| Regulatory Analysis Form | This space for use by IRRC |
|---|---|
| (1) Agency<br>PA Department of Health | |
| (2) I.D. Number (Governor's Office Use)<br>10-177 | IRRC Number: 2440 |

(3) Short Title

Amending the schedules of controlled substances.

| (4) PA Code Cite | (5) Agency Contacts & Telephone Numbers |
|---|---|
| 28 PA Code § 25.72 | Primary Contact: Carol Williams (717) 783-8665<br>Secondary Contact: Janice Staloski (717) 783-1379 |

| (6) Type of Rulemaking (check one) | (7) Is a 120-Day Emergency Certification Attached? |
|---|---|
| Proposed Rulemaking<br>√ Final Order Adopting Regulation<br>Final Order, Proposed Rulemaking Omitted | ✓ No<br>Yes: By the Attorney General<br>Yes: By the Governor |

(8) Briefly explain the regulation in clear and non technical language.

The Department adopts amendments the schedule of controlled substances at 28 Pa. Code § 25.72. These regulations contain five schedules of controlled substances which categorize substances according to different potentials for abuse and medical use. A controlled substance is placed in Schedule I when there is a high potential for abuse; no currently accepted medical use in the United States; and a lack of accepted safety for use under medical supervision. The final rulemaking schedules five substances in Schedule I.

1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) will be scheduled as Schedule I controlled substances.

## Regulatory Analysis Form

The final rulemaking to the Schedule I of controlled substances follow similar actions by the Federal Drug Enforcement Agency (DEA).

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The amendments to the schedules of controlled substances are promulgated pursuant to Sections 3 and 4 of the act (35 P.S. §§ 780-103 and 780-104). The final rulemaking is also promulgated pursuant to Section 2102(g) of the Administrative Code of 1929, (71 P.S. § 532(g)). Section 3 of the act provides that the Secretary controls all substances listed in Schedules I - V of the act. Subsection 3(a) of the act (71 P.S. § 780-103(a)) provides that the Secretary may add a substance as a controlled substance, and that before doing so, shall request advice in writing from the Board as to whether a substance should be added as a controlled substance. The Secretary sought that advice, and the Board provided it following its April 21, 2004, meeting. The Board recommended that the substances 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) be added as Schedule I controlled substances.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No. The final rulemaking is not mandated, however, it would comport with general Federal scheduling of these substances.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

These substances are currently scheduled by the Federal Government as Schedule I controlled substances. The fact that these substances are not scheduled as Schedule I controlled substances at the State level hinders law enforcement agencies in their prosecution for illegal sale and illegal possession. These substances are abused and have a high potential for abuse; there is no currently accepted medical use for these substances; and there is a lack of accepted safety for use under medical supervision. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule I of controlled substances, and the Secretary adopted that advice.

The final regulation schedules 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) as Schedule I substances.

## Regulatory Analysis Form

(11) State the public health, safety, environmental substances for control or general welfare risks associated with non-regulation.

There are great public health, safety and general welfare risks associated with not scheduling these substances as set forth in the final rulemaking. Substantial risk of abuse, accompanied by non-scheduling, causes a greater risk of illegal drug use and abuse with little or no tools provided to law enforcement to assist it in fighting that problem. This final regulation addresses these problems.

(12) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The general public will benefit from the scheduling of 1 - (3 – trifluoromethylphenyl) Piperazine (FMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) to Schedule I since doing so will allow for better enforcement and control of the drug abuse problems in the Commonwealth.

(13) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Department knows of no one who will be adversely affected by the regulations.

(14) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All people in the Commonwealth will be required to comply with the regulations.

(15) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The Drug, Device, and Cosmetic Board convened a public hearing on the matter on April 21, 2004. The meeting notice was published in the Pennsylvania Bulletin at 34 Pa. B. 2135 (April 17, 2004).

## Regulatory Analysis Form

The Board heard the petitions of the Office of Attorney General which requested that 1 - (3 – trifluoromethylphenyl) Piperazine (FMPP), n-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) –Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) be scheduled as Schedule I controlled substances. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule I of controlled substances, and did so. The Secretary directed that these substances be scheduled.

