For the reasons discussed, I certify this proposed regulation:

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

(2) Would not affect intrastate aviation in Alaska, and

(3) Would 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 airworthiness directive:

Airbus Helicopters Deutschland GmbH (AHD): Docket No. FAA–2021–0126; Project Identifier MCAI–2020–00266–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by April 19, 2021.

(b) Affected ADs

None.

(c) Applicability

This airworthiness directive (AD) applies to Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 D–2 helicopters, certificated in any category, with a Titanium (Ti) bolt part number EN3740–060022F marked with manufacturer monogram ''D'' or with an illegible manufacturer monogram, installed on the aft connection of the tail rotor ball bearing control.

(d) Subject

Joint Aircraft System Component (JASC) Codes: 1430, Fasteners; and 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD defines the unsafe condition as a Ti-bolt with hydrogen embrittlement. This condition could result in failure of the tail rotor ball bearing control Ti-bolt and subsequent loss of tail rotor control.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within 50 hours time-in-service or 3 months, whichever occurs first, remove any Ti-bolt identified in paragraph (c) of this AD, located on the aft connection of the tail rotor ball bearing rod end (item 5) and at the input lever (item 2) as shown in Figure 1 to Airbus Helicopters Alert Service Bulletin (ASB) No. ASB MBB–BK117 D–2–00A–001, Revision 1, dated October 16, 2019, from service.

(2) As of the effective date of this AD, do not install a Ti-bolt identified in paragraph (c) of this AD on the aft connection of the tail rotor ball bearing control of any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Strategic Policy Rotorcraft Section, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

(2) For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD No. 2019–0258, dated October 18, 2019. You may view the EASA AD on the internet at *https://www.regulations.gov* in the AD Docket.

Issued on February 22, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives Compliance & Airworthiness Directive, Aircraft Certification Service.

[FR Doc. 2021–03955 Filed 3–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–476]

Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2′-fluoro *ortho*-fluorofentanyl), *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4′-methyl acetyl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl), *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl), *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl), *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl), 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl), *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act. These ten specific substances fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. If finalized, this action would make permanent the existing 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 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

DATES: Comments must be submitted electronically or postmarked on or before April 2, 2021.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 2, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–476'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The Drug Enforcement Administration (DEA) 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 to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Easter Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: 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/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the 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 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 confidential business information to be redacted within the comment.

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

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in a 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, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (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 (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of U.S. Department of Health and Human Services (HHS) (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl

fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), the then-Acting Administrator of DEA published an order in the **Federal Register** (83 FR 5188) temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA upon finding that these substances pose an imminent hazard to the public safety. The 10 substances named in this proposed rule (2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) meet the existing definition of fentanyl-related substances. On April 19, 2019, DEA specifically identified four of these 10 substances (2′-fluoro *ortho*-fluorofentanyl, β′-phenyl fentanyl, *ortho*-methyl acetylfentanyl, and thiofuranyl fentanyl) as meeting the definition of fentanyl-related substances. 84 FR 16397. Although DEA did not issue a **Federal Register** publication to identify the other six substances, the February 6, 2018, temporary scheduling order emphasized that, even still, a substance is controlled by virtue of the order if it falls within the definition of fentanyl-related substances. 83 FR 5188, 5189. As discussed below in Factor 3, all 10 substances meet the definition as they are not otherwise controlled in any other schedule (*i.e.,* not included under another Administration Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition.

That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the 10 specific substances already covered by that order, was set to expire on February 6, 2020. However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress overrode and extended that expiration date until May 6, 2021, by enacting on February 6, 2020 the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103). By operation of law, the temporary control of fentanyl-related substances, which includes these 10 covered substances, will remain in effect until May 6, 2021, unless DEA permanently places them in schedule I prior to May 6, 2021. As discussed in the above Legal Authority section, proceedings under 21 U.S.C. 811(a) may be initiated by the Administrator of DEA on his own motion.

The Acting Administrator, on his own motion, is initiating proceedings to permanently schedule the following 10 fentanyl-related substances: 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. DEA gathered the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these 10 fentanyl-related substances, as well as for six other fentanyl-related substances (benzodioxole fentanyl, crotonyl fentanyl, fentanyl carbamate, *ortho*-fluoro isobutyryl fentanyl, *ortho*-fluoroacryl fentanyl, and *para*-fluoro furanyl fentanyl). On April 3, and October 2, 2019, the then-Acting Administrator submitted this data to the Assistant Secretary, and requested that HHS provide DEA with a scientific and medical evaluation and a scheduling recommendation for the 16 fentanyl-related substances named above, in accordance with 21 U.S.C. 811(b) and (c).

