

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

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

Petitioner,

-against-

SMOKEN, LLC, doing business as
VILLAGE SENSATIONS,

Respondent.
-----X

**ORDER TO SHOW CAUSE
WITH A TEMPORARY
RESTRAINING ORDER**

Index No.: _____

RJI No.: _____

Assigned to Justice: _____

Upon reading and filing the annexed Verified Petition, verified on July 9, 2012; and the Affirmation of Sandra Giorno-Tocco, Assistant Attorney General, affirmed to on July 9, 2012; and the Affidavits of Senior Investigator Chad Shelmidine, sworn to on June 26, 2012, and Maja Lundborg-Gray, MD, FAAEM, FACEP, sworn to on July 5, 2012, and the exhibits annexed thereto, and

Upon the motion of ERIC T. SCHNEIDERMAN, Attorney General of the State of New York, attorney for the Petitioner, it is

ORDERED that the Respondent in the above-entitled action show cause at a Term of this Court, to be held at the Supreme Court, located at 111 Dr. Martin Luther King Jr. Blvd., White Plains, New York 10601, 13202, on the ___ day of July, 2012, at 10:00 o'clock in the forenoon of that day, or as soon thereafter as counsel may be heard, why an order should not be made, pursuant to Executive Law § 63(12) and General Business Law, Article 22-A:

- a. enjoining Respondent, his agents, trustees, servants, employees, successors, heirs and assigns, or any other person under his direction and control, whether acting individually or in concert with others, or through any corporate or other entity or device through which he may now or

hereafter act or conduct business ("Respondent"), from offering for sale and/or selling mislabeled drugs;

- b. enjoining Respondent from offering for sale and/or selling misbranded drugs;
- c. enjoining Respondent from offering for sale and/or selling products as designer drugs or other street drug alternatives that are not approved for human consumption;
- d. enjoining Respondent from selling nitrous oxide without first obtaining an exemption from the Commissioner of the New York State Department of Health;
- e. enjoining Respondent from engaging in the fraudulent, deceptive and illegal practices alleged in the petition;
- f. requiring that Respondents comply with any and all state, local or federal labeling requirements.
- g. requiring Respondent to prepare an accounting of all commodities he sold, or offered for sale, from January 1, 2012 to July 10, 2012 including the (i) name of the product, (ii) the manufacturer and/or distributor of the product, (iii) a description of the product, (iv) the retail price of the product, and (v) the number units of the product sold;
- h. pursuant to GBL § 350-d, imposing a civil penalty of \$5,000 for each deceptive act committed by Respondent;
- i. pursuant to CPLR § 8303(a)(6), granting costs to the State of New York of \$2,000; and
- j. for such other and further relief as the court deems just and proper.

IT APPEARING that a cause of action for temporary injunctive relief exists under Executive Law § 63(12), General Business Law § 349, and CPLR §§ 6301 and 6313, and that Respondent has engaged in repeated and persistent illegal, fraudulent and deceptive acts and practices which have caused and will continue to cause immediate and irreparable injury to members of the public unless Respondent is restrained before a hearing can be held, it is

ORDERED that pending the hearing and determination of this proceeding, and to

protect the public health, Respondent, its agents, employees, successors, and assigns, and any other person under their direction and control, whether acting individually or in concert with others, or through any corporate or other entity or device, is hereby temporarily restrained, pursuant to CPLR §§ 6301 and 6313 from offering for sale or selling mislabeled and/or misbranded drugs, from offering for sale and/or selling products as designer drugs or other street drug alternatives that are not approved for human consumption, and from selling nitrous oxide to the public;

SUFFICIENT CAUSE appearing to me therefore,

LET service of one copy of this order and supporting papers on Respondent on or before the ____ day of July, 2012 be deemed due and sufficient service hereof.

Pursuant to CPLR § 403(b), answering papers, if any, are required to be served at least two days before the return date of this special proceeding. If, however, this Order to Show Cause is served at least twelve days before the return date, answering papers, if any, are required to be served at least seven days before the return date.

Dated: White Plains, New York
July __, 2012

ENTER

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

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

Petitioner,

VERIFIED PETITION

-against-

SMOKEN, LLC, doing business as
VILLAGE SENSATIONS,

Respondent.

The People of the State of New York, by their attorney, Eric T. Schneiderman, Attorney
General of the State of New York, allege as follows:

PRELIMINARY STATEMENT

1. Petitioner brings this special proceeding pursuant to New York Executive Law ("Exec. Law") § 63(12) and New York General Business Law ("GBL") § 349 to enjoin Respondent Smoken, LLC, doing business as Village Sensations, from engaging in deceptive, fraudulent and illegal practices in connection with its business (commonly known as a "head shop"). Respondent sells so-called designer drugs, which are synthetic versions of illegal drugs, as well as other street drug alternatives, which are products that are marketed with claims that the effect of their use mimics controlled substances. Designer drugs and other street drug alternatives [hereinafter "designer drugs"] are marketed to avoid the provisions of existing drug laws; they are intended to stimulate, sedate or cause hallucinations or euphoria when ingested or inhaled. Petitioner also seeks civil penalties and costs, as authorized by statute, to be paid to the State of New York.

2. The sale of designer drugs has contributed to a public health crisis in New York State and across the nation. These products are sold by head shops for their psychoactive effects akin to those obtained from illegal drug use. Many of these products are packaged with innocuous names and bright graphics to give the misleading impression that their use is harmless. Others are packaged and named to mimic illegal drugs or legal prescription drugs. The products target people who wish to engage in recreational legal drug use and/or do not want to risk a positive drug test. Many products are insufficiently labeled, mislabeled and/or misbranded, lacking identification of ingredients, adequate directions for use, adequate warning labels, and/or manufacturer information. In addition, some products that bear labels stating “not fit for human consumption” are deceptively misrepresented by head shops to consumers as drugs with psychoactive properties.

3. Misrepresenting products as safe for human consumption and selling products that are insufficiently labeled or mislabeled is inherently misleading and dangerous. Consumers cannot make informed decisions about the safety of the products they are purchasing without knowing the contents of the products and how they are intended to be used. Some of these products may cause serious health effects such as agitation, tachycardia (rapid heartbeat), hallucinations, seizures, extreme paranoia, panic, vomiting, mood swings, intense cravings to redose, suicidal or homicidal thoughts, or even death. Consumers who experience dire health consequences as a result of ingesting these products are at further risk. Without being able to disclose to emergency personnel and health care providers the chemicals they have ingested, the users of these products may not receive appropriate medical treatment.

4. New York State has enacted a comprehensive statutory scheme with respect to the labeling of commodities and drugs. For example, the New York State Agriculture & Markets

Law (hereinafter "Ag. & Mkts. Law") § 194 regulates labeling of commodities, including non-prescription drugs. The New York State Education Law (hereinafter "Educ. Law") § 6802 proscribes misbranding of all drugs. Crucial to protecting the health of all New Yorkers is enforcement of the state's laws prohibiting mislabeling of commodities and misbranding of drugs.

5. In addition, the New York State Public Health Law (hereinafter "Pub. Health Law") § 3380 proscribes the retail sale of nitrous oxide to the public. Respondent offers for sale and sells nitrous oxide canisters to the public.

PARTIES AND JURISDICTION

6. Petitioner is the People of the State of New York, by their attorney, Eric T. Schneiderman, Attorney General of the State of New York

7. Respondent Smoken, LLC is located in Rockland County. Respondent does business as Village Sensations. Village Sensations is located at 111 Main Street, Nanuet, NY 10954-2885. A business certificate was filed in Rockland County on October 6, 2009 and an amended business certificate was filed in October of 2011. On January 8, 2010, Respondent filed a Certificate of Assumed Name in order to do business as Village Sensations. Smoken, LLC and Village Sensations shall hereinafter be referred to as "Respondent" or "Village Sensations."

8. Petitioner brings this proceeding pursuant to Exec. Law § 63(12) which authorizes the Attorney General to seek injunctive relief, restitution, damages and costs when any person or entity has engaged in repeated fraudulent or illegal acts or has otherwise engaged in persistent fraud or illegality in the conduct of its business, and pursuant to GBL Article 22-A, which

authorizes the Attorney General to seek injunctive relief, restitution and civil penalties against any person or business entity that has engaged in deceptive business practices.

9. Petitioner has timely served Respondent with pre-litigation notice pursuant to GBL § 349(c).

FACTS

10. Respondent owns and operates a "head shop" that specializes in the retail sale of drug paraphernalia for the consumption of cannabis and other illegal substances, as well as the sale of designer drugs. Designer drugs are marketed as innocuous products but are designed to stimulate, sedate or cause hallucinations or euphoria when ingested or inhaled. Many of these products are harmful to consumers.

11. The Office of the New York State Attorney General Eric T. Schneiderman ("OAG") conducted an undercover investigation that revealed extensive evidence that Village Sensations offers for sale and sells mislabeled and misbranded designer drugs and nitrous oxide to the public. The Food and Drug Administration (FDA) also considers any product that is promoted as a street drug alternative to be an unapproved new drug and misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §§ 321(p)(1), 352(f)(1).

12. Village Sensations offers for sale and sells these products in such a manner as to either explicitly or implicitly misrepresent the products as designer drugs.

13. As detailed below, Village Sensations offers for sale and sells, *inter alia*, the following designer drugs: Kratom and "Mollys Mosquito Caps." Village Sensations also offers for sale and sells canisters of nitrous oxide, despite its lack of an exemption by the Commissioner of the State Health Department to sell such products. Indeed, New York State

Law does not allow exemptions for retail sale of nitrous oxide to the public without an exemption.

14. On May 29, 2012, at approximately 12:00 P.M., Chad Shelmidine, a Senior Investigator employed by the Department of Law ("Inv. Shelmidine"), posing as a consumer, went to Village Sensations' store, located at 111 Main Street, Nanuet, New York, to purchase merchandise.

15. Village Sensations offers for sale and sells "kratom," a popular designer drug or street drug alternative. In fact, Village Sensations' sales staff offers kratom as a designer drug to be consumed with tea.

16. Inv. Shelmidine purchased two specific brands of kratom. The first package is labeled as "Mr. Nice Guy: Bureaucrat" ("Mr. Nice Guy"). According to the product's packaging, Mr. Nice Guy contains two grams of "kratom extract". The printed description on the label describes kratom extract as "among the highest quality Kratom products in the world", and that the "most mature leaves are combined with the most advanced extraction methods on Earth to produce a nearly perfect powder." The label further indicates that the product is "NOT FOR HUMAN CONSUMPTION." The package bears a picture of a "smiley face" with "X's" for eyes, an inversion of the "un-smiley face" commonly used as a symbol by poison control centers. Although the label of "Mr. Nice Guy" states that the product is not for human consumption, Village Sensations clearly sells and offers for sale kratom as a designer drug.

17. The second brand of kratom Inv. Shelmidine purchased is labeled as "Experience: Da Pimp Bomb." The product is listed as "Kratom 15X." According to the package the contents are "100% Effective-100% Organic." The ingredients are identified as 100% Pure Extracted *Mitragyna Speciosa* Leaf" (the pharmacological name for kratom), and the manufacturer is listed

as "Experience Alternatives Inc", but no contact information is provided. A printed warning states: "Use with caution. Do not use while operating a motor vehicle or machinery, if you are pregnant or nursing, or if you are taking any prescription or non-prescription drugs." There is a disclaimer that this product has not been evaluated by the FDA & is not intended to treat, prevent or cure or diagnose any illness. The label further states that one "[m]ust be 18 years of age to use this product." The label fails to provide any health warnings with regard to the use of the product.

18. According to the United States Department of Justice Department of Drug Enforcement Administration (DEA), kratom is a tropical tree native to Southeast Asia. Like other psychostimulant drugs, consumption of kratom leaves (or extract) produces both stimulant effects in low doses, and sedative effects in high doses and can lead to addiction. Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion. Withdrawal effects include symptoms of hostility, aggression, mood swings, runny nose, achy muscles and bones, and jerky movement of the limbs. There is no legitimate medical use for kratom in the United States.

