MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

1096

2001 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1096

2001 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1096

House Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date Jan 16, 2001

Tape Number	Side A	Side B	Meter #
2	X		0-10.95
Committee Clerk Signature			

Minutes:Chairman R. Berg, Vice-Chair G. Keiser, Rep. M. Ekstrom, Rep. R. Froelich, Rep. G. Froseth, Rep. R. Jensen, Rep. N. Johnson, Rep. J. Kasper, Rep. M. Klein, Rep. Koppang, Rep. D. Lemieux, Rep. B. Pietsch, Rep. D. Ruby, Rep. D. Severson, Rep. E. Thorpe.

Chairman Berg: Let's open the hearing on HB 1096.

Howard Anderson Jr., R. Ph.: *Executive Director of the ND Board of Pharmacy*

written testimony

Rep Ekstrom: In section 7, does the pharmacy ever receive that original perscription as part of the record?

Anderson: No, under this that should not be necessary.

Chairman Berg: Is there any risk of someone else using that original perscription?

Anderson: No because that is part of the chart work.

Rep Ekstrom: With the liabilty chain of command, when only a fax is evidence that may become a little hairy.

Anderson: I don't think that will be a problem, it's just speeding up the perscription to the pharmacist.

Chairman Berg: Any other questions? Any one else here to testify on HB 1096? With that we'll close the hearing on HB 1096.

Rep Ekstrom: I recommend a do pass.

Rep Johnson: I second.

Chairman Berg: Motion is carried. **14 aye, 0 nay, 1 absent. Rep Kasper carries.**

Date: 1-16-01
Roll Call Vote #: 1

2001 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. ~~Click here to type Bill/Resolution No.~~ 1096

House Industry, Business and Labor Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass

Motion Made By Ekstrom Seconded By Johnson

Representatives	Yes	No	Representatives	Yes	No
Chairman- Rick Berg	✓		Rep. Jim Kasper	✓	
Vice-Chairman George Keiser	✓		Rep. Matthew M. Klein	✓	
Rep. Mary Ekstorm	✓		Rep. Myron Koppang	✓	
Rep. Rod Froelich	✓		Rep. Doug Lemieux	✓	
Rep. Glen Froseth	✓		Rep. Bill Pietsch	✓	
Rep. Roxanne Jensen	✓		Rep. Dan Ruby	✓	
Rep. Nancy Johnson	✓		Rep. Dale C. Severson	✓	
			Rep. Elwood Thorpe	A	

Total (Yes) 13 No 0

Absent 2

Floor Assignment Koppang

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1096: Industry, Business and Labor Committee (Rep. Berg, Chairman) recommends **DO PASS** (13 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). HB 1096 was placed on the Eleventh order on the calendar.

2001 SENATE INDUSTRY, BUSINESS AND LABOR

HB 1096

2001 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1096

Senate Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date February 14, 2001.

Tape Number	Side A	Side B	Meter #
1	x		29.2 to 40
Committee Clerk Signature	Dora E Perez		

Minutes:

The meeting was called to order. All committee members present. Hearing was opened on HB 1096 relating to the practice of pharmacy.

Howard Anderson, Executive Director, ND Board of Pharmacy, in favor. Written testimony attached.

Senator Mutch: page 1 line 23 "otherwise permitted" refers to what?

H Anderson: refers to limitations within their specialty.

Senator Espegard: Would this apply to optometrists prescribing medication other than for glaucoma?

H Anderson: No.

Galen Jordre, ND Pharmaceutical Assn. In favor

No opposing testimony. Hearing closed.

Discussion held. **Senator Klein**: Motion: do pass. **Senator Espegard**: Second.

Roll call vote: 7 yes; 0 no. Motion carried. Floor assignment : **Senator Espegard.**

Date: 2/14/01
Roll Call Vote #: 1

2001 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1096

Senate Industry, Business and Labor Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass

Motion Made By S Klein Seconded By S Espegaard

Senators	Yes	No	Senators	Yes	No
Senator Mutch - Chairman	✓		Senator Every	✓	
Senator Klein - Vice Chairman	✓		Senator Mathern	✓	
Senator Espegard	✓				
Senator Krebsbach	✓				
Senator Tollefson	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Sen Espegaard

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
February 14, 2001 11:44 a.m.

