MICROFILM DIVIDER

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

ROLL NUMBER

DESCRIPTION

1055

2007 HOUSE HUMAN.SERVICES

HB 1055

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB1055

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 01/09/2007

Recorder Job Number: 780

Committee Clerk Signature Judy Kitsch

Minutes:

Chairman Price: Calling the session to order and opening HB1055 for testimony.

Howard Anderson, Executive Director of ND State Board of Pharmacy: See attached. I have also passed out proposed amendments to fix mistakes made when I drafted the bill, as attached.

Chairman Price: Are there any street names we would recognize?

Mr. Anderson: We use chemical names, plus street people often inter mix them.

Chairman Price: Any more testimony in favor? Anyone having opposition to HB1055? Hearing none we will close HB1055.

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB1055

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 01-09-2007

Recorder Job Number: 783

Committee Clerk Signature Judy Schock

Minutes:

Chairman Price: Let's look at HB 1055.

Representative Porter: I think to get things moving, I would move the Board of Pharmacy's proposed amendments. Representative Kaldor: I second the motion.

Representative Conrad: I make a motion for a due pass of amendments on HB 1055.

Representative Uglem: I second the motion.

Adopted by the Human Services Committee
January 9, 2007

House Amendments to HB 1055 (78054.0101) - Human Services Committee 01/10/2007

Page 5, line 1, remove "Glutethimide."

Page 5, line 2, remove "k."

Page 5, line 3, replace "l. Levo-alphaacetylmethado" with "k. Levo-alphaacetylmethadol"

Page 5, line 4, replace "m." with "l."

Page 5, line 5, replace "n." with "m."

Page 5, line 6, replace "o." with "n."

Page 5, line 7, replace "p." with "o."

Page 5, line 8, replace "q." with "p."

Page 5, line 9, replace "r." with "q."

Page 5, line 11, replace "s." with "r."

Page 5, line 12, replace "t." with "s."

Page 5, line 13, replace "u." with "t."

Page 5, line 14, replace "v." with "u."

Page 5, line 15, replace "w." with "v."

Page 5, line 16, replace "x." with "w."

Page 5, line 17, replace "y." with "x."

Page 5, line 18, replace "z." with "y."

Page 5, line 19, replace "aa." with "z."

Page 5, line 20, replace "bb." with "aa."

Page 5, after line 27, insert:

"b. Glutethimide."

Page 5, line 28, overstrike "b." and insert immediately thereafter "c.", remove the overstrike over "~~Pentobarbital~~", and remove "Glutethimide"

Page 5, line 29, after "~~c.~~" insert "d." and remove the overstrike over "~~Phenoxylidine.~~"

Page 5, line 30, after "~~d.~~" insert "e." and remove the overstrike over "~~Secobarbital.~~"

House Amendments to HB 1055 (78054.0101) - Human Services Committee 01/10/2007

Page 7, line 27, remove "g." and overstrike "Glutethimide."

Page 7, line 28, replace "h." with "g."

Page 7, line 29, replace "i." with "h."

Page 7, line 30, replace "j." with "i."

Page 7, line 31, replace "k." with "j."

House Amendments to HB 1055 (78054.0101) - Human Services Committee 01/10/2007

Page 8, line 1, replace "l." with "k."

Page 8, line 2, replace "m." with "l."

Page 8, line 3, replace "n." with "m."

Page 8, line 4, replace "o." with "n."

Page 13, line 6, remove the overstrike over "~~m. Clexazolam.~~"

Page 13, line 7, remove the overstrike over "~~n.~~" and remove "m."

Page 13, line 8, remove the overstrike over "~~o.~~" and remove "n."

Page 13, line 9, remove the overstrike over "~~p.~~" and remove "o."

Page 13, line 10, remove the overstrike over "~~q.~~" and remove "p."

Page 13, line 11, remove the overstrike over "~~r.~~" and remove "q."

Page 13, line 12, remove the overstrike over "~~s.~~" and remove "r."

Page 13, line 13, remove the overstrike over "~~t.~~" and remove "s."

Page 13, line 14, remove the overstrike over "~~u.~~" and remove "t."

Page 13, line 15, remove the overstrike over "~~v.~~" and remove "u."

Page 13, line 16, remove the overstrike over "~~w.~~" and remove "v."

Page 13, line 17, remove the overstrike over "~~x.~~" and remove "w."

Page 13, line 18, remove the overstrike over "~~y.~~" and remove "x."

Page 13, line 19, remove the overstrike over "~~z.~~" and remove "y."

Page 13, line 20, remove the overstrike over "~~aa.~~" and remove "z."

Page 13, line 21, remove the overstrike over "~~bb.~~" and remove "aa."

Page 13, line 22, remove the overstrike over "~~cc.~~" andremove "bb."

Page 13, line 23, remove the overstrike over "~~dd.~~" and remove "cc."

Page 13, line 24, remove the overstrike over "~~ee.~~" and remove "dd."

Page 13, line 25, remove the overstrike over "~~ff.~~" and remove "ee."

Page 13, line 26, remove the overstrike over "~~gg.~~" and remove "ff."

Page 13, line 27 , remove the overstrike over "~~hh.~~" and remove "gg."

Page 13, line 28, remove the overstrike over "~~ii.~~" and remove "hh."

Page 13, line 29, remove the overstrike over "~~jj.~~" and remove "ii."

Page 13, line 30, remove the overstrike over "~~kk.~~" and remove "jj."

Page 13, line 31, remove the overstrike over "~~ll.~~" and remove "kk."

House Amendments to HB 1055 (78054.0101) - Human Services Committee 01/10/2007

Page 14, line 1, remove the overstrike over "~~mm.~~" and remove "ll."

