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BOARD OF PHARMACY  
 State of North Dakota

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Clark Dalrymple, Governor

Mark J. Hardy, PharmD, R.Ph.  
 Assistant Executive Director  
 Howard C. Anderson, Jr, R.Ph.  
 Executive Director

**Legislative Administrative Rules Committee**  
**3:10 PM - Wednesday - March 13, 2013**  
**Prairie Room - State Capitol Building**

Chairman Koppelman, members of the Administrative Rules Committee, thank you for the opportunity to discuss the following rule change with you.

North Dakota Administrative Code 61-13-01 Controlled Substance Schedules

1. This rule did not result from statutory changes made by the Legislative Assembly.
2. These rules are not related to any federal statute or regulation, although there are similar chemical substances that are scheduled by the DEA in Schedule I.
3. As you may remember, in February 2010 the Board of Pharmacy adopted emergency rules on specific spice cannabinoids. During the 2011 Legislative Session that language was codified. The Board of Pharmacy began receiving reports of additional spice cannabinoids and bath salts that were being uniquely identified outside of the list of the substances that were previously scheduled. The Board worked with the Attorney General's Office to begin drafting legislation to be introduced during the current Legislative Session. Based on the increasing sale of these illicit substances and spice cannabinoids and a suggestion from Chairman Koppelman during an interim meeting, it was determined that we could not delay in taking action and an Emergency Rule by the Board of Pharmacy was necessary to help protect the public from the sale and movements of these dangerous spice cannabinoids and bath salts. Attorney General Stenehjem attended the November 21, 2012 Board Meeting to formally request the Board's assistance in moving forward in adopting an emergency rule. The Board of Pharmacy was very supportive of this action and expressed desire to take the steps for the public's safety.

Our office worked with the Attorney General's staff member Edward Erickson to outline the specific steps necessary, with an abundance of caution, to safeguard the process and follow the statutory changes that were updated on the adoption of emergency rules. We looked specifically at the court cases of *State-v-Nickel* and *State-v-Gibson* to ensure issues that were identified in those court cases were addressed within our process of adopting these emergency rules. The Board held a special meeting on November 30, 2012, at which we heard from Attorney General Wayne Stenehjem, Charlene Schweitzer, a forensic scientist with the North Dakota Crime Lab, members of the public who have been affected by these substances and emergency room practitioners who have seen and treated individuals that had ingested these substances – all supported the scheduling of these substances as quickly as possible. We had no comments that opposed the actions of the rule. The Board of Pharmacy adopted the emergency rule on that date. The Board of Pharmacy addressed the imminent peril to the health, safety and welfare of North Dakota citizens in the adoption of these rules, the necessary consultation and the factors and findings of NDCC 19-03 were also addressed and are included in my testimony. The emergency rules along with the letter from the Governor were submitted to the Legislative Council that afternoon for publishing on the website.

The Board then took steps to ensure the public was informed of the adoption of these emergency rules by issuing a Newspaper Notice along with publication on both the Board of Pharmacy's and the Attorney General's website. The Board held a public hearing on the emergency rules on January 9<sup>th</sup>, 2013 in Fargo, ND at which time no members of the public appeared to comment and no comments were received during the open comment period.

4. There were no verbal or written comments submitted to the Board office objecting to the adoption of these rules.
5. The approximate cost of the rule hearings was considerably more than average, since in the abundance of caution, we provided extra notice to the public to avoid any legal challenge to the Board's rule making process. The cost totaled \$10,536.71.
6. These rules were adopted to protect the public from the specified spice cannabinoids and bath salts substances and future chemical deviations that could be ingested, inhaled or injected for illicit purposes that are detrimental to their health.