Module No: SR-27-3306
Carrier: Espegard
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

HB 1096: Industry, Business and Labor Committee (Sen. Mutch, Chairman) recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1096 was placed on the Fourteenth order on the calendar.

2001 TESTIMONY

HB 1096

Board of Pharmacy
STATE OF NORTH DAKOTA
EDWARD T. SCHAFER, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
P.O. Box 1354
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WILLIAM J. GROSZ, Sc.D., R.Ph.
Wahpeton, Treasurer
HOWARD C. ANDERSON, Jr., R.Ph.
Turtle Lake, Executive Director

HOUSE BILL No. 1096
INDUSTRY, BUSINESS AND LABOR COMMITTEE
TUESDAY- JANUARY 16, 2001 – 2:00 PM – PEACE GARDEN ROOM

Chairman Berg, members of the Industry, Business and Labor Committee, for the record I am Howard C. Anderson, Jr., R.Ph., Executive Director of the North Dakota State Board of Pharmacy.

Thank you for the opportunity to appear before you today. This Bill was introduced at the request of the State Board of Pharmacy and contains changes necessary to help pharmacists care for their patients and primarily expands our laws to the greatest extent possible under the federal regulations.

Sections 1 - 2 and 8 change the definition of prescription drug in the various sections in the North Dakota Law to include the Rx Only language adopted by the Food and Drug Administration. Manufacturers, packagers and labelers of prescription medication asked the FDA to simplify and shorten the designation of a prescription drug since the caution: "Federal Law Prohibits Dispensing Without Prescription" took up too much room on the label.

Section 3 changes NDCC 19-03 to match the language which you changed two years ago in 19-02.1-01 and 43-15-01(24) during the Fifty-Sixth Legislative Assembly.

Sections 4-5-6 are scheduling or rescheduling of Controlled Substances, which the Board of Pharmacy acting as the Controlled Substances Board has scheduled administratively during the past two years, to keep North Dakota's drug schedules in conformity with those of the Drug Enforcement Administration.

Page 2 line 11, places Gamma-hydroxybutyric acid in Schedule I, unless it is specifically listed in another schedule as an approved drug product.

Page 3 – line 5 under e. Dronabinol and f. Gamma-hydroxybutyric acid are placed in schedule III when they are marketed as approved drug products. Ketamine, which is a drug used for induction of anesthesia, has also been placed in scheduled III.

On page 5 line 16 Zaleplon has been added to the list of Schedule IV Controlled Substances and on line 28 Modafinil is also in Schedule IV.

The change on page 6 line 6 brings us into concurrence with the DEA Regulations which were changed to allow the facsimile of a prescription signed by the practitioner before faxing to serve as the original prescription of the physician, to be retained by the pharmacy for that purpose. Prior regulations would have required pharmacists to get an original signature before we could have dispensed the medication.

Thank you very much, I will be happy to answer any question you might have.

Howard C. Anderson, Jr., R.Ph.

Board of Pharmacy
STATE OF NORTH DAKOTA
EDWARD T. SCHAFER, Governor

COPY

OFFICE OF THE EXECUTIVE DIRECTOR
P.O. Box 1354
Bismarck, North Dakota 58502-1354
Telephone (701) 328-9535
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July 21, 1999

Mr. Rolf P. Sletten
Executive Secretary/Treasurer
ND Board of Medical Examiners
418 East Broadway Avenue
Bismarck ND 58501

Dear Mr. Sletten:

The Board of Pharmacy has taken administrative action consistent with the issuance of the final rule by Acting Deputy Administrator of the **D**rug **E**nforcement **A**dministration (DEA) placing the substance synthetic Dronabinol [(-)-Δ9 -(trans)-Tetrahydrocnnabinol] in sesame oil and encapsulated in gelatin capsules in a product approved by the Food and Drug Administration (FDA) from Schedule II into Schedule III the **C**ontrolled **S**ubstances **A**ct (CSA), by the Authority of NDCC 19-03.1-02 subsection 4.