Upon evaluating the scientific and medical evidence, on July 2, 2020, the Assistant Secretary submitted to the Acting Administrator, HHS's scientific and medical evaluation and scheduling recommendation for 11 of the 16 fentanyl-related substances, including the 10 named substances in this proposed rule as well as crotonyl fentanyl.[1] Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed these documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of the 10 substances in accordance with 21 U.S.C. 811(c). On October 2, 2020, DEA issued a final order (85 FR 62215) for crotonyl fentanyl to remain as a schedule I substance under the CSA in order to meet the United States' obligations under the 1961 Single Convention on Narcotic Drugs (Single Convention), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended.[2] As such, crotonyl fentanyl will not be discussed further in this scheduling action.

Proposed Determination To Permanently Schedule 2′-Fluoro ortho-Fluorofentanyl, 4′-Methyl Acetyl Fentanyl, β-Methyl Fentanyl, β′-Phenyl Fentanyl, ortho-Fluorobutyryl fentanyl, ortho-Methyl Acetylfentanyl, ortho-Methyl Methoxyacetyl Fentanyl, para-Methylfentanyl, Phenyl Fentanyl, and Thiofuranyl Fentanyl

As discussed in the background section, the Acting Administrator is initiating proceedings to permanently add 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl to schedule I. DEA has reviewed the scientific and medical evaluation and scheduling recommendation from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of these 10 substances. Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's July 2, 2020, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–476.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse:[3]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a

[1] HHS' scientific and medical evaluation for the other five fentanyl-related substances (benzodioxole fentanyl, fentanyl carbamate, *ortho*-fluoro isobutyryl fentanyl, *ortho*-fluoroacryl fentanyl, and *para*-fluoro furanyl fentanyl) is ongoing. DEA will not further discuss these five substances in this proposed rule.

[2] In November 2019, the Director-General of the World Health Organization recommended to the Secretary-General that crotonyl fentanyl be placed in Schedule I of the Single Convention. On May 7, 2020, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 63rd session in March 2020, the Commission on Narcotic Drugs voted to place crotonyl fentanyl in Schedule I of the Single Convention (CND Mar/63/2).

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); *reprinted in* 1970 U.S.C.C.A.N. 4566, 4603.

hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The abuse potential of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is associated with their pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances, which have a high potential for abuse. Similar to morphine and fentanyl, these 10 substances have been shown to bind and act as mu-opioid receptor agonists.

These 10 substances have no approved medical use in the United States and have been encountered on the illicit drug market. The use of some fentanyl-related substances has been associated with adverse health outcomes, including death. The appearance of several substances structurally related to fentanyl in the illicit drug market has resulted in a significant increase in drug overdose deaths in the United States. According to the Centers for Disease Control and Prevention (CDC) overdose death data for 2018, there continues to be an increase in the number of deaths related to synthetic opioids. Opioids were involved in about 70 percent of all drug-involved overdose deaths in 2018. Further, CDC reports demonstrate that the increase in synthetic opioid overdose deaths are largely attributed to an increase in the supply of illicitly manufactured fentanyl and substances structurally related to fentanyl. Because 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are not Food and Drug Administration (FDA)-approved drug products, a practitioner may not legally prescribe them, and these substances cannot be dispensed to an individual. Therefore, the use of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is without medical advice, and accordingly leads to the conclusion that these 10 substances are abused for their opioidergic properties.

