Regulatory Analysis Form	This space for use by IRRC
(1) Agency PA Department of Health	
(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 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. 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 proposed regulation would reschedule or schedule five substances. Estazolam would be rescheduled from Schedule I to Schedule IV. Buprenorphrine would be rescheduled from Schedule V to Schedule III. Butorphanol, sibutamine and zolpidem would be scheduled as Schedule IV controlled substances.

Regulatory Analysis Form

The proposed amendments to the schedules 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 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 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 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 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 would resolve 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 exist 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 would also resolve 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 also 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.

Regulatory Analysis Form

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 would allow 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 would provide 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 proposed regulation would address 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 would benefit from its being rescheduled. Patients in need of the drug would be able to obtain it more readily and physicians would not be subject to criminal prosecutions for prescribing it.

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

Regulatory Analysis Form

(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 of Health 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 of Health, 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.

Regulatory Analysis Form

(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 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.

(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 would have 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 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.

(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						

Regulatory Analysis Form

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 would be 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.

Regulatory Analysis Form

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 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.

(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 (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?

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 would be no measurable change in existing reporting, record keeping or other paperwork requirements.

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.

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 would be no measurable change in existing reporting, record keeping or other paperwork requirements.

(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?

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 (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 would be needed.

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)

#2340

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 _____
DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-173	1/22/03
FEB 14 2003	DATE OF ADOPTION: _____	DATE OF APPROVAL
	Robert S. Zimmerman, Jr.	(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)
☐ 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

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 (Act) (P.L. 233, No. 64) (35 P.S. § 780-101 et seq.) The Department proposes to amend 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 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 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 DEA regulations as a Schedule IV controlled substance, there is a

substance is listed by 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. Rescheduling would also allow for resolution of conflicting issues between physicians prescribing the substance and law enforcement officials who enforce the Act. The Board unanimously approved a motion to authorize the Secretary of Health to reschedule the substance.

The Board also 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, significant abuse and diversion of buprenorphine has been in many countries, the potential for abuse is less than the substances listed in Schedules I and II and there is currently accepted medical use in the United States. Buprenorphine is used in treatment of narcotic addiction. Rescheduling allows access to users for treatment, but adds controls to minimize diversion. The Board unanimously approved a motion to authorize the Secretary to reschedule the substance.

The Secretary of Health, 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.

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 prosecution for illegal sale and illegal possession. These substances are abused but 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. 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 scheduled.

The proposed regulation would reschedule estazolam, previously listed in Schedule I of the schedule of controlled substances, to Schedule IV, would reschedule buprenorphine, previously listed in Schedule V of the schedule of controlled substances, to Schedule III, and would schedule butorphanol, sibutramine and zolpidem as Schedule IV substances.

B. REQUIREMENTS OF THE AMENDMENT

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

a. The substance estazolam would be deleted from Schedule I and rescheduled on Schedule II.

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

c. The substance butorphanol would be scheduled on Schedule IV.

d. The substance sibutamine would be scheduled on Schedule IV.

e. The substance zolpidem would be schedule on Schedule IV.

C. AFFECTED PERSONS

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

The general public would 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 would allow for better enforcement and control of the drug abuse problems in the Commonwealth. Patients in need of buprenorphine for treatment would still have access to it through their physicians and drug abuse treatment clinics, but the changes would allow for stronger controls to minimize the risk that the substance will be diverted for illicit use.

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 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 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 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. § 745.1 et seq., the Department submitted a copy of the proposed regulations on April 17, 2003 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: 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, 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 John Hair 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:

* * *

[(x) Estazolam.]	
[(xi)] (x)	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.
[(xxii)] (xx)	Nordiazepam.
[(xxi)] (xxii)	Oxazolam.
[(xxiii)] (xxi)	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 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)] (2) 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

April 11, 2003

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. 10-173
Amendments to Schedules of Controlled Substances

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 April 26, 2003. 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 Deborah Griffiths, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Robert S. Muscalus, D.O.
Acting Secretary of Health

Enclosures

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

bcc: Robert S. Muscalus, D.O.
Richard Lee
Brian Ebersole
Deborah Griffiths
Steven V. Turner
Barbara J. Holland
Yvette M. Kostelac
Keith B. Fickel

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-173
SUBJECT:	Controlled Substances, Drugs, Devices & Cosmetics
AGENCY:	Department of Health

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
4-17-03		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
4-17-03		
4-17-03		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
4-17-03		
4/17/03		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
4/17/03		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

February 20, 2003