

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU

----- X
PEOPLE OF THE STATE OF NEW YORK, by
ERIC T. SCHNEIDERMAN, Attorney General of the
State of New York,

Petitioner,

-against-

DAZE, INC.; KIM FULCHER (a/k/a KIM TASIK),
individually and as principal of DAZE, INC.; and
RYAN FULCHER, individually and as principal of
DAZE, INC.,

Respondents.
----- X

Index No. 12-8678

AFFIRMATION

MARSHA W. YEE, an attorney duly admitted to practice law in the State of New York, affirms the following to be true, subject to the penalties for perjury:

1. I am an Assistant Attorney General in the Office of Eric T. Schneiderman, Attorney General of the State of New York ("OAG"), assigned to the Nassau Regional Office. I am fully familiar with the facts and circumstances set forth in this affirmation, based upon my communications with other OAG staff and my review of documents and other evidence contained in the files of the OAG's Nassau office.
2. I submit this affirmation in support of Petitioner's application for an Order and Judgment permanently enjoining Respondents from engaging in deceptive, fraudulent and illegal business practices, requiring that Respondents produce an accounting of mislabeled and/or misbranded products sold, and awarding penalties and costs to the State of New York.
3. Unless otherwise indicated, I make this affirmation upon information and belief, based upon my communications with other OAG staff and my review of documents and other evidence on file with the OAG's Nassau office.

INTRODUCTION

4. This case is brought in response to the proliferation of “designer drugs” that are being marketed and offered for sale to New York consumers. Designer drugs, referred to as “street drug alternatives” by the federal Food and Drug Administration (“FDA”), generally have one or more of the following characteristics: (1) they are “manufactured, marketed, or distributed as alternatives to illicit street drugs”; (2) they are “intended to be used for recreational purposes to effect psychological states (e.g., to get high, to promote euphoria, or to induce hallucinations),” and/or (3) they are marketed with claims that they “mimic the effects of controlled substances.” FDA, U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY - STREET DRUG ALTERNATIVES (2000), annexed hereto as Exhibit 1. The FDA “considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act.” *Id.*

5. The growth in the market for designer drugs poses a danger to consumers (*See* Affidavit of Dr. Maja Lundborg-Gray (“Lundborg-Gray Aff.”) ¶ 3). Some designer drugs may cause serious health effects, including long-term disability or even death (*Id.* ¶¶ 4, 5, 10, 12).

6. Misrepresenting products as safe for human consumption and selling products that are mislabeled or misbranded is misleading and dangerous. Without knowing the contents of such products or how they are intended to be used, consumers cannot make informed decisions about what they are purchasing and whether those products are safe to ingest. Additionally, consumers who experience serious health consequences may not receive appropriate medical treatment because they are only able to provide emergency personnel and health care providers with little or inaccurate information about the substances they ingested (*Id.* ¶¶ 16-19).

7. Legislatures and regulatory authorities have been adding designer drugs to lists of controlled substances. For example, in 2011 the United States Drug Enforcement Administration (“DEA”) used its emergency scheduling authority to temporarily ban three synthetic stimulants that serve as the active ingredient in the substance popularly known as “bath salts”: (1) Mephedrone; (2) 3,4-methylenedioxypropylamphetamine (MDPV); and (3) Methylone. Press Release, DEA, *DEA Moves to Emergency Control Synthetic Stimulants; Agency Will Study Whether To Permanently Control Three Substances* (September 7, 2011), annexed hereto as Exhibit 2.

8. In 2011, the DEA also implemented emergency bans on numerous synthetic drugs, including chemicals used to make “fake pot” products. Press Release, DEA, *Chemicals Used in “Spice” and “K2” Type Products Now Under Federal Control and Regulation; DEA Will Study Whether To Permanently Control Five Substances* (March 1, 2011), annexed hereto as Exhibit 3.

9. As of June 2012, both houses of the federal legislature have passed a bill that would permanently ban numerous chemicals marketed as “bath salts,” including MDPV and Mephedrone, and “incense,” or synthetic marijuana. Press Release, DEA, *Congress Agrees to Add 26 Synthetic Drugs to Controlled Substances Act* (June 19, 2012), annexed hereto as Exhibit 4; *Bath Salts Face Federal Ban*, Press & Sun-Bulletin (Binghamton, NY), June 28, 2012, attached hereto as Exhibit 5. This bill is awaiting the President’s signature.

10. The New York state legislature has also acted to ban such substances. In 2011, the Public Health Law was amended to prohibit the sale of bath salts containing certain chemicals: 4-Methylmethcathinone, also known as Mephedrone, and Methylenedioxypropylamphetamine, also known as MDPV. N.Y. PUB. HEALTH LAW § 3306.