7. A regulatory analysis was prepared and a copy is enclosed. There are always some questions about how much lost sales could occur when people may no longer sell these products, however it is not in the public interest to foster upon them drugs which might be harmful, either intentionally or unknowingly.
8. An economic impact statement and regulatory analysis of impact on small entities was prepared to provide this additional information.
9. The only fiscal impact these rules will have on state revenues would be the decreased tax income generated by the sale of these illicit substances. There will be no fiscal impact on the North Dakota Board of Pharmacy by the adoption of these rules.
10. There was no constitutional taking assessment as no property was being seized as a direct result of this rule.
11. These rules were adopted as an emergency interim final rule under NDCC 28-32-03, pursuant to authority granted by the Legislature in NDCC 19-03.1-02. A copy of the Governor's letter is enclosed and we have discussed the issues which caused the Board of Pharmacy to take this action, rather than waiting for the legislative session. It is important to note that House Bill 1070 has passed both the House and Senate, and if it is signed by the governor, will make these changes to codify the language in the rule to NDCC 19-03. Protection of the public's health is the main purpose of the Board of Pharmacy, and this rule making authority under the Controlled Substances Act has served to provide this ability while we wait for your legislative session to move these substances from the rule to the statute, should you concur.

Respectfully,

Mark J. Hardy, PharmD  
Assistant Executive Director

Emergency Rule Draft Motion and Findings  
Board of Pharmacy Special Meeting 11/30/12 10AM  
Harvest Room, ND State Capital

Senior Member Gary Dewhirst stated we have heard from those that are knowledgeable about the dangers of these substances and feel that it is our duty as the Board of Pharmacy to take action.

**Motion made by Board Member Gayle Ziegler to adopt the draft version of the changes to 61-13 Controlled substances as an emergency rule based on the following findings that are taken from today's meeting:**

- The chemical groups identified in the rule have a significant abuse history
- Abuse is widespread and growing across North Dakota with deaths specifically tied to these types of substances
- The medical impact of these substances on humans is largely unknown but the current users are abusing these products to get the hallucinogenic and stimulant effects they create.
- These substances and their analogs present an immediate peril to the general public of residents of North Dakota.
- By nature of the new substances chemical structure, these compounds can cause severe psychic or physiological dependence ,have a high potential for abuse, and have no accepted medical use and thus fit under the category of Schedule I substances
- The approach of scheduling these groups based off of changes that could be made to the core chemical structure is necessary to ensure we are being proactive, to the greatest extent possible, to assure the safety of the public
- Imminent peril threatens public health, safety, or welfare, which would be abated by emergency effectiveness of these rules

**Seconded by Public Member Fran Gronberg**

**Roll Call vote –**

**Bonnie Thom – Aye**

**Fran Gronberg – Aye**

**Diane Halvorson – Aye**

**Gayle Ziegler – Aye**

**Shane Wendel – Aye**

**Gary Dewhirst – Aye**

**The motion carried for the Board of Pharmacy to adopt the emergency rule on the scheduling of these substances**



— State of —  
**North Dakota**

*Office of the Governor*

Jack Dalrymple  
*Governor*

November 30, 2012

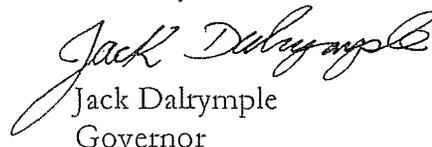
Howard C. Anderson, Jr, R. Ph.  
Executive Director  
1906 E Broadway Ave  
Bismarck ND 58501

Dear Dr. Anderson,

I received your request for approval of emergency rulemaking to adopt North Dakota Administrative Code Chapter 61-13-01-03 regarding Controlled Substances Scheduling.

I have reviewed the request pursuant to N.D.C.C. § 28-32-03 and I find that an emergency rulemaking is reasonably necessary to prevent an imminent threat to public health, safety and welfare, and I therefore approve adoption of your proposed rules as interim final rules.

Sincerely,

  
Jack Dalrymple  
Governor

37:7:58



Wayne Stenehjem  
ATTORNEY GENERAL

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ADDENDUM A

November 15, 2012

My name is Wayne Stenehjem, and I'm Attorney General of North Dakota.

Among other duties, I oversee the ND Bureau of Criminal Investigation, the State Crime Lab, and provide legal representation and certain enforcement assistance for state agencies, including the State Department of Health.

Synthetic drug abuse has exploded in North Dakota over the last four years which presents many unforeseen challenges for law enforcement and prosecutors in the State. In 2011, the Legislature scheduled seven chemical groups of synthetic cannabinoids, which were being sold as "incense," and several synthetic cathinones, which were being sold as "bath salts." These substances were sold as allegedly legal alternatives to controlled substances, and, despite their labels stating the products were "not for human consumption," the substances are smoked, snorted, and ingested for the purpose of getting high.