(16) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

These amendments will not significantly affect costs or savings by the regulated community. These amendments will not require any new legal, accounting, or consulting procedures not already being undertaken by the regulated community.

(17) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

The amendment will have no measurable fiscal impact on local government, because a system already exists for the oversight of controlled substances, and the regulations will simply add additional substances to the list of controlled substances.

(18) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures that may be required.

The amendment will have no measurable fiscal impact on the State government. An administrative paperwork system is already in place and will not measurably change with the rescheduling or scheduling of controlled substances and the regulations will simply add additional substances to the list of controlled substances.

(19) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

## Regulatory Analysis Form

| | Current FY Year | FY +1 Year | FY +2 Year | FY +3 Year | FY +4 Year | FY +5 Year |
|---|---|---|---|---|---|---|
| **SAVINGS:** | $N/A | $ | $ | $ | $ | $ |
| **Regulated Community** | | | | | | |
| **Local Government** | | | | | | |
| **State Government** | | | | | | |
| **Total Savings** | | | | | | |
| | | | | | | |
| **COSTS:** | | | | | | |
| **Regulated Community** | | | | | | |
| **Local Government** | | | | | | |
| **State Government** | | | | | | |
| **Total Costs** | | | | | | |
| **REVENUE LOSSES:** | | | | | | |
| **Regulated Community** | | | | | | |
| **Local Government** | | | | | | |
| **State Government** | | | | | | |
| **Total Revenue Losses** | | | | | | |

(20a) Explain how the cost estimates listed above were derived.

N/A

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

| Program | FY -3 | FY –2 | FY -1 | Current FY |
|---|---|---|---|---|
| N/A | | | | |
| | | | | |
| | | | | |
| | | | | |

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs. The benefits are described above.

There will be no apparent adverse effects and costs.

## Regulatory Analysis Form

(22) Describe the non-regulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

There are no alternative non-regulatory approaches.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

There are no alternative regulatory approaches.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No. These amendments conform with Federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The amendment to schedule follows similar action by the Federal government. This amendment will not put Pennsylvania at a competitive disadvantage with other states.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No. The regulations will not affect existing or proposed regulations of the promulgating agency or other State agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings or informational meetings are scheduled at this time. Prior to publication as proposed rulemaking, the Drug Device and Cosmetic Board convened a public hearing on the matter, as described in item (16) above. The Department then provided for a 30-day public comment period when the regulations were published as proposed. The Department did not receive any public comment.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements?
None.

## Regulatory Analysis Form

(29) Please list any special provisions that have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The amendment will become effective upon publication as final in the Pennsylvania Bulletin.

(31) Provide the schedule for continual review of the regulation.

The amendment will be effective immediately upon final adoption. The schedules of controlled substances are continually monitored and updated as needed.

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INDEPENDENT REGULATORY REVIEW COMMISSION

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2440

DO NOT WRITE IN THIS SPACE

| Copy below is hereby approved as to form and legality. Attorney General. | Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by: | Copy below is hereby approved as to form and legality. Executive or independent agencies. |
|---|---|---|
| BY _____ DEPUTY ATTORNEY GENERAL | DEPARTMENT OF HEALTH (AGENCY) | BY _____ DAVID J. DEVRIES |
| _____ DATE OF APPROVAL | DOCUMENT/FISCAL NOTE NO. 10-177 | 7.26.05 DATE OF APPROVAL |
| | DATE OF ADOPTION: _____ | EXECUTIVE (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable title~~) |
| | X _____ BY: Calvin B. Johnson, M.D., M.P.H. | |
| Check if applicable. Copy not approved. Objections attached. | TITLE: Secretary of Health | Check if applicable. No Attorney General approval or objection within 30 days after submission. |

**DEPARTMENT OF HEALTH**

**FINAL RULEMAKING**

**TITLE 28. HEALTH AND SAFETY**

**PART III. PREVENTION OF DISEASE**

**[28 Pa. Code Chapter 25]**

The Department of Health (Department) hereby adopts amendments to the schedules of controlled substances under the powers and duties contained in the Controlled Substances, Drug, Device and Cosmetic Act (P.L. 233, No. 64) (35 P.S. §§ 780-101-780-144) (Act) to read as set forth in Annex A.