There are no legitimate drug channels for 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl as marketed FDA-approved drug products, but these substances are available for purchase from legitimate chemical companies for research purposes. However, despite the limited legitimate research use of these 10 substances, reports from public health and law enforcement data indicate that all 10 substances are being abused and taken in amounts sufficient to create a hazard to an individual's health. Data from forensic databases can be used as an indicator of illicit activity with drugs and abuse [4] within the United States. According to the National Forensic Laboratory Information System (NFLIS),[5] which collects and analyzes drug exhibits submitted to Federal, State, and local forensic laboratories, there were 235 total reports of seven of the 10 substances (4′-methyl acetyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) between 2017 and 2020 (queried on July 16, 2020). In 2017 and 2018, U.S. Customs and Border Protection (CBP) reported that two other of the 10 substances (2′-fluoro *ortho*-fluorofentanyl and β′-phenyl fentanyl) have been positively identified in seized drugs, respectively. In 2018, *ortho*-methyl methoxyacetyl fentanyl was positively identified in an exhibit submitted to NMS laboratories for analysis by the Department of Homeland Security. Consequently, the positive identification of the 10 substances in law enforcement encounters indicates that these substances are being abused, and thus pose safety hazards to the health of users.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are pharmacologically similar to other schedule I and schedule II mu-opioid receptor agonist substances. The abuse potential (assessed by drug discriminative studies) of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl show that these substances share discriminative stimulus effects similar to fentanyl and morphine. Similar to schedule I and II opioid analgesics, these 10 substances bind to and activate the mu-opioid receptor. Additionally, behavioral studies in animals demonstrate these 10 substances produce analgesic effects similar to fentanyl and morphine. Pre-treatment with naltrexone, an opioid antagonist, attenuated analgesic effect of these 10 substances, as well as fentanyl and morphine. These data indicate that the 10 substances are mu-opioid receptor agonists with effects on the central nervous system. Data from drug discrimination studies showed that these 10 substances share discriminative stimulus effects similar to those of morphine. Thus, it is concluded from *in vitro* and *in vivo* pharmacological studies that the effects of the 10 substances are similar to that of fentanyl and morphine and are mediated by mu-opioid receptor agonism.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are synthetic opioids of the 4-anilidopiperidine structural class, which includes fentanyl. As defined in the February 6,

[4] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[5] NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

2018, temporary order, fentanyl-related substances include any substance not otherwise controlled in any schedule (*i.e.,* not included under any other Administration Controlled Substance Code Number) that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) replacement of the *N*-propionyl group by another acyl group.

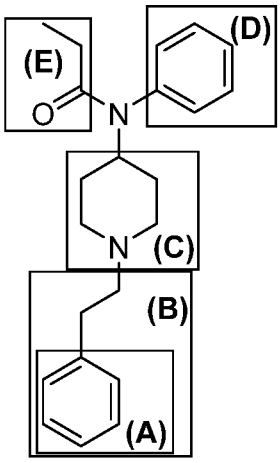

Figure 1: Regions of the chemical structure of fentanyl described in the definition of a fentanyl-related substance

According to the February 6, 2018, temporary scheduling order, the existence of a substance with any one, or any combination, of above-mentioned modifications (see Figure 1) would meet the structural requirements of the definition of fentanyl-related substances. The present 10 substances fall within the definition of fentanyl-related substances by the following modifications:

1. 2′-Fluoro *ortho*-fluorofentanyl: Substitution on the phenethyl group with a halo group and substitution on the aniline ring (meets definition for modifications B and D);

2. 4′-methyl acetyl fentanyl: Substitution on the phenethyl group with an alkyl group and replacement of the *N*-propionyl group by another acyl group (meets definition for modifications B and E);

3. β-methyl fentanyl: Substitution on the phenethyl group with an alkyl group (meets definition for modification B);

4. β′-phenyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E);

5. *ortho*-fluorobutyryl fentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

6. *ortho*-methyl acetylfentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

7. *ortho*-methyl methoxyacetylfentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

8. *para*-methylfentanyl: Substitution on the aniline ring (meets definition for modification D);

9. phenyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E); and

10. thiofuranyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E).

No study has been undertaken to evaluate the efficacy, toxicology, and safety of the 10 substances in humans. It can be inferred from data obtained from animal studies that these 10 substances have sufficient distribution to the brain to produce depressant effects similar to that of other mu-opioid receptor agonists such as fentanyl. Data from *in vitro* receptor binding studies show that these 10 substances, similar to fentanyl, display high selectivity for the mu-opioid receptor over other opioid receptor subtypes.

There are no FDA-approved marketing applications for a drug product containing 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl for any therapeutic indication in the United States. Moreover, there are no clinical studies or petitions which have claimed an accepted medical use in the United States for these 10 substances.

