DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–313F]

RIN 1117–AB26

Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice

ACTION: Final rule.

SUMMARY: This rulemaking corrects Title 21 Code of Federal Regulations (CFR) by deleting regulations which list the substances benzylfentanyl and thenylfentanyl as being temporarily subject to schedule I controls under the emergency scheduling provisions of the Controlled Substances Act (CSA). The temporary scheduling of benzylfentanyl and thenylfentanyl expired on November 29, 1986. DEA determined that these compounds were both essentially inactive, with no evidence of abuse potential. As such, these compounds are no longer schedule I controlled substances and all references to these compounds are being deleted from DEA regulations.

DATES: This rulemaking becomes effective June 29, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152 at (202) 307–7183.

SUPPLEMENTARY INFORMATION: The CSA was amended by the Comprehensive Crime Control Act of 1984 (Pub. L.98–473) which became effective on October 12, 1984. This Act included a provision (21 U.S.C. 811(h)) which allows the DEA Administrator to place a substance, on a temporary basis, into schedule I when necessary to avoid an imminent hazard to the public safety. This emergency scheduling authority permits scheduling a substance that is not currently controlled, is being abused, and is a risk to the public health while the formal rulemaking procedures (21 U.S.C. 811) described in the CSA are being conducted. A temporary scheduling order may be issued for one year with a possible extension of up to six months if formal scheduling procedures have been initiated. The proposal and order are published in the **Federal Register** as are the proposals and orders for formal scheduling. The emergency scheduling authority was given to DEA in an effort to streamline the scheduling process in response to the growing problem of controlled substance analogues (“designer drugs”).

On October 29, 1985, DEA published a Final Rule (50 FR 43698) which temporarily placed Acetyl-alpha-methylfentanyl, Alpha-methylthiofentanyl, Beta-hydroxyfentanyl, Beta-hydroxy-3-methylfentanyl, 3-Methylthiofentanyl, Thiofentanyl, Benzylfentanyl and Thenylfentanyl into schedule I of the CSA. This control action became effective on November 29, 1985.

These substances were emergency scheduled based on their appearance in the illicit market, their similarity in chemical structure to that of controlled substances, and the likelihood that they would produce pharmacological effects similar to those of prototypic schedule I or II substances. Often there is no biological data available prior to the emergency control of illicitly produced and abused substances. Therefore, information derived from structure-activity relationship considerations plays an important role in emergency scheduling. To keep an emergency scheduled substance in schedule I, DEA must initiate traditional scheduling procedures (21 U.S.C. 811) for that substance during the one year period in which it is emergency controlled and complete the action before the expiration of 18 months. The time limitations of emergency scheduling underscore the need for timely abuse liability data and the need to determine the most efficient tests to provide the data necessary to make permanent scheduling decisions. During the one-year temporary scheduling period, DEA must acquire sufficient data to make a determination as to whether the emergency scheduled substance should remain under the CSA. Often the substances have never been studied nor are they available for study. DEA, as soon as possible after identifying a newly abused substance, provides for the synthesis of this substance for analytical reference standards and biological testing. Only then can the appropriate pharmacological and abuse liability tests be conducted.

In an effort to assess the addiction liability of these compounds, DEA contracted studies of each of the temporarily scheduled fentanyl compounds at the University of Michigan Medical School in Ann Arbor and at the Medical College of Virginia in Richmond. The studies indicated that while most of the fentanyl compounds had abuse liability profiles that warranted control, two of these temporarily scheduled compounds (benzylfentanyl and thenylfentanyl) did not have an addiction-forming or addiction-sustaining liability similar to morphine.

Based on the results of these studies, on November 28, 1986, the DEA extended the temporary scheduling of six of these substances in schedule I. However, benzylfentanyl and thenylfentanyl were specifically omitted from this extension (and any future permanent control) because the pharmacological and biological testing of the substances, which included assessment of morphine-like activity, addiction liability, and analgesic effect, indicated that the compounds were both essentially inactive, with no evidence of abuse potential.

Both of these substances were temporarily controlled because they were initially found in street samples with other fentanyl analogues and were most likely unreacted intermediates in the synthesis of the target fentanyl analogues. The DEA, having concluded that these two drugs lacked morphine-like addictive properties, allowed the temporary regulation of benzylfentanyl and thenylfentanyl to expire on November 29, 1986. Therefore, these two substances were no longer regulated as controlled substances upon that date. In contrast, however, DEA chose to extend temporary control of the other four fentanyl compounds in a Final Rule published November 26, 1986 (51 FR 42834) and permanently controlled them in a Final Rule published May 29, 1987 (52 FR 20070).

Action of This Rulemaking

After the temporary listing of benzylfentanyl and thenylfentanyl expired in November of 1986, these compounds were no longer controlled under the CSA. However, DEA never deleted 21 CFR 1308.11(g)(1) and (g)(2) that reference the listing of these compounds temporarily in schedule I. This rulemaking hereby corrects the CFR to delete 21 CFR 1308.11(g)(1) and (g)(2) which previously stated:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers 9818
(2) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers 9834

This action therefore corrects part 1308 to remove any reference to control of benzylfentanyl and thenylfentanyl in schedule I.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. The temporary placement of benzylfentanyl and thenylfentanyl in Schedule I expired on November 29, 1986. The substances were never scheduled and should have been removed from Title 21 of the Code of Federal Regulations, part 1308. This Final Rule corrects this by removing benzylfentanyl and thenylfentanyl from the listing of controlled substances in schedule I. As this Final Rule makes a technical correction by removing benzylfentanyl and thenylfentanyl from the Code of Federal Regulations, DEA finds it unnecessary and impracticable to permit public notice and comment. Therefore, DEA is publishing this document as a final rule. Further, as the removal of these substances prevents confusion about the scheduling of these substances, DEA finds there is good cause to make this final rule effective immediately upon publication.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This action removes the substances benzylfentanyl and thenylfentanyl from the schedules of controlled substances. These substances were temporarily scheduled in 1985 under the emergency scheduling provisions (21 U.S.C. 811, 21 CFR 1308.11(g)) and that temporary scheduling expired on November 29, 1986; however, the substances were never removed from the listing.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is not "a significant regulatory action." Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

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 amended 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) unless otherwise noted.

■ 2. Section 1308.11 is amended by revising paragraph (g) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(g) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) [Reserved.]

(2) [Reserved.]

Dated: June 19, 2010.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–222F]

RIN 1117–AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This rulemaking finalizes a November 12, 2008, Notice of Proposed Rulemaking in which DEA proposed that chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, be automatically exempt from regulatory controls under the Controlled Substances Act (CSA). DEA is seeking through this rulemaking to exempt only those chemical mixtures that do not represent a significant risk of diversion. This regulation makes GBL chemical mixtures, in concentrations greater than 70 percent, subject to List I chemical regulatory requirements of the CSA, except if exempted through an existing categorical exemption. DEA is taking this action because there is a serious threat to the public safety associated with the ease by which GBL is chemically converted to the schedule I controlled substance gamma-hydroxybutyric acid (GHB).

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption. As a result, DEA regulations provide for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration criteria.

DATES: This rulemaking becomes effective July 29, 2010. Persons seeking registration must apply on or before July 29, 2010 to continue their business pending final action by DEA on their application.