The rescheduling of this substance is effective thirty days from the notice published in the Federal Register – July 2, 1999 pages 35928-35930 (Vol 64, No. 127). The North Dakota State Board of Pharmacy places these substances into Schedule III of the North Dakota Uniform Controlled Substances Act.

Sincerely,

Howard C. Anderson, Jr., R.Ph.
Executive Director

HCA/eh

CC David A. Lindell, J.D.
Special Assistant Attorney General

DESIGNATION OF DRONABINOL INTO SCHEDULE III OF THE UNIFORM CONTROLLED SUBSTANCES ACT PURSUANT TO CHAPTER 19-03.1-02 SUBSECTION 4 of the North Dakota Century Code.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) transferring a drug between schedules of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811. With the issuance of this final rule the Deputy Administrator transfers from Schedule II to Schedule II of the CSA the drug containing synthetic Dronabinol [(-)-Δ9 -(trans)-Tetrahydrocnnabinol] in sesame oil and encapsulated in gelatin capsules in a product approved by the Food and Drug Administration (FDA). This rule also designates this drug as a Schedule III non-narcotic substance requiring an import/export permit. As a result of this rule, the regulatory controls and criminal sanctions of Schedule II will be applicable to the manufacture, distribution, importation and exportation of this drug.

The Scheduling of this substance is effective thirty days from the notice published in the Federal Register – July 2, 1999 pages 35928-35930 (Vol 64, No. 127).

LATELINES

Clinton browses new Walgreens

As part of his national swing to convince businesses to set up shop in pockets of poverty, President Clinton browsed through a new Walgreens drugstore in East St. Louis, Ill. Opened June 7, the Walgreens store is the neighborhood's first new retail outlet in 40 years. Residents of the chronically depressed city hold 70% of the 31 retail jobs in the $3.8 million store. Clinton applauded Walgreens' commitment to developing inner-city stores. Walgreens president and COO David Bernauer said the Deerfield, Ill., chain's drugstores serve inner-city neighborhoods as a health-care provider, convenience store, and grocery store.

State OKs access to alternative care

Washington will become the first state to require managed care plans and insurance companies to allow their customers nearly unfettered access to practitioners of alternative medicine, under draft rules that were expected to be adopted at press time. The regulation, crafted by Washington insurance commissioner Deborah Senn, calls for health insurers to incorporate different categories of providers into their coverage. The health-care practitioners benefiting from the law include acupuncturists, naturopaths, massage therapists, licensed midwives, nurse practitioners, physician assistants, and dietitians. In order to qualify for the law, all health-care professionals must be licensed and certified by the state.

Glaxo tops among R.Ph.s in survey

Glaxo came out on top in a Scott-Levin study of pharmacists' opinions of drug manufacturers. The study, Pharmaceutical Sales Force Structures and Strategies 1998, based its rankings on quality and familiarity data from the study population. Among the runners-up were Schering, Merck, and Astra Merck (which rose from 11th in the 1997 study). Scott-Levin surveyed 1,542 pharmacists overall—768 chain, 774 independent. (Glaxo Wellcome was identified as "Glaxo" by many pharmacists, despite the fact that no part of the company goes by that name anymore.)

Childhood vaccines: A cautionary note

The U.S. Public Health Service and the American Academy of Pediatrics have issued a joint statement urging the elimination of mercury content in hepatitis B vaccines and other childhood immunization products. In addition, the statement is rolling back universal recommendations that all infants receive inoculations against hepatitis B at birth. These cautionary actions were based on a hearing that scrutinized the safety of a mercury compound—thimerosol—used as a preservative in the hepatitis B, diphtheria, pertussis, acellular pertussis, tetanus, and HIB vaccines. Cumulative effects of ingesting mercury can result in brain damage; most infants have received a total of 15 doses of mercury-containing vaccines by the age of six months.

Canadian company buys Snyder Drug

Canadian drugstore owner The Katz Group will move into the U.S. chain industry by purchasing Snyder Drug Stores Inc., which is based in Minneapolis. Financial terms were not disclosed. The sale is expected to close in early October, assuming regulatory approval. Snyder's operates 141 company-owned and independent stores in five states. The Katz Group, based in Edmonton, Alberta, is a leading Canadian drugstore operator, with annual revenues of more than $800 million (Canadian). The company operates more than 300 units in five Canadian provinces under the Pharma Plus Drug Mart, Rexall Drug Store, and Medicine Shoppe Pharmacy banners.

