GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health
Addiction Prevention and Recovery Administration

Federal Regulation Advisory

Date: March 2, 2011

To: Substance Abuse Treatment and Recovery Support Service Providers, Prevention Centers

From: Roula K. Sweis, M.A., Psy.D.
Deputy Director for Treatment and Recovery Support Services

RE: K-2, Spice Classified as Schedule I Controlled Substance

On March 1, 2011, the Department of Justice, Drug Enforcement Administration (DEA) issued a final order which classifies five synthetic cannabinoids as Schedule I controlled substances. Spice, K-2 was included among these five newly controlled substances.

By classifying Spice, K-2 as a Schedule I drug, the full effect of the Controlled Substances Act (CSA) and its implementing regulation will be imposed on the manufacture, distribution, possession, importation, and exportation of the substance.

Enclosed in this advisory is the Federal Register excerpt which provides additional information about this change. Please ensure that all staff at your organization are aware of this new regulation and that practices, policies, or information distributed about K-2, Spice reflect this new classification as a controlled substance.

If you have any questions related to this advisory, please contact Roula Sweis at Roula.sweis@dc.gov; or 202-727-8940 or visit the DEA's website at www.justice.gov/dea.

Rules and Regulations

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–345F]

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

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

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily place five synthetic cannabinoids into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions. 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-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (CP–47,497), and 5-(1,1-dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP–47,497 C8 homologue). This action is based on a finding by the 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. As a result of this order, the full effect of the CSA and its implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

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, telephone (202) 307–7183, fax (202) 353–1263, or e-mail *ode@usdoj.gov*.

DATES: *Effective Date:* March 1, 2011.

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 during pendency of proceedings under 21 U.S.C. 811(a)(1). 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 DEA Administrator (28 CFR 0.100).

As per section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)), the Deputy Administrator, now Administrator, transmitted notice of her intention to temporarily place JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services (HHS) in a letter dated October 6, 2010. In response to this notification, the Assistant Secretary of Health, HHS communicated in a letter dated November 22, 2010, to the then-DEA Acting Administrator that there are no exemptions or approvals in effect for JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol under Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355). The substances are not listed in any other schedule in 21 U.S.C. 812.

A notice of intent to temporarily place JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol into Schedule I of the CSA was published in the **Federal Register** on November 24, 2010 (75 FR 71635). Before making a finding that temporarily placing a substance into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors (factors 4, 5, and 6) set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are the history and current pattern of abuse, the scope, duration, and significance of abuse, and what, if any, risk there is to the public health, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

The temporary placement of these five synthetic cannabinoids into Schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety. First, these substances are not intended for human consumption, but there has been a rapid and significant increase in abuse of these substances in the United States. As a result of this abuse, synthetic cannabinoids are banned in at least 18 states in the United States and several countries, and all five branches of the U.S. military prohibit military personnel from possessing or using synthetic cannabinoids. Second, law enforcement has seized synthetic cannabinoids in conjunction with controlled substances and based on self-reports to law enforcement and health care professionals, synthetic cannabinoids are abused for their psychoactive properties. Third, numerous state and local public health departments and poison control centers have issued health warnings describing the adverse health effects associated with synthetic cannabinoids. Based on scientific data currently available, these five substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

History and Current Pattern of Abuse

A "cannabinoid" is a class of chemical compounds in the marijuana plant that are structurally related. The cannabinoid Δ9-tetrahydrocannabinol (THC) is the primary psychoactive constituent of marijuana. "Synthetic cannabinoids" are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principle of marijuana.

Two of the five synthetic cannabinoids (CP–47,497 and cannabicyclohexanol) were synthesized in the early 1980s for research purposes

in the investigation of the cannabinoid system. JWH–018, JWH–073, and JWH–200 were prepared in the mid-1990s and evaluated to further advance understanding of drug-receptor interactions regarding the cannabinoid system. Developed and evaluated as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids. Furthermore, these five synthetic cannabinoids are not intended for human consumption.

The emergence of these five synthetic cannabinoids represents a recent phenomenon in the U.S. designer drug market. Since the initial identification of JWH–018 by U.S. forensic laboratories, many additional synthetic cannabinoids including JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol have been identified in related herbal incense products and plant food. These synthetic cannabinoids have purported psychotropic effects when smoked or ingested. These substances are typically found in powder form or are dissolved in appropriate solvents, such as acetone, before being sprayed on the plant material contained in the herbal incense products.

The popularity of these THC-like synthetic cannabinoids has significantly increased throughout the United States, and they are being abused for their psychoactive properties as reported by law enforcement, the medical community, and through scientific literature.

Some of the product names include, but are not limited to, "Spice," "K2," and many more. Due to sophisticated marketing, the products that contain these five THC-like synthetic cannabinoids are perceived as "legal" alternatives to marijuana despite the fact that they are typically advertised as herbal incense or plant food (Bonsai-18) by Internet retailers, tobacco shops, head shops, and other domestic brick and mortar retail venues, and labeled "Not For Human Consumption." No evidence exists that these synthetic cannabinoids have value as an additive to herbal incense products due to the absence of odor associated with the substances.

