Approved: 2-10-98
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on February 5, 1998 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Emalene Correll, Legislative Research Department
Robin Kempf, Legislative Research Department
Norman Furse, Revisor of Statutes
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

Larry Froelich, Executive Director, Kansas Board of Pharmacy

Others attending: See attached list

Hearing on SB 484 - Requirements for pharmacists filling transferred prescriptions

Larry Froelich, Executive Director, Kansas Board of Pharmacy, submitted written testimony in support of **SB 484** which concerns the procedures for filling transferred prescriptions that are included in the Pharmacy Practice Act. The bill strikes antiquated language included in current law that describes the way a paper record keeping system must be updated to reflect the transfer of a prescription from one pharmacy to another. Mr. Froelich noted that most pharmacies now use computerized record keeping systems, and the bill would remove the need for updating a paper record keeping system. However, for some prescriptions that contain federally controlled substances, federal regulations mandate the updating of the paper record keeping system, and the bill would add language that would require pharmacies to follow federal regulations in those instances. Mr. Froelich also requested a change in the effective date of the bill from "statute book" to "Kansas Register" in order to comply with federal regulations. (See Attachment 1) During Committee discussion it was suggested that the language "prescription transfer information" on page 2, line 8 of the bill be clarified by striking the word "information".

There were no opponents on **SB 484**.

Action on SB 484

Senator Jones made a motion to amend **SB 484** by striking the word "information" on page 2, line 8, and that the effective date of **SB 484** be changed to "Kansas Register", seconded by Senator Hardenburger. The motion carried.

Senator Hardenburger made a motion that the Committee recommend SB **484 as amended** favorably for passage, seconded by Senator Becker. The motion carried.

Hearing on SB 485 - Schedule IV controlled substances

Larry Froelich, Board of Pharmacy, submitted written testimony in support of **SB 485** which would amend the Uniform Controlled Substances Act, and add to schedule IV of the act, the substances Sibutramine and Butorphanol. It was pointed out that the Board of Pharmacy believes that the Drug Enforcement Administration has reviewed the information available on these products and has determined that both products warrant being listed as Schedule IV controlled substances. (Attachment 2) During Committee discussion it was questioned when the federal government would schedule the controlled substances, and the Chair announced that the hearing on the bill will be closed, but action on the bill would be held until that information is obtained.

Hearing on SB 507 - Pharmacy practice act amendments, civil fines, licenses suspension or revocation

Larry Froelich, Board of Pharmacy, addressed the Committee in support of **SB 507** which would license pharmacists for a biennial period, affect language referencing continuing education requirements, allow the Board to take action against a pharmacist license based on action that has been done by another jurisdiction, and allow the maximum fining amount to change from $500 per violation to $5,000 per violation. Mr. Froelich also proposed additional language that would require examination fees be paid directly to the examination service as noted in his written testimony. (Attachment 3) Committee discussion related to changes in the bill that would affect continuing education requirements from annual to biennially, clarification of language in the bill relating to odd and even numbered licensees paying the examination fee, and a follow-up on the fiscal note of the bill relating to changes in the examination fees paid directly to the examination service.

Adjournment

The meeting was adjourned at 11:00 a.m.

The next meeting is scheduled for February 10, 1998.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
GUEST LIST

DATE: 2-5-98

NAME	REPRESENTING
Larry Froelich	Bd. of Pharmacy

Kansas State Board of Pharmacy

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900 S.W. JACKSON STREET, ROOM 513
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STATE OF KANSAS

BILL GRAVES
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EXECUTIVE DIRECTOR
LARRY C. FROELICH

BOARD ATTORNEY
DANA W. KILLINGER

1998 KANSAS LEGISLATIVE SESSION

Senate Bill No. **484**

PHARMACY PRACTICE ACT

Senate Committee on Public Health and Welfare

Thursday, February 5, 1998

SENATOR SANDY PRAEGER, Chairperson,
SENATOR LARRY SALMANS, Vice Chairperson,
COMMITTEE MEMBERS

Madam Chairman and members of the committee, my name is Larry Froelich and I serve as the executive secretary to the Board of Pharmacy. I appear before you today on behalf of the board in support of **SB 484**.

K.S.A. 65-1656 is entitled "Transfer of prescriptions and files from one pharmacy to another, establishing conditions and exceptions to such transfers." I would like to take a few moments to explain current procedure, and then explain the how these proposed changes would effect current practice.