4. *Its History and Current Pattern of Abuse:* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, like other substances structurally related to fentanyl, are disguised as a ''legal''

alternative to fentanyl. Between 2017 and 2020, law enforcement officials in the United States encountered these 10 substances.

5. *The Scope, Duration, and Significance of Abuse:* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, similar to other substances structurally related to fentanyl, are often used as recreational drugs. The recreational use of these 10 substances and other fentanyl-related substances continues to be of significant concern as the United States currently is in the midst of an opioid epidemic. These substances are distributed to users, often with unpredictable outcomes. Because users of these fentanyl-related substances and their associated drug products are likely to obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to abusers. Evidence that these 10 substances are being abused and trafficked is confirmed by law enforcement encounters. NFLIS contained 235 reports of 4′-methyl acetyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl from Federal, State, and local forensic laboratories between 2017 and 2020. In 2017 and 2018, CBP reported that 2′-fluoro *ortho*-fluorofentanyl and β′-phenyl fentanyl have been positively identified in seized drugs, respectively. In 2018, *ortho*-methyl methoxyacetyl fentanyl was positively identified in an exhibit submitted to NMS laboratories for analysis by the Department of Homeland Security.

6. *What, if Any, Risk There Is to the Public Health:* The increase in opioid overdose deaths in the United States has been exacerbated by the availability of potent synthetic opioids such as fentanyl and structurally related substances in the illicit drug market. These substances have a history of being trafficked as replacements for heroin and other synthetic opioids. Increasingly, law enforcement has encountered fentanyl and substances structurally related to fentanyl in counterfeit prescription opioids, heroin, and other street drugs such as cocaine, methamphetamine, and synthetic cannabinoids. Fentanyl is a potent synthetic opioid that is primarily prescribed for acute and chronic pain and is approximately 100 times more potent than morphine. As such, fentanyl has a high risk of abuse, dependence and overdose that can lead to death. Because fentanyl-related substances, as defined in the February 6, 2018, temporary order, have similar chemical structure to fentanyl, these substances are expected to have similar biological effects. In *in vitro* and *in vivo* studies, 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl produced pharmacological effects similar to fentanyl. Thus, these 10 substances pose the same qualitative public health risks as heroin, fentanyl, and other mu-opioid receptor agonists.

According to a CDC report, from 2013 to 2017, opioid-related overdose deaths in the United States increased 90 percent from 25,052 to 47,600. The increase in the number of opioid-related deaths was primarily driven by illicitly manufactured fentanyl.[6] According to CDC 2018 provisional data, there were 68,500 drug overdose fatalities; of those, 47,600 (~69 percent) involved an opioid. The use of some fentanyl-related substances has been associated with adverse health outcomes, including death.

7. *Its Psychic or Physiological Dependence Liability:* There are no pre-clinical and clinical studies that have evaluated the dependence potential of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. These 10 substances are mu-opioid receptor agonists, and discontinuation of the use of mu-opioid receptor agonists such as fentanyl and morphine is known to cause withdrawal indicative of physical dependence. Opioid withdrawal includes nausea and vomiting, depression, agitation, anxiety, craving, sweats, hypertension, diarrhea, and fever.

8. *Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA:* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are not considered immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. As such, DEA hereby proposes to permanently schedule 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule I of the CSA.

Proposed 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 Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) 2′-Fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, β*-methyl fentanyl,* β*′-phenyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a high potential for abuse.*

According to HHS, 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, similar to fentanyl, are mu-opioid receptor agonists. These

[6] If evidence of prescription or illicit use was not available, fentanyl was categorized as illicitly-manufactured fentanyl (''IMF'') because the vast majority of fentanyl overdose deaths involve IMF. Gladden RM, O'Donnell J, Mattson CL, Seth P. Changes in Opioid-Involved Overdose Deaths by Opioid Type and Presence of Benzodiazepines, Cocaine, and Methamphetamine—25 States, July–December 2017 to January–June 2018. MMWR Morb Mortal Wkly Rep. 30; 68(34):737–744.

substances have analgesic effects, and these effects are mediated by mu-opioid receptor agonism. HHS states that substances that produce mu-opioid receptor agonist effects in the central nervous system (*e.g.,* morphine and fentanyl) are considered as having a high potential for abuse. Data obtained from drug discrimination studies indicate that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl fully substituted for the discriminative stimulus effects of morphine.

