Identifier 2017–CE–039–AD.

(a) Comments Due Date

We must receive comments by January 5, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pilatus Aircraft Limited Model PC–7 airplanes, manufacturer serial numbers 101 through 618, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 32: Landing Gear.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the brakes remaining activated after release of the brake pedal. We are issuing this AD to prevent the brakes from remaining activated after the brake pedal has been released, which could lead to asymmetric braking and subsequent loss of control.

(f) Actions and Compliance

Unless already done, within the next 90 days after the effective date of this AD, modify the brake pedal interconnecting tie rods by removing the bonding straps and attachment hardware following sections A, B, and C of the Accomplishment Instructions in Pilatus Service Bulletin 32–028, dated September 20, 2017.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the Federal Office of Civil Aviation (FOCA), which is the aviation authority for Switzerland.

(h) Related Information

Refer to MCAI FOCA AD HB–2017–002, dated October 20, 2017; and Pilatus Service Bulletin No. 32–028, dated September 20, 2017, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1079. For service information related to this AD, contact PILATUS Aircraft Ltd., Customer Technical Support (MCC), P.O. Box 992, CH–6371 Stans, Switzerland; phone: +41 (0)41 619 67 74; fax: +41 (0)41 619 67 73; email: *techsupport@pilatus-aircraft.com;* Internet: *http://www.pilatus-aircraft.com.* You may review this referenced service information at the FAA, Policy and Innovation Division, 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 November 9, 2017.

Pat Mullen,

Acting Deputy Director, Policy & Innovation Division, Aircraft Certification Service.

[FR Doc. 2017–25006 Filed 11–20–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–474]

Schedules of Controlled Substances: Temporary Placement of Cyclopropyl Fentanyl into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide (cyclopropyl fentanyl), into Schedule I. This action is based on a finding by the Administrator that the placement of this synthetic opioid into Schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of this synthetic opioid.

DATES: November 21, 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: This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) to add cyclopropyl fentanyl to Schedule I under the Controlled Substances Act.[1] The temporary scheduling order will be published in the **Federal Register**, but will not be issued before December 21, 2017.

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place cyclopropyl fentanyl in Schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated August 28, 2017. The Assistant Secretary responded to this notice of intent by letter dated September 6, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for cyclopropyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of cyclopropyl fentanyl into Schedule I of the CSA. Cyclopropyl fentanyl is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for cyclopropyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Cyclopropyl Fentanyl

The recent identification of cyclopropyl fentanyl in drug evidence and the identification of this substance in association with fatal overdose events indicate that this substance is being abused for its opioid properties. No approved medical use has been identified for cyclopropyl fentanyl, nor has it been approved by the FDA for human consumption.

Available data and information for cyclopropyl fentanyl, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–474.

Factor 4. History and Current Pattern of Abuse

The recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. Cyclopropyl fentanyl has been encountered by law enforcement and public health officials beginning as early as May 2017. The DEA is not aware of any laboratory identifications of this substance prior to 2017. Adverse health effects and outcomes of cyclopropyl fentanyl abuse are consistent with those of other opioids and are demonstrated by fatal overdose cases involving this substance.

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. Data from STRIDE and STARLiMS were queried on August 25,

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] 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.

2017. STARLiMS registered a total of three reports containing cyclopropyl fentanyl from California, Connecticut, and New York. Of these three exhibits, one had a net weight of approximately one kilogram. According to STARLiMS, the first laboratory submission of cyclopropyl fentanyl occurred in Connecticut in June 2017.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state and local forensic laboratories across the country. NFLIS registered 10 reports containing cyclopropyl fentanyl from state or local forensic laboratories in Oklahoma in July 2017 (query date: August 29, 2017).[3]

In addition to data recorded in NFLIS and STARLiMS, cyclopropyl fentanyl was identified in drug evidence submitted to state and local forensic laboratories in Georgia and Pennsylvania. Cyclopropyl fentanyl was confirmed in combination with U–47700, another synthetic opioid temporarily controlled in Schedule I of the CSA, in 24 glassine paper packets submitted to a law enforcement forensic laboratory in Pennsylvania.[4] A law enforcement forensic laboratory in Georgia confirmed [5] the presence of cyclopropyl fentanyl in counterfeit oxycodone tablets which also contained U–47700. The distribution of cyclopropyl fentanyl in these forms, and in combination with another synthetic opioid, suggests that this substance was marketed as heroin or prescription opioids in the illicit market.