It is widely, perhaps universally, known that these products are sold solely for the purpose of human consumption and ingestion, and that they have psychoactive and mind altering effects. Some of the newer compounds have never been researched or studied on humans so users are test subjects each time they use one of these substances.

When the chemical groups were scheduled, we thought we had taken care of the problem. However, the manufacturers of these substances changed the chemical structure, making the new substances similar to, but different from, the chemical classes that were controlled.

Law enforcement, prosecutors, and medical providers began seeing the same products, labeled with such names as “New Dimension,” “Spark,” and “100% Pure Evil,” now containing a non-controlled synthetic. Reports were coming in of juveniles overdosing on very small amounts of these substances. People who were smoking these substances were combative with police. Users told police they thought they were having a heart attack; they thought their hearts were going to jump out of their chests. Police have also responded to hospital emergency rooms where users have been foaming at the mouth and incoherent.

In June 2012, in the Grand Forks area, two teenagers died and at least one other overdosed on a synthetic cathinone known as 2C-I with the street name, Smiles. In that case, witnesses described the victims as thrashing about and growling and one of the victims was pounding his head into the ground before he stopped breathing.

Unfortunately, because none of these substances are controlled, the distributors of these drugs cannot be charged with any drug trafficking crimes. We have no way, under state law, of prohibiting these dealers from selling these new substances.

These new substances have fallen through the cracks of our current statutes. In the Grand Forks case of the distribution of 2C-I which resulted in the deaths of the two teenagers, the federal government, through the controlled substance analog statute, was able to charge the distributors of 2C-I with drug trafficking offenses. A controlled substance analog is a chemical which is similar to a controlled substance, but is not itself specifically controlled. Drug Enforcement Administration chemists have confirmed that the new synthetic cannabinoids available since the 2011 legislation, including XLR-11, are analogs of the synthetic cannabinoids that are controlled. North Dakota needs a controlled substance analog statute so law enforcement and prosecutors are able to stop the distribution of substances that are similar to controlled substances, yet different enough to be “legal.”

In or around March of 2012, and on or about July 12, 2012 two North Dakota consumers reported that they purchased one gram of the product for approximately \$20. "New Dimension" has been shown to contain JWH-018, AKB 48 and URB-754, which are known synthetic cannabinoids, with a likely effect similar to those of THC, a cannabinoid naturally present in cannabis. One of the consumers used a pipe to smoke "New Dimension" and reported to law enforcement that smoking the product gives him "a euphoric relief." The second consumer smoked the product in a "joint" and reported to law enforcement that smoking the product gave him a buzz. The second consumer also allowed another person to smoke some of the joint. Shortly after, this person, a 21 year old male, called 911 in distress, breathing heavily and complaining that he felt as if his heart was going to explode, that his heart was racing and that he needed help. Police and ambulance were dispatched and they found him wandering in a field. He appeared distraught and upset and his face was flushed. He was transported by ambulance to the hospital.

The sale of street drug alternatives has had a damaging and serious effect on the public health in North Dakota and elsewhere. Street drug alternatives are known to cause serious health effects, such as agitation, extreme nervousness, nausea, vomiting, tachycardia (fast, racing heartbeats), dangerously elevated blood pressures, tremors and seizures, hallucinations, severe paranoia, and even death. The products also are extremely habit forming and may cause an intense craving to redose. The products often cause extremely violent behavior, which causes users to harm themselves or others. Users often demonstrate extreme strength, with totally irrational behavior and responses. Over the last several years, there has been a dramatic increase in emergency calls and patients being brought to emergency departments with adverse health effects resulting from ingesting or inhaling a street drug alternative of unknown content.

The street drug alternatives are marketed to target people who are experimenting with "legal highs" or who want to get high without risking positive drug test results. The products are well known among

this group of consumers as a product that may allow them to experience a high legally and without detection.