Current practice: A patient takes a prescription into the pharmacy for initial filling. The prescription is entered into the computer system at the pharmacy. Upon filling, the computer generates a hard copy prescription from the entered information which is then attached to the prescription that the patient brought into the pharmacy. This is then filed away. When the patient requests a refill, the prescription number is entered into the computer system and brought up onto the screen where it is processed for refilling. All records of the transaction are maintained in the computer with reports generated at the end of the day showing which prescriptions have been filled and the quantities, etc. When a patient asks a pharmacist at another store to fill their prescription, the pharmacist at the second pharmacy calls the first pharmacy and obtains all the required information from the first pharmacist. The pharmacist at the first pharmacy gets all the information from the computer screen. Once the transfer has been completed, the pharmacist at the first pharmacy must then retrieve the prescription from their files and **write void** on the face of the prescription. If it were not for this final step, the pharmacist would never access the original prescription after the initial filling.

Changed practice: The same scenario would exist in the transfer process except that the pharmacist at the first pharmacy would not have to retrieve the original prescription from the files to write void on the prescription. Rather, the pharmacist can void the prescription in the computer system. If the pharmacist relies daily on the computer system to refill prescriptions, it makes more sense to

make sure that the prescription is voided at the point that the prescription is being refilled from. I believe the intent of the law to void the prescription was to make sure that the pharmacist does not refill a prescription after it has been transferred to another pharmacy. This prevents the patient from having multiple prescriptions available for refilling of the same medication. Consumer protection will remain in effect, and will allow the pharmacy to void the prescription on the computer screen which is accessed more frequently.

The second change adds language that references the code of federal regulations section 1306.25. This language is proposed to reference the transfer of controlled substance prescriptions.

Although the original wording of the bill suggests that it take effect when published in the statute book, I would like to request that the committee favorably pass this out of committee after changing the verbiage to state "after publication in the *Kansas Register*".

I will be glad to answer any questions the committee may have.

Kansas State Board of Pharmacy

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1998 KANSAS LEGISLATIVE SESSION
Senate Bill No. **485**

CONTROLLED SUBSTANCES ACT

Senate Committee on Public Health and Welfare

Thursday, February 5, 1998

SENATOR SANDY PRAEGER, Chairperson,
SENATOR LARRY SALMANS, Vice Chairperson,
COMMITTEE MEMBERS

Madam Chairperson and members of the committee, my name is Larry Froelich and I serve as the executive secretary to the Board of Pharmacy. I appear before you today on behalf of the board in support of **SB 485**.

K.S.A. 65-4111 is entitled "Substances included in Schedule IV." I have enclosed copies of the applicable Federal Register that pertains to each requested medication. I am also enclosed copies of letters to the President of the Senate and Speaker of the House discussing the intent of this bill as required by K.S.A. 65-4102.

The Board of Pharmacy believes that the Drug Enforcement Administration (DEA) has reviewed the information available on these products, and has determined that both products warrant being listed as Schedule IV controlled substances. When a product is placed into the schedule IV category, it is subject to a new prescription every six months and/or five refills, whichever comes first.

Butorphanol is sold under the trade names: Stadol®, Torbugesic® and Torbutrol®.

Sibutramine is sold under the trade name Meridia®.

I will be glad to answer any questions the committee may have.

by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 97–ASO–26." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class E airspace area at New Bern, NC. The required weather observation information is available on a continuous basis to the air traffic control facility providing service to New Bern, Craven County, NC, Airport. Therefore, the Class E surface area airspace at New Bern, NC, meets the requirement for modification from part time to continuous. Class E airspace areas designated as a surface area for an airport are published in Paragraph 6002 of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

ASO NC E2—New Bern, NC [Revised]

New Bern, Craven County Regional Airport, NC
(Lat 35°04'21" N, long. 77°02'37" W)
New Bern VOR/DME
(Lat 35°04'23" N, long 77°02'42" W)

Within a 4-mile radius of Craven County Regional Airport and within 2.4 miles each side of New Bern VOR/DME 038° and 210° radials, extending from the 4-mile radius northeast and southwest of the VOR/DME.

* * * * *

Issued in College Park, Georgia, on November 24, 1997.