11. In March 2012, New York State Health Commissioner Nirav Shah issued an order for summary action that banned the sale and distribution of synthetic marijuana products in the

State. “Synthetic marijuana” consists of plant material coated by chemicals that mimic THC, the active ingredient in marijuana, and was being sold as a “legal alternative” to marijuana with brand names such as “Spice,” “K2,” “Mr. Nice Guy,” and “Galaxy Gold.” The order states that “synthetic cannabinoids have been linked to severe adverse reactions, including death and acute renal failure, and reported side effects include: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities; seizures; and syncope (loss of consciousness).” Order for Summary Action, In the Matter of the Sale and Distribution of Synthetic Cannabinoids, annexed hereto as Exhibit 6.

12. Despite these actions at the federal and state levels, the problem of designer drugs persists because manufacturers have been misbranding products to disguise their intended use and/or rapidly changing the formulation of prohibited compounds, oftentimes without disclosing content, in order to circumvent lists of controlled substances. *See, e.g.*, Ex. 3 (noting that certain brands of synthetic marijuana “are labeled as herbal incense to mask their intended purpose”); Ex. 5 (“Manufacturers make minor chemical changes to stay ahead of legal restrictions.”).

13. In response to this growing problem, the OAG commenced a statewide investigation that focused upon deceptive and illegal labeling of designer drugs (the “Investigation”). As part of this Investigation, undercover investigators visited head shops in twelve counties to purchase such products, and found widespread selling of designer drugs, which are oftentimes deceptively marketed as innocuous products such as “incense,” “glass cleaner,” “bath salts,” “potpourri,” “sachets,” “dietary supplements,” or other common household products. Moreover, nitrous oxide, a deadly “party” gas, was being offered for sale at nearly every location that was investigated even though New York State prohibits the retail sale of nitrous oxide to the public (*Id.*).

14. In addition, the Investigation revealed that the labels of these designer drugs often omit manufacturer information, product content, and/or potential safety and health risks associated with product use, and/or falsely describe their intended uses. The Investigation also revealed that these store were promoting and encouraging the consumption or inhalation of products that are labeled, in sum or substance, “not for human consumption.”

FACTS

15. Kim Fulcher (a/k/a Kim Tasik), and upon information and belief Ryan Fulcher, own and operate Daze, a store that specializes in the retail sale of designer drugs and drug paraphernalia.

16. On June 15, 2012, Ryan Fannon, an Investigator Trainee employed by the OAG (“Investigator Fannon”), visited Daze posing as a consumer interested in purchasing merchandise (Affidavit of Ryan Fannon (“Fannon Aff.”) ¶¶ 1, 2).

17. Investigator Fannon purchased three boxes of Salvia Zone saliva, “Serenity,” and “Nightlights” (*Id.* ¶¶ 10, 13, 15, 16).

18. These products constitute drugs because they are “[a]rticles (other than food) intended to affect the structure or any function of the body of man.” N.Y. EDUC. LAW § 6802(7)(c).

VIOLATION OF AGRICULTURE AND MARKETS LAW § 194

19. New York Agriculture & Markets Law § 194 prohibits selling, offering or exposing for sale any commodity that is labeled with any false description or false indication of, among other things, its number, quantity, weight or measure. N.Y. AGRIC. & MKTS. LAW § 194.

20. The term “commodities” is defined to include non-prescription drugs. *Id.* § 191(1)(b)(4).

21. A “label” is defined as “any written, printed, or graphic matter affixed to, applied to, attached to, blown into, formed, molded into, embossed on, or appearing upon or adjacent to a consumer commodity or a package containing any consumer commodity, for purposes of branding, identifying, or giving any information with respect to the commodity or to the contents of the package.” N.Y. COMP. CODES R. & REGS. tit. 1, § 221.2(e). A label must identify the commodity in the package “by its common or usual name, description, generic term, or the like,” *id.* § 221.3(a), and provide the name and address of the manufacturer, packer or distributor, *id.* § 221.4(a), and the quantity, such as the weight, of the product, *id.* § 221.5.

22. Respondents have repeatedly offered to sell and/or sold mislabeled drugs in violation of Agriculture and Markets Law § 194.

23. The following products are mislabeled because they fail to include the name and/or address of its manufacturer, packer or distributor: Salvia Zone salvia, “Serenity,” and “Nightlights.”

24. “Nightlights” is also mislabeled because its label fails to provide any information about the product’s identity (*e.g.*, by its common or usual name, description, or generic term), aside from “Metaphysical Crystal Capsules.”