Synthetic pot changed to Schedule III

DEA has moved Marinol (dronabinol) from a Schedule II controlled substance to Schedule III, which removes state triplicate-Rx requirements and permits telephone orders and refills. It took Unimed Pharmaceuticals more than three years to win rescheduling. FDA approved the synthetic form of THC, the active ingredient in marijuana, in 1985 for the treatment of chemotherapy-induced nausea. Eventually, the FDA and the White House Office of National Drug Control Policy supported rescheduling. Unimed and co-marketer Roxane Laboratories said it was the first time a drug has gone from Schedule II to Schedule III. Marinol also is indicated for appetite loss or anorexia associated with AIDS.

Judge approves error settlement

A federal judge approved a $2 million settlement in a lawsuit brought by the family of a toddler who ingested amoxapine dispensed in a non-childproof vial by a pharmacy in Lancaster, Pa. The suit charged that the boy, Jayln Ruiz, now five years old, lapsed into a coma for three weeks at the time of the incident and needs therapy for permanent brain damage. A trust fund will be established that will allow the boy to receive funds to enhance his quality of life and still remain eligible for public assistance.

Ms. Heidi Heitkamp, J.D.
Attorney General
State of North Dakota
600 E Boulevard Ave
Bismarck ND 58505-0040

Dear Ms. Heitkamp:

Dr. Charles D. Peterson
Dean
North Dakota State University
College of Pharmacy
Box 5055 - University Station
Fargo ND 58105-5055

Dear Dr. Peterson:

Constance B. Kalanek, PhD., RN
Executive Director
ND State Board of Nursing
919 S 7th Street Suite #504
Bismarck ND 58504-5881

Dear Dr. Kalanek:

Dr. Wayne A. Mattern
President
Board of Dental Examiners
1714 N 9th Street
Bismarck ND 58501
Dear Dr. Matter:

Dr. Lee Hofsommer
Secretary/Treasurer
Board of Podiatry Registry
1402 25th Street S
Fargo ND 58103

Dear Dr. Hofsommer:

Dr. John Boyce
Executive Secretary
Board of Vet Med Examiners
P O Box 5001
Bismarck ND 58502-5001

Dear Dr. Boyce

Dean Wilson
UND School of Medicine
P O Box 9037
Grand Forks ND 58202-9037

Dear Dean Wilson:

Same letter sent to all concerning rescheduling

(m) *Primary protective barrier for mammography x-ray systems.* For mammography x ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed 2.58×10^{-4} C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99-16835 Filed 7-1-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308, 1312

[DEA-180F]

Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(-)-Δ^9-(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This is a final rule of the Deputy Administrator of the Drug Enforcement Administration (DEA) transferring a drug between schedules of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811. With the issuance of this final rule, the Deputy Administrator transfers from schedule II to schedule III of the CSA the drug containing synthetic dronabinol [(-)-Δ^9-(*trans*)-tetrahydrocannabinol] in sesame oil and encapsulated in soft gelatin capsules in a product approved by the Food and Drug Administration (FDA). This rule also designates this drug as a schedule III non-narcotic substance requiring an import/export permit. As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, importation and exportation of this drug.

EFFECTIVE DATE: July 2, 1999.

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

SUPPLEMENTARY INFORMATION:

Background

Dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of Δ^9-(*trans*)-tetrahydrocannabinol [(-)-Δ^9-(*trans*)-THC], which is believed to be the major psychoactive component of *Cannibus sativa L.* (marijuana). On May 31, 1985, FDA approved for marketing the product Marinol® which contains synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules—for the treatment of nausea and vomiting associated with cancer chemotherapy. Following this FDA approval, DEA issued a final rule on May 13, 1986, transferring FDA-approved products of the same formulation as Marinol® from schedule I to schedule II of the CSA in accordance with 21 U.S.C. 811(a). (For simplicity within this document, the term "Marinol®" will be used hereafter to refer to Marinol® and any other products, which may by approved by FDA in the future, that have the same formulation as Marinol®.) The 1986 rescheduling of Marinol® was based on a medical and scientific evaluation and scheduling recommendation from the Assistant Secretary for Health in accordance with 21 U.S.C. 811(b). The transfer of Marinol® to schedule II did not affect the CSA classification of pure dronabinol, which—as a tetrahydrocannabinol with no currently accepted medical use in treatment in the United States—remains a schedule I controlled substance. On December 22, 1992, FDA expanded Marinol®'s indications to include the treatment of anorexia associated with weight loss in patients with AIDS.