19. Village Sensations also offers for sale "Mollys Mosquito Caps," another type of designer drug. Inv. Shelmidine purchased a package of this product. According to the DEA, "Mollys" is the street name for MDMA, popularly known as "ecstasy," a prohibited controlled substance. "Mollys," derived from the word "molecules," has also been used as a street name for several analogues to MDMA including Methylenedioxypropylone (MDPV), a prohibited psychoactive drug that is commonly known as "bath salts."

20. The label bears the warning that "Mollys" is "Not For Human Consumption". The label indicates that the package contains "one cap". There are no ingredients identified on the label or health warnings. Beyond a colorful rendition of what appears to be a mosquito, the product does not disclose a suggested use. Thus, despite the description on the product label, Village Sensations offers for sale and sells "Mollys Mosquito Caps" as a designer drug.

21. Village Sensations also offers for sale and sells i-crème Fine Gourmet Crème Chargers, containing nitrous oxide. Inv. Shelmidine purchased a box of this product. Nitrous oxide is also known by the slang term "laughing gas." When it is inhaled, nitrous oxide has analgesic and euphoric effects on the user. Nitrous oxide chargers can be used to make whip cream, but are frequently misused by people to 'get high.' A device known as a "cracker" is used to 'crack' the seal of the nitrous oxide chargers to inhale the gas. After piercing the seal, the cracker allows the gas to escape in a controlled fashion. A balloon is attached to the cracker to capture the gas and allow it to absorb enough heat to be inhaled safely. It is then inhaled by the user to get high.

22. According to the packaging, the box contained twenty-four cream chargers, each charger containing 10 cm² pure nitrous oxide (N₂O). The box includes instructions that the chargers are specially for the preparation of food and not for any other purpose, and cautions "not for inhalation." The label instructs "keep out of reach of children," but does not state an age requirement for purchase. The label is misleading because in New York State such canisters cannot be sold for any reason to persons under age 21 and cannot be sold at retail by a "headshop". The box states that the product is imported from "France, Switzerland or Hungary," but includes no address or contact information for the manufacturer, distributor or packer.

23. Village Sensations offers for sale and sells whipped cream chargers that state on their packaging that they are not to be inhaled. Village Sensations sells these nitrous oxide chargers with the implied knowledge that they will be used for the purpose of inhalation of the nitrous gas to get high.

**FIRST CAUSE OF ACTION
VIOLATION OF EXEC. LAW 63(12)
REPEATED ILLEGALITY
VIOLATION OF AG. & MKTS. LAW § 194
(FALSE LABELING)**

24. New York State Ag. & Mkts. § 194 proscribes false labels on commodities sold, offered or exposed for sale, or any false description respecting the number, quantity weight or measure of such commodity.

25. The definition of a commodity as set forth in Ag. & Mkts. § 191 includes, *inter alia*, non-prescription drugs. New York State law defines a drug as an “article[] (other than food) intended to affect the structure or any function of the body of man or animals.” NYS Educ. Law § 6802.

26. Title 1 of the New York State Codes, Rules and Regulations (N.Y.C.R.R.) defines a label 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, indentifying, or giving any information with respect to the commodity or to the contents of the package.” A label must identify the product’s identity (common or usual name, description, generic term), the name and address of the manufacturer, packer or distributor, and the weight or quantity of the product.

27. The following products offered and sold by Respondent to the retail public are intended to affect the function of the human body: kratom, "Mollys Mosquito Caps", and nitrous

oxide. They are thus classifiable as non-prescription drugs and are commodities under New York State Ag. & Mkts. § 191(4).

28. The above product labels do not satisfy the requirements for commodity labeling pursuant to the Ag. and Mkts. Law. The labels on each of these products are insufficient and fail to properly identify the name and address of the manufacturer, packer or distributor. In addition, the label on the "Mollys Mosquito Caps" product fails to provide any information about the product's identity (common or usual name, description, generic term) and consequently constitutes an additional infraction of the Ag. & Mkts. labeling requirements.

29. By selling, offering and exposing commodities for sale that do not satisfy New York State law regarding product labeling and by selling, offering and exposing falsely described commodities, Respondent has repeatedly and persistently violated the New York State Ag. & Mkts. Law.

**SECOND CAUSE OF ACTION
VIOLATION OF EXEC. LAW § 63(12)
REPEATED ILLEGALITY
VIOLATION OF NYS EDUC. LAW § 6815
(MISBRANDING OF DRUGS)**

30. Misbranding of drugs is proscribed by the New York State Educ. Law.

31. Pursuant to the Educ. Law § 6802, drugs are defined, in part, as "[a]rticles (other than food) intended to affect the structure or any function of the body of man or animals."

32. The following products sold by Respondent are drugs pursuant New York State Educ. Law § 6802 since they constitute articles (other than food) intended to affect the structure or any function of the body of man or animals: Kratom, "Mollys Mosquito Caps", and nitrous oxide.

33. A drug is deemed to be misbranded pursuant to Educ. Law § 6815(2)(a)-(i) if:

- a. its labeling is false or misleading in any particular or, if in package form, it fails to bear a label containing the name of 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;
- b. required information is not prominently and conspicuously placed on the label in such terms to render it to be likely read and understood by ordinary individuals under customary conditions and purchase of use;
- c. its label fails to bear adequate directions for use;
- d. 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;
- e. it as an imitation of another drug, or 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; 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 thereof.

34. In considering whether a drug is misbranded because it is misleading, the court must consider (i) the representations made or suggested by the manufacturer, but also (ii) in view of those representations, the failure of the manufacturer to disclose material facts with respect to the consequences which may result from the customary or usual use of the drug. Educ. Law § 6802(13).

35. "Mr. Nice Guy: Bureaucrat" (kratom) is misbranded for the following reasons:.

- a. It fails to bear a label containing the name of and place of business of the manufacturer, packer or distributor.
- b. The label is misleading because it bears the warning "not for human consumption" when, in fact, this product is customarily and usually consumed by the user with tea to produce an intoxicating effect.
- c. The label fails to identify potential health effects that may result from customary and usual use of this drug, which may include anything from

sedation or stimulant effects to psychosis, hallucinations, delusion and confusion.

36. "Experience: Da Pimp Bomb" (kratom) is misbranded for the following reasons:
- a. The label fails to disclose the place of business of the manufacturer, packer or distributor.
 - b. The label and directions for use are misleading. The label does not identify potential health effects from customary and usual use of this drug, which may include anything from sedation or stimulant effects to psychosis, hallucinations, delusion and confusion.
 - c. The product claims to be "100% Organic," but lists no certifying agency.
 - d. The product lists a potency of "15x" but includes no reference indicating what this value represents chemically.
37. "Mollys Mosquito Caps" is misbranded for the following reasons:
- a. The label fails to bear adequate directions for use, nor any explanation or suggestion of the product's purpose.
 - b. The label fails to disclose the name and place of business of the manufacturer, packer or distributor.
 - c. The label does not identify potential health effects from customary and usual use of this drug, which may include anything from sedation or stimulant effects to psychosis, hallucinations, delusion, confusion and death.
 - d. The label is misleading. Though the label states that the product is "not intended for human consumption," this drug is customarily and usually ingested by the user to produce an intoxicating effect.
 - e. The label does not state the potency of the product, nor whether it is dangerous to health with the frequency or duration prescribed, recommended or suggested by the description "one cap."
38. "i-crème Fine Gourmet Crème Chargers" is misbranded for the following reasons:
- a. The label fails to disclose the name and address for the manufacturer, distributor or packer; only the brand "i-crème Fine Gourmet Creme Chargers" is identified.
 - b. Though the package contains the warning "[n]ot for inhalation" and "[m]isuse can be dangerous to your health," the warning appears on the side of the box in small cursive writing along with other information and instruction, and can easily be overlooked. In addition, the warning fails to disclose that nitrous oxide can cause not only health problems, but also accidents and death.
 - c. The label states "keep out of reach of children." This statement is insufficient and misleading; in New York State, whip cream chargers can

not be sold at retail by "headshops", and under no circumstances may a whip cream charger be sold to a person under age 21.

39. Educ. Law §§ 6811(9) and (11) makes it a misdemeanor to sell, or receive in commerce, a misbranded drug. The labels of the kratom, "Mollys Mosquito Caps", and nitrous oxide products are misbranded.

40. By offering for sale and/or selling misbranded drugs, Respondent has repeatedly and persistently violated New York Educ. Law, Ch. 16, Title VIII, Art. 137.

**THIRD CAUSE OF ACTION
VIOLATION OF EXEC. LAW § 63(12)
REPEATED ILLEGALITY
VIOLATION OF NYS PUB. HEALTH LAW § 3380
(ILLEGAL SALE OF NITROUS OXIDE)**

41. New York State Pub. Health Law § 3380 proscribes selling nitrous oxide to the public for the purpose of intoxication.

42. Pub. Health Law § 3380(5)(b) prohibits any person from selling any canister or other container of nitrous oxide unless granted an exemption by the Commissioner of the State Health Department.

43. Pursuant to the Pub. Health Law § 3380(5)(d), there can be no exemptions for retail sale of nitrous oxide to the public, except under the conditions set forth in § 3380(5)(f).

44. To the extent that Pub. Health Law § 3380(5)(f) allows a seller to apply for an exemption to sell nitrous oxide to the public at retail, Respondent is not eligible for such an exemption since it sells drug-related paraphernalia and other items used for the inhalation of nitrous oxide in its retail stores. Pub. Health Law § 3380(5)(f)(v).

45. Respondent sells cases of nitrous oxide chargers at retail to the public for the purpose of causing a condition of intoxication, inebriation, excitement, stupefaction, or dulling of the brain or nervous system.

46. By offering for sale, and/or selling nitrous oxide for the purpose of causing a condition of intoxication, inebriation, excitement, stupefaction, or dulling of the brain or nervous system, Respondent repeatedly and persistently violated the New York Pub. Health Law.

**FOURTH CAUSE OF ACTION
PURSUANT TO EXEC. LAW 63(12)
FRAUD AND ILLEGALITY
VIOLATIONS OF GBL § 349
(DECEPTIVE ACTS AND PRACTICE)**

47. GBL § 349 declares unlawful any deceptive acts or practices in the conduct of any business, trade or commerce in this state.

48. Respondent has engaged in deceptive acts and practices including the following: (1) offering for sale and selling mislabeled and/or misbranded products for consumer use; (2) offering for sale and selling mislabeled and/or misbranded products making it impossible for customers to make an informed decision as to the intended use of the products, and the safety and health-related risks associated with the products; (3) deceptively marketing and promoting illegal products as legal, such as the nitrous oxide products; (4) repeatedly encouraging consumers to ingest or smoke products that it sells without disclosure of product ingredients, manufacturer information, dietary information, and/or other warnings; and (5) encouraging and promoting the use of products that are specifically labeled "not for human consumption" for ingestion and/or inhalation by consumers.

49. As set forth above, Respondent offered for sale mislabeled and misbranded drugs.

50. By offering for sale and/or selling mislabeled and misbranded drugs, respondent has repeated and persistently violated GBL § 349.

**FIFTH CAUSE OF ACTION
PURSUANT TO EXEC. LAW § 63(12):
FRAUD**

51. Exec. Law § 63(12) defines "fraud" or "fraudulent" to include any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense or unconscionable contractual provisions.

52. By offering for sale, and/or selling mislabeled and misbranded drugs, respondent has repeated and persistently engaged in fraud in violation of Exec. Law, § 63(12).