Nancy B. Shelton,
Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–32035 Filed 12–5–97; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 173P]

Schedules of Controlled Substances: Proposed Placement of Sibutramine into Schedule IV

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Acting Deputy Administrator of the DEA to place the substance, sibutramine, including its salts and optical isomers into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) that sibutramine be added to Schedule IV and on an evaluation of the relevant data by the DEA. If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule IV on those who handle sibutramine and products containing sibutramine.

DATES: Comments, objections, and requests for a hearing must be received on or before January 7, 1998.

ADDRESSES: Comments, objections and requests for a hearing should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attn.: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, (202) 307–7183.

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SUPPLEMENTARY INFORMATION:
Sibutramine is an amphetamine analogue pharmacologically similar to other anorectic agents that produce central nervous system stimulation and amphetamine-like effects in humans and animals. Sibutramine hydrochloride will be marketed under the trade name of MERIDA as an oral anorectic for the long term management of obesity.

The Acting Deputy Administrator of the DEA received a letter dated November 12, 1997 from the Acting Assistant Secretary for Health, on behalf of the Secretary of the DHHS, recommending that the substance, sibutramine, and salts and isomers thereof, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the letter from the Assistant Secretary was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Control of Sibutramine and its Salts in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(b)] and the summarized recommendations regarding the placement of sibutramine into Schedule IV of the CSA.

The factors considered by the Assistant Secretary for Health with respect to the drug sibutramine were:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary of Health, the FDA New Drug Application (NDA) approval on November 22, 1997, and a DEA review, the Acting Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Sibutramine has a low potential for abuse relative to the drugs or other substances in Schedule III.

(2) Sibutramine has a currently accepted medical use in treatment in the United States.

(3) Abuse of sibutramine may lead to limited physical dependence and psychological dependence relative to the drugs or other substances in Schedule III.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR. In the event that comments, objections or requests for a hearing raise one or more issues which the Acting Deputy Administrator finds warrants a hearing, the Acting Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking on the record after opportunity for a hearing. Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Sibutramine is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marked once it is placed into Schedule IV of the CSA. This proposed rule, if finalized, will allow these entities to have access to a new pharmaceutical product.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, drug traffic control, narcotics, prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

§ 1308.14 [Amended]

2. Section 1308.14 is proposed to be amended by redesignating the existing paragraph (e)(10) as (e)(11) and adding a new paragraph (e)(10) to read as follows:

§ 1308.14 Schedule IV

* * * * *

(10) Sibutramine 1675

* * * * *

Dated: December 2, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97-31951 Filed 12-5-97; 8:45 am]

BILLING CODE 4410-09-M

2-3

Subject: Butorphanol moves to C-IV
Date: Wed, 1 Oct 1997 13:15:23 -0700
From: Ken Reed <gumdr@gumdr.com>
Reply-To: dental-drugs@stat.com
To: dental-drugs@stat.com

[Federal Register: October 1, 1997 (Volume 62, Number 190)]
[Rules and Regulations] [Page 51370-51371]

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308 [DEA-166F]
Schedules of Controlled Substances Placement of Butorphanol Into Schedule IV

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of butorphanol and products containing butorphanol.

EFFECTIVE DATE: October 31, 1997.

FOR FURTHER INFORMATION CONTACT:
Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Butorphanol is classified as an opioid agonist-antagonist analgesic that is marketed as a prescription drug under the trade name Stadol for the relief of moderate to severe pain in humans. It is also marketed as a veterinary product under the trade names Torbugesic and Torbutrol for use in horses and dogs. It was first marketed as an injectable product in 1979. Although there was limited abuse of the injectable product among certain populations, significant abuse was not observed until after the nasal spray was introduced in 1992.

The Acting Deputy Administrator of the DEA received a letter dated September 30, 1996, from the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services (DHHS), recommending that the drug product, Stadol NS Nasal Spray, be placed into Schedule IV of the CSA. Enclosed with the September 30, 1996, letter from the Assistant Secretary was a scientific and medical evaluation prepared by the Food and Drug Administration (FDA). The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)). Correspondence from the Acting Assistant Secretary for Health dated June 19, 1997, confirmed that the DHHS recommendation included the substance butorphanol and its salts and isomers. The Acting Deputy Administrator of the DEA, in a July 10, 1997, Federal Register notice (62 FR 37004 proposed to place butorphanol into Schedule IV of the CSA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for a hearing in writing on the proposed scheduling of butorphanol until August 11, 1997. DEA received nine comments regarding the proposal. Comments in support of the proposal

were received from six organizations: National Association of Boards of Pharmacy, Missouri Department of Mental Health, Missouri Department of Health, Missouri Department of Economic Development's State Board of Registration for the Healing Arts, Texas State Board of Pharmacy and Public Citizen. The American Veterinary Medical Association noted that controlled substances are subject to additional recordkeeping and storage requirements, but recognized the abuse potential of butorphanol. It recommended that if butorphanol is to be controlled, it be classified at a level no greater than Schedule IV.

