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

(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 Secondary Contact: Janice Staloski (717) 783-1379

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

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

The Department proposes to amend 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 proposed regulation would schedule 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) would be scheduled as Schedule I controlled substances.

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

The proposed amendments to the regulation at 28 Pa. Code Chapter 25 were approved by the Pennsylvania Drug, Device, and Cosmetics Board on April 21, 2004.

(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 proposed pursuant to Sections 3 and 4 of the act (35 P.S. §§ 780-103 and 780-104). The amendment is also proposed 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 their 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 proposed regulation 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 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.

The proposed regulation would 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.

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(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. 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 proposed regulation would address 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 would benefit from the rescheduling 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 and 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 would be adversely affected by the proposed 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 would be required to comply with the proposed 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. 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 would not significantly affect costs or savings by the regulated community. These amendments would 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 would have no measurable fiscal impact on local government, because a system exists for the oversight 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 would have no measurable fiscal impact on the State government. An administrative paperwork system is already in place and would not measurably change with the rescheduling or scheduling 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				

(20) 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 would 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 would 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. Depending upon the nature and volume of comments received on the proposed amendment, the Department will form an advisory committee or workgroup, conduct workshops or participate in other regulatory review activities with the regulated community, as appropriate, in preparing the final form regulation. At the present time, however, the Department does not anticipate that such will be needed.

(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 would become effective upon publication as final in the Pennsylvania Bulletin.

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

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

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: Amy M. Elliott DEPUTY ATTORNEY GENERAL SEP 28 2004 DATE OF APPROVAL	DEPARTMENT OF HEALTH (AGENCY) DOCUMENT/FISCAL NOTE NO. 10-177 DATE OF ADOPTION: _____ BY: _____ Calvin B. Johnson, M.D., M.P.H. TITLE: Secretary of Health	BY: Tanya Gladhill 9.1.04 DATE OF APPROVAL Asst. (~~Deputy~~ General Counsel) (~~Chief Counsel, Independent Agency~~) (Strike inapplicable title)
☐ Check if applicable. Copy not approved. Objections attached.		☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

DEPARTMENT OF HEALTH

PROPOSED RULEMAKING

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASE

[28 Pa. Code Chapter 25]

Notice is hereby given that the Department of Health (Department) proposes to amend 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). The Department proposes to amend 28 Pa. Code § 25.72 (relating to schedules of controlled substances) to schedule 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) as Schedule I substances, 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).

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.

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. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule I of controlled substances. The Secretary then directed that the substances be scheduled.

The proposed regulation would 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.

B. REQUIREMENTS OF THE AMENDMENT

The proposed amendments would schedule substances on the lists of schedules of controlled substances as follows:

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) would be scheduled as Schedule I.

C. AFFECTED PERSONS

The general public would benefit from the scheduling of these substances because it would allow for state law enforcement officials to begin 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 would also benefit because they would be better equipped to enforce the laws to protect the citizens of the state.

D. FISCAL IMPACT

The proposed amendments to the schedules of controlled substances would have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public.

E. PAPERWORK REQUIREMENTS

A system already exists for the handling of controlled substances under the Controlled Substance, Drug, Device and Cosmetic Act and the proposed amendments would not increase paperwork.

F. EFFECTIVE DATE/SUNSET DATE

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

G. STATUTORY AUTHORITY

The amendment to the schedules of controlled substances is proposed under sections 3 and 4 of the act (35 P.S. §§ 780-103 and 780-104). The amendment is also proposed under 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 their 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.

H. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Department submitted a copy of the proposed regulations on October 13, 2004 to the Independent Regulatory Review Commission and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed regulation, the Department has 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(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed regulations within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the

General Assembly and the Governor of comments, recommendations or objections raised.

I. CONTACT PERSON

Interested persons are invited to submit all questions, comments, suggestions or objections regarding the proposal 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, within 30 days after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who require an alternative format of the proposal; for example, large print, audiotape, Braille, should contact Carol Williams at (717) 783-8665, 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.

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-trifluoromethylphenyl) Piperazine (TFMPP)

(xxx) N-Benzylpiperazine (BZP)

(xxxi) Alpha-Methyltryptamine (AMT)

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

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

* * *

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

October 13, 2004

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Proposed Regulations No. 10-177
Controlled Substances, Drugs, Devices & Cosmetics

Dear Mr. Nyce:

Enclosed are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15).

Section 5(g) of the Regulatory Review Act, 71 P.S. §745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on October 23, 2004. A 30-day comment period is provided.

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, the agency shall submit to the Commission a copy of the agency's response to the 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.

The Department will provide the Commission within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Dawn Anderson, Director of the Office of Policy, at (717) 787-4525.

Sincerely,

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

Enclosures

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

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-177
SUBJECT:	Controlled Substances, Drugs, Devices & Cosmetics
AGENCY:	Department of Health

2440

TYPE OF REGULATION

X Proposed Regulation

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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
10-13-04		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
10/13/04		
		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
10/13/04		
10/13/04		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
10/13/04		LEGISLATIVE REFERENCE BUREAU (for Proposed only)