Regulatory Analysis Form	This space for use by IRRC
(1) Agency PA Department of Health	2004 JAN 28 PM 3:23 REVIEW COMMISSION
(2) I.D. Number (Governor's Office Use) 10-173	IRRC Number: 2340

(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: John Hair (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 is amending 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. A controlled substance is placed in Schedule III when there is a potential for abuse less than the substances listed in Schedules I and II; a well documented and currently accepted medical use in the United States; and when abuse may lead to moderate or low physical dependence. A controlled substance is placed in Schedule IV when there is a low potential for abuse relative to substances in Schedule III; currently accepted medical use in the United States; and limited physical or psychological dependence liability relative to the substances listed in Schedule III. A controlled substance is placed in Schedule V when there is a low potential for abuse relative to the substances listed in Schedule IV; currently accepted medical use in the United States; and limited physical dependence or psychological dependence liability relative to substances listed in Schedule IV.

The regulation reschedules or schedules five substances. Estazolam is rescheduled from Schedule I to Schedule IV. Buprenorphrine is rescheduled from Schedule V to Schedule III. Butorphanol, sibutamine and zolpidem is scheduled as Schedule IV controlled substances.

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

The amendments to the regulation at 28 Pa. Code Chapter 25 were approved by the Pennsylvania Drug, Device, and Cosmetics Board on December 12, 2002.

(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 adopted pursuant to Sections 3 and 4 of the Act, (35 P.S. §§ 780-103 and 780-104.) The amendment is also adopted pursuant to Section 2102(g) of the Act of April 9, 1929, (P.L. 177), as amended, known as the Administrative Code of 1929, 71 P.S. § 532(g). Section 3 of the Act provides that the Secretary of Health (Secretary) shall control all substances listed in Schedule I through V of the Act. Subsection 3(c) (71 P.S. § 780-103(c)) provides that the Secretary shall not reschedule any controlled substance unless specifically authorized by the Drug, Device and Cosmetic Board to do so. The Board has so authorized the Secretary to do so in this case. Subsection 3(a) (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 the advice in writing from the Board whether a substance should be added as a controlled substance. Such advice was sought and received by the Secretary from the Board. The Board recommended that the substances butorphanol, sibutramine and zolipiden be added as Schedule IV 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.

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

The rescheduling of estazolam resolves a conflict between state and Federal Drug Enforcement Agency (DEA) scheduling of this substance. Estazolam is a Schedule IV controlled substance at the Federal level. As a Schedule I substance at the state level, serious problems existed relating to the inability of physicians to prescribe the substance and how law enforcement officials prosecute. Resolution of this conflict is critical since estazolam is commonly prescribed for the short-term management of insomnia.

The rescheduling of buprenorphine also resolves a conflict between state and Federal DEA scheduling. The recent move by the Federal government to reschedule the substance to a Schedule III controlled substance provides a compelling rationale for the state to similarly reschedule the substance. Buprenorphine products have been diverted from legitimate channels through theft, doctor shopping and fraudulent prescriptions. Significant amounts of buprenorphine have been trafficked across international borders and law enforcement authorities have seized large amounts of buprenorhine involved in these activities.

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The above data suggest that the abuse potential of buprenorphine is high and closely resembles other narcotics in Schedule II. However, buprenorphine is a safer drug in overdose than other Schedule II narcotics. Therefore, buprenorphine appears to have somewhat less abuse potential than Schedule I or II narcotic substances but more abuse potential than partial agonists in Schedule IV.

The scheduling of butorphanol, sibutramine and zolpidem allows law enforcement to improve enforcement and prosecution for the illegal manufacture, transport, distribution, sale, possession and use of these substances. The abuse of these substances has experienced a tremendous growth over the past several years. The scheduling of these substances as controlled substances provides law enforcement with much needed tools to address this problem.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

There is little risk associated with not rescheduling estazolam, however, such rescheduling is needed for the reasons stated above. There are great public health, safety and general welfare risks associated with not rescheduling buprenorphine and with failing to schedule butorphanol, sibutamine and zolpidem. Substantial risk of abuse, accompanied by inappropriate scheduling (lower schedule), or 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 the problem. This regulation addresses these problems.

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

Patients using and physicians prescribing estazolam will benefit from its being rescheduled. Patients in need of the drug will be able to obtain it more readily and physicians will not be subject to criminal prosecutions for prescribing it.

The general public benefits from the rescheduling of butorphanol, sibutramine and zolpidem to Schedule IV. Rescheduling buprenorphine and including the other drugs on Schedule IV allows for better enforcement and control of the drug abuse problems in the Commonwealth. Patients in need of buprenorphine for treatment still have access to it through their physicians and drug abuse treatment clinics, but the change allows for stronger controls to minimize the risk that the substance will be diverted for illicit use.