The Petition To Reschedule Marinol®

On February 3, 1995, UNIMED Pharmaceuticals, Inc. petitioned the Administrator of DEA to transfer Marinol® from schedule II to schedule III. In response to this petition, and in view of supplemental information that UNIMED provided to DEA on December 11, 1996, DEA had to determine whether this proposed rescheduling of Marinol® would comport with United States obligations under the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). See 21 U.S.C. 811(d). Under the Psychotropic Convention, dronabinol and all dronabinol-containing products, such as Marinol®, are listed in schedule II. As a result, the United States is obligated under the Psychotropic Convention to impose certain restrictions on the export and import of Marinol®. DEA has concluded that, in order for the United States to continue to meet its obligations under the Psychotropic Convention, DEA will continue to require import and export permits for international transactions involving Marinol®, even though Marinol® will be transferred to schedule III of the CSA. (As set forth below, to accomplish this, DEA is hereby amending 21 CFR 1312.30 to require import and export permits for international transactions involving Marinol®.)

After determining that Marinol® could be transferred to schedule III while maintaining the controls required by the Psychotropic Convention, and after gathering the necessary data, on August 7, 1997, DEA requested from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), a scientific and medical evaluation, and recommendation, as to whether Marinol® should be rescheduled, in accordance with 21 U.S.C. 811(b).

On September 11, 1998, the Acting Assistant Secretary for Health sent to DEA a letter recommending that Marinol® be transferred from schedule II to schedule III of the CSA. Enclosed with the September 11, 1998, letter was a document prepared by the FDA entitled "Basis for the Recommendation for Rescheduling Marinol® Capsules from schedule II to schedule III of the Controlled Substances Act (CSA)." In this document, the FDA defines the Marinol® product as "an FDA-approved drug product containing synthetically produced dronabinol dissolved in sesame oil and encapsulated in soft

gelatin capsules (2.5 mg, 5 mg, and 10 mg per dosage unit)." The document contained a review of the factors which the CSA requires the Secretary to consider, which are set forth in 21 U.S.C. 811(c).

The Proposed Rule

On November 7, 1998, the then-Acting Deputy Administrator of DEA published a notice of proposed rule making in the **Federal Register** (63 FR 59751), proposing to transfer Marinol® from schedule II to schedule III of the CSA. The proposed rule was based on the DHHS scientific and medical evaluation and scheduling recommendation and DEA's independent evaluation. Also under the proposed rule, 21 CFR 1312.30 would be amended to include Marinol® as a schedule III non-narcotic controlled substance specifically designated as requiring import and export permits pursuant to 21 U.S.C. 952(b)(2) and 953(e)(3). As discussed above, this proposed amendment to 21 CFR 1312.30 is necessary for the United States to continue to meet its obligations under the Psychotropic Convention. The notice of proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to DEA on or before December 7, 1998.

Comments From the Public

DEA received comments regarding the proposed rule from ten persons. Nine of the commenters supported the proposed rule. One commenter objected to the proposed rule and requested a hearing thereon. The comments are briefly summarized below.

The nine commenters who supported the proposed rule included organizations, physicians, and one individual. Eight of the nine commenters who supported the proposed rule expressed the opinion that Marinol® is a safe and effective alternative to smoking marijuana for treatment of nausea and loss of appetite and has low abuse potential.

One commenter who supported the proposed rule expressed the view that the rescheduling of Marinol® should not serve as a substitute for making marijuana legally available for medical use. This commenter stated that it supported the use of marijuana for medical purposes and, therefore, wished to emphasize that the proposed rule affected the CSA status of Marinol®—not that of marijuana, which remains a schedule I controlled substance.