## A. PURPOSE OF THE AMENDMENT

The Act recognizes the fact that there is a need to control substances which have potential for abuse while also recognizing that some of those substances have medical uses. The Act provides for a system of five schedules of controlled substances as a means of grouping potentially dangerous substances based on their differing potentials for abuse and on their potential for medical use. Penalties for illegal use of the controlled substances vary according to the schedule on which the substance is listed. The health and safety of the public is protected by having a substance placed on the proper schedule. Additionally, proper scheduling ensures appropriate enforcement when a substance is abused or otherwise used illegally.

The Act requires that a controlled substance be placed in Schedule I when there is: (1) a high potential for abuse; (2) no currently accepted medical use in the United States; and (3) a lack of accepted safety for use under medical supervision.

The Drug, Device and Cosmetic Board (Board) met on April 21, 2004. The meeting notice was published in the Pennsylvania Bulletin at 34 Pa. B. 2135 (April 17, 2004). At the meeting, the Board heard the petitions of the Office of Attorney General which

requested that 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) be scheduled as Schedule I controlled substances. The Office of Attorney General presented evidence that these substances are currently scheduled by the Federal Government as Schedule I controlled substances. The fact that these substances are not scheduled at the State level hinders law enforcement agencies in their prosecution for illegal sale and illegal possession. These substances are abused and have a high potential for abuse. There is no currently accepted medical use for these substances in the United States. Further, there is a lack of accepted safety for use under medical supervision.

Based on this information, the Board approved a motion to provide written advice to the Secretary to add these substances to Schedule I of controlled substances, and did so. The Secretary then directed that the substances be added to Schedule I controlled substances. The Department published proposed rulemaking at 34 Pa. B. 5807 (October 23, 2004), proposing to schedule 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) as Schedule I substances. The Department provided a 30-day public comment period.

**B. SUMMARY**

The Department received no comments to the proposed rulemaking, and is adopting its proposed amendments to 28 Pa. Code § 25.72 (relating to schedules of controlled substances) without change. 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) will be scheduled as Schedule I substances.

## C. AFFECTED PERSONS

The general public will benefit from the scheduling of these substances because it would allow for state law enforcement officials to work to remove these substances from the Commonwealth and allow for enforcement and control of the drug abuse problems in the Commonwealth. State law enforcement officials also will benefit because they will be better equipped to enforce the laws to protect the citizens of the state.

## D. FISCAL IMPACT

The amendment to the schedules of controlled substances has no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public. This amendment does not significantly affect costs or savings by the regulated community. These amendments do not require any new legal, accounting or consulting procedures not already being undertaken by the regulated community. There is no measurable fiscal impact on local government because a system exists for the oversight of controlled substances, and there is no measurable fiscal impact on state government.

## E. PAPERWORK REQUIREMENTS

A system already exists for the handling of controlled substances under the Controlled Substance, Drug, Device and Cosmetic Act and the amendments will not increase paperwork for state or local government or the regulated community.

## F. EFFECTIVE DATE/SUNSET DATE

The amendments will become effective immediately upon publication as final rulemaking. There is no sunset date; the regulations will be continually monitored and updated as needed.

## G. STATUTORY AUTHORITY

The amendment to the schedules of controlled substances is made under sections 3 and 4 of the act (35 P.S. §§ 780-103 and 780-104). The amendment is also made under section 2102(g) of the Administrative Code of 1929 (71 P.S. § 532(g)).

Section 3 of the act (35 P.S. § 780 – 103), provides that the Secretary controls all substances listed in Schedules I - V of the act. Section 3(c) of the act (35 P.S. § 780-103(c)) provides that the Secretary shall not reschedule any controlled substance unless specifically authorized by the Board to do so. Subsection 3(a) of the act (71 P.S. § 780-103(a)), provides that the Secretary may add a substance as a controlled substance, and that before doing so, shall request advice in writing from the Board as to whether a substance should be added as a controlled substance. The Secretary sought that advice, and the Board provided it following its April 21, 2004, meeting. The Board

recommended that the substances 1 - (3 – trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy – 4- (N) – Propylthiophenethylamine, and 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT) be added as Schedule I controlled substances. The Secretary then decided that these substances be scheduled as Schedule I controlled substances.

