WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Form #3

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2006 JUL 18 P 3:28

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: §60A-10-7(b)

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 11

TITLE OF RULE BEING AMENDED: Ephedrine and Pseudoephedrine Control

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Will S. Dayton

Authorized Signature

$5.20

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

July 18, 2006

Betty Ireland, Secretary of State
State Capitol Complex, Building 1, Suite 157-K
1900 Kanawha Blvd, East
Charleston, WV 25305-0770

Dear Secretary Ireland:

I am writing to approve a proposed rule amendment by the Board of Pharmacy being filed as a legislative rule and previously approved as an emergency rule, 15 CSR 11, Ephedrine and Pseudoephedrine Control. Thank you for your cooperation in this important matter.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 07-18-2006

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

304-558-0558

LEGISLATIVE RULE TITLE: ~~15 CSR 11- Ephedrine and Pseudoephedrine Control~~

1. Authorizing statute(s) citation §~~60A-10-7(b)~~

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   May 2, 2006

   b. What other notice, including advertising, did you give of the hearing?

   Info was on website and filing was addressed at 6 continuing education programs for pharmacists throughout state in May and June.

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   June 9, 2006; 4:00 p.m. public comment period ended.

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 18, 2006

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

William T. Douglass, Jr.
Executive Director and General Counsel
304-558-0558- phone

304-558-0572- fax

wdouglass@wvbop.com

g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 11

Ephedrine and Pseudoephedrine Control

This rule amends the current Series 11, entitled "Ephedrine and Pseudoephedrine Control" This rule adds two drug products to the supplemental list referred to in West Virginia Code §60A-10-7 (b). The Superintendent of the West Virginia State Police sent a letter to the Board on April 6, 2006 asking the Board to add the following products to the list:

1. Products that contain pseudoephedrine and triolidine; and
2. Products that contain pseudoephedrine and loratidine.

STATEMENT OF CIRCUMSTANCES

Title 15

Legislative Rules

Series 11

Ephedrine and Pseudoephedrine Control

Superintendent of West Virginia State Police via April 6, 2006 letter recommended that the Board add two drug products to the supplemental list of restricted products: products containing pseudoephedrine and tripolodine and products containing pseudoephedrine and loratidine. The products have been found in numerous clandestine laboratories in the manufacture of methamphetamine.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 25301

Phone Number: 304-558-0558 Email: wdouglass@wvbop.com

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

No impact on costs and revenues of state government expected except for possible reduction in law enforcement costs of responding to methamphetamine related crimes.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase Decrease (use "-")	Next Increase Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Rule is only adding two drug product classifications to supplemental list of products containing pseudoephedrine that are restricted to sale from behind the pharmacy counter. No known impact on state revenue or expenditures as result of adding products to list.

Date: 07-18-06

Signature of Agency Head or Authorized Representative

[signature]

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2006 JUL 18 P 3:28

OFFICE WEST VIRGINIA SECRETARY OF STATE

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 11
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

§15-11-1. General.

1.1. Scope. --- To establish rules for ephedrine and pseudoephedrine control in West Virginia including pharmacy reporting requirements; notification processes; and special registration for distributors. .

1.2. Authority. --- W. Va. Code §60A-10-1 et.seq .

1.3. Filing Date. –

1.4. Effective Date. --

§15-11-2. Definitions.

2.1. "Central repository" refers to the central repository designated by the Board for the collection of controlled substance information. It may be a vendor designated by the Board and under contract with the Board to act as the central repository.

2.2."Schedule V pseudoephedrine products" means any compound, mixture or preparation containing as its single active ingredient ephedrine, pseudoephedrine or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers, including any drug products added to the supplemental list pursuant to West Virginia Code §60A-10-7, except products which are for pediatric use primarily intended for administration to children under the age of twelve.

2.3 The following products have been added to the supplemental list pursuant to West Virginia Code §60A-10-7:

(a) products that contain pseudoephedrine and tripolidine; and

(b) products that contain pseudoephedrine and loratadine.

§15-11-3. Pharmacy Requirements

3.1. Schedule V pseudoephedrine prod -ucts may be sold, delivered, or provided only in licensed pharmacies by a pharmacist or registered pharmacy technician and may not be sold, delivered, or provided to any person who is under the age of eighteen.

3.2. Schedule V pseudoephedrine products shall be kept behind the pharmacy counter and all storage of these products shall be in a controlled and locked access location that is not accessible by the general public.

3.3. The pharmacist and all registrants with access to the Schedule V pseudoephedrine products have an affirmative duty to guard against the theft and diversion of the products.

3.4. Any pharmacy that sells Schedule V pseudoephedrine products shall require the person purchasing, receiving or otherwise acquiring the drug product to:

(a) Produce a drivers license or government-issued photo identification showing his or her date of birth; and

(b) sign a form containing the information required by subsection 4.1 of this rule and attest-

ing to the validity of the information. The signature may be captured electronically and the information maintained as an electronic record as long as a hard copy may be produced upon request.