Bristol-Myers Squibb commented that the abuse potential of butorphanol nasal spray is low, as evidenced by the low number of adverse reaction reports received by the company per number of prescriptions. Bristol-Myers Squibb did support the placement of butorphanol in Schedule IV. Fort Dodge Animal Health commented that there was little abuse of the butorphanol veterinary products and did not support the scheduling of the veterinary products. This scheduling action, however, is based on the abuse and dependence potentials of the substance butorphanol. It was determined that butorphanol, whether administered orally, intravenously, or intranasally, had an abuse potential consistent with control in Schedule IV of the CSA. Furthermore, available data does not differentiate the abuse potential of butorphanol-containing human products from that of veterinary products. Fort Dodge presented no additional data in this regard.

Based on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act [21 U.S.C. 811(b)], and the independent review of the DEA, the Acting Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Butorphanol has a low potential for abuse relative to the drugs or other substances in Schedule III;

(2) Butorphanol has a currently accepted medical use in treatment in the United States; and

(3) Abuse of butorphanol may lead to limited physical dependence and psychological dependence relative to the drugs or other substances in Schedule III.

Based on these findings, the Acting Deputy Administrator of the DEA concludes that butorphanol, including its salts and isomers, warrants control in Schedule IV in the CSA. The Schedule IV controls of butorphanol will be effective on October 31, 1997, except as indicated below. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding butorphanol. The applicable regulations are as follows:

1. Registration. Any person who manufactures, distributes, dispenses, imports or exports butorphanol activities or who engages in research or conducts instructional activities with butorphanol, or who proposes to engage in such activities, must submit an application for Schedule IV registration in accordance with Part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently lawfully engaged in any of the above activities must submit an application for registration by October 31, 1997. Any such person may then continue their lawful activities until the Administration has approved or denied that application.

2. Security. Butorphanol must be manufactured, distributed and stored in accordance with Secs. 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

2-5

3. Labeling and Packaging. All labels on commercial containers of, nd all labeling of, butorphanol which is distributed on and after April 1, 1998 shall comply with the requirements of Secs. 1302.03-1302.07 of Title 21 of the Code of Federal Regulations. Any commercial containers of butorphanol packaged on or before April 1, 1998 and not meeting the requirements specified in Secs. 1302.03-1302.07 of Title 21 of the Code of Federal Regulations shall not be distributed on or after July 1, 1998.

4. Inventory. Registrants possessing butorphanol are required to take inventories pursuant to Secs. 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. Records. All registrants must keep records pursuant to Secs. 1304.03, 1304.04 and 1304.21-1304.23 of Title 21 of the Code of Federal Regulations.

6. Prescriptions. All prescriptions for butorphanol are to be issued pursuant to Secs. 1306.03-1306.06 and 1306.21-1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for products containing butorphanol issued on or before October 31, 1997, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after April 1, 1998.

7. Importation and Exportation. All importation and exportation of butorphanol shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. Criminal Liability. Any activity with butorphanol not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after October 31, 1997.

In accordance with the provisions of 21 U.S.C. 811(a) of the CSA, this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Butorphanol products are prescription products. Handlers of butorphanol also handle other controlled substances which are already subject to the regulatory requirements of the CSA.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Acting Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby amends 21 CFR part 1308 as follows.

PART 1308--[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by adding a new paragraph (f)(2) to read as follows:

Kansas State Board of Pharmacy

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STATE OF KANSAS

EXECUTIVE DIRECTOR
LARRY C. FROELICH

BOARD ATTORNEY
DANA W. KILLINGER

BILL GRAVES
GOVERNOR

February 3, 1998

The Honorable Representative Shallenburger
Speaker of the House
Topeka State Capitol, Room 380-W
Topeka, Kansas

Dear Representative Shallenburger:

I serve as the executive secretary of the Kansas Board of Pharmacy. Pursuant to K.S.A. 65-4102, the Board of Pharmacy is to submit its proposal to the Speaker of the House and the President of the Senate with a listing of medications for scheduling as controlled substances.