WHEREFORE, the People of the State of New York, pursuant to the powers vested by New York State Executive Law § 63(12) respectfully request judgment as follows:

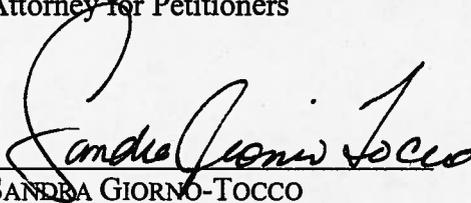
- a. permanently enjoining Respondent, and its agents, trustees, servants, employees, successors, heirs and assigns, or any other person under its direction and control, whether acting individually or in concert with others, or through any corporate or other entity or device through which it may now or hereafter act or conduct business ("Respondent"), from offering for sale and/or selling mislabeled drugs in violation of Ag. & Mkts. Law § 194;
- b. permanently enjoining Respondent from offering for sale and/or selling misbranded drugs in violation of Educ. Law §§ 6802 and 6815;
- c. permanently enjoining Respondent from misleadingly offering for sale and/or selling products as designer drugs or other street drug alternatives, including encouraging ingestion of products that are labeled or specifically designated "not for human consumption;"
- d. permanently enjoining Respondent from offering for sale and selling nitrous oxide to the public in violation of Pub. Health Law § 3380;
- e. permanently enjoining Respondent, from engaging in the fraudulent, deceptive and illegal practices alleged in the petition in violation of GBL § 349;
- f. requiring that Respondent comply with any and all state, local or federal labeling requirements;
- g. requiring Respondent to prepare an accounting of all commodities it sold, or offered for sale, from January 1, 2012 to July 10, 2012, including the (i) name of

the product, (ii) the manufacturer and/or distributor of the product, (iii) a description of the product, (iv) the retail price of the product, and (iv) the number units of the product sold;

- h. pursuant to GBL § 350-d, imposing a civil penalty of \$5,000 for each deceptive act committed by Respondent;
- i. pursuant to CPLR § 8303(a)(6), granting costs to the State of New York of \$2,000; and
- j. for such other and further relief as the court deems just and proper.

Dated: White Plains, New York
July 9, 2012

ERIC T. SCHNEIDERMAN
Attorney General of the State of New York
Attorney for Petitioners



SANDRA GIORNO-TOCCO
Assistant Attorney General
Of Counsel
101 East Post Road
White Plains, NY 10601

GARY BROWN
Assistant Attorney General in Charge
Of Counsel

ROBERT A. ADAMO
Volunteer Assistant Attorney General
Of Counsel

To: Smoken LLC, d/b/a Village Sensations
Respondent
111 Main Street
Nanuet, NY 10954

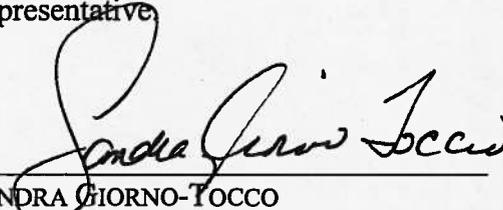
VERIFICATION

STATE OF NEW YORK)
) ss.:
COUNTY OF WESTCHESTER)

SANDRA GIORNO-TOCCO, being duly sworn, deposes and says: she is an Assistant Attorney General in the office of Eric T. Schneiderman, Attorney General of the State of New York, and is duly authorized to make this verification.

She has read the foregoing petition and knows the contents thereof, and the same is true to her own knowledge, except as to matters therein stated to be alleged on information and belief, and as to those matters she believes them to be true.

The reason this verification is not made by petitioners is that petitioners are a body politic. The Attorney General is their statutory representative.



SANDRA GIORNO-TOCCO

Sworn to before me this
9th day of July, 2012



Assistant Attorney General
of the State of New York

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

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

AFFIRMATION

Petitioner,

Index No.:

-against-

Date Filed:

SMOKEN, LLC, doing business as,
VILLAGE SENSATIONS,

Assigned To:

Respondent.
-----X

SANDRA GIORNO-TOCCO, an attorney duly admitted to practice law in the State of New York, affirms the following under the penalties of 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 Westchester Regional Office. I am fully familiar with the facts and circumstance of this proceeding, which are based on investigative materials contained in the files of the Attorney General's office.

2. I submit this Affirmation in support of Petitioner's application for an Order and Judgment permanently enjoining Respondent from engaging in deceptive, fraudulent and illegal business practices, requiring that Respondent produce an accounting of mislabeled and misbranded products sold and awarding and penalties and costs to the State of New York.

3. Unless otherwise indicated, I make this affirmation upon information and belief, based upon my investigation, a review of documents and other evidence on file with the Department of Law.

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. They typically are (i) “manufactured, marketed, or distributed as alternatives to illicit street drugs;” (ii) “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 (iii) “claim to have effects on the user that “mimic the effects of controlled substances.” See Exhibit III-1 (FDA Guidance for Industry Street Drug Alternatives).

5. It is indisputable that the growth in the market for designer drugs and other street drug alternatives poses a danger to the American population. See Affidavit of Maja Lundborg-Gray, M.D., FAAEM, FACEP, sworn to on July 5, 2012, (“Lundborg-Gray Aff.”), ¶ 3, Exhibit I. Users of these products can experience severe health effects, some resulting in long-term disability or even death. See Lundborg-Gray Aff., ¶ 5, Exhibit I. The FDA also 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. See Exhibit III-1.

6. Selling products for human consumption that are insufficiently labeled or mislabeled is inherently dangerous. Consumers cannot make informed decisions about the safety of the products they purchase. And, without knowing what drugs or substances people have ingested, medical personnel are hindered in their ability to provide immediate and appropriate medical care. See Lundborg-Gray Aff., ¶¶ 2-3, Exhibit I.

7. To combat the problem of designer drugs, law enforcement authorities have been acting to include designer drugs within the list of prohibited controlled substances. For example, in 2011 the United States Drug Enforcement Administration (“DEA”) used its emergency scheduling authority to temporarily ban three synthetic stimulants, Mephedrone, 3,4-methylenedioxypyrovalerone (MDPV) and Methyone, chemicals that serve as the active ingredient in the substance popularly known as “bath salts.” See Exhibit III-2 (“DEA Moves to Emergency Control Synthetic Stimulants; Agency Will Study Whether To Permanently Control Three Substances,” September 7, 2011).

8. In March of 2011 and June of 2012, the DEA also implemented emergency bans on numerous formulas of synthetic cannabanoids, also known as “fake pot” products. See Exhibit III-3, (“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). See also Exhibit III-4 (“Congress Agrees to Add 26 Synthetic Drugs to Controlled Substances Act,” June 19, 2012).

9. As of this date, both houses of the federal legislature have passed “H.R. 1254: Synthetic Drug Control Act of 2011,” which would permanently classify 26 additional synthetic chemicals (including “bath salts” and synthetic marijuana analogues) as prohibited substances. See Exhibit III-5 (H.R. 1254: “Synthetic Drug Control Act of 2011, 112th Congress, 2011–2012. Text as of Dec 8, 2011). The bill is awaiting the President’s signature.

10. The New York legislature has also taken action to ban these 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 - - which are known to have hallucinogenic effects. Public Health Law § 3306: (f)(5)(Methcathinone); (f)(9)(4-Methylmethcathinone); (f)(10) (Methylenedioxypropylamphetamine).

11. Earlier this year, State Health Commissioner Nirav Shah issued an order of summary action banning the sale of synthetic marijuana products in New York State. These substances, generally referred to as “synthetic marijuana,” consist of plant material coated by chemicals that mimic THC, the active ingredient in marijuana. These products are being sold as a “legal alternative” to marijuana in head shops, convenience stores, smoke shops, and tobacco stores 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 commonly cause: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities; seizures; and syncope (loss of consciousness).” The Commissioner's order called for sales and distribution of these products to cease immediately. See Exhibit III-6 (Order, *In The Matter The Sale And Distribution Of Synthetic Cannabinoids*, NYS Commissioner of Health, March 28, 2012).

12. Nonetheless, the problem of designer drugs persists, because manufacturers have been misbranding products to disguise their intended use. In addition, manufacturers rapidly change the synthetic formulation of prohibited compounds, without disclosing content, allowing them to circumvent lists of controlled substances. As one early “designer drug” chemist explained:

When a new type of active compound is discovered in pharmaceutical-chemical research, whether by isolation from

a plant drug or from animal organs, or through synthetic production as in the case of LSD, then the chemist attempts, through alterations in its molecular structure, to produce new compounds with similar, perhaps improved activity, or with other valuable active properties. We call this process a chemical modification of this type of active substance. Of the approximately 20,000 new substances that are produced annually in the pharmaceutical-chemical research laboratories of the world, the overwhelming majority are modification products of proportionally few types of active compounds.

See Albert Hofmann, LSD: My Problem Child, p. 12 (1980), cited in Gregory Kau, Flashback to the Federal Analog Act of 1986, 156 U. Pa. L. Rev. 1078, 1084 (2008), annexed as Exhibit III-7 hereto.

13. In response to this growing problem, the Attorney General commenced a statewide investigation focusing on deceptive and illegal labeling of designer drugs (“the Investigation”). As part of this Investigation, undercover investigators visited head shops in twelve counties and made purchases of these products. The Investigation revealed that there is widespread sale of designer drugs and street drug alternatives at these establishments, which are deceptively marketed as innocuous products such as “incense,” “glass cleaner,” “bath salts,” “potpourri,” “sachets,” “dietary supplements,” or other common household products. Furthermore, nitrous oxide, a deadly “party” gas which is illegal to sell at retail to the public in New York State was being offered for sale at nearly every location that was investigated.

14. The Attorney General’s Investigation revealed that (i) the labeling of these designer drugs is insufficient, often omitting manufacturer information, product content, and/or safety and health risks associated with product use, (ii) the labeling on these designer drugs falsely describes their intended uses, (iii) head shops sell products that are labeled “not for human consumption,” with accoutrements that can only be used for one purpose - human

consumption, (iv) head shops promote and encourage the ingestion or inhalation of products that are labeled "not fit for human consumption," and (iv) head shops are selling nitrous oxide in violation of New York State Law.

FACTS

15. Respondent, Smoken, LLC, which does business as Village Sensations (hereinafter "Respondent" or "Village Sensations"), is a New York, limited liability company, located at 111 Main Street, Nanuet, New York, in Rockland County. See Affidavit of Department of Law Senior Investigator Chad Shelmidine ("Inv. Shelmidine"), sworn to on June 26, 2012 ("Shelmidine Aff."), ¶¶ 3-5, Exhibit II .

16. Village Sensations is a retail outlet that is commonly known as a "head shop" and operates a website on the Internet address "<http://villagesensations.com>". Webster's dictionary defines a head shop as "a shop specializing in articles (such as pipes and roach clips) of interest to drug users." As set forth below, among the products offered for sale and sold by Village Sensations are drug paraphernalia used for consumption of cannabis and other recreational drugs, as well as accoutrements such as pipes and other smoking devices. See Shelmidine Aff., ¶¶ 1-7, Exhibit II.

17. On May 29, 2012, Inv. Shelmidine visited Village Sensations posing as a consumer interested in purchasing merchandise. While in the store, Inv. Shelmidine observed, *inter alia*, various intoxicants and synthetic drugs. See Shelmidine Aff., ¶ 7, Exhibit II.

18. Inv. Shelmidine purchased four products: 1) "Mr. Nice Guy: Bureaukrat", 2) "Experience Da Pimp Bomb", 3) "Mollys Mosquito Caps" and 4) "i-Crème Fine Gourmet Crème Chargers". See Shelmidine Aff., ¶¶ 9-30, Exhibit II. The total for the four items was

\$97.54. See Shelmidine Aff., ¶ 30, Exhibit II; see also Exhibit II-6 (photograph of sales receipt).

19. These products constitute drugs because they are "articles [other than food] intended to affect the structure or any function of the body of man or animals." New York Education Law ("Educ. Law") § 6802.

VIOLATION OF AGRICULTURE AND MARKETS LAW § 194

20. Agriculture and Markets Law ("Ag. & Mkts.") § 194 proscribes false labels on commodities sold, offered or exposed for sale, or any false description respecting the number, quantity, weight, or measure. Commodities include non-prescription drugs. Ag. & Mkts. Law § 191(1)(b)(4).