(2) 2′-Fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no currently accepted medical use in treatment in the United States.

According to HHS, there are no FDA-approved new drug applications for 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in the United States. There are no known therapeutical applications for these fentanyl-related substances and thus they have no currently accepted medical use in the United States.[7]

(3) There is a lack of accepted safety for use of 2′-fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision.

Because 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no FDA-approved medical use and have not been thoroughly investigated as new drugs, their safety for use under medical supervision is undetermined. Thus, there is a lack of accepted safety for use of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for handling 2′-fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

If this rule is finalized as proposed, 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl would continue[8] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, research, and conduct of instructional activities, including the following:

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) 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, or who desires to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is required to be registered with 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.* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are subject to schedule I 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. Non-practitioners handling 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl also must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

[7] Although there is no evidence suggesting that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[8] 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, are covered by the February 6, 2018, temporary scheduling order, and are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 5188.

4. *Quota.* Only registered manufacturers are permitted to manufacture 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) 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 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) 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.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is required to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed 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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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 proposed rule does not have tribal implications warranting the application of E.O. 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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have already established and implemented the systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 57 registrations authorized to handle the fentanyl-related substances as a class, which include 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 57 registrations represent 51 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this proposed rule.

A review of the 57 registrations indicates that all entities that currently handle fentanyl-related substances, including 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl

methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β-methyl fentanyl, β′-phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. Therefore, DEA anticipates that this proposed 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 eight affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* 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 million or more (adjusted annually for inflation) in any 1 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.

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, DEA proposes to amend 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), 956(b), unless otherwise noted.

■ 2. In § 1308.11:
■ a. Redesignate paragraph (75) as paragraph (b)(84);
■ b. Add paragraph (b)(83);
■ c. Redesignate paragraphs (b)(65) through (71) as paragraphs (b)(76) through (82);
■ d. Add a new paragraph (b)(75);
■ e. Redesignate paragraphs (b)(60) through (64) as paragraphs (b)(70) through (74);
■ f. Add a new paragraph (69);
■ g. Redesignate paragraphs (b)(56) through (59) as paragraphs (b)(65) through (68);
■ h. Add a new paragraph (64);
■ i. Redesignate paragraph (b)(55) as paragraph (b)(63);
■ j. Add new paragraphs (b)(61) and (62);
■ k. Redesignate paragraphs (b)(45) through (54) as paragraphs (b)(51) through (60);
■ l. Add new paragraph (b)(50);
■ m. Redesignate paragraphs (b)(37) through (44) as paragraphs (b)(42) through (49);
■ n. Add a new paragraph (b)(41);
■ o. Redesignate paragraph (b)(36) as paragraph (b)(40);
■ p. Add a reserved paragraph (b)(39);
■ q. Redesignate paragraphs (b)(22) through (35) as paragraphs (b)(25) through (38);
■ r. Add a reserved paragraph (b)(24);
■ s. Redesignate paragraphs (b)(17) through (21) as paragraphs (b)(19) through (23); and
■ t. Add new paragraphs (b)(17) and (18).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(17) Beta-methyl fentanyl (*N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; other name: β-methyl fentanyl) 9856
(18) Beta′-phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide; other names: β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl) 9842

* * * * * * *

(41) 2′-Fluoro *ortho*-fluorofentanyl (*N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide; other name: 2′-fluoro 2-fluorofentanyl) 9829

* * * * * * *

(50) 4′-Methyl acetyl fentanyl (*N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide) 9819

* * * * * * *

(61) *ortho*-Fluorobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide; other name: 2-fluorobutyryl fentanyl) 9846
(62) *ortho*-Methyl acetylfentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; other name: 2-methyl acetylfentanyl) 9848

* * * * * * *

(64) *ortho*-Methyl methoxyacetyl fentanyl (2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; other name: 2-methyl methoxyacetyl fentanyl) 9820

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(69) *para*-Methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; other name: 4-methylfentanyl) 9817

* * * * * * *

(75) Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide; other name: benzoyl fentanyl 9841

* * * * * * *

(83) Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide; other names: 2-thiofuranyl fentanyl; thiophene fentanyl) 9839