Based on law enforcement encounters, these five substances are typically found laced on plant material. The plant material is packaged in small pouches or packets, and is being sold over the Internet, in tobacco and smoke shops, drug paraphernalia shops, gas stations, and convenience stores as herbal incense products, giving customers of all ages direct access to these five substances. Research articles propose that the packaging is professional and conspicuous, targeting young people, possibly eager to use cannabis, but who are afraid of the judicial consequences and/or association with illicit drugs.

According to Internet discussion boards and law enforcement encounters reported directly to DEA, these five synthetic cannabinoids are being both abused alone and/or being sprayed on plant material (which is then smoked). The most common route of administration of these synthetic cannabinoids is by smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers).

These five 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. There is little information regarding the pharmacology, toxicology, and safety of these substances in humans given the minimal amount of pre-clinical investigations undertaken regarding these substances; therefore, the full danger of these drugs has not yet been determined.

As of January 31, 2011, 18 states in the United States and other countries have controlled one or more of the five synthetic cannabinoids. Moreover, all five branches of the military prohibit their personnel from possessing or using synthetic cannabinoids associated with products such as Spice and K2.

Scope, Duration, and Significance of Abuse

According to forensic laboratory reports, the initial appearance of these synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection first encountered products such as Spice.

The increasing abuse of the five synthetic cannabinoids is demonstrated by the increase in federal, state, and local law enforcement activity associated with these substances. The National Forensic Laboratory Information System, a national repository for drug evidence analyses from forensic laboratories across the United States, has reported in excess of 500 exhibits containing synthetic cannabinoid from January 2010 through September 2010. These exhibits came from numerous states across the nation including Alabama, Arkansas, California, Florida, Hawaii, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Nevada, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Virginia.

Even though there is no evidence of legitimate non-research related use for these synthetic cannabinoids, multiple shipments of JWH–018 and JWH–073 have been encountered by U.S. Customs and Border Protection in 2010. One enforcement operation encountered five shipments of JWH–018 totaling over 50 kilograms (110.2 pounds) of powder. In addition, bulk loads of JWH–018 and JWH–200 have been encountered by law enforcement in 2010. For example, in Casper, Wyoming, DEA agents encountered large quantities of herbal incense products laced with the synthetic cannabinoid JWH–018 in conjunction with methamphetamine and other illegal drugs in execution of search and arrest warrants.

On March 24, 2010, the American Association of Poison Control Centers reported receiving 112 calls from 15 states related to synthetic cannabinoids to U.S. poison centers since 2009. Just nine months later, the number of calls increased to over 2,700 from 49 states and the District of Columbia.

What, If Any, Risk There Is to the Public Health

Health warnings have been issued by numerous state and local public health departments and poison control centers describing the adverse health effects associated with these synthetic cannabinoids and their related products, including agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness.

Smoking these synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects has been identified as a reason for emergency room visits and calls to poison control centers. In a fact sheet by the National Drug Court Institute, the problem of synthetic cannabinoid abuse is described as "significant and disturbing." This is supported by information that was communicated to DEA from one of the major private toxicology laboratories. Based on laboratory findings from drug screens for the period of July 2010 through November 2010, over 3,700 specimens tested positive for either JWH–018 or JWH–073. They also indicated that they were finding 30–35% positivity for specimens submitted by juvenile probation departments.

Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes

observed in marijuana abuse. In addition, based on law enforcement encounters reported directly to DEA, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals have suffered from intense hallucinations. Moreover, emergency department physicians and toxicologists have reported the adverse health effects associated with smoking herbal incense products laced with these substances. Furthermore, based on law enforcement encounters, suspected Driving Under the Influence of Drug incidents are attributed to the smoking of synthetic cannabinoids. For example, in September 2010, police in Nebraska responded to an incident involving a teenage male who had careened his truck into the side of a residence. After striking the residence and several more items, the teen continued several more yards before coming to a complete stop. Prior to crashing the truck, the individual had driven past a junior high school and nearly struck a child. Upon further investigation, the driver of the vehicle admitted to smoking "Wicked X," a product marketed as "herbal incense" and known to contain synthetic cannabinoids, prior to the accident. Preliminary toxicology reports indicated that the individual did not have any alcohol or other illegal substances in his system.

Detailed chemical analyses by DEA and other investigators have found these synthetic cannabinoids spiked on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the synthetic cannabinoid found on the plant material and the amount. As proposed in scientific literature, the risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids spiked on the plant material.

Self-reported abuse of these THC-like synthetic cannabinoids either alone (*e.g.*, in pills with the substance in powder form) or spiked on plant material appear extensively on Internet discussion boards, and abuse has been reported to public health officials and law enforcement. The abuse of these substances spiked on plant material is corroborated by forensic laboratory analysis of products encountered by law enforcement.