21. Respondent repeatedly sells mislabeled commodities in violation of Ag. & Mkts. Law § 194. The following products are mislabeled because they fail to include the name and/or address of the manufacturer, packer or distributor;

- a. "Mr. Nice Guy: Bureaucrat" (kratom). See Shelmidine Aff., ¶¶ 10-13, Ex. II-2.
- b. "Experience Da Pimp Bomb" (kratom). See Shelmidine Aff., ¶¶ 17-21, Ex. II-4.
- c. "Mollys Mosquito Caps". See Shelmidine Aff., ¶ 14, Ex. II-3.
- d. "i-Crème Fine Gourmet Crème Chargers" (nitrous oxide). See Shelmidine Aff., ¶¶ 23-28, Ex. II-5.

The label on "Experience Da Pimp Bomb" is further mislabeled because it fails to provide the weight or the quantity of the product. See Shelmidine Aff., ¶¶ 17-21, Exhibit II-4.

22. In addition, the label on the "Mollys Mosquito Caps" product fails to provide any information about the product's identity (common or usual name, description,

generic term), and consequently constitutes an additional infraction of the Ag. & Mkts.

labeling requirements. See Shelmidine Aff., ¶ 15, Exhibit II.

VIOLATION OF EDUCATION LAW § 6815

23. Educ. Law § 6815 proscribes misbranding of drugs. A drug is misbranded if the label contains false or misleading information about the product, fails to contain manufacturer information, fails to conspicuously place required information so that it is easily readable by ordinary individuals under customary conditions and purchase of use, fails to bear adequate directions for use, lacks adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, lacks warnings against unsafe dosage or methods of use, imitates another drug or the trademark, label, container or identifying name or design of another drug, or if the product is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling. Educ. Law § 6815(2)(a)-(i)

24. Respondent has repeatedly sold misbranded drugs in violation of Educ. Law § 6815.

25. "Mr. Nice Guy" kratom is misbranded because it fails to bear a label containing the name of and place of business of the manufacturer, packer or distributor. Educ. Law § 6815(2)(b). "Mr. Nice Guy" is also misbranded because the label is misleading. The label bears the warning "not for human consumption," however kratom is customarily ingested to produce both stimulant effects in low doses, and sedative effects in high doses. See Dr. Lundborg-Gray Aff., ¶ 10, Exhibit I. Indeed, when Inv. Shelmidine asked Respondent's clerk how to use the powder form of the kratom, the clerk responded that it is mixed with tea. See Shelmidine Aff., ¶ 16, Exhibit II. Further, the label indicates that

the product is among the highest quality kratom in the world, and that the most mature leaves combined with the most advanced extraction methods on earth are used to produce a nearly perfect product, which, despite the "not for consumption" disclaimer, further suggests that the product is indeed intended for human consumption. Finally, the "Mr. Nice Guy" label fails to reveal any facts about potential health effects that may result from customary and usual use of this drug. See Shelmidine Aff., ¶ 13, Exhibit II.

26. The kratom product referred to as "Experience: Da Pimp Bomb" is misbranded because the label fails to disclose the place of business of the manufacturer. Educ. Law § 6815(2)(b). In addition, the label fails to describe weight or quantity of the product in violation of Educ. Law § 6815(2)(b). Respondent's store clerk told Inv. Shelmidine that the 15X on the packaging referred to the strength or potency of the content. See Inv. Shelmidine's Aff., at ¶ 18, Exhibit II. Further, when Inv. Shelmidine asked the clerk what type of pipe he should use with the kratom products, the store clerk responded, "[y]ou're not smoking it. It's a tea base." The clerk went on to inform Inv. Shelmidine that, "[t]here's no more spice or herbal incense" because of recent laws. See Shelmidine Aff., ¶ 22, Exhibit II. Also, the package claims the sole ingredient is 100% Pure Extracted *Microgyna Speciosa* Leaf, but like the Mr. Nice Guy kratom, it too fails to identify potential health effects from customary and usual use of this drug, which may include anything from sedation or stimulant effects to psychosis, hallucinations, delusion and confusion. See Dr. Lundborg-Gray Aff., ¶ 10, Exhibit I.

27. "Molly Mosquito Caps" is misbranded because the label fails to disclose the name of and place of business of the manufacturer, packer or distributor in violation of Educ. Law § 6815(2)(b). The label fails to identify the commodity in the package by its common

or usual name, description, generic term, or the like. In addition, the label and directions for use are misleading. Though the label states that the product is “not intended for human consumption,” this drug is customarily ingested by the user to produce an intoxicating effect and is deemed highly dangerous by the DEA.¹ See *Dr. Lundborg-Gray Aff.*, ¶ 15, Exhibit I. Yet, the label fails to provide any warnings of its potential dangerous health effects. As such, “Mollys Mosquito Caps” is misbranded pursuant to Educ. Law § 6815.

28. The package of i-Crème Fine Gourmet Crème Chargers (nitrous oxide) is misbranded and thus in violation of Educ. Law § 6815(2)(b) because it fails to include the name and address of the manufacturer, packer or distributor. See *Shelmidine Aff.*, ¶¶ 23-25, Exhibit II. The package indicates that the product is to be used for preparation of food only. Consumers are instructed to not inhale the contents and that misuse can be dangerous to your health. The label also warns to keep out of reach of children. Despite of these warnings, the packaging is still misleading. These warnings appear on the side of the box, in small cursive writing, along with other information regarding contents. Thus, the warning “misuse can be dangerous to your health” is not prominently and conspicuously placed and can be easily overlooked. Furthermore, the warning is over-generalized and thus not sufficient. Nitrous oxide can cause not only health problems, but also accidents and death. See *Dr. Lundborg-Gray Aff.*, ¶ 15, Exhibit I.

29. Finally, the label states to keep nitrous oxide cartridges out of the reach of children. This statement is misleading; in New York State, whip cream chargers cannot be

¹ See United States D.E.A. Press Release, “20 Charged With Conspiracy to Distribute Synthetic Drug ‘Molly,’” August 16, 2011, *available at* <<http://www.justice.gov/dea/pubs/states/newsrel/2011/nyc081611.html>> (“Synthetic drugs such as ‘Molly’ are extremely dangerous and pose a significant health risk to those who abuse this substance. DEA and our law enforcement partners will continue to investigate any and all drug trafficking organizations that place lives at risk by selling these dangerous substances”).

sold at retail without an exemption, and under no circumstances may a whip cream charger be sold to a person under age 21. Therefore, the i-Crème Fine Gourmet Crème Chargers purchased by Inv. Shelmidine are misbranded because the package does not provide manufacturer, packer or distributor information and its labeling is misleading.

VIOLATION OF PUBLIC HEALTH LAW § 3380

30. Respondent has sold nitrous oxide to the public in violation of Public Health Law (“Pub. Health Law”) § 3380.

31. Respondent has nitrous oxide chargers on display at its establishment. See Shelmidine Aff., ¶¶ 23-25, Exhibit II. Inv. Shelmidine purchased a box containing twenty-four Crème Fine Gourmet Cream Chargers and advised Respondent’s clerk that he also wanted to purchase a “cracker”. A cracker is used to break the charger and a balloon is used to capture the gas in order to inhale the drug. See Shelmidine Aff., ¶¶ 26-28, Exhibit II. Respondent therefore had knowledge of Inv. Shelmidine’s intended use of the product, and proceeded to sell him the nitrous oxide.

DECEPTIVE ACTS AND PRACTICES

32. Respondent repeatedly offers for sale and sells products for consumer use that are, in fact, misbranded and mislabeled drugs. The products are marketed in misleading packaging that fails to disclose required information, including manufacturer and distributor information, product ingredients, and/or potential health risks with customary use. See generally Shelmidine Aff., ¶¶ 12-25, Exhibit II.

33. Respondent repeatedly offers for sale and sells products for human consumption even though the labeling contradicted that use. See Shelmidine Aff., ¶¶ 12-25, Exhibit II.

34. Respondent deceptively markets and sells an illegal product as legal, e.g., the retail sale of nitrous oxide to the public. See Shelmidine Aff., ¶¶ 23-25, Exhibit II.

NEED FOR TEMPORARY RESTRAINING ORDER

35. The evidence submitted by the Attorney General, including the Affidavit of Senior Investigator Chad Shelmidine, sworn to June 26, 2012, with Exhibits, and the Affidavit of Dr. Maja Lundborg-Gray, sworn to July 5, 2012, with Exhibits, clearly demonstrates that Respondent is fraudulently and illegally selling misbranded and mislabeled designer drugs and that these drugs present serious harm to the public.

36. Without a temporary restraining order prohibiting Respondent Smoken, LLC, doing business as Village Sensations, from selling misbranded and mislabeled drugs, there is a great likelihood that Respondent will, in fact, continue to sell these products and that these sales will result in irreparable injury to individuals who consume these products.

37. Pursuant to Section 202.7(f) of the Uniform Rules of the Trial Courts, on July 9, 2012, I called the attorney for Respondent 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, on or about 10:00 A.M., at the Calendar Office of the Supreme Court, Westchester County.

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

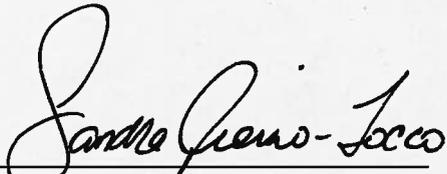
CONCLUSION

39. Respondent continues to engage in deceptive, fraudulent and illegal acts set forth in this affirmation and petition and unless enjoined, 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 will permit the appropriate regulating authorities to deal with the products for what they truly are: Drugs. With that transparency can be real debates as to the products' safety, risks, quality control, and until such time, these dangerous products must be removed from the shelves.

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

Dated: White Plains, New York
July 9, 2012



SANDRA GIORNO-TOCCO

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

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

Petitioner,

Index No.: _____

-against-

IAS Part _____

SMOKEN, LLC, doing business as
VILLAGE SENSATIONS,

Assigned to Justice _____

Respondent.

-----X
**ATTORNEY GENERAL'S MEMORANDUM OF LAW
IN SUPPORT OF THE VERIFIED PETITION FOR INJUNCTIVE RELIEF,
PENALTIES AND COSTS**

ERIC T. SCHNEIDERMAN
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State of New York
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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

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THE PEOPLE OF THE STATE OF NEW YORK,
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the State of New York,

Petitioner,

-against-

SMOKEN, LLC, doing business as
VILLAGE SENSATIONS,

Respondent.

-----X

PRELIMINARY STATEMENT

Petitioner brings this summary proceeding pursuant to New York Executive Law ("Exec. Law") § 63(12) and New York General Business Law ("GBL") § 349 to enjoin Respondent, Smoken, LLC, doing business as Village Sensations (hereinafter referred to as "Respondent" or "Village Sensations"), from engaging in deceptive, fraudulent and illegal practices in connection with its business. Respondent sells or offers for sale, *inter alia*, so-called "designer drugs," which are synthetic versions of illegal drugs, as well as other street drug alternatives (referred to collectively as "designer drugs"). Designer drugs are manufactured, marketed and distributed as alternatives to illegal street drugs. Designer drugs are intended to stimulate, sedate or cause hallucinations or euphoria when ingested or inhaled and are often marketed with claims that use mimics the effect of controlled substances. Petitioner also seeks costs and civil penalties, as authorized by statute, to be paid to the State of New York.

The sale of designer drugs has contributed to a public health crisis in New York and across the nation. These products are typically packaged with innocuous names and bright

graphics, and target people who are experimenting with legal highs or who want to get high without risking a positive drug test. Many products are misbranded or mislabeled, lacking identification of ingredients, directions for use and/or manufacturer information.

Selling products that are misbranded or mislabeled is inherently misleading and dangerous. Without knowing the contents of the products and how they are intended to be used, consumers are left in the dark about what they are purchasing and whether the products are safe to ingest. Some of these products may cause serious health effects such as agitation, tachycardia (rapid heartbeat), hallucinations, seizures, extreme paranoia, panic, vomiting, mood swings, intense cravings to redose, suicidal or homicidal thoughts, or even death. Consumers who experience dire health consequences as a result of ingesting one of these products will be at further risk. Without being able to disclose to emergency personnel and health care providers the chemicals they have ingested, the users of these products may not receive appropriate medical treatment.

