

and other information in your case record, we will try to resolve it. * * *

(Emphasis added). We provide similar definitions of the terms “marked” and “extreme” in the listings section for children, with criteria appropriate to childhood.

Why are we providing a limited reopening of the public comment period?

In response to the NPRM, we received many public comments that seemed to misunderstand our current policy, what changes we were proposing, and how the proposals might affect adults and children. We believe that much of the confusion was caused by our failure to provide sufficiently detailed information about our current policies and where our proposals came from. We apologize for that omission, which we have corrected in this notice.

Although we received a wide variety of comments, we are reopening the public comment period on a limited basis to specifically address the misunderstanding of our current and proposed policy regarding the use of standardized tests. We are requesting public comment only on this issue in light of the clarification we are providing in this notice.

Many commenters focused on two aspects of our proposed rule: (1) A definition of “marked” based on a standardized test score that is two standard deviations below the mean; and, (2) a separate definition of “marked” based on functioning that would be the equivalent of such a score if there were a standardized test. As discussed above, neither of these proposals represents new policy; both are based on our longstanding rules. However, some commenters said that our proposal would encourage our adjudicators to use standardized tests. Many said that we should drop all reference to standardized tests in the mental illness sections of the proposed rules and that the change would reduce the number of children and adults with serious mental disorders who qualify for disability benefits. Some who are already beneficiaries or who have family members who are beneficiaries were concerned that they would lose their benefits.

We did not intend for, and do not believe that, our proposed rules would do any of these things. The childhood mental disorders listings have contained a provision defining “marked” limitation as a score that is two standard deviations below the mean on a standardized test for 20 years. We developed those rules with information

we received from a group of mental health experts. We did not propose to change that provision or the way we determine disability in children with serious mental disorders. We proposed only to extend the provision to adults since it has worked well in childhood claims.

The proposed rules for adults and children do not state that adjudicators should obtain standardized tests, encourage them to do so, or indicate that there are standardized tests for all serious mental disorders. Rather, our proposed rules state only that *if* a person has a standardized test and the scores are two standard deviations below the mean, the test will show that the person has a “marked” limitation. Consistent with our current childhood rules, the proposed rules also state that adjudicators must not rely on the results of standardized tests alone but must consider all of the evidence in the person’s case record.

Since the beginning of 2001, our functional equivalence regulation has contained an alternative rule defining “marked” limitation for children based on functioning that would be consistent with a score on a standardized test that is two standard deviations below the mean, if there were such a test. As with the provision for actual scores from an actual test, the rule provides that we will find that the child has a marked limitation if the child is functioning at that level. The regulation section, like the proposed rule for the mental disorders listings, also provides other definitions for the term “marked.” We began using this regulation in 1997, 13 years ago. The number of awards of children who apply for SSI has not fallen since that time.¹³ Given this experience, we believe that it was appropriate to include the rule in both the adult and child mental disorders listings.

Perhaps most importantly, it appeared that many commenters did not understand that we do not deny a person’s claim merely because his or her impairment(s) does not meet or medically equal the criteria of our listings. As under our current rules, adults with mental disorders who cannot perform their past work or a significant number of jobs in the national economy considering their age, education, and work experience would still be able to qualify under other rules we have for finding persons disabled.

¹³ You may look up our award data for children under SSI by year in the *SSI Annual Statistical Report*, available at: http://www.socialsecurity.gov/policy/docs/statcomps/ssi_asr/2009/ssi_asr09.pdf.

We also want to make clear that we do not reexamine the entitlement of beneficiaries when we revise listings. When we periodically perform continuing disability reviews to determine if beneficiaries are still disabled, we continue to use the same listing section we used to make our most recent favorable decision.¹⁴ Thus, beneficiaries who qualified under a current listing would continue to qualify as long as their impairments continued to meet or medically equal the current listing.

In light of the importance of this issue and the widespread misunderstanding of our proposed rules, we are reopening the comment period for the limited purpose of allowing interested persons to provide any additional comments they may have on our proposed policy regarding the use of standardized tests.

Michael J. Astrue,

Commissioner of Social Security.

[FR Doc. 2010–29577 Filed 11–23–10; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–345N]

Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I

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

ACTION: Notice of Intent.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily place five synthetic cannabinoids into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions under 21 U.S.C. 811(h) of the CSA. The substances are 1-pentyl-3-(1-naphthoyl)indole (JWH–018), 1-butyl-3-(1-naphthoyl)indole (JWH–073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200), 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497), and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP–47,497 C8 homologue). This intended action is based on a finding by the DEA Deputy

¹⁴ See 404.1594(c)(3)(i), 416.994(b)(2)(iv)(A), and 416.994a(b)(2).

Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Finalization of this action will impose criminal sanctions and regulatory controls of Schedule I substances under the CSA on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

FOR FURTHER INFORMATION CONTACT:

Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, telephone (202) 307-7183, fax (202) 353-1263, or e-mail ode@dea.usdoj.gov.

SUPPLEMENTARY INFORMATION:

Background

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. The Attorney General may extend the temporary scheduling up to six months. A substance may be temporarily scheduled under the emergency provisions of the CSA 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 under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA (28 CFR 0.100). The Administrator has re-delegated this function to the Deputy Administrator, pursuant to 28 CFR, appendix to subpart R, section 12.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Assistant Secretary for Health, delegate of the Secretary of Health and Human Services, of her intention to temporarily place a substance into Schedule I of the CSA. Comments submitted by the Assistant Secretary for Health in response to this notification, including whether there is an exemption or approval in effect for the substance in question under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration before a final order is published.

In making a finding that placing a substance temporarily into Schedule I of

the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows: (4) History and current pattern of abuse; (5) The scope, duration and significance of abuse; and (6) What, if any, risk there is to the public health.

Synthetic Cannabinoids

Synthetic cannabinoids have been developed over the last 30 years for research purposes to investigate the cannabinoid system. No legitimate non-research uses have been identified for these synthetic cannabinoids. They have not been approved by the U.S. Food and Drug Administration for human consumption. These THC-like synthetic cannabinoids, 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue), are so termed for their THC-like pharmacological properties. Though they have similar properties to *delta*-9-tetrahydrocannabinol (THC) found in marijuana and have been found to be more potent than THC in animal studies. Numerous herbal products have been analyzed and JWH-073, JWH-018, JWH-200, CP-47,497, and cannabicyclohexanol have been identified in varying mixture profiles and amounts spiked on plant material.

Factor 4. History and Current Pattern of Abuse

The emergence of these synthetic cannabinoids represents a recent phenomenon in the designer drug market. Since the initial identification of JWH-018 in December 2008, many additional synthetic cannabinoids with purported psychotropic effects have been identified in related products. The popularity of these THC-like synthetic cannabinoids has greatly increased in the United States and they are being abused for their psychoactive properties. Primarily found laced on plant material, these synthetic cannabinoids are also being abused alone as self-reported on Internet discussion boards. This abuse has been characterized by both acute and long term public health and safety problems. Even though there is no accepted use for these synthetic cannabinoids, multiple shipments of JWH-018 and JWH-073 have been intercepted by U.S. Customs

and Border Protection in 2010, with one being in excess of 50 kilograms. Additionally, bulk loads of JWH-018 and JWH-200 have been seized by law enforcement in 2010. In Casper, Wyoming, products seized in a raid, which were laced with synthetic cannabinoids, were found in conjunction with illicit drugs.

The products containing these THC-like synthetic cannabinoids are marketed as "legal" alternatives to marijuana and are being sold over the Internet and in tobacco and smoke shops, drug paraphernalia shops, and convenience stores. These synthetic cannabinoids alone or spiked on plant material have the potential to be extremely harmful due to their method of manufacture and high pharmacological potency. DEA has been made aware that smoking these synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects is identified as a reason for emergency room visits and calls to poison control centers.

As of October 15, 2010, 15 states in the United States, European and Scandinavian countries have controlled one or more of the synthetic cannabinoids DEA is temporarily scheduling here.

Factor 5. Scope, Duration and Significance of Abuse

According to forensic laboratory reports, the first appearance of these synthetic cannabinoids in the United States occurred in November 2008, when U.S. Customs and Border Protection analyzed "Spice" products. From January 2010 through September 2010, the National Forensic Laboratory Information System, a national repository of drug evidence analyses from forensic laboratories across the United States, reported over 500 exhibits relating to these synthetic cannabinoids from various States including Alabama, Arkansas, California, Florida, Hawaii, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Nevada, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Virginia. Additionally, the American Association of Poison Control Centers (AAPCC) has reported receiving over 1,500 calls as of September 27, 2010, relating to products spiked with these synthetic cannabinoids from 48 states and the District of Columbia.

Factor 6. What, if Any, Risk There Is to the Public Health

JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol share pharmacological similarities with the Schedule I substance THC. Health warnings have been issued by numerous state public health departments and poison control centers describing the adverse health effects associated with these synthetic cannabinoids and their related products including agitation, anxiety, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations and non-responsiveness. Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes observed in cannabis abuse. Emergency room physicians have reported admissions connected to the abuse of these synthetic cannabinoids. Additionally, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals suffer from intense hallucinations. Detailed chemical analysis by DEA and other investigators have found these synthetic cannabinoids spiked on plant material in products marketed to the general public. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids(s) spiked on the plant material.