According to the U.S. Customs and Border Protection, a number of the products and synthetic cannabinoids appear to originate from foreign sources. Product manufacturing operations encountered by law enforcement corroborate that the herbal incense products are manufactured in the absence of quality controls and devoid of regulatory oversight. Law enforcement has encountered the manufacture of herbal incense products occurring in such places as residential neighborhoods. These products and associated synthetic cannabinoids are readily accessible via the Internet.

Based on the above data, the continued uncontrolled manufacture, distribution, importation, exportation, and possession 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.

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, CP47,497, and cannabicyclohexanol indicate that these synthetic cannabinoids each has 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.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the 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-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol, and 5-(1,1-dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol in Schedule I of the CSA and finds that temporary placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Regulatory Requirements

With the issuance of this final order, JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importation, and exportation of a Schedule I controlled substance under the CSA.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports, exports, or possesses JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol or who engages in research or conducts instructional activities with respect to JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with 21 U.S.C. 823 and 958. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration and may not continue their activities until DEA has approved that application. Retail sales of Schedule I controlled substances to the general public are not allowed under the Controlled Substances Act.

2. *Security.* JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol are subject to Schedule I security requirements. Accordingly, appropriately registered DEA registrants must manufacture, distribute and store these substances in accordance with 1301.71; 1301.72(a), (c), and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations as of March 1, 2011.

3. *Labeling and packaging.* All labeling and packaging requirements for controlled substances set forth in Part 1302 of Title 21 of the Code of Federal Regulations shall apply to commercial containers of JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all labeling and packaging requirements.

4. *Quotas.* Quotas for JWH–018, JWH–073, JWH–200, CP–47,497, and cannabicyclohexanol will be established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every DEA registrant who possesses any quantity of JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol is required to keep inventory of all stocks of these substances on hand pursuant to 1304.03, 1304.04, and 1304.11 of Title 21 of the Code of Federal Regulations. Every current DEA registrant who desires registration in Schedule I for JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol shall conduct an inventory of all stocks of these substances. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all inventory requirements.

6. *Records.* All registrants who handle JWH–018, JWH–073, JWH–200, CP–

47,497, or cannabicyclohexanol are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all recordkeeping requirements.

7. *Reports.* All registrants are required to submit reports in accordance with 1304.33 of Title 21 of the Code of Federal Regulations. Registrants who manufacture or distribute JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol are required to comply with these reporting requirements and shall do so as of March 1, 2011.

8. *Order Forms.* All registrants involved in the distribution of JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol must comply with order form requirements of part 1305 of Title 21 of the Code of Federal Regulations as of March 1, 2011.

9. *Importation and Exportation.* All importation and exportation of JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol must be conducted by appropriately registered DEA registrants in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after March 1, 2011.

10. *Criminal Liability.* The manufacture, distribution, dispensation, or possession with the intent to conduct these activities; possession; importation; or exportation of JWH–018, JWH–073, JWH–200, CP–47,497, or cannabicyclohexanol not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act occurring as of March 1, 2011 is unlawful.

Executive Order 12988

This final temporary scheduling order 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 final temporary scheduling order 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 order does not have federalism implications warranting the application of Executive Order 13132.

Congressional Review Act

Pursuant to section 808(2) of the Congressional Review Act, the agency is not required to comply with the Act if it makes a good faith finding that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. It is in the public interest to schedule these cannabinoids immediately because they pose a public health risk. Use of materials spiked with these cannabinoids has been the cause of emergency room visits and calls to poison control centers. The adverse health effects associated with these synthetic cannabinoids and their related products include agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness. The materials have been marketed on products that are available to the general public, and their manufacture is devoid of quality controls and unregulated.

This temporary scheduling action is taken pursuant to section 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. Section 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie section 811(h), that is, DEA's need to move quickly to place these five cannabinoids into Schedule 1 because they pose a threat to public health, it would be contrary to the public interest to delay implementation of the temporary scheduling order by requiring DEA to undertake the procedures necessary to comply with the Congressional Review Act prior to the order taking effect.

Unfunded Mandates Reform Act of 1995

This final temporary scheduling order 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.

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)), the Administrator hereby amends 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), 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, its optical, positional, and geometric isomers, salts and salts of isomers—7297 (Other names: CP–47,497)

(2) 5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol, its optical, positional, and geometric isomers, salts and salts of isomers—7298 (Other names: cannabicyclohexanol and CP–47,497 C8 homologue)

(3) 1-Butyl-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7173 (Other names: JWH–073)

(4) 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7200 (Other names: JWH–200)

(5) 1-Pentyl-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7118 (Other names: JWH–018 and AM678)

Dated: February 18, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–4428 Filed 2–28–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 541

[Docket No. BOP–1118–F]

RIN 1120–AB18

Inmate Discipline Program/Special Housing Units: Subpart Revision and Clarification

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule; delay of effective date.

SUMMARY: In this document, the Bureau of Prisons delays the effective date of the final rule that appeared in the **Federal Register** on December 8, 2010, (75 FR 76263) and the subsequent correction which appeared in the