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

§ 39.13 [Amended]
1. The FAA amends §39.13 by adding the following new airworthiness directive:


(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 EN3740–0600022F 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 75062; 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.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

21 CFR Part 1308

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-fluorotolylfentanyl), 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 methoxyacetyl fentanyl), 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 (thioufuranyl 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
Distribution, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 2′-fluoro ortho-flurofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β′-methyl fentanyl, ortho-fluoro-butyrylfentanyl, ortho-methyl methoxyethylacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiophenyl 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 in accordance with 21 CFR 1316.45 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 in response to this docket 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 individual’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-fluoro-butyrylfentanyl.
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 Analouges 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 carbanilate, ortho-fluoro isobutryryl 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. 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 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:

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

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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 in 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-furoxylenyl, 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 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. Post-treatment with naltrexone, an opioid antagonist, attenuates 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,
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 monocyte, whether or not further substituted in or on the monocyte;
- (B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo, haloalkyl, amino or nitro groups;
- (C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxy, halo, haloalkyl, amino or nitro groups;
- (D) replacement of the aniline ring with any aromatic monocyte whether or not further substituted in or on the aromatic monocyte; 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](image)

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 methoxycetylfentanyl: 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 methoxycetyl 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 methoxycetyl 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 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 acetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl from Federal, State, and local forensic laboratories between 2017 and 2018. 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 acetyl fentanyl, 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 23,052 to 47,600. The increase in the number of opioid-related deaths was primarily driven by illicitly manufactured fentanyl. 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 acetyl fentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are 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 acetyl fentanyl, 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 acetyl fentanyl, 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 acetyl fentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are mu-opioid receptor agonists. These substances...
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 morphine. These findings 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 have no currently accepted medical use in the United States.7

(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 are subject to 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 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.
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, 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, 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 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, 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.
methoxyacetyl fentanyl, para-methylnepentyl, 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 methoxycetanoyl 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:

§1308.11 Schedule I.

(a) The additions to read as follows:

(b) 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-[(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-phenylpropionyl 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-methylphenyl)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

(69) para-Methylnopentyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; other name: 4-methylnopentyl) .......................... 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
D. Christopher Evans, Acting Administrator.

[FR Doc. 2021–04214 Filed 3–2–21; 8:45 am]
BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

Air Plan Approval; AL; NOx 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 (NOx) SIP Call obligations for large non-electricity generating units (non-EGUs), to repeal the State’s previously sunsetted NOx 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 NOx SIP Call, including alternative monitoring options for certain sources for NOx 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” (NOx SIP Call). The NOx SIP Call required eastern states, including Alabama, to submit SIPs that prohibit excessive emissions of ozone season NOx by implementing statewide emissions budgets.1 The NOx SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NOx emissions, one of the precursors of ozone.2 EPA developed the NOx Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NOx SIP Call. This trading program allowed the following sources to participate in a national 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 NOx SIP Call also identified potential reductions from cement kilns and stationary internal combustion engines.

To comply with the NOx 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 NOx SIP Call in 2001. See 66 FR 36019 (July 16, 2001). The approved revision required EGUs and large non-EGUs in the State to participate in the NOx Budget Trading Program beginning in 2004. In 2005, Alabama submitted, and EPA approved, a SIP revision to address additional emissions reductions required for the NOx 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) NOx 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 (PM2.5) NAAQS and was designed to mitigate the impact of transported NOx emissions with respect to ozone and PM2.5. 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 NOx was implemented beginning in 2009, EPA discontinued administration of the NOx Budget Trading Program; however, the requirements of the NOx 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

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1 See 63 FR 57356 (October 27, 1998).
2 As originally promulgated, the NOx 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 NOx emissions, and annual NOx emissions.