Page 14, line 2, remove the overstrike over "~~nn.~~" and remove "mm."

Page 14, line 3, remove the overstrike over "~~oo.~~" and remove "nn."

Page 14, line 4, remove the overstrike over "~~pp.~~" and remove "oo."

Page 14, line 5, remove the overstrike over "~~qq.~~" and remove "pp."

Page 14, line 6, remove the overstrike over "~~rr.~~" and remove "qq."

Page 14, line 7, remove the overstrike over "~~ss.~~" and remove "rr."

Page 14, line 9, replace "ss." with "tt."

Page 14, line 10, replace "tt." with "uu."

Page 14, line 11, replace "uu." with "vv."

Page 14, line 12, replace "vv." with "ww."

Page 14, line 13, replace "ww." with "xx."

Page 14, line 14, replace "xx." with "yy."

House Amendments to HB 1055 (78054.0101) - Human Services Committee 01/10/2007

Page 16, line 2, remove "2782"

Renumber accordingly

Date: 1/9/08
Roll Call Vote #: 1

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES HB 1055 Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Accept Amendments from Board
Do Pass as Amended

Motion Made By Rep Porter Seconded By Rep Kaldor

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman			Kari L Conrad		
Vonnie Pietsch – Vice Chairman			Lee Kaldor		
Chuck Damschen			Louise Potter		
Patrick R. Hatlestad			Jasper Schneider		
Curt Hofstad					
Todd Porter					
Gerry Uglem					
Robin Weisz					

Total (Yes) "Click here to type Yes Vote" No "Click here to type No Vote"

Absent

Floor Assignment

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

Date: 4/10/8
Roll Call Vote #: 2

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES HB 1055 Committee

Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do pass as Amended

Motion Made By Rep Conrad Seconded By Rep Uglem

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman	✓		Kari L Conrad	✓	
Vonnie Pietsch – Vice Chairman	✓		Lee Kaldor	✓	
Chuck Damschen	✓		Louise Potter	✓	
Patrick R. Hatlestad	✓		Jasper Schneider	✓	
Curt Hofstad	✓				
Todd Porter	✓				
Gerry Uglem	✓				
Robin Weisz	✓				

Total (Yes) 12 No 0

Absent 0

Floor Assignment Rep. Hofstad

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

1055 - ?

REPORT OF STANDING COMMITTEE

HB 1055: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (12 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1055 was placed on the Sixth order on the calendar.

Page 5, line 1, remove "Glutethimide."

Page 5, line 2, remove "k."

Page 5, line 3, replace "l. Levo-alphaacetylmethado" with "k. Levo-alphaacetylmethadol"

Page 5, line 4, replace "m." with "l."

Page 5, line 5, replace "n." with "m."

Page 5, line 6, replace "o." with "n."

Page 5, line 7, replace "p." with "o."

Page 5, line 8, replace "q." with "p."

Page 5, line 9, replace "r." with "q."

Page 5, line 11, replace "s." with "r."

Page 5, line 12, replace "t." with "s."

Page 5, line 13, replace "u." with "t."

Page 5, line 14, replace "v." with "u."

Page 5, line 15, replace "w." with "v."

Page 5, line 16, replace "x." with "w."

Page 5, line 17, replace "y." with "x."

Page 5, line 18, replace "z." with "y."

Page 5, line 19, replace "aa." with "z."

Page 5, line 20, replace "bb." with "aa."

Page 5, after line 27, insert:

"b. Glutethimide."

Page 5, line 28, overstrike "b." and insert immediately thereafter "c.", remove the overstrike over "~~Pentobarbital~~", and remove "Glutethimide"

Page 5, line 29, after "~~c.~~" insert "d." and remove the overstrike over "~~Phencyclidine.~~"

Page 5, line 30, after "~~d.~~" insert "e." and remove the overstrike over "~~Secobarbital.~~"

Page 7, line 27, remove "g." and overstrike "Glutethimide."

Page 7, line 28, replace "h." with "g."

Page 7, line 29, replace "i." with "h."

Page 7, line 30, replace "j." with "i."

Page 7, line 31, replace "k." with "j."

Page 8, line 1, replace "l." with "k."

Page 8, line 2, replace "m." with "l."

Page 8, line 3, replace "n." with "m."

Page 8, line 4, replace "o." with "n."

Page 13, line 6, remove the overstrike over "~~m.Cloxazolam.~~"

Page 13, line 7, remove the overstrike over "~~n.~~" and remove "m."

Page 13, line 8, remove the overstrike over "~~o.~~" and remove "n."

Page 13, line 9, remove the overstrike over "~~p.~~" and remove "o."

Page 13, line 10, remove the overstrike over "~~q.~~" and remove "p."

Page 13, line 11, remove the overstrike over "~~r.~~" and remove "q."

Page 13, line 12, remove the overstrike over "~~s.~~" and remove "r."

Page 13, line 13, remove the overstrike over "~~t.~~" and remove "s."

Page 13, line 14, remove the overstrike over "~~u.~~" and remove "t."

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Page 13, line 20, remove the overstrike over "~~aa.~~" and remove "z."

Page 13, line 21, remove the overstrike over "~~bb.~~" and remove "aa."

Page 13, line 22, remove the overstrike over "~~cc.~~" andremove "bb."

Page 13, line 23, remove the overstrike over "~~dd.~~" and remove "cc."

Page 13, line 24, remove the overstrike over "~~ee.~~" and remove "dd."

Page 13, line 25, remove the overstrike over "~~ff.~~" and remove "ee."

Page 13, line 26, remove the overstrike over "~~gg.~~" and remove "ff."

Page 13, line 27 , remove the overstrike over "~~hh.~~" and remove "gg."

