



State of North Dakota
John Hoeven, Governor

LEGISLATIVE COUNCIL
STATE CAPITOL
600 EAST BOULEVARD
BISMARCK, ND 58505-0360
FEB 26 2010

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February 26, 2010

Mr. John Walstad
Code Reviser
ND Legislative Council
600 E Blvd – Capitol Bldg
Bismarck ND 58505-0360

Dear Mr. Walstad:

Enclosed please find a copy of the New Article to NDAC Title 61 – Article 61-13 Controlled Substances, along with a copy of the written and a summary of the oral comments received on the rule at the Board of Pharmacy meeting held last night. Also enclosed is the notice of hearing for the rule.

The Board of Pharmacy "may add substances to... substances enumerated in the schedule[] in section[] 19-03.1-05... [relating to Schedule 1 substances]." NDCC 19-03.1-02(1). The proposed interim final rule is issued under that authority.

Also enclosed is a copy of the letter from ND Governor John Hoeven authorizing the emergency rule making for these rules.

The North Dakota State Board of Pharmacy adopted these rules at a special meeting held pursuant to notice on February 25th, 2010 at 9:04 PM. The Board of Pharmacy adopted these rules as an interim final rule. Please publish these rules in the North Dakota Administrative Code with the earliest possible effective date.

Sincerely,

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

HCA/eh

Enclosure(s)


NOTICE OF INTENT TO
ADOPT, AMEND AND REPEAL ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota Board of Pharmacy will hold a public hearing to address proposed adoption of a New Article to NDAC Title 61 – Article 61-13 Controlled Substances. The hearing will be held at 2:00 p.m. on Saturday, April 24, 2010, Grand International Hotel, 1505 North Broadway, Minot, ND 58703-0777. The purpose of the rule is to schedule substances which have an actual or relative potential for abuse; and which bear risk to the public health by unknown individuals using them by inhaling the smoke, vapors or by ingesting the substance. The proposed rule is not expected to have an impact on the regulated community in excess of \$50,000. No taking of real property is involved in this rulemaking action.

The proposed rule may be reviewed at the office of the North Dakota Board of Pharmacy located at 1906 East Broadway Avenue, Bismarck, ND 58502. A copy of the proposed rule may be requested by writing to the above address, emailing ndboph@btinet.net, or calling 701-328-9535. Written or oral comments on the proposed rule sent to the above address or phone number and received by May 17, 2010 will be fully considered.

If you plan to attend the public hearing and will need specific facilities or assistance relating to a disability, please contact the North Dakota Board of Pharmacy at the above phone number or address at least three days prior to the public hearing.

DATED this 26th day of February 2010.


Howard C. Anderson, Jr, R.Ph, Executive Director
North Dakota Board of Pharmacy



— State of —
North Dakota
Office of the Governor

John Hoeven
Governor

February 25, 2010

Howard C. Anderson, Jr., R.Ph.
Executive Director
North Dakota Board of Pharmacy
P.O. Box 1354
Bismarck, ND 58502-1354

Dear Howard,

On February 25, 2010, I received your request for approval of emergency rulemaking to create a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," which adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

I have reviewed the request pursuant to N.D.C.C. § 28-32-03(2) and find that emergency rulemaking is necessary to abate an imminent peril that threatens public health and safety.

Sincerely,

A handwritten signature in black ink that reads "John Hoeven".

John Hoeven
Governor

38:34:58

I am Gayle Ziegler President of the Board of Pharmacy and I will be acting as officer for this public meeting.

It is now 9:04 PM on Thursday February 25, 2010 on a conference call or in the conference room of the Board of Pharmacy Office at 1906 East Broadway in Bismarck, North Dakota.