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(14) 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.)

None known.

(15) 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 pharmacies and pharmacists in the Commonwealth, physicians, hospitals, and certain health clinics and drug distributors, manufacturers and distributors who are already complying with the current regulations.

(16) 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 December 12, 2002.

The meeting notice was published in the Pennsylvania Bulletin at 32 Pa. B. 5713 (November 16, 2002).

The Board heard the petition of Abbott Laboratories, which requested that estazolam be rescheduled from Schedule I to Schedule IV. The Board unanimously approved a motion to authorize the Secretary to reschedule the substance.

The Board heard the petition of the Department, which requested that buprenorphine be rescheduled from Schedule V to Schedule III. The Board unanimously approved a motion to authorize the Secretary to reschedule the substance.

The Secretary, upon being authorized by the Drug, Device and Cosmetic Board, directed that the substance estalozam and buprenorphine be rescheduled.

The Board heard the petitions of the Office of Attorney General which requested that butorphanol, including its salts and optical isomers, and sibutramine and zolpidem be scheduled as Schedule IV controlled substances. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule IV of controlled substances. The Secretary directed that these substances be scheduled.

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(17) 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 do 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.

(18) 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 has no measurable fiscal impact on local government because a system exists for the oversight of controlled substances.

(19) 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 has no measurable fiscal impact on state government.

(20) 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.

	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						

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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.

(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 are no apparent adverse effects and costs.

(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.

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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 reschedule follows similar action by the Federal government. This amendment does 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.

(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 will be held. Prior to publication as proposed rulemaking the Drug Device and Cosmetic Board convened a public hearing on the matter, as described in (16), above.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements?

Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

While there may be some change associated with moving a substance from one schedule to another or by adding several substances, there is no measurable change in existing reporting, record keeping or other paperwork requirements.

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(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.

There are no special provisions associated with this regulation.

(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 amendments will become effective upon publication of final rulemaking in the Pennsylvania Bulletin.

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

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)

#2340

2004 JAN 28 PM 3:23

REVIEW COMMISSION

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 Tanya C. Hubbs
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-173	1/9/04 DATE OF APPROVAL
	DATE OF ADOPTION: _____	Asst. (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (Strike inapplicable title)
☐ Check if applicable. Copy not approved. Objections attached.	BY: _____ Calvin B. Johnson, M.D., M.P.H. 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 (Act) (P.L. 233, No. 64) (35 P.S. § 780-101 et seq.) The Department amends 28 Pa. Code § 25.72 (relating to schedules of controlled substances) to reschedule the substance estazolam from Schedule I to Schedule IV, to reschedule the substance buprenorphine from Schedule V to Schedule III, and to schedule butorphanol, sibutramine and zolpidem as Schedule IV controlled substances, as set forth in Annex A hereto.

A. PURPOSE OF THE AMENDMENTS

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 Act requires that a controlled substance be placed in Schedule III when there is: (1) a potential for abuse less than the substances listed in Schedules I and II; (2) there is well documented and currently accepted medical use in the United States; and (3) abuse may lead to moderate or low physical dependence or high psychological dependence.

The Act requires that a controlled substance be placed in Schedule IV when there is: (1) a low potential for abuse relative to substances listed in Schedule III; (2) currently accepted medical use in the United States; and (3) limited physical dependence or psychological dependence liability or both relative to the substances listed in Schedule III.

The Act requires that a controlled substance be placed in Schedule V when there is: (1) a low potential for abuse relative to the substances listed in Schedule IV; (2) currently accepted medical use in the United States; and (3) limited physical dependence or psychological dependence liability or both relative to the substances listed in Schedule IV.

The Drug, Device and Cosmetic Board met on December 12, 2002. The meeting notice was published in the Pennsylvania Bulletin at 32 Pa. B. 5713 (November 16, 2002).

The Board heard the petition of Abbott Laboratories, which requested that estazolam be rescheduled from Schedule I to Schedule IV. The petition was based on the fact that the substance is listed by Drug Enforcement Agency (DEA) regulations as a Schedule IV

controlled substance, there is a low potential for abuse and it has current acceptable medical use in the United States. As a Schedule I substance at the state level, serious problems existed relating to the inability of physicians to prescribe the substance and how law enforcement officials prosecute crimes relating to the illegal manufacture, distribution and possession of the substance. Resolution of this conflict is critical since estazolam is commonly prescribed for the short-term management of insomnia. Rescheduling would allow for the resolution of these conflicting issues between physicians prescribing the substance and law enforcement officials who enforce the Act. Based on this information, the Board unanimously approved a motion to authorize the Secretary of Health (Secretary) to reschedule the substance.