Page 13, line 28, remove the overstrike over "~~ii.~~" and remove "hh."

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Page 13, line 31, remove the overstrike over "~~ll.~~" and remove "kk."

Page 14, line 1, remove the overstrike over "~~mm.~~" and remove "ll."

Page 14, line 2, remove the overstrike over "~~nn.~~" and remove "mm."

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Page 14, line 4, remove the overstrike over "~~pp.~~" and remove "oo."

Page 14, line 5, remove the overstrike over "~~qq.~~" and remove "pp."

Page 14, line 6, remove the overstrike over "~~rr.~~" and remove "qq."

Page 14, line 7, remove the overstrike over "~~ss.~~" and remove "rr."

Page 14, line 9, replace "ss." with "tt."

Page 14, line 10, replace "tt." with "uu."

Page 14, line 11, replace "uu." with "vv."

Page 14, line 12, replace "vv." with "ww."

Page 14, line 13, replace "ww." with "xx."

Page 14, line 14, replace "xx." with "yy."

Page 16, line 2, remove "2782"

Renumber accordingly

2007 SENATE JUDICIARY

HB 1055

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. **HB 1055**

Senate **Judiciary Committee**

☐ Check here for Conference Committee

Hearing Date: March 7, 2007

Recorder Job Number: 4589

Committee Clerk Signature Marie L Sollers

Minutes: Relating to ND Century Code relating to controlled substances.

Senator David Nething, Chairman called the Judiciary committee to order. All Senators were present except for Sen. Olafson. The hearing opened with the following hearing:

Testimony in Favor of the Bill:

Howard Anderson Jr., Executive Dir. Board of Pharmacy introduced and reviewed the bill – Att. #1. On page 17 line 16, we used to cross check prescriptions by calling the Doctors office we were able to catch fraud. The state required it but Federal Law did not. The process was time consuming and pharmacist are filling more prescriptions then they have time for

Sen. Lyson asked stated that he is not worried what the pharmacists think. Mr. Anderson spoke of the process at there annual meetings it a 2/3rds vote to not do this. The bordering states do not require this process.

Sen. Marcellais asked questions in regards to Canada and the importation of prescriptions. They discussed this in detail.

Testimony Against the bill:

None

Testimony Neutral to the bill:

None

Senator David Nething, Chairman closed the hearing.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. **HB 1055**

Senate **Judiciary Committee**

☐ Check here for Conference Committee

Hearing Date: March 12, 2007

Recorder Job Number: 4881

Committee Clerk Signature Maria L Ahlberg

Minutes: Relating to ND Century Code relating to controlled substances.

Senator David Nething, Chairman called the Judiciary committee to order. All Senators were present. The hearing opened with the following committee work:

The committee spoke to no amendments being brought forth before the committee.

Sen. Nelson made the motion to Do Pass HB 1055 and **Sen. Marcellais** seconded the motion. All members were in favor and the motion passes.

Carrier: **Sen. Lyson**

Senator David Nething, Chairman closed the hearing.

Date: 3-12-07
Roll Call Vote # 1 of 1

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1055

Senate Judiciary Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass

Motion Made By Sen. Nelson Seconded By Sen. Marcellais

Senators	Yes	No	Senators	Yes	No
Sen. Nething			Sen. Fiebiger		
Sen. Lyson			Sen. Marcellais		
Sen. Olafson			Sen. Nelson		

Total Yes 6 No 0

Absent 0

Floor Assignment Sen. Lyson

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

REPORT OF STANDING COMMITTEE

HB 1055, as engrossed: Judiciary Committee (Sen. Nething, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1055 was placed on the Fourteenth order on the calendar.

2007 TESTIMONY

HB 1055

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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Bonnie J. Thom, R.Ph.
Granville, President
Gary W. Dewhirst, R.Ph.
Hettinger, Senior Member
Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
Laurel Haroldson, R.Ph.
Jamestown
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

TESTIMONY ON HOUSE BILL No. 1055
CONTROLLED SUBSTANCES RESCHEDULING

HOUSE HUMAN SERVICES COMMITTEE
8:00 AM – FORT UNION ROOM – TUESDAY- JANUARY 9TH, 2007

Chairman Price and members of the House Human Services 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 speak with you today.

This Bill is one that comes to you periodically to reschedule those new drugs, or in a few cases drugs that have been moved from one of the federal controlled substances schedules to the next. This rescheduling keeps our law consistent with the federal law in almost all cases, and allows our law enforcement agencies to charge offenders using these drugs illegally with consistency between state and federal laws.

The rescheduling or scheduling uses chemical names, which most of you will not be familiar with, so please do not be afraid to ask questions, if I do not know the answer, I will find it for you.

On page 1, line 19, we have the first addition to Schedule I of the Hallucinogenic Substances. Schedule I are those drugs that have been identified, but have no accepted medical use in the United States. We also have new listings on page 2 line 4 and 22 under this category. There is also one new listing in Schedule I under the category of Stimulants on page 4, line 11.

If you go to page 5 we are now under Schedule II of the Controlled Substances Act, which includes drugs approved for human use, but in the highest schedule for addiction potential. Here we see on line one Glutethimide, which should be on line 28. It has been moved from Schedule III to Schedule II in our laws to match the federal schedule. On line 3 we see Levo-alphaacetylmethadol (LAAM) which is one of the drugs sometimes used in registered narcotic treatment programs to detoxify or maintain patients who are heroin addicts. There should be an l at the end of that word, and I have prepared an amendment to correct this, as well as to remove line 1 Glutethimide, which is correctly depicted on line 28. Also, an amendment corrects the erroneous elimination of the Pentobarbital, Phencyclidine and Secobarbital on lines 28, 29 and 30, which should not have been crossed out, just moved down.