25. “Nightlights” is also mislabeled because its label does not provide the quantity of the product.

26. Finally, given that Daze sold it to Investigator Fannon in response to his request for kratom, which is typically consumed or smoked, “Nightlights” is also mislabeled because its package falsely and/or misleadingly (1) describes its contents as “[n]ot for human consumption,” and (2) instructs the user to “[p]lace cap[sule] in window sill or on top of door frame to keep away negative energies and bad dreams.”

VIOLATION OF EDUCATION LAW § 6815

27. Under the New York Education Law, it is unlawful to sell or offer for sale any drug that is misbranded. N.Y. EDUC. LAW § 6811(9); *see also id.* § 6811(11), (12).
28. Under Education Law § 6815, a drug is deemed to be misbranded if, among other things:
- a. “its labeling is false or misleading in any particular,” N.Y. EDUC. LAW § 6815(2)(a);
 - b. in package form, it fails to bear a label containing “the name and place of business of the manufacturer, packer or distributor,” and “an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count,” *id.* § 6815(2)(b);
 - c. required information is not prominently placed on the label with conspicuousness and “in such terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use,” *id.* § 6815(2)(c);
 - d. its label fails to bear “adequate directions for use,” and it lacks “adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users,” *id.* § 6815(2)(f);
 - e. it is “an imitation of another drug,” “offered for sale under the name of another drug,” or “bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug,” *id.* § 6815(2)(h); or
 - f. “it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling,” *id.* § 6815(2)(i).
29. Respondents have repeatedly offered to sell and/or sold misbranded drugs in violation of the New York Education Law.
30. The Salvia Zone products are misbranded for the following reasons:
- a. their labels fail to provide the place of business for their manufacturer, packer or distributor;

- b. their labels fail to fully disclose the products' potential health effects;
 - c. their labels fail to disclose the effects associated with each specific level, despite their labels' claim that "[i]t is extremely important that the product be used in accordance with its color-coded potency system" "to allow[] users to become comfortable with the effects associated with each specific level before proceeding on to the next"; and
 - d. their labels appear to disclaim the customary or usual use of these products, which is to obtain salvia's hallucinogenic effects, by claiming that Salvia Zone is intended as a tool for self-exploration.
31. The "Serenity" product is misbranded for the following reasons:
- a. its label fails to provide the street address of the place of business for its manufacturer, packer or distributor;
 - b. its label fails to identify the product's potential health effects; and
 - c. its label falsely and/or misleadingly identifies its contents as "Dietary Supplement," given that Daze sold "Serenity" to Investigator Fannon in response to his request for kratom.
32. The "Nightlights" product is misbranded for the following reasons:
- a. its label fails to provide the name and place of business for its manufacturer, packer or distributor;
 - b. its label fails to provide any statement, let alone an accurate one, of the package's quantity;
 - c. its label fails to identify potential health effects from the product's customary or usual usage; and
 - d. its label falsely and/or misleadingly (1) describes its contents as "[n]ot for human consumption," and (2) instructs the user to "[p]lace cap[sule] in window sill or on top of door frame to keep away negative energies and bad dreams," given that Daze sold "Nightlights" to Investigator Fannon in response to his request for kratom, which is typically consumed or smoked.

DECEPTIVE ACTS AND PRACTICES

33. Respondents repeatedly offer for sale and/or sell products that are mislabeled and/or misbranded drugs. The labels of such products fail to disclose required information, including, but not limited to, manufacturer, distributor or packer information, product ingredients, and/or potential health risks.

34. Respondents repeatedly offer for sale and sell products for human consumption or inhalation even though their labels state, in sum or substance, “not for human consumption.”

NEED FOR TEMPORARY RESTRAINING ORDER

35. The evidence submitted by the OAG, including the Lundborg-Gray Affidavit and the Fannon Affidavit, clearly demonstrates that Respondents have been fraudulently and illegally selling mislabeled and/or misbranded designer drugs and that such drugs present serious harm to the public.

36. Without a temporary restraining order prohibiting Respondents from selling mislabeled and/or misbranded drugs, there is a great likelihood that Respondents will continue to sell these products and that these products will result in irreparable injury to individuals who consume these products.

37. On July 9, 2012, I called Greg Lisi, attorney for Respondents, to notify him that Petitioner will be making this application for an Order to Show Cause with a temporary restraining order on July 10, 2012 at about 10:30 a.m. at the Supreme Court, Nassau County.