New York State has enacted a comprehensive statutory scheme with respect to the labeling of commodities and drugs. For example, the New York State Agriculture and Markets Law (hereinafter "Ag. & Mkts. Law") § 194 regulates labeling of commodities, including non-prescription drugs. Title 1, Part 221 of the New York Codes, Rules and Regulations (hereinafter "N.Y.C.R.R."), provides basic labeling requirements for commodities. The New York State Education Law (hereinafter "Educ. Law") § 6802 proscribes misbranding of all drugs. In addition, the New York State Public Health Law (hereinafter "Pub. Health Law") § 3380 proscribes the retail sale of nitrous oxide to the public. Respondent offers for sale and sells nitrous oxide canisters to the public. Crucial to

protecting the health of all New Yorkers is enforcement of the state's laws prohibiting mislabeling of commodities and misbranding of drugs and the sale of nitrous oxide.

STATEMENT OF FACTS

A. Background

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. They typically are (i) "manufactured, marketed, or distributed as alternatives to illicit street drugs;" (ii) "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 (iii) "claim to have effects on the user that "mimic the effects of controlled substances." See Affirmation of Assistant Attorney General Sandra Giorno-Tocco, affirmed on July 9, 2012 (hereinafter "Giorno-Tocco Aff."), ¶ 4, Exhibit III-1 annexed thereto (FDA Guidance of Industry, Street Drug Alternatives). The FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and misbranded drug in violation of sections 505 and 502 of the Federal Food, Drug and Cosmetic Act. 21 USC §§ 321(p)(1), 352(f)(1). See Giorno-Tocco Aff., ¶ 5, Exhibit III-1 annexed thereto.

To combat the problem of designer drugs, law enforcement authorities have been acting to include designer drugs within the list of prohibited controlled substances. For example, in 2011 the United States Drug Enforcement Administration ("DEA") used its emergency scheduling authority to temporarily ban three synthetic stimulants, Mephedrone, 3,4-methylenedioxypropylvalerone (MDPV) and Methylone, chemicals that serve as the active

ingredient in the substance popularly known as "bath salts." In March of 2011 and June of 2012, the DEA also implemented emergency bans on numerous formulas of synthetic cannabinoids, also known as "fake pot" products. As of this date, both houses of the federal legislature have passed "H.R. 1254: Synthetic Drug Control Act of 2011," which would permanently classify 26 additional synthetic chemicals (including "bath salts" and synthetic marijuana analogues) as prohibited substances. See *Giorno-Tocco Aff.*, ¶¶ 7-9, Exhibits III-2 and III-5 annexed thereto.

The New York legislature has also taken action to ban these substances. In 2011, the Pub. Health Law was amended¹ to prohibit the sale of bath salts containing certain chemicals -- Methcathinone, 4-Methylmethcathinone (also known as Mephedrone) and Methylenedioxypropylamphetamine (also known as MDPV) -- which are known to have hallucinogenic effects.

Earlier this year, State Health Commissioner Nirav Shah issued an Order of summary action banning the sale of synthetic marijuana products in New York State. These substances, generally referred to as "synthetic marijuana", consist of plant material coated by chemicals that mimic THC, the active ingredient in marijuana. These products are being sold as a "legal alternative" to marijuana in convenience stores, smoke shops, and tobacco stores 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 commonly cause: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities; seizures; and syncope (loss of

¹ Public Health Law § 3306.

consciousness)." The Commissioner's order called for sales and distribution of these products to cease immediately. See Giorno-Tocco Aff., ¶ 11, Exhibit III-6 annexed thereto.

Nonetheless, the problem of designer drugs persists, because manufacturers have been misbranding products to disguise their intended use. In addition, manufacturers rapidly change the synthetic formulation of prohibited compounds, without disclosing content, allowing them to circumvent lists of controlled substances. As one early "designer drug" chemist explained:

When a new type of active compound is discovered in pharmaceutical-chemical research, whether by isolation from a plant drug or from animal organs, or through synthetic production as in the case of LSD, then the chemist attempts, through alterations in its molecular structure, to produce new compounds with similar, perhaps improved activity, or with other valuable active properties. We call this process a chemical modification of this type of active substance. Of the approximately 20,000 new substances that are produced annually in the pharmaceutical-chemical research laboratories of the world, the overwhelming majority are modification products of proportionally few types of active compounds.

See Giorno-Tocco Aff., ¶ 12, Exhibit III-7, annexed thereto.

The Attorney General's Statewide Investigation

In response to this growing problem, the Attorney General commenced a statewide investigation earlier this year focused on the retail sale of designer drugs at head shops across New York State (the "Investigation"). Giorno-Tocco Aff., ¶13. The Investigation revealed that numerous head shops in New York State are selling designer drugs by deceptively marketing them as innocuous products such as "incense," "glass cleaner," "bath salts," "potpourri," "sachets," "dietary supplements," or other common household products. Furthermore, nitrous oxide, a deadly "party" gas which is illegal to sell to the public without special dispensation, but which the law does not allow exemptions for a head shop for retail

sale, was being offered for sale at nearly every location that was investigated. *Giorno-Tocco Aff.*, ¶ 14.

The Attorney General's investigation has revealed that the labeling of these products is insufficient, often omitting the true contents of the products and falsely describing their intended use. *Giorno-Tocco Aff.*, ¶ 15.

B. Products Purchased From Respondent's Store, Village Sensations, located at 111 Main Street, Nanuet, New York.

On May 29, 2012, Department of Law Senior Investigator Chad Shelmidine (hereinafter "Inv. Shelmidine"), visited Respondent's store, Village Sensations, located at 111 Main Street, Nanuet, New York for the purpose of buying merchandise. Inv. Shelmidine was undercover, posing as a consumer. See Affidavit of Inv. Shelmidine, sworn to on June 26, 2012 (hereinafter "Shelmidine Aff."), ¶¶ 3-5, Exhibit II. Inv. Shelmidine purchased four products from Village Sensations: 1) "Mr. Nice Guy: Bureaucrat" (kratom), 2) "Experience Da Pimp Bomb" (kratom), 3) "Mollys Mosquito Caps" and 4) "i-crème Fine Gourmet Crème Chargers" (nitrous oxide). See Shelmidine Aff., ¶¶ 9-30, Exhibit II. The total for the four items was \$97.54. See Shelmidine Aff., ¶ 30, Exhibit II-6 (copy of the sales receipt for the products purchased).

Kratom

Village Sensations offers for sale and sells "kratom," a popular designer drug or street drug alternative. According to the DEA, kratom is a tropical tree native to Southeast Asia. Like many psychostimulant drugs, consumption of kratom leaves (or extract) produces both stimulant effects in low doses, and sedative effects in high doses and can lead to addiction. See *Giorno-Tocco Aff.*, ¶ 25. Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic

symptoms, including hallucinations, delusion, and confusion. Withdrawal effects include symptoms of hostility, aggression, mood swings, runny nose, achy muscles and bones, and jerky movement of the limbs. There is no legitimate medical use for kratom in the United States. See Affidavit of Dr. Maja Lundborg-Gray (hereinafter "Dr. Lundborg-Gray Aff."), sworn to on July 5, 2012, ¶¶ 4-5, Exhibit I. Kratom is manufactured to be a "pain reliever" and has been identified by the DEA's Office of Diversion Control as a "Drug and Chemical of Concern."² See Giorno-Tocco Aff., ¶ 26.

Inv. Shelmidine purchased two specific brands of kratom. See Shelmidine Aff., ¶¶ 9-13, 16-22. The first package bears the label "Mr. Nice Guy: Bureaucrat" ("Mr. Nice Guy"). See generally Exhibit II-2 (photographs of "Mr. Nice Guy" kratom package). The package indicates that it contains two grams of kratom identified as "kratom extract." According to the label, the product is not intended for human consumption. However, the label indicates that "Mr. Nice Guy is among the highest quality Kratom products in the world," and that the "most mature leaves are used combined with the most advanced extraction methods on earth to produce this nearly perfect powder." The aforementioned statements are written below a "smiley face" with "X's" for eyes, a sarcastic inversion of the "un-smiley face" commonly used as a symbol by poison control centers. Beyond a reference to the website www.Mr-Nice-Guy.com, the label on this product does not identify any manufacturer, distributor or packer information.

Inv. Shelmidine also purchased a package of "Experience Da Pimp Bomb". See generally Exhibit II-4 (photographs of "Experience" kratom package). The product is listed as "Kratom 15X." According to the label, the product is "100% Effective-100% Organic."

² DEA, *Drugs and Chemicals of Concern, KRATOM (Mitragnya speciosa korth)*, December 2010, available at http://deadiversion.usdoj.gov/drugs_concern/kratom.htm

The ingredients are listed as 100% Pure Extracted Mitragyna Speciosa Leaf" (the pharmacological name for kratom), and the manufacturer is listed as "Experience Alternatives Inc" with no geographic location. The package further contains the following warning:

"Use with caution. Do not use while operating a motor vehicle or machinery, if you are pregnant or nursing, or if you are taking any prescription or non-prescription drugs. This product has not been evaluated by the FDA & is not intended to treat, prevent or cure or diagnose any illness. Must be 18 years of age to use this product."

The package does not describe the weight of the product contained within, nor does it explain the reference to "15X".

When Inv. Shelmidine inquired of Respondent's store clerk how one would use these kratom products, the clerk responded that the products are designed to be consumed with tea and not smoked. See Shelmidine Aff., ¶¶ 16, 21-22, Exhibit II.

"Mollys Mosquito Caps"

Inv. Shelmidine also purchased a package of "Molly's Mosquito Caps." See Shelmidine Aff., ¶ 14, Exhibit II-3 (photographs of "Mollys Mosquito Caps"). The package does not disclose any ingredients, manufacturing and distributor information, or warnings. Beyond a colorful rendition of what appears to be the image of a mosquito, the label does not disclose a suggested or common use. According to the label, the product is not intended for human consumption and contains "one cap". The label fails to identify the identity of the product and the potential health effects that may result from customary and usual use of this product.

According to the DEA, "Mollys" is the street name for MDMA, popularly known as "ecstasy," a prohibited controlled substance. "Mollys," derived from the word "molecules,"

has also been used as a street name for several analogues to MDMA including Methylenedioxypropylvalerone (MDPV), a prohibited psychoactive drug that is commonly known as "bath salts." See Giorno-Tocco Aff., ¶ 27.

Cream Nitrous Oxide Chargers

Inv. Shelmidine observed a box of nitrous oxide chargers on display on a shelf behind the counter and asked to purchase a box. See Shelmidine Aff., ¶¶ 23-25, Exhibit II; see generally Exhibit II-5 annexed thereto (photographs of the cream chargers). The box contained twenty-four chargers, each charger containing 10 cm² pure nitrous oxide (N₂O).

Nitrous oxide can be used to make whipped cream and is sold for that purpose as dessert "cream chargers." Cream chargers, however, are frequently misused by people to get high by inhaling the gas. Nitrous oxide is an inhalant that is often inhaled using a "cracker" to open the cream charger, and a balloon into which the nitrous oxide is discharged and then inhaled by the user. According to the Nitrous Oxide Alert Bulletin issued by the Massachusetts Department of Health, "the painkilling and numbing qualities of nitrous oxide begin to take effect when the gas is at concentrations of 10 percent. At higher concentrations, approaching 50%, a sense of well-being or euphoria is experienced. A person experiencing the effects of nitrous oxide may have slurred speech, have difficulty in maintain his or her balance or walking, be slow to respond to questions, be immune to any stimulus such as pain, loud noise, and speech, lapse into unconsciousness (at higher concentrations)." See Dr. Lundborg-Gray Aff., ¶ 15, Exhibit I.

The box includes instructions that the chargers are specially made for the preparation of food and not for any other purpose, and cautions "do not inhale contents." The label instructs "keep out of reach of children," but does not state an age requirements for purchase.

In New York State, nitrous oxide canisters cannot be sold for any reason to persons under age 21 and can not be sold at retail. The box states that the product is imported from "France, Switzerland or Hungary," but includes no address or contact information for the manufacturer, distributor or packer of the product. See *Giorno-Tocco Aff.*, ¶ 29.