The Board heard the petition of the Department, which requested that buprenorphine be rescheduled from Schedule V to Schedule III. The petition was based on the fact that the DEA has rescheduled the substance from Schedule V to Schedule III, there has been significant abuse and diversion of buprenorphine in many countries, the potential for abuse of buprenorphine is less than the substances listed in Schedules I and II and there is a currently accepted medical use for this substance in the United States. The abuse potential of buprenorphine is high and closely resembles other narcotics in Schedule II, however, buprenorphine is a safer drug in overdose than other Schedule II narcotics. Therefore, buprenorphine appears to have somewhat less abuse potential than Schedule I or II narcotic substances, but more abuse potential than partial agonists in Schedule IV.

Further, buprenorphine is used in treatment of narcotic addiction. Rescheduling allows access to users for treatment, but adds controls to minimize the risk that the substance will be diverted for illicit use. Based on this information, the Board unanimously approved a motion to authorize the Secretary to reschedule the substance.

The Secretary, upon being authorized by the Drug, Device and Cosmetic Board, directed that the substances estalozam and buprenorphine be rescheduled.

The Board heard the petitions of the Office of Attorney General, which requested that butorphanol, including its salts and optical isomers, and sibutramine and zolpidem, be scheduled as Schedule IV controlled substances.

The scheduling of butorphanol, sibutramine and zolpidem allows law enforcement to improve enforcement and prosecution for the illegal manufacture, transport, distribution, sale, possession and use of these substances. There has been a tremendous increase in abuse of these substances over the past several years. These substances are currently scheduled by the DEA as Schedule IV controlled substances. The fact that these substances are not scheduled at the state level hinders law enforcement agencies in their prosecutions for illegal sale and illegal possession of these drugs, so that including them in Schedule IV would provide law enforcement with much needed tools to address this problem.

Further, although these substances are abused, they have a low potential for abuse relative to substances in Schedule III. There is current accepted medical use in the United States for these substances. Butorphanol is classified as an opiate agonist-antagonist analgesic for the relief of moderate to severe pain. Sibutamine is an amphetamine analog that produces central nervous system stimulation and is used for long-term management of obesity. Zolpidem is a sedative.

Based on this information, the Board approved a motion to provide written advice to the Secretary to add these substances to Schedule IV of controlled substances. The Secretary then directed that the substances be added to Schedule IV of controlled substances.

The Department then published proposed rulemaking at 33 Pa. B. 2169 (May 3, 2003). The Department proposed scheduling estazolam, previously listed in Schedule I of the schedule of controlled substances, to Schedule IV, buprenorphine, previously listed in Schedule V of the schedule of controlled substances, to Schedule III, and would have scheduled butorphanol, sibutramine and zolpidem as Schedule IV 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 § 25.72 (relating to schedules of controlled substances) without change. The amendments reschedule or schedule substances on the lists of schedules of controlled substances as follows:

a. The substance estazolam is deleted from Schedule I and rescheduled on Schedule IV.

b. The substance buprenorphine is deleted from Schedule V and rescheduled on Schedule III.

c. The substance butorphanol is scheduled on Schedule IV.

d. The substance sibutamine is scheduled on Schedule IV.

e. The substance zolpidem is scheduled on Schedule IV.

C. AFFECTED PERSONS

Patients using and physicians prescribing estazolam will be affected by its rescheduling. Patients in need of the drug will be able to obtain it more readily and physicians will not be subject to criminal prosecutions for prescribing it.

All pharmacies and pharmacists in the Commonwealth, physicians, hospitals, and certain health clinics and drug distributors, manufacturers and distributors who are already complying with the current regulations will also be affected. They will have to become aware of which substances have been scheduled or rescheduled and deal with those substances appropriately.

The general public will be affected, and will benefit from the rescheduling of buprenorphine and the addition of butorphanol, sibutramine and zolpidem to Schedule IV. Rescheduling buprenorphine and including the other drugs in Schedule IV allows for better enforcement and control of the drug abuse problems in the Commonwealth.

Patients in need of buprenorphine for treatment will continue to have access to it through their physicians and drug abuse treatment clinics, but the changes in scheduling will allow for stronger controls to minimize the risk that the substance will be diverted for illicit use.

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. These amendments do 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 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 amendment does not increase paperwork.