3.5. Each pharmacy, pharmacist, and registered pharmacy technician involved in the sale of the product have the responsibility to ensure that the information required in this rule provided by the customer is recorded accurately.

3.6. The bound record book kept for distribution of Schedule V exempt narcotics pursuant to West Virginia Board of Pharmacy Rule, Rules of the Board of Pharmacy for the Uniform Controlled Substances Act, 15 CSR 2.7.19.1(e), may be used for recording the information required by this rule.

§15-11-4. Prescription Monitoring Program.

4.1. After January 1, 2006, each time any Schedule V pseudoephedrine product is transferred, sold, or delivered, the pharmacist or pharmacy technician shall electronically transmit not less than monthly to the central repository the following information:

(a) The date of the transaction;

(b) The name, address and driver's license or state-issued identification number of the purchaser; and

(c) The name, National Drug Code (NDC) number, quantity of packages and total gram weight of the product or products purchased, received or otherwise acquired.

4.2. The information may be transmitted at any time during the month as a batch transmission and may be sent with the Schedule II, III, and IV information.

4.3. The Board and the central repository shall receive the electronic transmission of the information required to be provided by and through the use of a secure upoload from the pharmacy via the internet or other means approved by the Board. The pharmacy shall retain the information until transmission to the central repository has been confirmed.

§15-11-5 Lawful possession of Schedule V pseudoephedrine products

5.1 The following persons are allowed to lawfully possess Schedule V pseudoephedrine products while in the course of legitimate business:

(a) Any Schedule V pseudoephedrine-only limited pharmaceutical distributor, or it agents, licensed by the Board;

(b) Any wholesale distributor, or its agents, licensed by the Board;

©) Any manufacturer of controlled substances, or its agents, licensed by the Board;

(d) a pharmacist licensed by the Board or a pharmacy technician registered with the Board or other pharmacy employee under the direct supervision of a pharmacist;

(e) health care professionals appropriately licensed and engaged in legitimate patient care: and

(f) persons possessing the products pursuant to a valid prescription.

§15-11-6 Prescriptions for Schedule V pseudoephedrine products

6.1 Products containing pseudoephedrine that are dispensed pursuant to a valid prescription are exempt from classification as Schedule V and

are subject to the requirements of non-scheduled prescription drugs. Any product that is dispensed by prescription must be provided in a container that is supplied by the pharmacy and must be labeled with the information required on a prescription label.

§15-11-7. Thirty day requirement

7.1 Pharmacists and registered pharmacy technicians that sell Schedule V pseudoephedrine products shall exercise reasonable care to ensure that the purchaser has not purchased more than three packages or more than nine grams of pseudoephedrine in a 30-day period. The nine-gram limit applies to the amount of pseudoephedrine contained in products purchased, not the overall weight of the product including all ingredients.

§15-11-8. Records and invoices.

8.1 Any pharmacy, wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall keep readily retrievable records and invoices documenting the sale and distribution of these products. All pharmacy log records of sales of Schedule V pseudoephedrine products shall be kept for a minimum of five years from the date of sale or distribution.

§15-11-9. Registration to sell, distribute, or transfer Schedule V pseudoephedrine products.

9.1 Every wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall obtain a registration annually from the Board.

9.2 Any facility that holds a license as a pharmacy, manufacturer, or wholesaler from the Board shall not need to obtain an additional permit to sell, distribute, or transfer Schedule V pseudoephedrine products or be required to meet any additional storage or security requirements.

9.2 Any facility that does not hold a license as a pharmacy, manufacturer, or wholesaler from the Board may apply for and be granted a limited Schedule V pseudoephedrine distributor license. An applicant for this registration shall meet the following conditions:

(a) The applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;

(b) The applicant's sales are not limited to pseudoephedrine items alone, or to pseudoephedrine items in conjunction with other items associated with the illegal manufacture of methamphetamine or other controlled drugs;

©) The applicant does not have a history of association with the diversion of pseudoephedrine; or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs

(d) The applicant verifies that Schedule V pseudoephedrine products shall be stored in a locked area that is monitored and the applicant has established security measures to guard against diversion; and

(e) The applicant submits a fully completed application to the Board with a fee of $200 for annual registration.

9.3. All licenses allowing the sale, distribution, or transfer of Schedule V pseudoephedrine products expire on June 30th of each year, and shall be

renewed on an annual basis.

§15-11-10. Supplemental List

10.1 The Superintendent of the State Police and the Executive Director of the Board shall meet at least quarterly to identify drug products which are a designated precursor, in addition to those that contain as their single active ingredient ephedrine, pseudoephedrine, or phenylpropanolamine, that are commonly being used in the production and distribution of methamphetamine.

10.2. The Superintendent of the State Police shall demonstrate by empirical evidence those drug products being used in the manufacture of methamphetamine and recommend the addition of these products to the list of Schedule V pseudoephedrine products.

10.3. The Board, upon receiving a recommendation from the Superintendent of the State Police, shall promulgate emergency and legislative rules to implement an updated supplemental list of Schedule V pseudoephedrine products.