38. There has been no previous application for the relief requested herein.

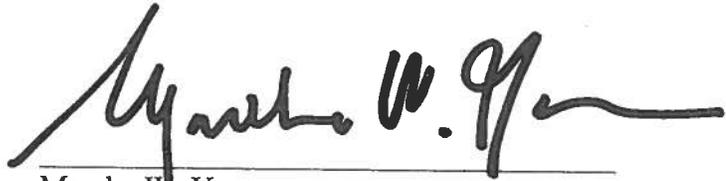
CONCLUSION

39. Respondents continue to engage in deceptive, fraudulent and illegal acts set forth in this affirmation and the petition. Unless enjoined, Respondents will continue to engage in those acts. The Attorney General is bringing this action to force compliance with State labeling

and consumer protection laws. Transparency in the labeling and sale of these dangerous products would enable potential and actual consumers to be better informed about the contents of these products and would facilitate the appropriate regulatory authorities in addressing these products as drugs.

WHEREFORE, it is respectfully requested that the relief requested in the Verified Petition be granted, together with civil penalties and costs as set forth by statute, and with such other and further relief as this Court deems just and proper.

Dated: July 10, 2012
Mineola, New York



Marsha W. Yee
Assistant Attorney General

Guidance for Industry

Street Drug Alternatives

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
March 2000
Compliance**

Guidance for Industry

Street Drug Alternatives

Additional copies of this Guidance are available from:

*Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857
(Phone 301-827-4573)
Internet: <http://www.fda.gov/cder/guidance/index.htm>.*

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
March 2000
Compliance**

Guidance for Industry¹

Street Drug Alternatives

I. INTRODUCTION

This guidance is intended for those persons who are manufacturing, marketing, or distributing alternatives to illicit street drugs. FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act (the Act). Such violations may result in regulatory action, including seizure and injunction.

II. BACKGROUND

The Agency has become aware of the proliferation of various products that are being manufactured, marketed, or distributed as alternatives to illicit street drugs (*street drug alternatives*). FDA is concerned that these products are being abused by individuals, including minors, and pose a potential threat to the public health.

Street drug alternatives are generally labeled as containing botanicals, and some are also labeled as containing other ingredients, such as vitamins, minerals, or amino acids. They are marketed under a variety of brand names with claims implying that these products mimic the effects of controlled substances. Many of these products are promoted on the Internet and in counterculture magazines as alternatives to illicit street drugs such as MDMA (4-methyl-2, dimethoxyamphetamine), a methamphetamine analogue, also known as *ecstasy*, *XTC*, and *X*. Other examples of products whose names imply street drug alternative use are *e-Ludes*, *Hextacy*, and *Herbal Koke*.

These products are intended to be used for recreational purposes to effect psychological states (e.g., to get high, to promote euphoria, or to induce hallucinations) and have potential for abuse. FDA considers these street drug alternatives to be unapproved new drugs and misbranded drugs under sections 505 and 502 of the Act.

¹This guidance has been prepared by the Office of Compliance, Division of Labeling and Nonprescription Drug Compliance, in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration. This guidance represents the Agency's current thinking on street drug alternatives. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

FDA is also aware that some of these street drug alternatives are being marketed as dietary supplements. FDA does not consider street drug alternatives to be dietary supplements. The term *dietary supplement* as defined in section 201(ff) of the Act means, inter alia, a product "intended to supplement the diet." While the Act does not elaborate on the meaning of this phrase, many congressional findings, set forth in the Dietary Supplement Health and Education Act of 1994, suggest that dietary supplements are intended to be used to augment the diet to promote health and reduce the risk of disease. FDA does not believe that street drug alternatives are intended to be used to augment the diet to promote health or reduce the risk of disease. Moreover, FDA considers the diet to be composed of usual food and drink that may be designed to meet specific nutritional requirements. Illicit street drugs are not food or drink, and neither they, nor alternative street drugs, can be said to supplement the diet. Rather, these products are intended to be used for recreational purposes to effect psychological states (e.g., to get high, to promote euphoria, or to induce hallucinations). Accordingly, street drug alternatives are not intended to supplement the diet and are not dietary supplements. This position is consistent with that set forth at 62 Fed. Reg. 30678, 30699-700 (June 4, 1997).

III. POLICY

FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act. Such violations may result in regulatory action, including seizure and injunction



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DEA Moves to Emergency Control Synthetic Stimulants
Agency Will Study Whether To Permanently Control Three Substances

SEP 07 – WASHINGTON, D.C. – The United States Drug Enforcement Administration (DEA) is using its emergency scheduling authority to temporarily control three synthetic stimulants (Mephedrone, 3,4 methylenedioxypyrovalerone (MDPV) and Methylone). This action was necessary to protect the public from the imminent hazard posed by these dangerous chemicals. Except as authorized by law, this action will make possessing and selling these chemicals or the products that contain them illegal in the U.S. for at least one year while the DEA and the United States Department of Health and Human Services (DHHS) further study whether these chemicals should be permanently controlled.