ARGUMENT

POINT I

RESPONDENT'S ACTIVITIES CONSTITUTE REPEATED AND PERSISTENT FRAUD AND ILLEGALITY IN VIOLATION OF EXEC. LAW § 63(12)

A. Introduction

Exec. Law § 63(12) empowers the Attorney General to bring a special proceeding for permanent injunctive relief whenever any person or business engages in persistent or repeated "fraud or illegality." "Repeated" is defined as conduct which affects more than one person. It is not necessary to establish a large percentage of violations under § 63(12). State v. Princess Prestige, 42 N.Y.2d 104 (1977). The Attorney General is only required to show that "any number of separate and distinct fraudulent or illegal acts which affect more than one individual." Abrams v. 21st Cent. Leisure Spa Int'l Ltd., 153 Misc.2d 938, 944 (Sup. Ct. N.Y. Co. 1991). The existence of some satisfied customers is no defense. State v. Midland Equities, 117 Misc.2d 203, 207 (Sup. Ct. N.Y. Co. 1982).

B. Respondent Has Engaged in Repeated and Persistent Illegal Conduct

Respondent has engaged in repeated and persistent illegality in violation of Exec. Law § 63(12). A violation of state, federal or local law constitutes illegality within the meaning of Exec. Law § 63(12) and is actionable thereunder when persistent or repeated. State v. Princess Prestige, 42 N.Y.2d at 105; State v. Empyre Inground Pools, Inc., 227

A.D.2d 731, 732-733 (3d Dep't 1996); State v. E.F.G. Baby Products Co., 40 A.D.2d 364, 366 (3d Dep't 1973); State v. Anderson, 137 A.D.2d 259, 265 (4th Dept 1988); State v. Scottish American. Ass'n, 52 A.D.2d 528 (1st Dept 1976), appeal dismissed, 39 N.Y.2d 1057 (1976).

1. Respondent Has Engaged in Repeated Illegality in Violation of Exec. Law § 63(12) by Violating Ag. & Mkts. Law § 194 (False Labels).

Respondent has repeatedly and persistently sold commodities that are falsely labeled in violation of the Ag. & Mkts. Law. Ag. & Mkts. Law § 194 proscribes false labels on commodities sold, offered or exposed for sale, or any false description.

No individual, ... [or] corporation [...] shall put upon any commodity sold, offered or exposed for sale or upon any container, package, ticket or label used in relation to such commodity [...] any false description or false indication of or respecting the number, quantity weight or measure of such commodity or any part thereof; or sell or offer or expose for sale any commodity which is falsely described or indicated in any of the manners or in any of the particulars as specified in this article or rules and regulations promulgated hereunder [...]

Consumer commodities are defined in Ag. & Mkts. Law § 191 to include non-prescription drugs. New York State law defines a drugs as "articles (other than food) intended to affect the structure or any function of the body of man or animals." Educ. Law § 6802.³ "Mr. Nice Guy" (kratom), "Experience: Da Pimp Bomb" (kratom), "Mollys Mosquito Caps" and Nitrous Oxide are drugs since they affect the structure, or any function of the body by stimulating, sedating or causing hallucinations or euphoria when ingested or inhaled. See Dr. Lundborg-Gray Aff., ¶¶ 5, 10 and 15, Exhibit I; see also Giorno-Tocco Aff., ¶ 27. Since "Mr. Nice Guy" (kratom), "Experience: Da Pimp Bomb" (kratom), "Mollys

³ The New York definition is consistent with the federal definition of a "drug." See 21 U.S.C.A. § 321(g)(1)(c).

Mosquito Caps" and Nitrous Oxide are consumer commodities, each is subject to the labeling requirements of Ag. & Mkts. Law § 194 and the regulations thereto.

A label is "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, indentifying, or giving any information with respect to the commodity or to the contents of the package."⁴ 1 N.Y.C.R.R. 221.2(e).

N.Y.C.R.R. Title 1 sets forth the basic labeling requirements for commodities:

1. Each package must include a "declaration of identity" which shall identify the commodity in the package by its common or usual name, description, generic term, or the like. (See 1 N.Y.C.R.R. 221.3).
2. Any packaged commodity, kept, offered or exposed for sale, or sold shall include a "declaration of responsibility," and specify conspicuously on the label of the package, the name and address of the manufacturer, packer or distributor. The name shall be the actual corporate name, or when not incorporated, the name under which the business is conducted. The address shall include street address, city, state and ZIP code. (See 1 N.Y.C.R.R. 221.4(a))
3. Each package must include a "declaration of quantity," including the weight or quantity of the product. (See 1 N.Y.C.R.R. 221.5).

Respondent is selling mislabeled or insufficiently labeled products, and thus is violating the requirements that all consumer commodities, at a minimum, be labeled to describe the contents of the product, the name and place of business of the product's manufacturer, packer and distributor, and the weight or quantity of the product. See, e.g., Ag. & Mkts. Law § 194; 1 N.Y.C.R.R. 221.

⁴ A consumer package or "package of consumer commodity" is a "commodity in package form that is customarily produced or distributed for sale through retail sale agencies or instrumentalities for consumption by individuals, or use by individuals for the purposes of personal care or in the performance of services ordinarily rendered in or about the household or in connection with personal possessions." 1 N.Y.C.R.R. 221.2(b).

According to the label, "Mr. Nice Guy" is a "kratom extract" that is not for human consumption. Beyond a reference to the website www.Mr-Nice-Guy.com, the label on this product does not identify the name or place of business of the manufacturer, packer or distributor. Therefore, it is mislabeled under 1 N.Y.C.R.R. § 221.4.

The label of the second kratom product, "Experience Da Pimp Bomb" indicates that it is "[m]anufactured exclusively by ExperienceTM Alternatives Inc", but there is no indication of the location of the manufacturer. Therefore, the package is mislabeled under 1 N.Y.C.R.R. § 221.4. Further, the description "Kratom 15X" is not a "declaration of quantity" since Respondent's clerk explained to Inv. Shelmidine that it represented the varying strengths or potency of kratom. Therefore, this product is also mislabeled under 1 N.Y.C.R.R. § 221.5.

The "Mollys Mosquito Caps" label indicates that the content contains "one cap" and that it is not for human consumption. The label fails to identify the commodity in the package by its common or usual name, description, generic term, or the like, and thus it is mislabeled under 1 N.Y.C.R.R. § 221.3. Further, the package fails to specify conspicuously on the label, the name and address of the manufacturer, packer or distributor. Therefore, this product is also mislabeled under 1 N.Y.C.R.R. § 221.4.

The nitrous oxide cream chargers are packed in a box containing twenty-four 8 gram chargers. The brand is identified as i-Crème Fine Gourmet Crème Chargers. See Exhibit II-5 (photographs of the cream chargers). The package label fails to identify the name and address of the manufacturer, distributor or packer. Therefore, the package of Crème Fine Gourmet Cream Chargers is mislabeled under 1 N.Y.C.R.R. 221.4.

2. Respondent Has Engaged in Repeated Illegality in Violation of Exec. Law § 63(12) by Violating Education Law § 6815 (Misbranding of Drugs)

Respondent has repeatedly and persistently sold drugs in packaging that is misbranded in violation of the Educ. Law. As set forth in Point I(B)(1), "Mr. Nice Guy" (kratom), "Experience Da Pimp Bomb" (kratom), "Mollys Mosquito Caps" and Nitrous Oxide are drugs for purposes of Educ. Law § 6802 since they affect the structure, or any function of the body, by stimulating, sedating, or causing hallucinations or euphoria when ingested or inhaled. As such, the packaging must comply with the requirements of the Educ. Law.

A drug is misbranded if: (1) its labeling is false or misleading; (2) its package does not contain the name and place of business of the manufacturer, packer, or distributor and accurate quantity of the contents; (3) its labeling does not include adequate directions for use and adequate warnings where its use may be dangerous to health; (4) it is dangerous to health when used in the dosage suggested in the labeling. Educ. Law § 6815(2)(a), (b), (f), (i)

In addition, when determining whether a drug is misbranded because the labeling is misleading, there should be taken into account, *inter alia*, not only representations made or suggested by statement, word, design or device, but also the extent to which the labeling fails to reveal material facts about the consequences of the prescribed or customary use of the drug or device. Educ. Law § 6802(13). Here, the products are misbranded in different respects insofar as the deficiencies of their packages violate different sections of the Educ. Law, including §§ 6815(2)(a), (b), (f), (i).

"Mr. Nice Guy" kratom is misbranded because it fails to bear a label containing the identity and place of business of the manufacturer, packer or distributor. Educ. Law §

6815(2)(b). Also, the label is misbranded because it does not include adequate directions for use and adequate warnings where its use may be dangerous to the user's health. Educ. Law § 6815(2)(f). In addition, the label is misleading because it bears the warning "not for human consumption" when the product is customarily ingested to produce both stimulant effects in low doses, and sedative effects in high doses. Indeed, when Inv. Shelmidine asked Respondent's clerk how to use the powder form of the kratom, the clerk responded that you mix it with tea and that it should not be smoked. See Shelmidine Aff., ¶ 21, Exhibit II. Further, the label indicates that the product is among the highest quality kratom in the world, and that the most mature leaves combined with the most advanced extraction methods on earth are used to produce a nearly perfect product, which, despite the "not for consumption" disclaimer further suggests that the product is indeed intended for human consumption. Since the product label fails to reveal any facts about potential health consequences associated with its customary use, the label is misleading, and the product is misbranded pursuant to Educ. Law § 6802(13).

The kratom product referred to as "Experience: Da Pimp Bomb" is misbranded because the label fails to disclose the place of business of the manufacturer. Educ. Law § 6815(2)(b). In addition, the label fails to describe the weight or quantity of the product. Respondent's store clerk told Inv. Shelmidine that the "15X" on the packaging referred to the strength or potency of the content. See Inv. Shelmidine's Aff., ¶ 17, Exhibit II. Thus, the product is misbranded in violation of Educ. Law § 6815(2)(b). Moreover, the label is misleading because the product is identified as "100% Natural all Organic," but the claim is unfounded as the word "organic" cannot be used on a label without federal certification of

the operations/product.⁵ Therefore, the product is misbranded pursuant to Educ. Law § 6815(2)(a).

Additionally, the label does not identify potential health effects from customary and usual use of this drug, which may include anything from sedation or stimulant effects to psychosis, hallucinations, delusion and confusion. According to the DEA, long-term users of kratom have experienced anorexia, weight loss, insomnia, skin darkening, dry mouth, frequent urination and constipation. Low doses may cause increased alertness, physical energy, talkativeness, and sociable behavior while high doses may cause sedative effects. In addition, kratom consumption can lead to addiction. When individuals are addicted to kratom, their psychotic symptoms may include hallucinations, delusion, and confusion. Withdrawal effects include symptoms of hostility, aggression, mood swings, runny nose, achy muscles and bones, and jerky movement of the limbs. See Dr. Lundborg-Gray Aff., ¶ 10, Exhibit I. Though the sole ingredient is 100% Pure Extracted *Microgyna Speciosa* Leaf, the package does not provide any potential and dangerous consequences of its use. By failing to include warnings of its potential dangerous health effects, the label of "Experience Da Pimp Bomb" is misleading. Therefore, this drug is misbranded pursuant to the Educ. Law §§ 6815 and 6802(13).

"Molly Mosquito Caps" is misbranded because the label fails to disclose the name of and place of business of the manufacturer, packer or distributor in violation of Educ. Law § 6815(2)(b). The label fails to identify the commodity in the package by its common or usual

⁵ Federal regulations provide detailed requirements for the farm production methods and products that can be used when farmers and food manufacturers wish to label their products "certified organic." 7 USC 6501, et seq., and 7 CFR 205.1, et seq. The word "organic" cannot be used on a label without federal certification of the operations/product. Misuse of the word (e.g., by an uncertified operator), is subject to a maximum \$11,000 fine. See 7 USC 6519 (misuse of label); 7 CFR 205.102 & 7 CFR 205.300.

name, description, generic term, or the like. In addition, the label and directions for use are misleading. Though the label states that the product is "not intended for human consumption," this drug is customarily ingested by the user to produce an intoxicating effect and is deemed highly dangerous by the DEA. See *Giorno-Tocco Aff.*, ¶ 27. Yet, the label fails to provide any warnings of its potential dangerous health effects. As such, "Mollys Mosquito Caps" is misbranded pursuant to Educ. Law § 6815.