The one commenter who objected to the proposed rule, and requested a hearing thereon, asserted that Marinol® should not be transferred to schedule III unless and until marijuana and all other THC-containing drugs are simultaneously and likewise rescheduled. This commenter asserted that Marinol® has the same potential for abuse as marijuana and all other THC-containing drugs. This commenter agreed with the proposed rule that Marinol®'s potential for abuse is less than the "high potential for abuse" commensurate with schedules I and II of the CSA. Accordingly, this commenter agreed that Marinol® should be transferred to a less restrictive schedule than schedule II. However, this commenter disagreed with what would be the resultant status of Marinol® vis-à-vis marijuana and THC if the NPRM becomes final: Marinol® would be in schedule III while marijuana and THC would remain in schedule I. This commenter asserted that the CSA prohibited transferring Marinol® to a less restrictive schedule unless marijuana and all THC-containing drugs are simultaneously transferred to the same schedule. DEA has determined that this commenter's objections are based on a misinterpretation of the CSA, which can be addressed, as a matter of law, without conducting a fact finding hearing. Accordingly, as this commenter presented no material issues of fact, DEA denied this commenter's request for a hearing.

Findings

Relying on the scientific and medical evaluation and scheduling recommendations of the Assistant Secretary for Health, and based on DEA's independent review thereof, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on information now available, Marinol® has a potential for abuse less than the drugs or other substances in schedules I and II,

(2) Marinol® is a FDA approved drug product and has a currently accepted medical use in treatment in the United States; and

(3) Abuse of Marinol® may lead to moderate of low physical dependence or high psychological dependence.

Rescheduling Action

Based on the above findings, the Deputy Administrator of the DEA concludes that Marinol® should be transferred from schedule II to schedule III. Schedule III regulations will, among other things, allow five prescription refills in six months and lessen record keeping requirements and distribution restrictions. The schedule III control of Marinol® will become effective July 2, 1999, except that certain regulatory provisions governing registrants who handle Marinol will take effect 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 III regulations regarding Marinol®. The applicable regulations are as follows.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports Marinol® or who engages in research or conducts instructional activities with Marinol®, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Marinol® must be manufactured, distributed and stored in accordance with §§ 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.

3. *Labeling and Packaging.* All commercial containers of Marinol®, which are packaged on or after January 3, 2000 must have the appropriate Schedule III labeling as required by §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Commercial containers of Marinol® packaged before January 3, 2000. After April 3, 2000, all commercial containers of Marinol must bear the CIII labels as specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Registrants possessing Marinol® are required to take inventories pursuant to §§ 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 §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* All prescriptions for Marinol® are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for Marinol® issued on or after July 2, 1900, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after January 2, 2000.

7. *Importation and Exportation.* Due to its international control status, import and export permits for Marinol® will be required in accordance with 21 CFR 1312.30. All importation and exportation of Marinol® shall be in compliance with part 1312 of Title 21 of the CFR.

8. *Criminal Liability.* Any activity with Marinol® not authorized by, or in violation of, the CSA or the Controlled

Substances Import and Export Act shall continue to be unlawful.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rule making "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 Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Marinol® is a prescription drug used to treat nausea due to cancer chemotherapy and AIDS wasting. Handlers of Marinol® are likely to handle other controlled substances used to treat cancer or AIDS which are already subject to the regulatory requirements of the CSA. Further, placement of Marinol® in schedule III of the CSA will mean a significant decrease in the regulatory requirements for persons handling Marinol®.

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 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, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1308

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

21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Narcotics, Reporting requirements.

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 Deputy Administrator hereby amends 21 CFR parts 1308 and 1312 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.

§ 1308.12 [Amended]

2. Section 1308.12 is amended by removing paragraph (f)(1) and redesignating the existing paragraph (f)(2) as (f)(1).

3. Section 1308.13 is amended by adding a new paragraph (g) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(g) *Hallucinogenic substances.*

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.

[Some other names for dronabinol: (6a*R*-*trans*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo [*b*,*d*]pyran-1-ol] or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

(2) [Reserved]

PART 1312—[AMENDED]

1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

2. Section 1312.30 is amended by adding a new paragraph (a) and reserving paragraph (b) to read as follows:

§ 1312.30 Schedule III, IV and V non-narcotic controlled substances requiring an import and export permit.