Evidence suggests that the pattern of abuse of fentanyl analogues, including cyclopropyl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of cyclopropyl fentanyl have been encountered in powder form, similar to fentanyl and heroin, and in counterfeit prescription opioid products (*i.e.* counterfeit oxycodone tablets). Cyclopropyl fentanyl was also confirmed in toxicology samples from fatal overdose cases.

Factor 5. Scope, Duration and Significance of Abuse

Reports collected by the DEA demonstrate that cyclopropyl fentanyl is being abused for its opioid properties. Abuse of cyclopropyl fentanyl has resulted in mortality (*see* DEA 3-Factor Analysis for full discussion). The DEA collected post-mortem toxicology and medical examiner reports on 115 confirmed fatalities associated with cyclopropyl fentanyl which occurred in Georgia (1), Maryland (24), Mississippi (1), North Carolina (75), and Wisconsin (14). It is likely that the prevalence of this substance in opioid related emergency room admissions and deaths is underreported as standard immunoassays may not differentiate this fentanyl analogue from fentanyl.

NFLIS and STARLiMS have a total of 13 drug reports in which cyclopropyl fentanyl was identified in drug exhibits submitted to forensic laboratories in 2017 from law enforcement encounters in California, Connecticut, New York, and Oklahoma. In addition to the data collected in these databases, cyclopropyl fentanyl was identified in drug evidence submitted to forensic laboratories in Georgia (counterfeit oxycodone preparation) and Pennsylvania (24 glassine paper packets).

The population likely to abuse cyclopropyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl and other fentanyl-related substances. This is supported by cyclopropyl fentanyl being identified in powder contained within glassine paper packets and counterfeit prescription opioid products. This is also demonstrated by routes of drug administration and drug use history documented in cyclopropyl fentanyl fatal overdose cases. Because abusers of cyclopropyl fentanyl obtain this substance through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.* use a drug for the first time) cyclopropyl fentanyl abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.).

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

With no legitimate medical use, cyclopropyl fentanyl has emerged on the illicit drug market and is being misused and abused for its opioid properties. Cyclopropyl fentanyl exhibits pharmacological profiles similar to that of fentanyl and other μ-opioid receptor agonists. The abuse of cyclopropyl fentanyl poses significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone. The toxic effects of cyclopropyl fentanyl in humans are demonstrated by overdose fatalities involving this substance.

Based on information received by the DEA, the misuse and abuse of cyclopropyl fentanyl lead to, at least, the same qualitative public health risks as heroin, fentanyl, and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

Cyclopropyl fentanyl has been associated with numerous fatalities. At least 115 confirmed overdose deaths involving cyclopropyl fentanyl abuse have been reported from Georgia (1), Maryland (24), Mississippi (1), North Carolina (75), and Wisconsin (14) in 2017. As the data demonstrate, the potential for fatal and non-fatal overdoses exists for cyclopropyl fentanyl and this substance poses an imminent hazard to the public safety.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the continued uncontrolled manufacture, distribution, importation, possession, and abuse of cyclopropyl fentanyl pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for cyclopropyl fentanyl in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for cyclopropyl fentanyl indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated August 28, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place this substance in Schedule I.

[3] Data are still being collected for May 2017–August 2017 due to the normal lag period for labs reporting to NFLIS.

[4] Email from Philadelphia Police Department—Office of Forensic Science, to DEA (August 18, 2017 11:09 a.m.) (on file with DEA).

[5] Laboratory report obtained from Division of Forensic Science, Georgia Bureau of Investigation.

Conclusion

This notice of intent initiates a temporary scheduling process and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule cyclopropyl fentanyl in Schedule I of the CSA, and finds that placement of this synthetic opioid into Schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of cyclopropyl fentanyl into Schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before December 21, 2017. Because the Administrator hereby finds that it is necessary to temporarily place cyclopropyl fentanyl into Schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling this substance will be effective on the date that order is published in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the temporary order, cyclopropyl fentanyl will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a Schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will 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. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(22) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(22) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: cyclopropyl fentanyl) . . . (9845)

* * * * *

Dated: November 13, 2017.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2017–25077 Filed 11–20–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0994]

RIN 1625–AA00

Safety Zone; Spa Creek, Annapolis, MD

AGENCY: Coast Guard, DHS.