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D. Christopher Evans,

Acting Administrator.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0129; FRL–10020–85–Region 4]

Air Plan Approval; AL; NO_X SIP Call and Removal of CAIR

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Alabama through a letter dated February 27, 2020, to add regulations maintaining compliance with the State's Nitrogen Oxide (NO_X) SIP Call obligations for large non-electricity generating units (non-EGUs), to repeal the State's previously sunsetted NO_X Budget Trading Program regulations, and to repeal the State's Clean Air Interstate Rule (CAIR) regulations. EPA is also proposing to conditionally approve into the SIP state regulations that establish monitoring and reporting requirements for units subject to the NO_X SIP Call, including alternative monitoring options for certain sources for NO_X SIP Call purposes. In addition, EPA is proposing to make ministerial changes to reflect the State's renumbering of an existing regulation for ''New Combustion Sources.''

DATES: Comments must be received on or before April 2, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0129 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under Clean Air Act (CAA or Act) section 110(a)(2)(D)(i)(I), also called the good neighbor provision, states are required to address the interstate transport of air pollution. Specifically, the good neighbor provision requires that each state's implementation plan contain adequate provisions to prohibit air pollutant emissions from within the state that will significantly contribute to nonattainment of the national ambient air quality standards (NAAQS), or that will interfere with maintenance of the NAAQS, in any other state.

In October 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone'' (NO_X SIP Call). The NO_X SIP Call required eastern states, including Alabama, to submit SIPs that prohibit excessive emissions of ozone season NO_X by implementing statewide emissions budgets.[1] The NO_X SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_X emissions, one of the precursors of ozone.[2] EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. This trading program allowed the following sources to participate in a regional cap and trade program: Generally EGUs with capacity greater than 25 megawatts (MW); and large industrial non-EGUs, such as boilers and combustion turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr). The NO_X SIP Call also identified potential reductions from cement kilns and stationary internal combustion engines.

To comply with the NO_X SIP Call requirements, in 2001, the Alabama Department of Environmental Management (ADEM) submitted a revision to add new rule sections to the SIP-approved version of Alabama Administrative Code Chapter 335–3–1, General Provisions, and Chapter 335–3–8, Control of Nitrogen Oxides Emissions. EPA approved the revision as compliant with Phase I of the NO_X SIP Call in 2001. *See* 66 FR 36919 (July 16, 2001). The approved revision required EGUs and large non-EGUs in the State to participate in the NO_X Budget Trading Program beginning in 2004. In 2005, Alabama submitted, and EPA approved, a SIP revision to address additional emissions reductions required for the NO_X SIP Call under Phase II. *See* 70 FR 76694 (Dec. 28, 2005).

In 2005, EPA published CAIR, which required several eastern states, including Alabama, to submit SIPs that prohibited emissions consistent with revised ozone season (and annual) NO_X budgets. *See* 70 FR 25162 (May 12, 2005); *see also* 71 FR 25328 (April 28, 2006). CAIR addressed the good neighbor provision for the 1997 ozone NAAQS and 1997 fine particulate matter ($PM_{2.5}$) NAAQS and was designed to mitigate the impact of transported NO_X emissions with respect to ozone and $PM_{2.5.}$ CAIR established several trading programs that EPA implemented through federal implementation plans (FIPs) for EGUs greater than 25 MW in each affected state, but not large non-EGUs; states could submit SIPs to replace the FIPs that achieved the required emission reductions from EGUs and/or other types of sources.[3] When the CAIR trading program for ozone season NO_X was implemented beginning in 2009, EPA discontinued administration of the NO_X Budget Trading Program; however, the requirements of the NO_X SIP Call continued to apply.

On October 1, 2007 (72 FR 55659), EPA approved revisions to Alabama's SIP that incorporated requirements for CAIR. Consistent with CAIR's

[1] *See* 63 FR 57356 (October 27, 1998).

[2] As originally promulgated, the NO_X SIP Call also addressed good neighbor obligations under the 1997 8-hour ozone NAAQS, but EPA subsequently stayed and later rescinded the rule's provisions with respect to that standard. *See* 65 FR 56245 (September 18, 2000); 84 FR 8422 (March 8, 2019).

[3] CAIR had separate trading programs for annual sulfur dioxide emissions, seasonal NO_X emissions, and annual NO_X emissions.