A Notice of Intent to temporarily control was published in the Federal Register today to alert the public to this action. This alert is required by law as part of the Controlled Substances Act. In 30 days or more, DEA intends to publish in the Federal Register a Final Order to temporarily control these chemicals for at least 12 months, with the possibility of a six-month extension. The final order will be published in the *Federal Register* and will designate these chemicals as Schedule I substances, the most restrictive category, which is reserved for unsafe, highly abused substances with no currently accepted medical use in the United States.

"This imminent action by the DEA demonstrates that there is no tolerance for those who manufacture, distribute, or sell these drugs anywhere in the country, and that those who do will be shut down, arrested, and prosecuted to the fullest extent of the law," said DEA Administrator Michele M. Leonhart. "DEA has made it clear we will not hesitate to use our emergency scheduling authority to control these dangerous chemicals that pose a significant and growing threat to our nation."

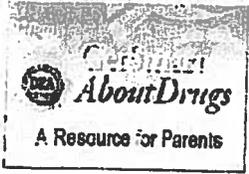
Over the past few months, there has been a growing use of, and interest in, synthetic stimulants sold under the guise of "bath salts" or "plant food". Marketed under names such as "Ivory Wave", "Purple Wave", "Vanilla Sky" or "Bliss", these products are comprised of a class of chemicals perceived as mimics of cocaine, LSD, MDMA, and/or methamphetamine. Users have reported impaired perception, reduced motor control, disorientation, extreme paranoia, and violent episodes. The long-term physical and psychological effects of use are unknown but potentially severe. These products have become increasingly popular, particularly among teens and young adults, and are sold at a variety of retail outlets, in head shops and over the Internet. However, they have not been approved by the FDA for human consumption or for medical use, and there is no oversight of the manufacturing process.

In the last six months, DEA has received an increasing number of reports from poison centers, hospitals and law enforcement regarding products containing one or more of these chemicals. Thirty-three states have already taken action to control or ban these or other synthetic stimulants. The Comprehensive Crime Control Act of 1984 amends the Controlled Substances Act (CSA) to allow the DEA Administrator to temporarily schedule an abused, harmful, non-medical substance in order to avoid an imminent hazard to public safety while the formal rule-making procedures described in the CSA are being conducted.

Editor's Note: DEA will issue an additional press release when the Final Order to Temporarily Control these chemicals is published in the Federal Register.



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Chemicals Used in "Spice" and "K2" Type Products Now Under Federal Control and Regulation
DEA Will Study Whether To Permanently Control Five Substances

MAR 01 - WASHINGTON, D.C. – The United States Drug Enforcement Administration (DEA) today exercised its emergency scheduling authority to control five chemicals (JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol) used to make so-called "fake pot" products. Except as authorized by law, this action makes possessing and selling these chemicals or the products that contain them illegal in the United States. This emergency action was necessary to prevent an imminent threat to public health and safety. The temporary scheduling action will remain in effect for at least one year while the DEA and the United States Department of Health and Human Services (DHHS) further study whether these chemicals should be permanently controlled.



Chemicals like K-2 and Spice are designated as Schedule I substances, the most restrictive category under the Controlled Substances Act.

The Final Order was published today in the *Federal Register* to alert the public to this action. These chemicals will be controlled for at least 12 months, with the possibility of a six month extension. They are designated as Schedule I substances, the most restrictive category under the Controlled Substances Act. Schedule I substances are reserved for those substances with a high potential for abuse, no accepted medical use for treatment in the United States and a lack of accepted safety for use of the drug under medical supervision.

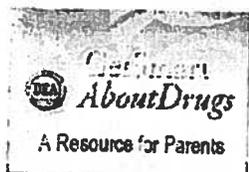
Over the past couple of years, smokeable herbal products marketed as being "legal" and as providing a marijuana-like high, have become increasingly popular, particularly among teens and young adults. These products consist of plant material that has been coated with research chemicals that claim to mimic THC, the active ingredient in marijuana, and are sold at a variety of retail outlets, in head shops, and over the Internet. These chemicals, however, have not been approved by the FDA for human consumption, and there is no oversight of the manufacturing process. Brands such as "Spice," "K2," "Blaze," and "Red X Dawn" are labeled as herbal incense to mask their intended purpose.