* * * * *

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product.

(b) [Reserved]

Dated: June 28, 1999.

Donnie R. Marshall,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 99-16833 Filed 7-1-99; 8:45 am]

BILLING CODE 4410-09-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[LA-29-1-7403; FRL-6370-8]

Approval and Promulgation of Air Quality Implementation Plans; Louisiana: Reasonable-Further-Progress Plan for the 1996–1999 Period, Attainment Demonstration, Contingency Plan, Motor Vehicle Emission Budgets, and 1990 Emission Inventory for the Baton Rouge Ozone Nonattainment Area; Louisiana Point Source Banking Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, the EPA is finalizing its approval of revisions to the Louisiana State Implementation Plan (SIP) for the Baton Rouge ozone nonattainment area. These revisions were submitted by the State of Louisiana for the purpose of satisfying the Post-1996 Rate-of-Progress (ROP), Attainment Demonstration and Contingency Plan requirements of the Federal Clean Air Act (the Act), which will aid in ensuring the attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. The EPA is also approving the associated 1999 Motor Vehicle Emissions Budgets (MVEBs) for the area.

The EPA is also taking final action to approve additional SIP revisions submitted by Louisiana including codifying revisions that were made to the 1990 base year emission inventory and submitted to the EPA as part of the Baton Rouge Post-1996 Rate-of-Progress Plan approved on October 22, 1996. Furthermore, the EPA is approving additional revisions to the 1990 base year emissions inventory submitted as part of the Post-1996 ROP Plan. The EPA is also approving the State's point source banking regulations. This rulemaking action is being taken under sections 110, 301, and part D of the Act.

EFFECTIVE DATE: This action is effective on August 2, 1999.

Board of Pharmacy
STATE OF NORTH DAKOTA
EDWARD T. SCHAFER, Governor

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HOUSE BILL No. 1096
SENATE INDUSTRY, BUSINESS AND LABOR COMMITTEE
WEDNESDAY- FEBRUARY 14, 2001 – 10:00 AM – ROOSEVELT ROOM

Chairman Mutch, members of the Industry, Business and Labor Committee, for the record I am Howard C. Anderson, Jr., R.Ph., Executive Director of the North Dakota State Board of Pharmacy.

Thank you for the opportunity to appear before you today. This Bill was introduced at the request of the State Board of Pharmacy and contains changes necessary to help pharmacists care for their patients and primarily expands our laws to the greatest extent possible under the federal regulations.

Sections 1 - 2 and 8 change the definition of prescription drug in the various sections in the North Dakota Law to include the Rx Only language adopted by the Food and Drug Administration. Manufacturers, packagers and labelers of prescription medication asked the FDA to simplify and shorten the designation of a prescription drug since the caution: "Federal Law Prohibits Dispensing Without Prescription" took up too much room on the label.

Section 3 changes NDCC 19-03 to match the language which you changed two years ago in 19-02.1-01 and 43-15-01(24) during the Fifty-Sixth Legislative Assembly.

Sections 4-5-6 are scheduling or rescheduling of Controlled Substances, which the Board of Pharmacy acting as the Controlled Substances Board has scheduled administratively during the past two years, to keep North Dakota's drug schedules in conformity with those of the Drug Enforcement Administration.

Page 2 line 11, places Gamma-hydroxybutyric acid in Schedule I, unless it is specifically listed in another schedule as an approved drug product.

Page 3 – line 5 under e. Dronabinol and f. Gamma-hydroxybutyric acid are placed in schedule III when they are marketed as approved drug products. Ketamine, which is a drug used for induction of anesthesia, has also been placed in scheduled III.

On page 5 line 16 Zaleplon has been added to the list of Schedule IV Controlled Substances and on line 28 Modafinil is also in Schedule IV.

The change on page 6 line 6 brings us into concurrence with the DEA Regulations which were changed to allow the facsimile of a prescription signed by the practitioner before faxing to serve as the original prescription of the physician, to be retained by the pharmacy for that purpose. Prior regulations would have required pharmacists to get an original signature before we could have dispensed the medication.

Thank you very much, I will be happy to answer any question you might have.

Howard C. Anderson, Jr., R.Ph.