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 amendments to the schedules of controlled substances are adopted pursuant to Sections 3 and 4 of the Act (35 P.S. §§ 780-103 and 780-104). The amendments are also adopted 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 shall control all substances listed in Schedule I through V of the Act. Subsection 3(c) (35 P.S. § 780-103(c)) provides that the Secretary shall not reschedule any controlled substance unless specifically authorized by the Drug, Device and Cosmetic Board to do so. The Board has authorized the Secretary to reschedule estazolam and buprenorphine.

Subsection 3(a) (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 December 12, 2002 meeting. The Board recommended that the substances butorphanol, sibutramine and zolipiden be added as Schedule IV 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)), on April 17, 2003, the Department submitted a copy of the notice of proposed rulemaking, published at 33

Pa. B. 2169, to IRRC and the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and comment.

Under section 5 (c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form rulemaking, the Department has considered all comments from IRRC, the Committees and the public.

Under section 5.1 (j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2), on _____, 2004, 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 _____, 2004, and approved the final-form rulemaking on _____, 2004.

I. CONTACT PERSON

Questions regarding these final-form regulations may be submitted to John C. Hair, 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 alternative formats; such as audio tape, Braille or for speech and/or hearing impaired persons, by using V/TT: (717) 783-6514 or the Pennsylvania AT&T Relay Services at 1-800-654-5984 [TT]. Persons who require an alternative format of this document (that is, large print, audio tape,

Braille) should contact Mr. Hair at the above listed address or telephone numbers so that he may make necessary arrangements.

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) A regulation of the Department, 28 Pa. Code § 25.72, is amended to read 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 of Health 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:

* * *

(x)	[Estazolam
(xi)]	Ethyl loflazepate.
[(xii)] (xi)	Fludiazepam.
[(xiii)] (xii)	Flunitrazepam.
[(xiv)] (xiii)	Haloxazolam.
[(xv)] (xiv)	Ketazolam.
[(xvi)] (xv)	Loprazolam.
[(xvii)] (xvi)	Lormetazepam.
[(xviii)] (xvii)	Medazepam.
[(xix)] (xviii)	Nimetazepam.
[(xx)] (xix)	Nitrazepam.
[(xxi)] (xx)	Nordiazepam.
[(xxii)] (xxi)	Oxazolam.
[(xxiii)] (xxii)	Pinazepam.
[(xxiv)] (xxiii)	Tetrazepam.
[(xxv)] (xxiv)	3, 4-Methylenedioxymethamphetamine (MDMA)
[(xxvi)] (xxv)	4-methylaminorex.
[(xxvii)] (xxvi)	Cathinone.
[(xxviii)] (xxvii)	Methcathinone HCL.
[(xxix)] (xxviii)	Dimethylamphetamine.

* * *

(d) *Schedule III.* In determining that a substance comes within this schedule, the Secretary will find: a potential for abuse less than the substances listed in Schedule I and II; well documented and currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence. The following classes of controlled substances are included in this schedule:

* * *

(10) Buprenorphine.

(e) *Schedule IV.* In determining that a substance comes within this schedule, the Secretary will find: a low potential for abuse relative to substances in Schedule III; currently accepted medical use in the United States; and limited physical or psychological dependence liability relative to the substances listed in Schedule III. The following controlled substances are included in this schedule:

(1) A material, compound, mixture or preparation, unless specifically excepted or unless listed in another schedule, which contains a quantity of the following substances:

* * *

(xxv) Estazolam.

(xxvi) Zolpidem.

* * *

(3) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including its salts, isomers whether optical position or geometric, and salts of the isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

* * *

(xi) Butorphanol.

(xii) Sibutramine.

* * *

(f) *Schedule V.* In determining that a substance comes within this schedule, the Secretary [shall] will find: a low potential for abuse relative to the substances listed in Schedule IV; currently accepted medical use in the United States; and limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV. The following controlled substances are included in this schedule:

* * *

(2) [Buprenorphine.

(3)] Propylhexadrine, except when labeled for over-the-counter drug sale in conformity with 21 CFR 1308.15 (relating to schedule V).

[(4)] (3) Pyrovalerone.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

January 28, 2004

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

Re: Department of Health – Final Regulations No. 10-173
Amendments to Schedules of Controlled Substances

Dear Mr. Nyce:

Enclosed are final-form regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). These regulations schedule and reschedule various substances on the Schedules of 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.

The Department received no comments on these regulations.

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 Dawn Jackson, Director of the Office of Policy, at (717) 787-4525 or Michael Yantis, Acting 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:	10-173
SUBJECT:	Prevention of Disease
AGENCY:	Department of Health

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

2004 JAN 28 PM 3:23
REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1/28/04	D. Lucker	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
1/28/04	Jd Chan	
1/28/04	Kristi Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
1/28	Lauraine Calvin	
1/28/04	Elena Page	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

January 12, 2004