Since 2009, DEA has received an increasing number of reports from poison control centers, hospitals and law enforcement regarding these products. At least 16 states have already taken action to control one or more of these chemicals. The Comprehensive Crime Control Act of 1984 amends the Controlled Substances Act (CSA) to allow the DEA Administrator to place a substance temporarily in schedule I when it is necessary to avoid an imminent threat to the public safety. Emergency room physicians report that individuals that use these types of products experience serious side effects which include: convulsions, anxiety attacks, dangerously elevated heart rates, increased blood pressure, vomiting, and disorientation.

"Young people are being harmed when they smoke these dangerous 'fake pot' products and wrongly equate the products' 'legal' retail availability with being 'safe,'" said DEA Administrator Michele M. Leonhart. "Parents and community leaders look to us to help them protect their kids, and we have not let them down. Today's action, while temporary, will reduce the number of young people being seen in hospital emergency rooms after ingesting these synthetic chemicals to get high."

>> Notice of Intent to Temporarily Control Five Synthetic Cannabinoids







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Date: June 19, 2012
Contact: DEA Public Affairs
Number: 202-307-7977

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Congress Agrees to Add 26 Synthetic Drugs to Controlled Substances Act

The Drug Enforcement Administration today commended House and Senate negotiators for agreeing on legislation to control 26 synthetic drugs under the Controlled Substances Act. These drugs include those commonly found in products marketed as "K2" and "Spice."

The addition of these chemicals to Schedule I of the Controlled Substances Act will be included as part of S. 3187, the Food and Drug Administration Safety and Innovation Act. Schedule I substances are those with a high potential for abuse; have no medical use in treatment in the United States; and lack an accepted safety for use of the drug.

In addition to scheduling the 26 drugs, the new law would double the length of time a substance may be temporarily placed in Schedule I (from 18 to 36 months). In addition to explicitly naming 26 substances, the legislation creates a new definition for "cannabinomimetic agents," creating criteria by which similar chemical compounds are controlled.

In recent years, a growing number of dangerous products have been introduced into the U.S. marketplace. Products labeled as "herbal incense" have become especially popular, especially among teens and young adults. These products consist of plant material laced with synthetic cannabinoids which, when smoked, mimic the delirious effects of THC, the psychoactive ingredient of marijuana. According to the United Nations Office on Drugs and Crime, more than 100 such substances have been synthesized and identified to date. DEA has used its emergency scheduling authority to place in schedule I several of these harmful chemicals.

Newly developed drugs, particularly from the "2C family" (dimethoxyphenethylamines), are generally referred to as synthetic psychedelic/hallucinogens. 2C-E caused the recent death of a 19 year-old in Minnesota.

The substances added to Schedule I of the Controlled Substances Act also include 9 different 2C chemicals, and 15 different synthetic cannabinoids.

The American Association of Poison Control Centers reported that they received 6,959 calls related to synthetic marijuana in 2011, up from 2,906 in 2010.

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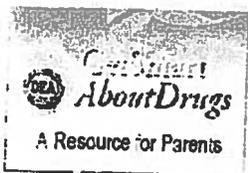
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Section: News

Bath salts face federal ban

June 28, 2012

Bath salts -- the kind that get you high, not the kind that get you clean -- could face a federal ban.

U.S. Sen. Charles Schumer, D-NY, announced Wednesday the Senate has passed legislation that would permanently ban the chemical compounds marketed as "bath salts" and "incense." Three bills relating to the substances -- bath salts, synthetic marijuana and synthetic hallucinogens -- are included in the Food and Drug Administration Safety and Innovation Act.

"Let this be a warning to those who make a profit manufacturing and selling killer chemical components to our teens and children in the Southern Tier: the jig is up," Schumer said.

Designed to mimic methamphetamine, the flaky white substance is snorted, injected, smoked or swallowed. Manufacturers make minor chemical changes to stay ahead of legal restrictions.

The legislation would specifically ban MDPV -- a chemical with the lengthy name of methylenedioxypropylvalerone -- and mephedrone, the active ingredients in products being sold under names such as Tranquility, Zoom, Ivory Wave, Red Dove, Legal Phunk and Vanilla Sky. These chemicals and 29 others would be added to Schedule I of the Controlled Substances Act, which classifies drugs that are illegal and cannot be prescribed under any circumstances.

According to reports, the chemicals found in bath salts cause effects similar to those of cocaine and methamphetamines, including hallucinations, paranoia and suicidal thoughts. Users taken to the hospital are often combative and extremely agitated, experts said. Several have died after overdoses or because of violent behavior -- which has even included cannibalism.