Self-reported abuse of these THC-like synthetic cannabinoids alone and spiked on plant material appear on Internet discussion boards. According to self-reports, these substances are cannabis-like (or THC-like) in their psychoactive effects and are more potent than THC in this regard. The most common route of administration of these synthetic cannabinoids is by smoking, using a pipe, water pipe, or rolling the drug-spiked plant material in cigarette papers.

The marketing of products that contain one or more of these synthetic cannabinoids is geared towards teens and young adults. Despite disclaimers that the products are not intended for human consumption, retailers promote that routine urinalysis tests will not typically detect the presence of these synthetic cannabinoids.

Furthermore, a number of the products and synthetic cannabinoids appear to originate from foreign sources and are manufactured in the absence of quality controls and devoid of regulatory oversight. These products

and associated synthetic cannabinoids are readily accessible via the Internet.

DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 U.S.C. 812). The data available and reviewed for JWH-073, JWH-018, JWH-200, CP-47,497, and cannabicyclohexanol indicate that these synthetic cannabinoids each have a high potential for abuse, no currently accepted medical use in treatment in the United States and are not safe for use under medical supervision.

Based on the above data, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol pose an imminent hazard to the public safety. DEA is not aware of any recognized therapeutic uses of these synthetic cannabinoids in the United States. As required by section 201(h)(4) of the CSA (21 U.S.C. 811(h)), the Deputy Administrator in a letter dated October 6, 2010, notified the Assistant Secretary of Health of the intention to temporarily place five synthetic cannabinoids in Schedule I.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Deputy Administrator has considered the available data and the three factors required to support a determination to temporarily schedule five synthetic cannabinoids: 1-butyl-3-(1-naphthoyl)indole, 1-pentyl-3-(1-naphthoyl)indole, 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole, 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol, and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol in Schedule I of the CSA and finds that placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Deputy Administrator finds that it is necessary to temporarily place these synthetic cannabinoids into Schedule I to avoid an imminent hazard to the public safety, the final order, if issued, will be effective on the date of publication of the order in the **Federal Register**. JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol will be subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importing and exporting of a Schedule I controlled substance under the CSA. Further, it is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration

of thirty days from the date of publication of this notice and the date that notification was transmitted to the Assistant Secretary for Health.

Regulatory Certifications*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), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This action provides a notice of intent to temporarily place 1-butyl-3-(1-naphthoyl)indole, 1-pentyl-3-(1-naphthoyl)indole, 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole, 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol, and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol into Schedule I of the CSA. DEA is not aware of any legitimate non-research uses for these synthetic cannabinoids in the United States.

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 \$126,400,000 or more (adjusting for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were 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 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 costs 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.

Under the authority vested in the Attorney General by section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, and section 12 of the Appendix to Subpart R), the Deputy Administrator hereby intends to order that 21 CFR part 1308 be 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 adding new paragraphs (g)(1), (2), (3), (4), and (5) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(g) * * *

(1) 5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol-7297

(Other names: CP-47,497)

(2) 5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol-7298

(Other names: cannabicyclohexanol and CP-47,497 C8 homologue)

(3) 1-Butyl-3-(1-naphthoyl)indole-7173

(Other names: JWH-073)

(4) 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200

(Other names: JWH-200)

(5) 1-Pentyl-3-(1-naphthoyl)indole-7118

(Other names: JWH-018 and AM678)

Dated: November 15, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010-29600 Filed 11-23-10; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0062]

RIN 1625-AA00

Safety Zone; Fleet Week Maritime Festival, Pier 66, Elliot Bay, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its regulation establishing a permanent safety zone extending 100 yards from Pier 66, Elliot Bay, WA to ensure adequate safety during the parade of ships and aerial demonstration for Fleet Week. This supplemental notice of proposed rulemaking introduces revisions to enforcement dates, times and location of this safety zone. This safety zone is necessary in order to restrict vessel movement for participant and spectator safety in the proximity of Pier 66, Elliot Bay, WA to provide unencumbered access for response craft in the event of an emergency during the annual parade of ships and aerial demonstration.

DATES: Comments and related material must be received by the Coast Guard on or before December 27, 2010.

ADDRESSES: You may submit comments identified by docket number USCG-2010-0062 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(4) *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail LTJG Ashley M. Wanzer, Sector Puget Sound Waterways

Management Division, Coast Guard; telephone 206-217-6175, e-mail SectorSeattleWWM@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2010-0062), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG-2010-0062" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½; by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may