This public meeting has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

Consideration of an emergency rule that creates a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

Information gathered at this meeting will be used by the Board of Pharmacy for it's deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting, and this meeting is being recorded, so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the meeting for comments:

William J. Nickel of Mandan, North Dakota 58554, expressed concerns that his shop sold some of the products which had been referred to in the public press and in which was eluded might contain some of these chemicals. However, the ingredients on the products he sells does not list any of the chemicals indicated in this rule making. The concern of Mr. Nickel's was primarily that it would be difficult for him to ascertain which of his products actually had the listed chemicals in them and that he felt that he was not responsible for the inappropriate use of his products by the people who purchased them. Mr. Nickel asked what the disposition of suspect products might be, if this rule passed tonight.

It was pointed out that once the rule was published by the Legislative Council, in it's present form, any products containing any of these ingredients would be illegal and would not be able to be sold or possessed.

Wayne Stenehjem, North Dakota Attorney General spoke, expressing support for the proposed Emergency Rule. General Stenehjem said that his Bureau of Criminal Investigation Agents, the State Crime Lab and other Law Enforcement Departments have found North Dakota citizens using these products in an inappropriate manner and that in several instances it has been reported that significant harm and hospitalizations have occurred as a result of use of products containing some of these substances. He also indicated that he supported the adoption of this rule and that he felt that those selling products, which the State Lab had

identified as containing these dangerous chemicals, either knew or should know, by the high price asked of these products relative to ordinary Incense or Bath Oil Salts, these products were being used inappropriately. General Stenehjem pointed out that the roll of his office and the Board of Pharmacy in supporting and hopefully adopting this rule was for the protection of the public health. Individuals using these products intentionally by inappropriate methods, or by inhaling the smoke or vapors from these products in legitimate fashion, not realizing that they contain dangerous chemicals were a significant risk to the public health. Scheduling these substances and thus making it known that they cannot be added as ingredients to what would otherwise appear to be safe products, will serve to protect the public from these chemicals, whether the individuals using them know they are in the products or if they are using them without knowing that these dangerous chemicals are included in the products.

Cassandra Nickel of Bismarck, ND 58504 pointed out that the selling of these products in their shop, which were purported to contain some of these chemicals, never indicated that these products should be used inappropriately. Most of these products are labeled as Incense or Bath Oil Salts and are labeled not for human consumption.

The State Board of Pharmacy Members offered comments, indicating that they supported their role in the protection of the public health. The scheduling of these substances is necessary to protect those individuals either using them inappropriately or using the products without knowing that these chemicals were contained in the products.

Board Members also pointed out that if legitimate medical uses could be found for these products, they could be moved to appropriate schedule. But, at this time there is no legitimate medical use for these products. They are used primarily in research for medical purposes. This research can continue under the Schedule I placement of these products until such time as legitimate uses are properly researched and the safety and effectiveness of the products documented.

Mike Mullen Assistant Attorney General pointed out that the rule will affect these products much like a food recall would affect a product that was determined to be adulterated by chemicals not listed on the packaging.

Howard Anderson, Jr, R.Ph., Executive Director of the ND State Board of Pharmacy pointed out some grammatical corrections in the Rule version that was sent out as part of the Notice, where two extra letters had been inserted in the chemical name of HU-211 and a couple of parentheses and brackets had been omitted. Also, Charles Peterson, Dean of NDSU College of Pharmacy had submitted a written comment in which he pointed out that he felt that “or injecting” should be added after ingesting to 61-13-01-01 – Purpose and Scope as how one of the ways users might abuse these substances. This suggestion was included in the final draft.

At the suggestion of Mick Mullen the table under 61-13-01-03 Scheduling was revised slightly to group into group 1 and group 2 the products being scheduled and the history, general authority and law implemented between the two groups eliminated.

A final copy with the above documented corrections was distributed at the meeting and was emailed to the Members of the Board of Pharmacy prior to final action.

CLOSING

Thank you all for participating. The Board of Pharmacy will use all of the information gathered at this meeting, in making their decision.

At this point, I will close the discussion on new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Bonnie Thom to adopt this interim final Rule represented by the corrected copy. On a vote by Roll Call: Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Pharmacist Detwiller – was absent from the Meeting The interim final rule was passed and declared adopted.