In 2010, the American Association of Poison Control Centers reported 303 bath salt-related calls to its centers. In 2011, that number sky rocketed to 5,833.

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Locally, the Binghamton Police Department said the issue is minimal within the city at this point, according to city spokesman Andrew Block. The Broome County Sheriff's Office has seen a few incidences involving bath salts, said Undersheriff Alex Minor.

"It's really nasty stuff," Minor said. "Fortunately, we haven't seen an awful lot of it."

However, panelists at a discussion on synthetic drugs earlier this month in Ithaca said they're turning up frequently in schools and the emergency room.

"We are finding it at the high school," Christine Barksdale, juvenile investigator for the Ithaca Police Department, said during the panel discussion. "Kids are having packets of it. We are having instances at the high school where kids are having hallucinations."

Steuben County has seen four gun-related incidents involving bath salts in the past five months, as well as a man who fired a shotgun in an occupied home and another who evaded police but drove to the station to turn himself in because he believed himself to be followed by the FBI and CIA.

Bath salts were among the substances seized during a Waverly drug bust in September. In January, the parents of an 11-month-old Ridgebury Township girl in Bradford County were charged after police said both were under the influence of bath salts. The Tioga County Sheriff's Office arrested a 23-year-old Berkshire woman in April on charges of criminal possession of both a controlled substance and drug paraphernalia after she was accused of having the substance.

And this month, an Oneida County man using the drug brandished an unloaded shotgun on a rooftop, yelling for people to get out of his yard even though there was nobody there. A woman believed to be using the drug lunged at a police officer and tried to bite his face in Utica; that same night, a 20-year-old man ripped a door off its hinges and was found punching a car after threatening to kill his mother, police said.

The legislation has now passed both houses, and is heading to President Barack Obama's desk for his signature.

The Associated Press and Gannett News Service contributed to this report.

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STATE OF NEW YORK : DEPARTMENT OF HEALTH
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IN THE MATTER

OF

THE SALE AND DISTRIBUTION
OF SYNTHETIC CANNABINOIDS

ORDER FOR
SUMMARY
ACTION

-----X

WHEREAS, a "cannabinoid" is a class of chemical compounds in the marijuana plant and the cannabinoid Δ^9 -tetrahydrocannabinol (THC) is the primary psychoactive constituent of marijuana. "Synthetic cannabinoids" encompass a wide variety of chemicals that are synthesized and marketed to mimic the action of THC. A "synthetic cannabinoid" is defined herein as any chemical compound that is a cannabinoid receptor agonist and includes, but is not limited to any material, compound, mixture, or preparation that is not listed as a controlled substance in the Schedule I through V of § 3306 of the Public Health Law, is not a federal Food and Drug Administration (FDA) approved drug, and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically exempted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:

- i. Naphthoylindoles. Any compound containing a 3-(1-Naphthyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any

- extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH 015, JWH 018, JWH 019, JWH 073, JWH 081, JWH 122, JWH 200, JWH 210, JWH 398, AM 2201, and WIN 55 212).
- ii. Naphthylmethyloindoles. Any compound containing a 1 H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH-175, and JWH-184).
- iii. Naphthylpyrroles. Any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH 307).
- iv. Naphthylmethyloindenes. Any compound containing a naphthylidene indene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH-176).

- v. **Phenylacetylindoles.** Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: RCS-8 (SR-18), JWH 250, JWH 203, JWH-251, and JWH-302).
- vi. **Cyclohexylphenols.** Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. (Other names in this structural class include but are not limited to: CP 47,497 (and homologues (analog)), cannabicyclohexanol, and CP 55,940).
- vii. **Benzoylindoles.** Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: AM 694, Pravadoline (WIN 48,098), RCS 4, and AM-679).

viii. [2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-de]-1, 4-benzoxazin-6-yl]-1-naphthalenylmethanone. (Other names in this structural class include but are not limited to: WIN 55,212-2).

ix. (6aR,10aR)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo[*c*]chromen-1-ol 7370. (Other names in this structural class include but are not limited to: HU-210).

x. Adamantoylindoles. Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the adamantyl ring system to any extent. (Other names in this structural class include but are not limited to: AM-1248).

xi. Any other synthetic chemical compound that is a cannabinoid receptor agonist that is not listed in Schedules I through V of § 3306 of the Public Health Law, or is not an FDA approved drug; and

WHEREAS, synthetic cannabinoids are frequently applied to plant materials and then packaged and marketed online, and in convenience stores, gas stations and smoke shops as incense, herbal mixtures or potpourri, and often carry a "not for human consumption" label, and are not approved for medical use in the United States; and