The legality of the street drug alternatives depends on the chemical structure and composition. The substance may have the same or similar effect on the human body as products banned as controlled substances under N.D.C.C. ch. 19-03.1. However, because this structure can be easily and quickly changed, the street drug alternatives avoid illegality, until regulators or the legislature can include them as a controlled substance and ban them, or prove them to be illegal as an “analogue” under 21 U.S.C. §802(32)(A). The street drug alternatives have shown to be even more dangerous and risky than the substances they attempt to mimic. However, they remain legal until they can be identified and banned by law or regulation.

My office has drafted proposed legislation to present to the next session of the legislature, but now I believe we cannot wait even three or four months to respond to this epidemic. Reports that I am receiving from law enforcement, the medical community, and citizens generally, tell me that we have an emergency situation here in North Dakota with these synthetics, and so I’m asking this Board to adopt emergency rules to add these synthetic substances to the Schedule of Controlled Substances.

Thank you.



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November 30, 2012

### **NDCC 28-32-08.1 – Regulatory Analysis**

#### **RE: NDAC Chapter 61-13 – Controlled Substances.**

Neither the Governor, nor a member of the Legislative Assembly has filed a written request for a Regulatory Analysis for this rule.

This proposed rule may have an impact on the regulatory community as a whole in excess of \$50,000, if a particular entity was selling more than \$50,000 worth of the products which this rule intends to make Schedule I therefore making their sale and possession illegal. We do not know that any individual entities are selling in excess of \$50,000, but that is a possibility. These substances are dangerous substances and even though their sales might be generating income for these individuals at this time, they are a danger to the public and that activity must be curtailed.

There are no other alternative for controlling these substances, which have no approved medical use in the United States and are a danger to the public who smokes, inhales, injects or ingests them. The Controlled Substances Act has been the standard method for regulating these products over time and placing them into Schedule I makes the possession or sale of these products illegal in North Dakota. Most of the entities affected by this rule will be small entities and a comparable small entity regulatory analysis has also been prepared and is available on the Boards website.

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Howard C Anderson, Jr, R.Ph.  
Executive Director



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### **NDCC 28-32-08.1 – Small Entity Economic Impact Statement**

#### **RE: NDAC 61-13 – Controlled Substances.**

All entities, including small entities are subject to the requirements of this rule, which makes these particular substances Schedule I Controlled Substances, their sale or possession are illegal for everyone.

Although there are no administrative costs involved with the compliance with this rule, there may be costs for those who have these chemicals on hand in their inventory, as they will be ineligible for possession or sale.

Private persons will be protected from purchasing and utilizing products which contain these chemicals and are not labeled as to the proper contents. Individuals will be warned by the inclusion in Schedule I of the Controlled Substances Act that these chemicals entities are Schedule I Controlled Substances, meaning they have no legitimate medical use in North Dakota and should not be purchased or used. Small entities who have these substances on hand must dispose of them, turn them over to law enforcement or immediately return them to their suppliers.

The effect of the proposed rule on state revenues could be negative if these substances were being sold and sales tax paid on the sale of these products. I have no estimate of the amount of these products being sold in North Dakota at the time of this rule.

There is no less intrusive or less costly alternative of achieving the scheduling of these controlled substances to protect the public from the potential harm by their exposure to these chemicals, either knowingly or unknowingly.

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### **NDCC 28-32-08.1 – Small Entity Regulatory Analysis**

#### **RE: NDAC Article 61-13 – Controlled Substances.**

The alternative for scheduling Controlled Substances are:

- To allow the federal government through the Drug Enforcement Administration [DEA] to schedule these substances;
- To schedule them with state legislation

There is no alternative in making these substances illegal to resolve the issue of harm occurring in the general public from the use of dangerous chemicals which are unregulated and products which contain them, without disclosure of the ingredients on the label.

The emergency rule was promulgated because we saw immediate harm occurring in the public, therefore a less stringent schedule would only have allowed more sales of dangerous chemicals to people unaware of the contents of the products they are purchasing and for more sales and hoarding to occur before the substances became illegal to possess or sell.

Exemption standards for small entities were not considered, as the same standards would need to apply to everyone.

Exemption standards for any size entities are not practical, as once these drugs are illegal, they are illegal for everyone.

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Howard C Anderson, Jr, R.Ph.  
Executive Director