10.4. The Board shall provide written notification to the pharmacist-in-charge of each pharmacy in West Virginia and to the West Virginia Community Pharmacy Council that Schedule V pseudoephedrine products must be sold, transferred or dispensed from behind a pharmacy counter and a list of brand name Schedule V pseudoephedrine products that are subject to this rule.

10.5. The Board shall provide written notification to the pharmacist-in-charge of each pharmacy in West Virginia and to the West Virginia Retailers Association, West Virginia Community Pharmacy Council, West Virginia Oil Marketers and Grocers Association, and West Virginia Wholesalers Association of each drug product added to the list of Schedule V pseudoephedrine products pursuant to the legislative rule referred to in subsection 10.3 of this rule. Any changes in pseudoephedrine products subject to this rule shall become effective 30 days after notice is provided pursuant to this section.

500 Arcola Road
Collegeville, PA 19426

Nancy M. McKee
Director
State Government Affairs

Wyeth

RECEIVED
JUN 08 2006
WV BOARD OF PHARMACY

June 7, 2006

George Karos
President
West Virginia Board of Pharmacy
Post Office Box 5655
Martinsburg, West Virginia 25402

Dear Mr. Karos:

On behalf of Wyeth, manufacturer of over the counter allergy, cough and cold medicines, I am submitting comments about the proposed amendment to 15 CSR 11, Ephedrine and Pseudoephedrine Control, which adds certain pseudoephedrine-containing medicines including medications containing pseudoephedrine and loratadine to the Schedule V list of chemicals.

We take seriously the Board of Pharmacy's and State Police's authority to add products to Schedule V. In making the determination of adding products to Schedule V, we trust that the Board of Pharmacy has reviewed substantial evidence that these specific products are being used to manufacture methamphetamine, including obtaining and reviewing official documentation from law enforcement agencies that shows the relative occurrences, or lack thereof, of the product being used in the illegal manufacture of methamphetamine.

As manufacturers of a medicine containing pseudoephedrine and loratadine, Alavert D, we are concerned that we were neither notified of this rule nor presented with evidence that our product has been found at clandestine labs by West Virginia State Police. As a result, it is unclear if our product is being used inappropriately. Since the proposed rule is not product specific, but subjects all products containing pseudoephedrine and loratadine to Schedule V, it could unduly restrict legitimate consumer access to products that may not be found at clandestine sites.

We also have trepidation about the timing of this proposed rule. Pseudoephedrine and loratadine combination medicines are used widely to treat allergy symptoms and this proposal comes at the peak of allergy season. At present, federal package

Wyeth

limits (3.6 grams daily and 9 grams in 30 days) for the sale of all pseudoephedrine-containing medicines are in effect and in a few months, the Federal Combat Methamphetamine Law (P.L. 109-177) will require all products containing pseudoephedrine to be placed behind any counter by September 30, 2006. Since we are in the height of allergy season coupled with the imminent implementation of the federal law, is it appropriate to further restrict access for the 700,000 legitimate West Virginians who annually purchase allergy, cough and cold products to treat their symptoms?

Under Schedule V, consumer access to these medications is cut off by almost ninety percent, as only twelve percent of retail stores in West Virginia have pharmacies. This rule will place an undue burden on West Virginia's rural residents, who represent more than fifty percent of the state's population. Before the West Virginia Board of Pharmacy changes current law, it should give the federal legislation a chance to work.

Thank you for the opportunity to comment. Should this rule go into effect, we respectfully request prompt notification of the final rule and implementation date.

Sincerely,

Nancy M. McKee

cc: William T. Douglass, Jr.
Executive Director and Counsel, West Virginia Board of Pharmacy

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

June 29, 2006

Nancy W. McKee, Director, State Government Affairs
Wyeth
500 Arcola Road
Collegeville, PA 19426

Dear Ms. McKee:

The West Virginia Board of Pharmacy met on June 17, 2006, in Elkins, WV, and considered your comments about the proposed amendment to 15 CSR 11. The Superintendent of the State Police stated that these products have been found in numerous clandestine laboratories and lab related incidents in various locations around the state. More importantly, these ingredients have been identified in clandestine lab samples which have been submitted to the West Virginia State Police Forensic Lab for analysis. Since the ingredients were found in the samples, the Superintendent and the Board felt it appropriate to add all products with those ingredients to the supplemental list rather then specific brand name products.

The Board shares your concern about restricting access by consumers to these products but the public safety is threatened more by the use of these products in the illegal manufacturing of methamphetamine. The state restriction of the single entity products has had a substantial impact on the ability of the criminal element to obtain those products for use in meth labs. As a result they have turned to the combination products being added to the list which contain a great deal of pseudoephedrine with a relatively small amount of another active ingredient. The federal law will not restrict those products to being behind a pharmacy counter with all its attendant security and recordkeeping requirements so the effectiveness of those future restrictions remains questionable.

The Board thanks you for your comments but will not be making any amendments to the rule pursuant to your stated concerns. The rule requires notice be made to certain organizations and each pharmacy in the state and the products are subject to the rule 30 days after this notice is given.

Sincerely,

George Karos

George Karos
Board President

cc
Board Members