On page 7, line 19 you will see we crossed off Buprenophine, because it has been moved to be more properly listed under narcotic drugs, rather than depressants. On Line 24 we have added a new drug Embutramide and on line 27 in my amendment, to cross off and move Glutethimide to it's appropriate location under Schedule II.

On page 9, line 11 Buprenorphine has been added, this is the drug now available to treat withdrawal or narcotics maintenance in some physician offices and the out-patient setting. It previously had been available as a pain medication.

Under Anabolic Steroids starting on page 9 line 12, you will see there have been many additions to this list. This is in response to all of the drugs which have been developed over the last few years, many of them to treat legitimate conditions, but unfortunately now used illegitimately as well. Some of the deletions, for example, on line 27, are because the drug has been more completely described on another line. This is also true of line 17 and 19 on page 10.

On page 12, line 6 you will see the inclusion of Dronabinol which is the FDA version of the active ingredient in marijuana. Also on page 12, line 28, my amendment will cross off or delete Butorphanol, as that has been included in a different schedule.

On page 13, line 6, my amendment will correct the cross through on Cloxazelam, which is an error.

On page 14, line 8 Sibutramine is crossed out as it has been moved to the appropriate area of Stimulants on line 29.

On the bottom of page 15, line 28 you will see the addition of the definition for Depressants under schedule V. On page 16, line 1 Pregabalin has been added to this classification, which previously had no drugs listed in schedule V. Although my amendment will eliminate the 2782 at the end of the sentence, which is actually the federal designated number for that controlled substance and is not applicable to the North Dakota schedule.

On page 17, I would like to discuss with you a bit about the changes we are suggesting. On line 2, we have added a limit to the time a Schedule II controlled substance can be filled. Originally when DEA began scheduling Schedule II controlled substances, no one had envisioned that anyone might need to hold narcotic prescriptions, which at that time were the only drugs in Schedule II. Since then many drugs to treat attention deficit disorders have been added to Schedule II and physicians not wishing to see patients on a

monthly basis, where writing more than one prescription at a time and saying "fill on April 1st, "fill on May 1st "- "fill on June 1st ". Recently DEA has gone back and forth in their rules, first allowing the practice, then disallowing it and now allowing it again under a more limited usage. Since the length of time a schedule III – IV or V prescription is good is only six months, it seems reasonable to limit a Schedule II prescription to the same time period. Of course the other three schedules can be refilled up to six months and with Schedule II there is no refilling allowed.

Beginning on line 16 and again on line 27 we are proposing to eliminate the requirement that was unique to North Dakota in that a prescription called in by a physician needed to be sent to that physician for his actual signature and returned within seven days. This was originally designed to give the physician a cross-check and to be sure that they had prescribed the drug and also for the pharmacy and pharmacy inspector to have hard evidence, that is the physician's signature, that this was an appropriate prescription. Other states do not require this, and physicians and pharmacists have asked us to eliminate this requirement. Eliminating this will streamline both pharmacy and physician operations a little bit.

Thank you. I have passed out copies of the proposed amendments to fix the mistakes made when I drafted this bill in the first place. I would also like to point out that none of these mistakes were the fault Legislative Council, they were all mine and I do apologize for the inconvenience.

AMDENMENT TO HOUSE BILL No. 1055

On page 5, line 1, remove Glutethimide and renumber the balance of the section accordingly.

On page 5, line 3, correct the spelling by adding an l at the end, so this reads Levo-alphaaetylmethadol (LAAM).

On page 5, line 28, line 29, line 30; add Glutethimide as b., but leave Pentobarbital, Phencyclidine and Secobarbital by removing the strikethrough and renumbering them accordingly. c would be Pentobarbital,; d. would be Phencyclidine; e. Secobarbital. These items were erroneously crossed out.

On page 7, line 27 strikethrough Glutethimide and renumber the remaining items in the section accordingly, as Glutethimide has been moved to another area.

On page 13, line 6 remove the strikethrough on Cloxazolam, as this is actually correct and should not have been deleted, and renumber the following items accordingly.

On page 16, line 2 remove 2782 at the end of this line, which is actually the Federal designation for this drug and has no applicability in North Dakota Law.

HH #1
3-7-07

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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Gary W. Dewhirst, R.Ph.
Hettinger, Senior Member
Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
Laurel Haroldson, R.Ph.
Jamestown
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

TESTIMONY ON HOUSE BILL No. 1055
CONTROLLED SUBSTANCES RESCHEDULING

SENATE JUDICIARY COMMITTEE
10:30 AM – FORT LINCOLN ROOM – WEDNESDAY- MARCH 7TH, 2007

Chairman Nething and members of the Senate Judiciary 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 speak with you today.

This Bill is one that comes to you periodically to reschedule those new drugs, or in a few cases drugs that have been moved from one of the federal controlled substances schedules to the next. This rescheduling keeps our law consistent with the federal law in almost all cases, and allows our law enforcement agencies to charge offenders using these drugs illegally with consistency between state and federal laws.

The rescheduling or scheduling uses chemical names, which most of you will not be familiar with, so please do not be afraid to ask questions, if I do not know the answer, I will find it for you.

On page 1, line 19, we have the first addition to Schedule I of the Hallucinogenic Substances. Schedule I are those drugs that have been identified, but have no accepted medical use in the United States. We also have new listings on page 2 line 4 and 22 under this category. There is also one new listing in Schedule I under the category of Stimulants on page 4, line 11.