The Drug Enforcement Administration (DEA) has published the scheduling of Butorphanol and Sibutramine in the *Federal Register*. I have enclosed copies of the applicable parts of the publications. The DEA has scheduled these medications as Schedule IV controlled substances. The Board of Pharmacy has requested that the Senate Committee on Public Health and Welfare review this proposal and the Board is respectfully requesting favorable passage of SB-485.

Please accept this letter as notice of the report for compliance of K.S.A. 65-4102. If I may answer any questions, or be of further help, please contact me at 296-8419.

Sincerely,

Larry Froelich, RPh
Executive Secretary

Enclosures

cc: Board members

Kansas State Board of Pharmacy

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STATE OF KANSAS

EXECUTIVE DIRECTOR
LARRY C. FROELICH

BOARD ATTORNEY
DANA W. KILLINGER

BILL GRAVES
GOVERNOR

February 3, 1998

The Honorable Senator Bond
President of the Senate
Topeka State Capitol, Room 359-E
Topeka, Kansas

Dear Senator Bond:

I serve as the executive secretary of the Kansas Board of Pharmacy. Pursuant to K.S.A. 65-4102, the Board of Pharmacy is to submit its proposal to the President of the Senate and the Speaker of the House with a listing of medications for scheduling as controlled substances.

The Drug Enforcement Administration (DEA) has published the scheduling of Butorphanol and Sibutramine in the *Federal Register*. I have enclosed copies of the applicable parts of the publications. The DEA has scheduled these medications as Schedule IV controlled substances. The Board of Pharmacy has requested that the Senate Committee on Public Health and Welfare review this proposal and the Board is respectfully requesting favorable passage of SB-485.

Please accept this letter as notice of the report for compliance of K.S.A. 65-4102. If I may answer any questions, or be of further help, please contact me at 296-8419.

Sincerely,

Larry Froelich, RPh
Executive Secretary

Enclosures

cc: Board members

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Kansas State Board of Pharmacy

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1998 KANSAS LEGISLATIVE SESSION
Senate Bill No. **507**

PHARMACY PRACTICE ACT

Senate Committee on Public Health and Welfare

Thursday, February 5, 1998

SENATOR SANDY PRAEGER, Chairperson,
SENATOR LARRY SALMANS, Vice Chairperson,
COMMITTEE MEMBERS

Madam Chairman and members of the committee, my name is Larry Froelich and I serve as the executive secretary to the Board of Pharmacy. I appear before you today on behalf of the board in support of **SB 507**.

The current licensing period for a pharmacist is an annual period, expiring June 30th of each year. The proposed change would license pharmacists for a biennial period. The licensing amounts would remain the same, currently $100 per year is the statutory maximum that the board has on these licenses, and this would change to $200 for two years. Additional changes would affect language referencing continuing education requirements, with no overall change in the amounts. The current requirement of 15 continued education hours for each one year period would change to 30 hours for the two year licensing period.

Another language change in the bill would allow the board to take action against a pharmacist license based on action that has been done by another jurisdiction. Using the evidence obtained by that jurisdiction as conclusive evidence for the Kansas Board of Pharmacy to act upon.

The last change to the Pharmacy Act would allow the maximum fining amount to change from $500 per violation to $5,000 per violation. All amounts collected by this increase would be credited to the state general fund.

I would like to suggest additional language to this bill. Taking language from a previous bill before this committee (SB-467), and adding the section: "The board may require that examination fees be paid directly to the examination service. Fees paid directly to the examination service for initial examination or any subsequent examination shall be in an amount determined by such service which amount shall be approved by the board." Although the original wording of the bill does not include this language, I would like to respectfully request that the committee favorably add this language. The board office has the candidate pay $300 for the exam with their application. With 20% of the money going to the general fund, the board nets $240. After the exam has been given, the exam is billed to the office for $250 which results in a loss to the board of $10 per exam.

If $250 is paid directly to the exam service and $50 to the board, the office would give $10 of that amount into the general fund. The general fund would net $10 per exam (as opposed to $60) and the board would net $40 per exam as opposed to **-$10**.

On behalf of the board, I respectfully request the committee's favorable passage and subsequent support of SB 507. I will be glad to answer any questions the committee may have.