## H. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 13, 2004, the Department submitted a copy of proposed rulemaking, published at 34 Pa. B. 5807 (October 23, 2004) to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for comment. In addition to submitting the proposed regulation, the Department provided the Commission and the Committees with a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

Under Section 5(c) of the Regulatory Review Act, IRRC and the Committees are to be provided with copies of comments received during the public comment period, as well as other documents when requested. The Department received no comments.

Under Section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2), on _____, 2005, the final-form rulemaking was (deemed) approved by the House and

Senate Committees. Under Section 5.1(e) of the regulatory Review Act, IRRC met on _____, 2005, and approved the final-form rulemaking on _____, 2005.

## I. CONTACT PERSON

Questions regarding this final-form rulemaking may be submitted to: Carol Williams, Director, Bureau of Community Program Licensure and Certification, Pennsylvania Department of Health, 132 Kline Plaza, Suite A, Harrisburg, Pennsylvania 17104, (717) 783-8665. Persons with a disability may submit questions in alternate formats; such as large print, audiotape or Braille, or, for speech and/or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services at 1-800-654-5984.

## J. FINDINGS

The Department finds:

(1) Public notice of the intention to adopt the amendment adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, no. 240) (45 P.S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law.

(3) The adoption of the final-form rulemaking in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

## K. ORDER

The Department, acting under the authorizing statutes, orders that:

(a) The regulation of the Department, 28 Pa. Code § 25.72, is hereby amended as set forth in Annex A.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

**ANNEX A**

**DEPARTMENT OF HEALTH**

**TITLE 28 – HEALTH AND SAFETY**

* * *

**PART III. PREVENTION OF DISEASES**

**CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS**

* * *

**§25.72. Schedules of controlled substances.**

* * *

(b) *Schedule I.* In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; no currently accepted medical use in the United States; a lack of accepted safety for use under medical supervision. The following controlled substances are included in this schedule:

* * *

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including the salts, isomers and salts of isomers:

* * *

(xxix) 1 – (3-fluoromethylphenyl) Piperazine (TFMPP)

(xxx) N-Benzylpiperazine (BZP)

(xxxi) Alpha-Methyltryptamine (AMT)

(xxxii) 2 – 5 Dimethoxy – 4 – (N) – Propylthiophenethylamine (2C-T-7)

(xxxiii) 5 – Methoxy – N, N – Diisopropyltryptamine (5-MEO-DIPT)

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

October 31, 2005

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health – Final Regulations No. 10-177
Amending the Schedules for Controlled Substances

Dear Mr. Kaufman:

Enclosed are final-form regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). This final-form regulation amends the schedules for controlled substances.

Section 5.1(a) of the Regulatory Review Act, 71 P.S.§745.5a(a), provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission a copy of the agency's response to comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments were previously forwarded to the Commission by the Department.

Section 5.1(e) of the Regulatory Review Act, 71 P.S. §745.5a(e), provides that the Commission may have until its next scheduled meeting which occurs no less than 30 days after receipt of these regulations, to approve or disapprove the final-form regulations.

POST OFFICE BOX 90, HARRISBURG, PA. 17108 717-787-6436

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Michael Yantis, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Calvin B. Johnson, M.D., M.P.H.
Secretary

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT**

| | |
|---|---|
| I.D. NUMBER: | 10-177 |
| SUBJECT: | Prevention of Disease - Amending the Schedules of Controlled Substances |
| AGENCY: | Department of Health |

# 2440

**TYPE OF REGULATION**

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

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INDEPENDENT REGULATORY REVIEW COMMISSION

**FILING OF REGULATION**

| DATE | SIGNATURE | DESIGNATION |
|---|---|---|
| 11/1/05 | Matthew McKinney | HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES |
| 11/1/05 | | |
| 11/1/05 | | SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE |
| 11/1/05 | | |
| 11/1/05 | Joseph F. Hoffman | INDEPENDENT REGULATORY REVIEW COMMISSION |
| | | ATTORNEY GENERAL (for Final Omitted only) |
| | | LEGISLATIVE REFERENCE BUREAU (for Proposed only) |

July 26, 2005