If you go to page 5 we are now under Schedule II of the Controlled Substances Act, which includes drugs approved for human use, but in the highest schedule for addiction potential. On line 2 we see Levo-alphaacetylmethadol (LAAM) which is one of the drugs sometimes used in registered narcotic treatment programs to detoxify or maintain patients who are heroin addicts. Here we see on line 28 Glutethimide, which has been moved from Schedule III to Schedule II in our laws to match the federal schedule.

On page 7, line 19 you will see we crossed off Buprenophine, because it has been moved to be more properly listed under narcotic drugs, on page 9 line 11, rather than depressants. On Line 24 we have added a new drug Embutramide and on line 27 we have crossed off and moved Glutethimide to it's appropriate location under Schedule II.

On page 9, line 11 Buprenorphine has been added as mentioned above, this is the drug now available to treat withdrawal or narcotics maintenance in some physician offices and the out-patient setting. It previously had been available as a pain medication.

Under Anabolic Steroids starting on page 9 line 15, you will see there have been many additions to this list. This is in response to all of the drugs which have been developed over the last few years, many of them to treat legitimate conditions, but unfortunately now used illegitimately as well. Some of the deletions, for example, on line 27, are because the drug has been more completely described on another line. This is also true of line 17 and 19 on page 10.

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On page 14, line 8 Sibutramine is crossed out as it has been moved to the appropriate area of Stimulants on line 29.

On the bottom of page 15, line 28 you will see the addition of the definition for Depressants under schedule V. On page 16, line 1 Pregabalin has been added to this classification, which previously had no drugs listed in schedule V.

On page 16, line 9 through 24, we have added some requirements to report to the Board of Pharmacy the theft or loss of controlled substances. Most of our pharmacies do make this report now, but at this time, there is no requirement in our law. Additionally, many pharmacies are uncertain about the details of this requirement. The pharmacies are now required to report to the Drug Enforcement Administration (DEA) within one business day of a theft or loss of a controlled substance, placing this identical information in our law and requiring reporting to the Board, will make it much easier for our pharmacists to locate the proper requirements and complete this report, thus keeping themselves out of trouble with the DEA and providing the Board of Pharmacy with necessary information on what is happening in our pharmacies. This is the same information that is required by DEA and will not duplicate the necessary steps that the pharmacy must currently take, except to fax the information to our Board Office.

On page 17, I would like to discuss with you a bit about the changes we are suggesting. On line 2, we have added a limit to the time a Schedule II controlled substance can be filled. Originally when DEA began scheduling Schedule II controlled substances, no one had envisioned that anyone might need to hold narcotic prescriptions, which at that time were the only drugs in Schedule II. Since then many drugs to treat attention deficit disorders have been added to Schedule II and physicians not wishing to see patients on a

monthly basis, where writing more than one prescription at a time and saying "fill on April 1st, "fill on May 1st "- "fill on June 1st ". Recently DEA has gone back and forth in their rules, first allowing the practice, then disallowing it and now allowing it again under a more limited usage. Since the length of time a schedule III – IV or V prescription is good is only six months, it seems reasonable to limit a Schedule II prescription to the same time period. Of course the other three schedules can be refilled up to six months and with Schedule II there is no refilling allowed.

Beginning on line 16 and again on line 27 we are proposing to eliminate the requirement that was unique to North Dakota in that a prescription called in by a physician needed to be sent to that physician for his actual signature and returned within seven days. This was originally designed to give the physician a cross-check and to be sure that they had prescribed the drug and also for the pharmacy and pharmacy inspector to have hard evidence, that is the physician's signature, that this was an appropriate prescription. Other states do not require this, and physicians and pharmacists have asked us to eliminate this requirement. Eliminating this will streamline both pharmacy and physician operations a little bit.

Thank you.

wholesalers, particularly secondary wholesalers, regarding access to pedigrees because the required information would travel with the product at all times, regardless of whether a party to the transaction is an authorized distributor of record.

Until the electronic pedigree is in widespread use, FDA believes that the multi-layer strategies and measures discussed in the FDA's Counterfeit Drug Final Report (Final Report) can help reduce the likelihood that counterfeit drugs will be introduced into the U.S. drug distribution system. These measures, combined with implementation of Radio Frequency Identification (RFID) technology, could provide effective long-term protections to help minimize the number of counterfeit drug products in the U.S. distribution system. As discussed in greater detail in the Final Report, such long-term measures include the following: Use of authentication technologies in products and packaging and labeling, in particular, for drugs most likely to be counterfeited; adoption of secure business practices by stakeholders; adoption of the revised model rules for wholesale distributor licensure by States; stronger criminal penalties and enforcement at the State and national levels; and education and outreach to stakeholders, including greater communication through the counterfeit alert network.

Although FDA is further delaying the effective date of §§ 203.3(u) and 203.50, the agency encourages wholesalers to provide pedigree information that documents the prior history of the product, particularly for those drugs most likely to be counterfeited, even when such a pedigree is not required by the act. The suggestion from the comments that there be a one-forward, one-back pedigree for those drugs most likely to be counterfeited until an electronic pedigree is uniformly adopted may have some merit. However, FDA believes legislative changes would be needed before it could adopt such a system.