The package of the nitrous oxide product whip cream charger package purchased by Inv. Shelmidine identifies the brand as "i-Crème Fine Gourmet Crème Chargers", but does not include any name or address of the manufacturer, packer or distributor. See Exhibit II-5. Thus, the product is misbranded pursuant to Educ. Law § 6815(2)(b). The package includes direction of use and warnings including a statement that dessert cream chargers should be used for the preparation of food only. Consumers are instructed "Do not inhale contents. Misuse can be dangerous to your health." The label also directs to keep the nitrous oxide chargers out of the reach of children. Despite these warnings, the packaging is still misleading. These warnings appear on the side of the box, in small cursive writing, along with other information regarding contents. Thus, the warning "misuse can be dangerous to your health" is not prominently and conspicuously placed and can be easily overlooked. See *Giorno-Tocco Aff.*, ¶¶ 28-29. Furthermore, the warning is over-generalized and thus not sufficient. Nitrous oxide can cause not only health problems, but also accidents and death. Breathing the pure gas can produce asphyxiation and cause suffocation. Exposure to concentrations of nitrous oxide in excess of 10% can compromise a person's ability to think and act safely and has been a factor in deaths related to accidents and car crashes. Long term exposure, even at very low level, may result in infertility or a vitamin B12 deficiency, which

causes anemia and nerve degeneration, producing painful sensations in limbs, unsteady gait, and loss of balance, irritability, and intellectual deterioration. See Dr. Lundborg-Gray Aff., ¶ 15, Exhibit I. Finally, while the label states to keep the nitrous oxide cartridges out of the reach of children, it fails to state that in New York State, whip cream chargers cannot be sold to a person under age 21. For all of the reasons stated, the label is false and misleading. Therefore, the package of i-Crème Fine Gourmet Crème Chargers purchased by Inv. Shelmidine is misbranded because it does not provide manufacturer, packer or distributor information and its labeling is misleading.

3. Respondent Has Engaged in Repeated Illegality in Violation of Exec. Law § 63(12) by Illegally Selling Nitrous Oxide in Violation of Pub. Health Law § 3380.

Pub. Health Law § 3380 specifically proscribes selling nitrous oxide to the public for the purpose of intoxication. The inhalation of nitrous oxide for purposes of inebriation, intoxication, excitement, stupefaction or euphoria is a dangerous practice among youths, which has led to death and injury. Sponsor Memo, Bill Jacket, L 1982, ch. 771 (Senator Goodhue). The purpose of this legislation was to ban the retail sale of nitrous oxide to prevent young people from purchasing it for “recreational use.” Sponsor Memo, Bill Jacket, L 1989, ch. 677 (Senator Masiello).

Pub. Health Law § 3380(2) states that: “No person shall, for the purpose of causing a condition of intoxication, inebriation, excitement, stupefaction, or the dulling of his brain or nervous system, intentionally smell or inhale the fumes from any hazardous inhalants or from any glue containing a solvent having the property of releasing toxic vapors or fumes; provided, that nothing in this section shall be interpreted as applying to the inhalation of any anesthesia or inhalant for medical or dental purposes.”

This section of the Pub. health Law also sets forth the prohibition against selling nitrous oxide:

No person shall sell, or offer to sell, to any other person any tube or other container of any hazardous inhalants or glue containing a solvent having the property of releasing toxic vapors or fumes: (a) if he has knowledge that the product sold, or offered for sale, will be used for the purpose set forth in subdivision two of this section. [...]" Further, "[n]o person shall sell any canister or other container of nitrous oxide unless granted an exemption pursuant to this subdivision.

Moreover, canisters or other containers of nitrous oxide can not be sold to a person under the age of twenty-one years under any circumstances. Pub. Health Law § 3380(4).

The Pub. Health Law directs the Commissioner of the State Department of Health to promulgate regulations to exempt specific products which must use nitrous oxide as a propellant, "provided such regulations shall prohibit the sale of such products at retail to the public." Pub. Health Law § 3380(5)(d). Further, the statute states that sellers cannot sell canisters containing nitrous oxide without dispensation from the State Department of Health Commissioner. Pub. Health Law § 3380(5)(b). In order to get such dispensation, the Commissioner must find no evidence of substantial misuse of the product and the seller must "take steps" to "prevent their sale of the product to any person, firm or corporation who or which sell drug-related paraphernalia as such term is defined by subdivision two of section eight hundred fifty of the general business law." Pub. Health Law § 3380(5)(f)-(v).

Respondent violated Pub. Health Law § 3380 on several grounds. First, Respondent offers for sale and sells cases of nitrous oxide chargers at retail to the public in violation of Pub. Health Law § 3380. See *Giorno-Tocco Aff.*, ¶ 18, Exhibit II. Second, Respondent's clerk sold the nitrous oxide to Inv. Shelmidine with the implied knowledge that he would

utilize the product for inhalation because Inv. Shelmidine asked to purchase a “cracker” (a canister opening device only needed for consumptive use of the gas), thereby constituting a separate violation of Pub. Health Law § 3380. See Shelmidine Aff., ¶¶ 26-28, Exhibit II. Lastly, Pub. Health Law § 3380(5)(a) provides that no person may sell nitrous oxide unless granted an exemption by the Commissioner of the State Health Department. Pub. Health Law § 3380(5)(d) provides:

The commissioner is directed to promulgate regulations to exempt specific products which must use nitrous oxide, or a mixture of nitrous oxide with other gases, as a propellant from the provisions of this chapter provided such regulations shall prohibit the sale of such products at retail to the public.

Since Respondent sells nitrous oxide “at retail to the public,” by definition he cannot have an exemption granted by the Commissioner of the State Health Department. To the extent that Pub. Health Law § 3380(5)(f) allows a seller to apply for an exemption to sell nitrous oxide to the public at retail, Respondent is not eligible for such an exemption since he sells drug-related paraphernalia and other items used for the inhalation of nitrous oxide in his retail store. Pub. Health Law § 3380(5)(f)(v).

For the reasons stated above, Respondent has clearly engaged in the illegal sale of nitrous oxide in violation of Pub. Health Law § 3380, and repeated illegality in violation of Exec. Law § 63(12).

4. Respondent Has Engaged in Repeated Illegality in Violation of Exec. Law § 63(12) by Violating GBL, Article 22-A.

As set forth in Point I.(C), infra, Respondent repeatedly and persistently violated GBL, Article 22-A and, thus, engaged in repeated and persistent illegality in violation of Exec. Law § 63(12).

C. Respondent Has Engaged in Repeated and Persistent Fraud in Violation of Exec. Law § 63(12) and Deceptive Practices in Violation of GBL § 349.

Exec. Law § 63(12) defines the words "fraud" or "fraudulent" to include "any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions." Courts have consistently applied an extremely broad view of what constitutes fraudulent and deceptive conduct in proceedings brought by the Attorney General under Exec. Law § 63(12). See, e.g., Lefkowitz v. Bull Investment Group, 46 A.D.2d 25, 28 (3d Dept. 1974), aff'd, 35 N.Y.2d 647 (1975); People v. 21st Century Leisure Spa Int'l Ltd., 153 Misc.2d 939, 943 (Sup. Ct. N.Y. Co. 1959). Thus, it is well-settled that traditional elements of common law fraud such as reliance, actual deception, knowledge of deception and intent to deceive are not required to establish liability for statutory fraud. See People v. Apple Health & Sports Clubs, Ltd., 206 AD.2d 266, 267 (1st Dept. 1994), appeal denied, 84 N.Y.2d 1004 (1994); State v. Ford Motor Co., 136 A.D.2d 154, 158 (3d Dept. 1988), aff'd, 74 N.Y.2d 495 (1989).

The test of fraudulent conduct under § 63(12) is whether the targeted act "has the capacity or tendency to deceive, or creates an atmosphere conducive to fraud." In re People v. Applied Card Systems, Inc., 27 A.D.3d 104, 107 (3d Dept. 2005), aff'd on other grounds, 11 N.Y.3d 105 (2008); State v. General Electric Co., 302 AD.2d 314 (1st Dept. 2003); see also Lefkowitz v. E.F.G. Baby Products Co., 40 A.D.2d 364 (3d Dept. 1973). Executive

Law § 63(12) protects the "credulous and the unthinking as well as the cynical and intelligent; the trusting as well as the suspicious." Guggenheimer v. Ginburg, 43 N.Y.2d 268, 273 (1977); People v. Applied Card Systems, Inc., 27 A.D.3d 104, 106 (3d Dept. 2005); State v. General Elec. Co., 302 A.D.2d at 314; People v. Dell, Inc., 21 Misc.3d 1110A, *4 (Sup. Ct. Alb. Co. 2008).

GBL § 349 is similarly broad. Like Exec. Law § 63(12), § 349 is "intended to be broadly applicable, extending far beyond the reach of common law fraud." State v. Feldman, 210 F. Supp.2d 294, 301 (S.D.N.Y. 2002). Indeed, a practice may carry the capacity to mislead or deceive a reasonable person and thus violate GBL § 349, but not be fraudulent under common law. Gaidon v. Guardian Life Ins. Co. of America, 94 N.Y.2d 330, 348 (1999). Even omissions may be the basis for claims under GBL § 349. People v. Applied Card Systems, Inc., 27 A.D.3d at 107.

GBL § 349(a) declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York. As with statutory fraud under Exec. Law § 63(12), intent, proof of actual deception and reliance are not elements of a cause of action under GBL § 349. See General Elec. Co., 302 A.D.2d at 315; People v. Network Assocs. Inc., 195 Misc.2d 348, 389 (Sup. Ct. N.Y. Co. 2003); In re State v. Colorado State Christian College of the Church of the Inner Power, Inc., 76 Misc.2d 50, 56 (Sup. Ct. N.Y. Co. 1973). Moreover, because GBL § 349 "was intended to 'afford a practical means of halting consumer frauds at their incipiency without the necessity to wait for the development of persistent frauds,'" Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 N.Y.2d 20, 25 (1995), the Attorney General may bring an action under this law before any consumer has been injured, and need not await consumer

complaints. See GBL § 349(b) (authorizing the Attorney General to seek injunctive relief when he believes a business "has engaged in or is about to engage in" deceptive acts or practices); Goshen v. Mut. Life Ins. Co. Of New York, 98 N.Y.2d 314, 324 (2002) ("Unlike private plaintiffs, the Attorney General may . . . seek injunctive relief [under GBL § 349] without a showing of injury"); Management Transaction Resources, Inc., 115 Misc.2d at 491 ("It is not necessary for the Attorney General to await consumer complaints before proceeding to enjoin").

Respondent has repeatedly and persistently engaged in deceptive acts and practices in the course of his business in violation of Exec. Law § 63(12) and GBL § 349. As set forth in Point I.(B)(1) and (2), supra, Respondent offered for sale and sold products for consumer use that are in fact drugs in misbranded and misleading packaging that fails to disclose the ingredients of the products and the safety and health-related risks associated with use. Respondent also sold products for human consumption even though the labeling contradicted that use. For example, though Mr. Nice Guy, a kratom product, was labeled "not for human consumption," Respondent discussed with Inv. Shelmidine how the product is ingested. See Shelmidine Aff., ¶ 21, Exhibit II. As set forth in Point I(B)(3), Respondent offered for sale and sold illegal products such as nitrous oxide. As set forth in the affidavit of Inv. Shelmidine, Respondent sold whip cream chargers that state on their packaging that they are not to be inhaled, with the implied knowledge that Inv. Shelmidine would utilize the product for inhalation because Inv. Shelmidine asked to purchase a "cracker" (a canister opening device only used for one purpose -- consumptive use of the gas). See Shelmidine Aff., ¶ 26, Exhibit II.

