



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-476]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is publishing this notice of intent to issue an order temporarily scheduling fentanyl-related substances that are not currently listed in any schedule of the Controlled Substances Act (CSA). The temporary order will place these substances in schedule I. This action is based on a finding by the Administrator that the placement of these synthetic opioids in schedule I is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose regulatory requirements under the CSA on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of these synthetic opioids, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to these substances.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: This notice of intent is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary order (in the form of a temporary amendment) placing fentanyl-related substances in schedule I of the Controlled Substances Act. The temporary scheduling order will be published in the *Federal Register* on or after [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Legal Authority

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

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355. 21 U.S.C.

811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

The Nature of the Problem and DEA's Approach to Correct It

It is well known that deaths associated with the abuse of substances structurally related to fentanyl¹ in the United States are on the rise and have already reached alarming levels. While a number of factors appear to be contributing to this public health crisis, chief among the causes is the sharp increase in recent years in the availability of illicitly produced, potent substances structurally related to fentanyl. Fentanyl is approximately 100 times more potent than morphine, and the substances structurally related to fentanyl that DEA will be temporarily controlling also tend to be potent substances. Typically, these substances are manufactured outside the United States by clandestine manufacturers and then smuggled into the United States.

Fentanyl is often mixed with heroin and other substances (such as cocaine and methamphetamine) or used in counterfeit pharmaceutical prescription drugs. As a consequence, users who buy these substances on the illicit market are often unaware of the specific substance they are actually consuming and the associated risk. According to the Centers for Disease Control and Prevention (CDC), drug overdose deaths involving synthetic opioids (excluding methadone), such as fentanyl and tramadol, increased from 5,544 in 2014 to 9,580 in 2015. According to provisional data released in August 2017

¹ As explained further below, in this document, the term "fentanyl-related substances" is defined to include substances structurally related to fentanyl but which are not controlled under a separate scheduling action (listed under another Administration Controlled Substance Code Number). Thus, all "fentanyl-related substances" are structurally related to fentanyl, but some fentanyl-related substances are controlled under separate scheduling actions.

by the CDC, National Center for Health Statistics (NCHS), an estimated 55 Americans are dying *every day* from overdoses of synthetic opioids (excluding methadone).² Drug overdose deaths involving synthetic opioids excluding methadone for the 12-month period ending in January of 2017 (20,145 deaths) more than doubled from the corresponding data for the period ending in January of 2016 (9,945 deaths).

DEA has responded to this crisis by issuing six temporary scheduling orders to control nine substances structurally related to fentanyl since 2015 and recently issued a notice of intent on November 21, 2017 to temporarily control another such substance. However, this approach has not been completely effective in preventing the emergence of new substances structurally related to fentanyl. This is because when DEA temporarily controls a given substance structurally related to fentanyl, illicit manufacturers located abroad begin producing new such substances through other structural modifications. Those new nonscheduled substances then are smuggled into the United States, where they are distributed by traffickers in this country as a purportedly "noncontrolled" substance.³ In this way, traffickers are effectively circumventing the temporary control mechanism that Congress established under 21 U.S.C. 811(h) to combat newly emerging dangerous drugs. Post mortem toxicology and medical examiner reports collected by the DEA show mortality connected to substances structurally related

² Provisional synthetic opioid death overdose counts are based on CDC data available for analysis as of August 6, 2017, based on the 12-month reporting period ending January 2017. See https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf accessed 09-06-2017.

³ Such trafficking is actually illegal as persons who do so can be prosecuted using the controlled substance analogue provisions of the CSA. 21 U.S.C. 802(32), 813. However, prosecution under the analogue provisions requires proof of additional elements not required for prosecuting trafficking in scheduled substances.

to fentanyl. Control of these substances is necessary to avoid an imminent hazard to the public safety.

Given the gravity of the ongoing fentanyl-related overdose crisis in the United States, protection of the public safety demands the utilization of 21 U.S.C. 811(h) in a manner that cannot be readily circumvented by drug traffickers. Specifically, in issuing the upcoming temporary scheduling order, DEA will exercise its authority to avoid an imminent hazard to the public safety by placing fentanyl-related substances, as defined later in this document, in schedule I. As explained below, these fentanyl-related substances – including those that have not yet been introduced by traffickers into the U.S. market – present a significant risk to the public health and safety and need to be controlled under section 811(h) to avoid an imminent hazard to the public safety. It should also be noted that none of the substances that will be temporarily controlled has an accepted medical use in the United States; nor is any of the substances the subject of an exemption or approval under section 505 of the FD&C Act. In accordance with section 811(h), if any exemption or approval is in effect under section 505 of the FD&C Act with respect to a substance that falls within the definition of a fentanyl-related substance set forth in this document, such substance will be excluded from the temporary scheduling order.