To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, to allow stakeholders to continue to move toward this goal, FDA has decided to delay the effective date of §§ 203.3(u) and 203.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

FDA is also further delaying the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. This further delay is necessary to give FDA additional time to address concerns about the requirements raised by affected parties and consider whether regulatory changes are appropriate and, if so, initiate such changes.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry by delaying the effect of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities while FDA works with industry to resolve concerns about these provisions either with the implementation of technological solutions (§§ 203.3(u) and 203.50) or the consideration of possible regulatory changes (§ 203.3(q)). Thus, this action is not a significant action as defined by the Executive order.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. In addition, given the imminence of the current compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for the requirements identified below, those companies affected would have to be preparing to comply with the April 1, 2004, compliance date. In accordance with 21 CFR 10.40(c)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

This action is being taken under FDA's authority under 21 CFR 10.35(a).The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: February 17, 2004

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6094 Filed 3–17–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–247F]

Schedules of Controlled Substances; Placement of 2,5-Dimethoxy-4-(n)-propylthiophenethylamine and N-Benzylpiperazine Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: This final rulemaking is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to place 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7) and N-benzylpiperazine (BZP) into Schedule I of the Controlled Substances Act (CSA). This action by the DEA Acting Deputy Administrator is based on a scheduling recommendation by the Department of Health and Human Services (DHHS) and a DEA review indicating that 2C–T–7 and BZP meet the criteria for placement in Schedule I of the CSA. This final rule will continue to impose the regulatory controls and criminal sanctions of Schedule I substances on the manufacture, distribution, and possession of 2C–T–7 and BZP.

EFFECTIVE DATE: March 18, 2004.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: On September 20, 2002, the Deputy Administrator of the DEA published two separate final rules in the **Federal Register** (67 FR 59161 and 67 FR 59163) amending § 1308.11(g) of Title 21 of the Code of Federal Regulations to temporarily place 2C–T–7, BZP and TFMPP (1-(3-trifluromethylphenyl)piperazine into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). These final rules, which became effective on the date of publication, were based on findings by the Deputy Administrator that the temporary scheduling of BZP, TFMPP and 2C–T–7 was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary

scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. On September 8, 2003, the Administrator published a notice of proposed rulemaking in the **Federal Register** (68 FR 52872) to place BZP, TFMPP and 2C–T–7 into Schedule I of the CSA on a permanent basis. The temporary scheduling of BZP, TFMPP and 2C–T–7 which would have expired on September 19, 2003, was extended to March 19, 2004 (68 FR 53289). One comment was received regarding the proposed placement of these substances in Schedule I of the CSA.

The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse and the relative potential for abuse for 2C–T–7, BZP and TFMPP. The Administrator has submitted these data to the Assistant Secretary for Health, Department of Health and Human Services (DHHS). In accordance with 21 U.S.C. 811(b), the Administrator also requested a scientific and medical evaluation and a scheduling recommendation for 2C–T–7, BZP and TFMPP from the Assistant Secretary of DHHS. On March 10, 2004, the Acting Assistant Secretary for Health recommended that 2C–T–7 and BZP be permanently controlled in Schedule I of the CSA. However, under recommendation of the Food and Drug Administration (FDA) and a scientific evaluation of the National Institute on Drug Abuse (NIDA), the DHHS did not recommend control of TFMPP. Accordingly, TFMPP will no longer be controlled under the CSA after March 19, 2004.

BZP is a piperazine derivative. This substance has not been evaluated or approved for medical use in the U.S. The available scientific evidence suggests that the pharmacological effects of BZP are substantially similar to amphetamine.

BZP is self-administered by monkeys maintained on cocaine and fully generalizes to amphetamine's discriminative stimulus in monkeys. The effects of BZP in amphetamine-trained monkeys strongly suggest that BZP will produce amphetamine-like effects in humans. BZP acts as a stimulant in humans and produces euphoria and cardiovascular changes including increases in heart rate and systolic blood pressure. BZP is about 20 times more potent than amphetamine in producing these effects. However, in subjects with a history of amphetamine dependence, BZP was found to be about 10 times more potent than amphetamine. The risks to the public health associated with amphetamine abuse are well known and documented. BZP is likely to share these same public health risks.

The abuse of BZP was first reported in late 1996 in California. Since that time, the DEA, state and local law enforcement agencies have encountered BZP in California, Connecticut, Florida, Illinois, Indiana, Iowa, Louisiana, Minnesota, Missouri, Nevada, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, Washington, DC, and Wisconsin. Since 2000, there have been 83 cases involving the seizure of nearly 18,000 BZP tablets and over 600,000 grams of BZP powder. Seizures involving the combination of TFMPP and BZP include over 55,000 tablets and over 80 grams of powder.

BZP has increasingly been found in similar venues as the popular club drug MDMA (also known as Ecstasy). BZP, often in combination with TFMPP, is sold as MDMA, promoted as an alternative to MDMA and is targeted to the youth population. BZP (alone or in combination with TFMPP) has been encountered in powder and tablet form and sold on the Internet.

2C–T–7 is the sulfur analogue of 4-bromo-2,5-dimethoxyphenethylamine (2CB) and shares structural similarity with other Schedule I phenethylamine hallucinogens including 2,5-dimethoxy-4-methylamphetamine (DOM) and 1-(4-bromo-2,5-dimethoxyphenyl)-2-aminopropane (DOB). Based on its structural similarity to 2CB, one would expect 2C–T–7's pharmacological profile to be qualitatively similar to 2CB.

2C–T–7 is abused for its action on the central nervous system (CNS), and for its ability to produce euphoria with 2CB-like hallucinations. 2C–T–7 has not been approved for medical use in the United States by the FDA and the safety of this substance for use in humans has never been demonstrated.

Drug discrimination studies in animals indicate that 2C–T–7 is a psychoactive substance capable of producing hallucinogenic-like discriminative stimulus effects (*i.e.*, subjective effects). 2C–T–7's subjective effects were shown to share some commonality with LSD; it partially substituted for LSD up to doses that severely disrupted performance in rats trained to discriminate LSD. In rats trained to discriminate DOM, 2C–T–7 fully substituted for DOM and was slightly less potent than 2CB in eliciting DOM-like effects. The ability of 2C–T–7 to function as a discriminative stimulus has been evaluated in rats trained to discriminative 1.0 mg/kg of 2C–T–7 from saline. After stimulus control was established, 2C–T–7, 2CB (0.6, 1.0, and 2.0 mg/Kg) and LSD (0.1 mg/kg) were substituted for 2C–T–7. Results suggest that both 2CB and LSD share 2C–T–7-like discriminative stimulus effects. 2CB generalized to the 2C–T–7 stimulus cue; 96 percent 2C–T–7-appropriate responding was observed. LSD elicited 95 percent 2C–T–7-appropriate responding.

