



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-597]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Correcting amendment.

SUMMARY: In the February 6, 2018, issue of the Federal Register, the Drug Enforcement Administration published a temporary scheduling order placing fentanyl-related substances, as defined in the order, and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers in schedule I of the Controlled Substances Act. That order was set to expire on February 6, 2020. However, the “Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act,” which became law on February 6, 2020, extended the temporary control of fentanyl-related substances until May 6, 2021. This correcting amendment reflects the new expiration date mandated by Congress for the temporary scheduling order.

DATES: This correcting amendment is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] through May 6, 2021, and is applicable beginning February 6, 2018 until May 6, 2021. If the temporary scheduling of fentanyl-related substances is made permanent, Drug Enforcement Administration (DEA) will publish a document in the Federal Register on or before May 6, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Background

In response to the rapid evolution of substances structurally related to fentanyl on the illicit drug market, the former Acting Administrator of DEA published a temporary scheduling order placing fentanyl-related substances, as defined in the order, in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 United States Code (U.S.C.) 811(h)(1). 83 FR 5188, February 6, 2018. That order was effective on the date of publication, and was based on findings by the former Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety. The temporary scheduling order was codified at 21 Code of Federal Regulations (CFR) 1308.11(h)(30). Under 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances was set to expire two years from the effective date of the scheduling order, *i.e.*, on February 6, 2020.

On February 6, 2020, the President signed the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act into law as Public Law 116-114. Section 2 of this Act stated, “notwithstanding any other provision of law, [21 CFR 1308.11(h)(30)] shall remain in effect until May 6, 2021.” Public Law 116-114 thereby ensured that there was no lapse in the temporary placement in schedule I of fentanyl-related substances. In other words, by operation of law, the temporary placement in

schedule I of fentanyl-related substances that began on February 6, 2018, has continued uninterrupted and will remain in effect until May 6, 2021, unless DEA permanently places such substances in schedule I prior to May 6, 2021.

Need for Correction

The February 6, 2018, temporary order placed fentanyl-related substances in 21 CFR 1308.11(h)(30). As discussed above, this order was set to expire on February 6, 2020, but that expiration date was overridden by Congress through enactment of Public Law 116-114. However, the CFR has not yet been updated to reflect the new expiration date. Rather, the reference to fentanyl-related substances in 21 CFR 1308.11(h)(30) was removed from the electronic version of the CFR after February 6, 2020 – even though fentanyl-related substances remained in schedule I by virtue of Public Law 116-114. In accordance with the public law, paragraph (h)(30) is hereby being put back into the CFR, along with the new expiration date of May 6, 2021.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is corrected by making the following correcting amendment:

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), 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:

(A)-(B) [Reserved]

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Uttam Dhillon,
Acting Administrator.

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