As a consequence, Respondent has engaged in repeated and persistent fraud and illegality in violation of Exec. Law § 63(12) and deceptive business practices in violation of GBL § 349.

POINT II

PETITIONERS ARE ENTITLED TO INJUNCTIVE RELIEF, PENALTIES AND COSTS

The Attorney General has been afforded a powerful arsenal of remedies under the consumer protection laws. Pursuant to Exec. Law § 63(12), courts are empowered to grant wide-ranging equitable relief to redress the kind of fraudulent and illegal conduct engaged in by respondents. Such remedial orders are to be broadly fashioned. See State v. Princess Prestige, 42 N.Y.2d 104 (1977); State v. Scottish American Association, 52 A.D.2d 528 (1st Dep't. 1976), app. dismissed, 39 N.Y.2d 1057 (1976); reported in full, 39 N.Y.2d 1033 (1976).

A. Respondent Should Be Enjoined From Engaging in Illegal, Deceptive and Fraudulent Business Practices

As set forth above, Respondent has repeatedly and persistently engaged in illegal, deceptive and fraudulent business practices. See Point I, infra. Courts routinely grant injunctions under such circumstances to prevent the continuance of illegal, deceptive or fraudulent business practices. See State v. Ford Motor Co., 74 N.Y.2d 495 (1989), State v. Princess Prestige, 42 N.Y.2d 104 (1977); State v. Daro Chartours, Inc., 72 A.D.2d 872 (2d Dep't. 1979). Thus, the Court should enjoin Respondent from engaging in the illegal, deceptive and fraudulent business practices set forth in the Verified Petition, to wit: selling misbranded and misleadingly labeled nonprescription drugs and selling nitrous oxide (i)

without an exemption, (ii) to the general retail public, and/or (iii) with knowledge, imputed or otherwise, that the nitrous oxide will be inhaled.

B. Respondent Should Be Required to Post a \$100,000 Bond

Respondent should be required to post a \$100,000 bond. The court's power to grant equitable relief includes the requirement of a performance bond and New York courts routinely require businesses that have engaged in illegal, deceptive or fraudulent business practices to file a bond. See, e.g., People v. Allied Marketing Group, 220 A.D. 2d 370 (1st Dep't 1995) (\$500,000 bond ordered); People v. Helena VIP Personal Introductions Services of New York, Inc., N.Y.L.J., 1/17/92, p.26 Col. 3 (Sup. Ct. N.Y. Co.), aff'd, 199 A.D.2d 186 (1st Dep't 1993) (\$500,000 bond required); People v. Empyre Inground Pools, 227 A.D.2d 731, 732 (\$100,000 required); Scottish American Ass'n, 52 A.D.2d 528 (\$100,000 bond)

Here Respondent illegally and deceptively sold designer drugs. According to Dr. Lundborg-Gray, a Fellow of the American Academy of Emergency Medicine, and a Fellow of the American College of Emergency Physicians:

[r]ecently the medical profession has been combating the public health challenge resulting from the use of these unlabeled, misbranded and misleadingly labeled designer drugs sold by headshops and other vendors. They pose an unreasonable risk of physical harm to the consuming public, and create an extremely dangerous situation both to the consumer, as well as to first responders. Poison Control numbers in New York State show a dramatic increase in calls related to all classes of these drugs over just the last three years.

See Dr. Lundborg-Gray Aff., ¶ 3, Exhibit I. Indeed, these designer drugs have contributed to a public health crisis in New York State and across the nation.

Respondent should be required to post a \$100,000 bond which he would forfeit if he sells (i) misbranded and/or misleadingly labeled drugs, or (ii) nitrous oxide.

C. Respondent Should Be Ordered to Pay Penalties and Costs

GBL § 350-d provides for the assessment of a civil penalty of up to \$5,000 for each and every deceptive act and false advertisement of the respondents. The principles governing the appropriate amount of a penalty for violation of a consumer protection statute are set forth in Meyers Bros. Parking Systems, Inc. v. Sherman, 87 A.D.2d 562, 563 (1st Dept. 1982), aff'd, 57 N.Y.2d 653 (1982). The penalty should not be so small as to represent merely a cost of doing business; to the contrary, the penalty should be large enough to serve as a warning to discourage the prohibited act. At the same time, the penalties imposed should not be “shocking to one’s sense of fairness.”

Here, the Court should impose an appropriate civil penalty taking into account the volume of designer drugs he sold. To aid in its determination, and pursuant to the its broad equitable powers in a proceeding under Exec. Law 63(12), the court should require Respondent to provide an accounting of both the cream chargers and misbranded and misleadingly labeled drugs he has sold in order to determine the full amount of penalties to be awarded. Courts regularly order such accountings as an aid in determining the extent of restitution and/or penalties to be awarded in a proceeding pursuant to Exec. Law § 63(12). See, e.g., People v. Telehublink Corp., 301 A.D.2d 1006, 1007 (3d Dept. 2003); People v. World Interactive Gaming Corp., 185 Misc. 2d 852, 865 (Sup. Ct. N.Y. Co. 1999); State v. Chazy Hardware, 176 Misc.2d 960, 961 (N.Y. Sup. Ct., Clinton Co.1998); State v. Lipsitz, 174 Misc.2d at 584; State v. Camera Warehouse, Inc., 130 Misc.2d 498, 499 (N.Y. Sup. Ct., Dutchess Co. 1985).

CPLR 8303(a)(6) provides that the court may award the Attorney General “a sum not exceeding two thousand dollars against each defendant” in an Exec. Law § 63(12) special

proceeding. Courts have routinely granted these costs. See e.g., State of New York v. Daro Chartours, Inc., 72 A.D.2d 872, 873 (3rd Dept. 1979); State v. Midland Equities of N.Y., Inc., 117 Misc.2d 203, 208 (Sup. Ct. N.Y. Co. 1982); People v. Therapeutic Hypnosis, 83 Misc.2d 1068, 1071-1072 (Sup. Ct. Albany Co. 1975); Lefkowitz v. Hotel Waldorf-Astoria Corp., 67 Misc.2d 90, 92 (Sup. Ct. N.Y. Co. 1971). Accordingly, this Court should impose \$2,000 in costs against Respondent.

D. The Court Should Grant the Temporary Restraining Order Requested in the Order to Show Cause.

Pursuant to Exec. Law § 63(12), courts are empowered to grant wide-ranging equitable relief, including temporary restraining orders or preliminary injunctions, to redress the kind of fraudulent or illegal conduct engaged in by Respondent. See, e.g., Apple Health & Sports Club, Ltd., 80 N.Y.2d 803, 807. The power of the court to grant, and the standing of the Attorney General to seek, broad remedial relief is not simply a matter of statutory authority under Exec. Law § 63(12), but is grounded in general equitable principles. Once the equitable jurisdiction of the court is invoked, the full range of equitable remedies becomes available to the court. The court's power is not to be limited except by a clear provision in the statute. Porter v. Warner Co., 328 U.S. 395, 397-98 (1946). Furthermore, where the public interest is served, the court's powers are even broader than in private litigation. Id. at 397-398. The court's power to grant equitable relief under consumer protection statutes includes the power to award interim ancillary relief. See, e.g., F.T.C. v. Southwest Sunsites, Inc., 665 F.2d 711, 718-719 (5th Cir.), cert. denied, 456 U.S. 973 (1982) ("In the exercise of this inherent equitable jurisdiction, the...court may order temporary, ancillary relief . . .").

Here, the granting of the temporary restraining order serves the interests of the public. An order restraining Respondent from deceptively marketing designer drugs and from offering for sale and selling mislabeled and misbranded products, as well as nitrous oxide, is necessary to protect the public.

Without the preliminary relief ordered by the Court, there is great likelihood that numerous consumers, unknown by the OAG at this time, will suffer irreparable harm if Respondent is permitted to deceptively market and sell mislabeled and misbranded drugs and/or nitrous oxide. Users of these drugs may experience dire health consequences, including death. In addition, users of the products sold by Respondent often present a danger to first responders and health care professionals due to violent behavior resulting from the consumption of these products. The Court should enjoin such attempts by Respondent during the pendency of this action.

According to Dr. Lundborg-Gray, who is board-certified in emergency medicine and a Fellow of both the American Academy of Emergency Medicine and the American College of Emergency Physicians:

Recently the medical profession has been combating the public health challenge resulting from the use of . . . unlabeled, misbranded and misleadingly labeled designer drugs sold by headshops and other vendors. They pose an **unreasonable risk of physical harm to the consuming public**, and create an extremely dangerous situation both to the consumer, as well as first responders.

For many presenting patients it is difficult to differentiate between a true psychiatric episode and the effects of these new, undisclosed intoxicants. Although many patients are treated and released, some experience severe outcomes, including organ failure and death.

Dr. Lundborg-Gray Aff., ¶¶3 and 19, Exhibit I (emphasis added).

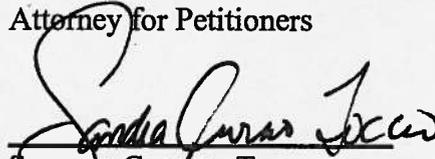
Without the temporary restraining order enjoining Respondent from deceptively marketing and selling mislabeled and misbranded drugs and/or nitrous oxide, there is an unreasonable risk that consumers will suffer physical harm.

CONCLUSION

For the reasons set forth above, the Court should grant the relief requested in Petitioner's Verified Petition.

Dated: White Plains, New York
July 9, 2012

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TABLE OF EXHIBITS

Exhibit	Description
Ex. I	Affidavit of Maja Lundborg-Gray, M.D., FAAEM, FACEP, sworn to on July 5, 2012, ("Lundborg-Gray Aff.")
Ex. I-A	Copy of Dr. Maja Lundborg-Gray's professional <i>curriculum vitae</i>
Ex. I-B	Drug Enforcement Administration, Office of Diversion Control, <i>Drug & Chemical Evaluation Section</i> , Drug Fact Sheet, "Salvia Divinorum And Salvinorin A"
Ex. I-C	"DEA Drug Fact Sheet, Kratom"
Ex. I-D	FDA, "Bad Bug Book. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook"
Ex. I-E	FDA News Release, April 27, 2012, "FDA challenges marketing of DMAA products for lack of safety evidence- Agency cites ten companies in warning letters"
Ex. I-F	S.K. Bhattacharya et al., "Psychopharmacological Studies on Nuciferine and Its Hofmann Degradation Product Atherospermine," <i>Psychopharmacology</i> , v. 59, pp 29-33 [1978]
Ex. I-G	"Nitrous Oxide Alert Bulletin", The Massachusetts Department of Public Health Bureau of Substance Abuse Services
Ex. II	Affidavit of Department of Law Senior Investigator Chad Shelmidine, sworn to on June 26, 2012, ("Shelmidine Aff.")
Ex. II-1	New York Department of State, Department of Corporations, filings for Smoken LLC, d/b/a Village Sensations
Ex. II-2	Photographs of purchase of "Mr. Nice Guy: Bureaukrat" Kratom
Ex. II-3	Photographs of purchase of "Mollys Mosquito Caps"
Ex. II-4	Photographs of purchase of "experience da*pimp BOMB: Kratom
Ex. II-5	Photographs of purchase of "Fine Gourmet Crème Chargers" of Nitrous Oxide
Ex. II-6	Copy of credit card receipt of products purchases from Respondent, Village Sensations
Ex. III-1	FDA Guidance for Industry Street Drug Alternatives
Ex. III-2	DEA Press release, September 7, 2011
Ex. III-3	DEA Press release, March 1, 2011
Ex. III-4	DEA Press release, June 19, 2012
Ex. III-5	H.R. 1254: "Synthetic Drug Control Act of 2011, 112th Congress, 2011-2012
Ex. III-6	Order, In The Matter The Sale And Distribution Of Synthetic Cannabinoids, NYS Commissioner of Health, March 28, 2012
Ex. III-7	Gregory Kau, <i>Flashback To The Federal Analog Act Of 1986: Mixing Rules And Standards In The Cauldron</i> ; 156 U. Pa. L. Rev. at 1084 (2008)