The subjective effects of 2C–T–7, like those of 2CB and DOM, appear to be mediated through central serotonin receptors. 2C–T–7 selectively binds to the 5–HT receptor system. Users indicate that the hallucinogenic effects of 2C–T–7 are comparable to those of 2CB and mescaline.

The abuse of stimulant/hallucinogenic substances in popular all night dance parties (raves) and in other venues has been a major problem in Europe since the 1990s. In the past several years, this activity has spread to the United States. MDMA and its analogues, are the most popular drugs abused at these raves. Their abuse has been associated with both acute and long-term public health and safety problems. These raves have also become venues for the trafficking and abuse of other controlled substances. 2C–T–7 has been encountered at raves in Wisconsin, California, and Georgia.

The abuse of 2C–T–7 by young adults in the United States began to spread in the year 2000. Since that time, 2C–T–7 has been encountered by law enforcement agencies in Wisconsin, Texas, Tennessee, Washington, Oklahoma, Georgia, and California. 2C–T–7 has been purchased in powder form over the Internet and distributed as such. In the United States, capsules containing 2C–T–7 powder have been encountered.

2C–T–7 can produce sensory distortions and impaired judgment can lead to serious consequences for both the user and the general public. To date, three deaths have been associated with the consumption of 2C–T–7 alone or in combination with MDMA. The first death occurred in Oklahoma during April of 2000; a young healthy male overdosed on 2C–T–7 following intranasal administration. The other two 2C–T–7 related deaths occurred in April 2001 and resulted from the co-abuse of 2C–T–7 with MDMA. One young man died in Tennessee while another man died in the state of Washington.

In 2002, law enforcement data identified an Internet site that sold 2C–T–7. This site was traced to an

individual in Indiana who had been selling large quantities of this substance since January 2000. Sales through this Internet site were thought to be the major source of this drug in the U.S. After further investigation, one clandestine laboratory was identified in Las Vegas, Nevada who was the supplier of 2–C–T–7 for the individual in Indiana.

The DEA received one comment from an organization in response to the proposed placement of 2C–T–7, BZP and TFMPP into Schedule I of the CSA. This organization did not support the proposed placement of these drugs into Schedule I on the following basis: (1) They felt insufficient data exists to support placement into Schedule I as the mere use of these substances was not abuse and (2) Prohibiting the possession of these substances is a substantial infringement of the fundamental right of adults to freedom of thought. Both the DEA and the DHHS have found that sufficient scientific, trafficking and abuse data, as summarized herein, does exist to place 2C–T–7 and BZP in Schedule I of the CSA on a permanent basis. As these substances have no legitimate medical use in the U.S., the trafficking in, and use by individuals for the psychoactive effects they produce, is considered abuse. In addition, the control of these substances in Schedule I of the CSA does not violate any legally protected right.

Based on all the available information gathered and reviewed by the DEA and in consideration of the scientific and medical evaluation and scheduling recommendation by the Assistant Secretary of the DHHS, the Acting Deputy Administrator has determined that sufficient data exist to support the placement of 2C–T–7 and BZP into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The Acting Deputy Administrator finds:

(1) 2C–T–7 and BZP have a high potential for abuse.

(2) 2C–T–7 and BZP have no currently accepted medical use in treatment in the United States.

(3) 2C–T–7 and BZP lack accepted medical safety for use under medical supervision.

In accordance with 21 U.S.C. 811(h)(5), the Acting Deputy Administrator hereby vacates the orders temporarily placing 2C–T–7, BZP and TFMPP into Schedule I of the CSA published in the **Federal Register** on September 20, 2002.

The Acting Deputy Administrator of the DEA hereby certifies that the placement of 2C–T–7 and BZP into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the control of two substances with no currently accepted medical use in the United States.

This final rule is not a significant regulatory action for the purposes of Executive Order (E.O.) 12866 of September 30, 1993. Drug Scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to provisions of E.O. 12866, section 3(d)(1).

This action has been analyzed in accordance with the principles and criteria in E.O. 13132, and it has been determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Requirements

With the issuance of this final order, 2C–T–7 and BZP continue to be subject to regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule I controlled substance, including the following:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports 2C–T–7 and BZP or who engages in research or conducts instructional activities with respect to 2C–T–7 and BZP or who proposes to engage in such activities must submit an application for Schedule I registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations (CFR).

2. *Security.* 2C–T–7 and BZP are subject to Schedule I security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75 (a) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2C–T–7 and BZP which are distributed on or after April 19, 2004, shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for 2C–T–7 and BZP are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of 2C–T–7 and BZP is required to keep an inventory of all stocks of the substances on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in Schedule I for 2C–T–7 and BZP shall conduct an inventory of all stocks of 2C–T–7 and BZP.

6. *Records.* All registrants are required to keep records pursuant to §§ 1304.03, 1304.04 and §§ 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants required to submit reports in accordance with § 1304.31 through § 1304.33 of Title 21 of the Code of Federal Regulations shall do so regarding 2C–T–7 and BZP.