WHEREAS, products containing synthetic cannabinoids are, in actuality, produced, distributed, marketed and sold, as a supposed "legal alternative" to marijuana and for the purpose of being consumed by an individual, most often by smoking, either through a pipe, a water pipe,

or rolled in cigarette papers; and

WHEREAS, synthetic cannabinoids have been linked to severe adverse reactions, including death and acute renal failure, and reported side effects include: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities; seizures; and syncope (loss of consciousness); and

WHEREAS, products containing synthetic cannabinoids have become prevalent drugs of abuse, especially among teens and young adults. Calls to New York State Poison Control centers relating to the consumption of synthetic cannabinoids have increased dramatically, with a total of 105 reported incidents of exposure to these substances having been reported since 2011, compared to four reported instances in 2009 and 2010. Over half of the calls to the Upstate Poison Control Center this year involved children under the age of 19 years of age. Nationally, poison control centers have received approximately 8,000 calls relating to exposure to these substances since 2011. Calls received by poison control centers generally reflect only a small percentage of actual instances of poisoning. Therefore, it is clear that many additional New York residents have been harmed as a result of using products containing synthetic cannabinoids; and

WHEREAS, on March 1, 2011, the United States Drug Enforcement Administration (DEA) temporarily scheduled five synthetic cannabinoids, JWH-018, JWH-073, JWH-200, CP 47, 497 and cannabicyclohexanol (CP 47, 497, C8, which is a homologue of CP 47, 497), as Schedule 1 substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]), in order to avoid an imminent hazard to public safety, because the substances have a high potential for

abuse and have no currently accepted medical use in treatment in the United States. On March 1, 2012, the federal DEA ban was extended for six months; and

WHEREAS, individuals and entities can avoid -- and have avoided -- the federal ban of specifically identified synthetic cannabinoids by developing or synthesizing cannabinoids that are not expressly covered under any such ban; and

WHEREAS, based upon the foregoing, the Commissioner of Health of the State of New York, after investigation, is of the opinion that the sale or distribution of products containing synthetic cannabinoids, including, but not limited to, the products identified in the Appendix, is an activity which constitutes danger to the health, safety and welfare of the people of the State of New York; and

WHEREAS, it therefore appears to be prejudicial to the interest of the people to delay action for fifteen (15) days until an opportunity for a hearing can be provided in accordance with the provisions of Public Health Law § 12-a.

NOW, THEREFORE, THE COMMISSIONER OF HEALTH DOES HEREBY ORDER THAT:

1) Pursuant to Public Health Law § 16, any individual or entity in the State of New York engaged in the sale or distribution of products containing synthetic cannabinoids, including, but not limited to, those products identified in the Appendix, and that receives notice of this Order, shall immediately cease the sale and/or distribution of said products in New York State.

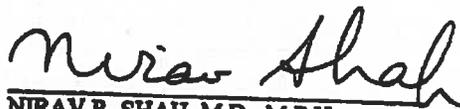
2) The presiding officer of each local health unit or local board of health in the State of New York, is hereby directed, pursuant to Public Health Law § 1303(4) and Title 10 NYCRR

8.5, to convene each such local health unit or local board of health as is necessary to disseminate this Order and to ensure compliance with this Order.

FURTHER, I DO HEREBY give notice that any individual or entity that receives notice of and is subject to this Order shall be provided an opportunity to be heard within fifteen (15) days of service of this Order, at the offices of the New York State Department of Health, to present proof that the sale or distribution of products containing synthetic cannabinoids does not constitute a danger to the health of the people of the State of New York. Any such individual or entity that wishes to avail themselves of this opportunity, should notify the Department of Health in writing, within five (5) days of receipt of service of this Order, to the following address: New York State Department of Health, Bureau of Administrative Hearings, Corning Tower, Room 2438, Governor Nelson A. Rockefeller Empire State Plaza, Albany, New York 12237. This notice may also be submitted by FAX at (518) 486-1858, or by email at mdf01@health.state.ny.us. The Department will, within five business days of its receipt of a request for hearing, provide written notice of the date, place and time of the scheduled hearing.

DATED: Albany, New York
March 28, 2012

NEW YORK STATE DEPARTMENT OF
HEALTH



NIRAV R. SHAH, M.D., M.P.H.
Commissioner of Health

APPENDIX

**K2
Spice
Chronic Spice
Spice Gold
Spice Silver
Skunk
Black Mamba
Zohai
Mr. Nice Guy
K3
K3 Legal
Genie
Sence
Smoke
Chill X
Earth Impact
Galaxy Gold
Space Truckin
Solar Flare
Moon Rocks
Aroma
Scope
Sky High**