What Will Be Controlled Under the Temporary Scheduling Order

When the temporary scheduling order is issued, fentanyl-related substances will be placed in schedule I of the CSA for two years. DEA may extend the temporary scheduling for an additional year (a total of three years) if proceedings to permanently schedule the substances are pending. DEA's intention is that the temporary scheduling

order will define fentanyl-related substances to 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, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;
- (C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, 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.

How DEA Will Identify Individual Fentanyl-Related Substances That Fall Within This Temporary Scheduling Order

As indicated, the temporary scheduling order that is the subject of this Notice of Intent will include all substances that fall within the above definition – even if such substances have not yet emerged on the illicit market in the United States. As a result, DEA cannot currently specify the chemical name of every potential substance that might fall under this new definition. In the future, if and when DEA identifies a specific new substance that falls under the definition, the agency will publish in the Federal Register, and on the agency website, the chemical name of such substance. Thus, the text of the

definition of fentanyl-related substance will include language indicating that it "includes, but is not limited to, the following substances:" It bears emphasis, however, that even in the absence of a future publication by DEA specifically identifying such a substance, the substance will be controlled by virtue of the temporary scheduling order – at the time the temporary scheduling order is published – if it falls within the definition of fentanyl-related substance.

Notification to the Secretary of Health and Human Services

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.⁴ On November 6, 2017, the Administrator transmitted notice by letter to the Assistant Secretary for Health of HHS of his intent to place fentanyl-related substances, unless listed in another schedule, in schedule I on a temporary basis. The Assistant Secretary responded by letter dated November 29, 2017, and advised that based on a review by the Food and Drug Administration (FDA), they are not aware of any investigational new drug applications or approved new drug applications for fentanyl-related substances as defined above under section 505 of the FD&C Act, 21 U.S.C. 355 and that HHS has no objection to the temporary placement of these substances into schedule I of the CSA. As indicated, in accordance with section 811(h), fentanyl-related substances will be defined under the

⁴ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

temporary scheduling order to exclude any substance for which an exemption or approval is in effect under section 505 of the FD&C Act.

Grounds for Temporary Scheduling Order

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). These factors include, but are not limited to, actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. *Id.* DEA has considered these factors for fentanyl-related substances, as defined above, and finds that the information is consistent across this class of substances. The DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at www.regulations.gov under Docket Number DEA-476.

Substances that are included in the above-listed structural modifications and any combination of these structural modifications have been found to cause pharmacological effects that are similar to those of fentanyl. It therefore is reasonable to expect that all such substances, even if they have yet to appear on the illicit market in the United States, share the dangerous and potentially lethal properties that have caused the recent spike in fentanyl-related overdose deaths in the United States. By temporarily placing these fentanyl-related substances in schedule I, it is DEA's intention to deter the production and introduction of these substances into the United States that traffickers might be considering – before such activity ever begins – thereby avoiding an imminent hazard to

the public safety. The alternative approach, of only temporarily controlling substances that have already appeared in the illicit U.S. market, is beneficial but has not eliminated the danger these newly created substances pose and is not as effective in preventing future deaths and serious injuries associated with these substances. In addition, by controlling fentanyl-related substances, the temporary scheduling order will facilitate the development of international, national, and local prevention strategies that decrease morbidity and mortality from overdoses caused by or associated with fentanyl-related substances.

For these reasons, DEA has concluded that issuing a temporary scheduling order is necessary to avoid an imminent hazard to the public safety.

Schedule I Classification

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

As indicated, DEA finds that the fentanyl-related substances that will be temporarily controlled have a high potential for abuse. Information provided by the Assistant Secretary of HHS indicates that these fentanyl-related substances, as defined, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision.

Conclusion

This notice of intent provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h)(1), of DEA's intent to issue a temporary scheduling order. The temporary placement of fentanyl-related substances in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Because the Administrator hereby finds that it is necessary to temporarily place fentanyl-related substances in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling these substances will be effective on the date that order is published in the *Federal Register*, and will be in effect for a period of two years. DEA may extend the temporary scheduling for an additional year (a total of three years) if proceedings to permanently schedule the substances are pending. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, fentanyl-related substances, as defined in the order, will be subject to the full range of regulatory, civil, and criminal provisions of the CSA that apply to schedule I controlled substances.

Regulatory Matters

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

that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

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

Since this notice of intent is not a “rule” as defined by 5 U.S.C. 601(2), it is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

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

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with

Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. In § 1308.11, add paragraph (h)(30), to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(30) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers 9850

(i) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], 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, alkoxy,

hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, 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.

(ii) This definition includes, but is not limited to, the following substances:

[Reserved]

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Dated: December 21, 2017

Robert W. Patterson,
Acting Administrator

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