8. *Order Forms.* All registrants involved in the distribution of 2C–T–7 and BZP must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations

9. *Importation and Exportation.* All importation and exportation of 2C–T–7 and BZP must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with 2C–T–7 and BZP not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after March 18, 2004, will continue to be unlawful.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping 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 re-delegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator amends 21 CFR Part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for Part 1308 continues to read as follows:

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

■ 2. Section 1308.11 is amended by:
■ A. Removing paragraphs (g)(3), (4) and (5) and redesignating paragraphs (g)(6) and (7) as (g)(3) and (4) respectively;
■ B. Redesignating existing paragraphs (d)(6) through (d)(31) as paragraphs (d)(7) through (d)(32) respectively;
■ C. Adding a new paragraph (d)(6),
■ D. Redesignating existing paragraphs (f)(2) through (f)(7) as paragraphs (f)(3) through (f)(8) respectively; and
■ E. Adding a new paragraph (f)(2) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(6) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C–T–7)	7348

* * * * * *

(f) * * *

(2) N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine)	7493

Dated: March 15, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04–6110 Filed 3–17–04; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 4654]

RIN 1400–AB49

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Elimination of Crew List Visas

AGENCY: Department of State.

ACTION: Interim final rule.

SUMMARY: This rule makes final on an interim basis the Department's proposed regulations regarding the elimination of crew list visas.

EFFECTIVE DATE: This rule takes effect on June 16, 2004.

Comment Date: Comments on the interim final rule must be received by May 17, 2004. The remaining 30 days until implementation will provide the Department time to evaluate and review public comments received and determine if any additional steps, including a possible extension of an additional 90 days, needs to be taken to ameliorate effects on the shipping industry.

ADDRESSES: Comments may be sent by regular mail to CA/VO/L/R, L–603, SA–1, 2401 E Street, NW., U.S. Department of State, Washington, DC 20520–0106; or by e-mail to *ackerrl@state.gov.* You may view this rule online at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ron Acker, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106, (202) 663–1205 or e-mail *ackerrl@state.gov.*

SUPPLEMENTARY INFORMATION: On December 13, 2002, the Department published a rule (67 FR 76711) proposing to eliminate crew list visas. The Department is now making final on an interim basis that proposed rule.

DHS has authorized this regulation pursuant to the Memorandum of Understanding Between the Secretaries of State and Homeland Security Concerning Implementation of Section 428 of the Homeland Security Act of 2002. The requirements of 22 CFR 41.42 are being removed in coordination with the removal of similar requirements by DHS in its corresponding regulations.

What Are the Statutory Authorities Pertaining to the Crew List Visa?

Authority for the issuance of a crew list visa is derived from sections 101(a)(15)(D) and 221(f) of the Immigration and Nationality Act, 8 U.S.C. 1101(a)(15)(D) and 1201(f), respectively. Section 101(a)(15)(D) exempts aliens serving in good faith as crewmen on board a vessel (other than a fishing vessel having its home port or an operating base in the United States, unless temporarily landing in Guam), or aircraft from being deemed immigrants. Section 221(f), permits an alien to enter the United States on the basis of a crew manifest that has been visaed by a consular officer. However, the latter section does not require a consular officer to visa a crew manifest and it authorizes the officer to deny admission to any individual alien whose name appears on a visaed crew manifest. Further, according to the wording of section 221(f) the use of the visaed crew list appears to have been intended principally as a temporary or emergency measure to be used only until such time as it becomes practicable to issue individual documents to each member of a vessel's or aircraft's crew.

Why Is the Department Eliminating the Crew List Visa?

The Department is eliminating the crew list visa for security reasons. Since the September 11, 2001 attacks, the Department made a review of its regulations to ensure that every effort is being made to screen out undesirable aliens. By eliminating the crew list visa, the Department will ensure that each crewmember entering the United States will be required to complete the nonimmigrant visa application forms, submit a valid passport and undergo an interview and background checks. Additionally, the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107–173) requires that all visas issued after October 26, 2004 have a biometric indicator. This means crew list visas would necessarily be eliminated by that date.

Did the Department Solicit Comments in the Proposed Rule?

The Department did solicit comments, and 82 were received. The text of about half the comments was identical. Most of the other letters expressed the same views, and some had additional comments. A summary of the comments received and the Department's responses follows.

While most of the commentaries requested that the crew list visa be maintained, others asked instead for a long phase-in period of up to a year in order to allow crewmembers time to get individual visas. While the Department agrees that there should be a phase-in period, because the principal purpose of eliminating the crew list visa is to enhance security, the Department does not agree that it should wait an entire year before requiring individual visas of crewmen. Therefore, the Department will make the rule effective ninety days after publication. The Department believes this will be sufficient time for most crewmen who wish to obtain visas to do so. This is especially true in light of the additional procedures the Department will be undertaking to expedite the issuance of individual visas as mentioned later in this discussion.

Several commenters requested that before determining whether to make the proposed rule final, the Department wait at least until the International Labor Organization (ILO) makes a decision on a proposal it has under consideration for a seafarer's ID document that would include biometrics. Most of these commenters felt that the proposed ID could serve as a substitute for a passport and that due to its security features would make crew list visas more secure, even in the absence of consular interviews of all crew members, which is typical when crew list visas are issued. While the Department recognizes that a seafarer's ID containing biometrics could be useful, it is likely to take years for such a document to be developed and adopted widely. Further, one of the principal reasons for requiring individual visas is the need, for security purposes, for a consular officer to personally interview each applicant. Adoption of the new ID card will not address the need for interviews.

Almost all of the commenters expressed concern about the difficulty of crewmen obtaining individual visas. It was stated that cargo shipping is generally routed at the last minute. Thus crewmembers frequently don't know in advance that they will travel to the United States. Further, schedules are