



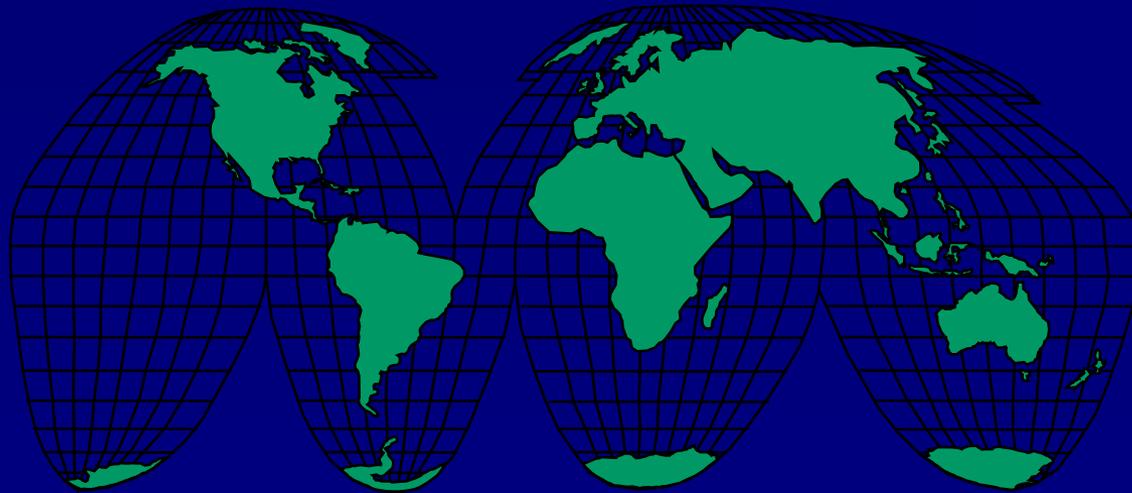
# IMPORT/EXPORT UNIT

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Pharmaceutical Industry Conference

Portland, Oregon

October 14 - 15, 2009





# IMPORT/EXPORT UNIT

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section



U.S. Department of Justice  
Drug Enforcement Administration  
Office of Diversion Control

**Daniel J. Gillen**  
Chief

DEA Headquarters  
Import/Export Unit (ODGI)  
Regulatory Section

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# PRESENTATION TOPICS

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Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Yellow Pages

Guiding Light

Helping Hands

Not A Quota Per Se

Trials and Tribulations

Gyro Bread

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# POINTS OF CONTACT

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

## DEA Form-161 (Exports) & DEA Form-357 (Imports)

1. Ms. Lisa Edelen (202) 307-7285
2. Ms. Chantay Cunningham (202) 307-7164

## DEA Form-236 (Import & Export Declarations)

1. Ms. Betty Veney (202) 307-7181
2. Ms. Beth Fox (202) 307-7222

## Another Important Telephone Number

1. Mr. Fac Simile (202) 307-7503



# MAIL & E-MAIL ADDRESSES

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

DEA Headquarters via U.S. Postal Service  
& Commercial Carriers

Drug Enforcement Administration  
Attn: Import/Export Unit (ODGI)  
8701 Morrissette Drive  
Springfield, VA 22152

E-Mail Address for Return Information

CSIMEX@USDOJ.GOV



# IMPORT/EXPORT FORM GUIDE

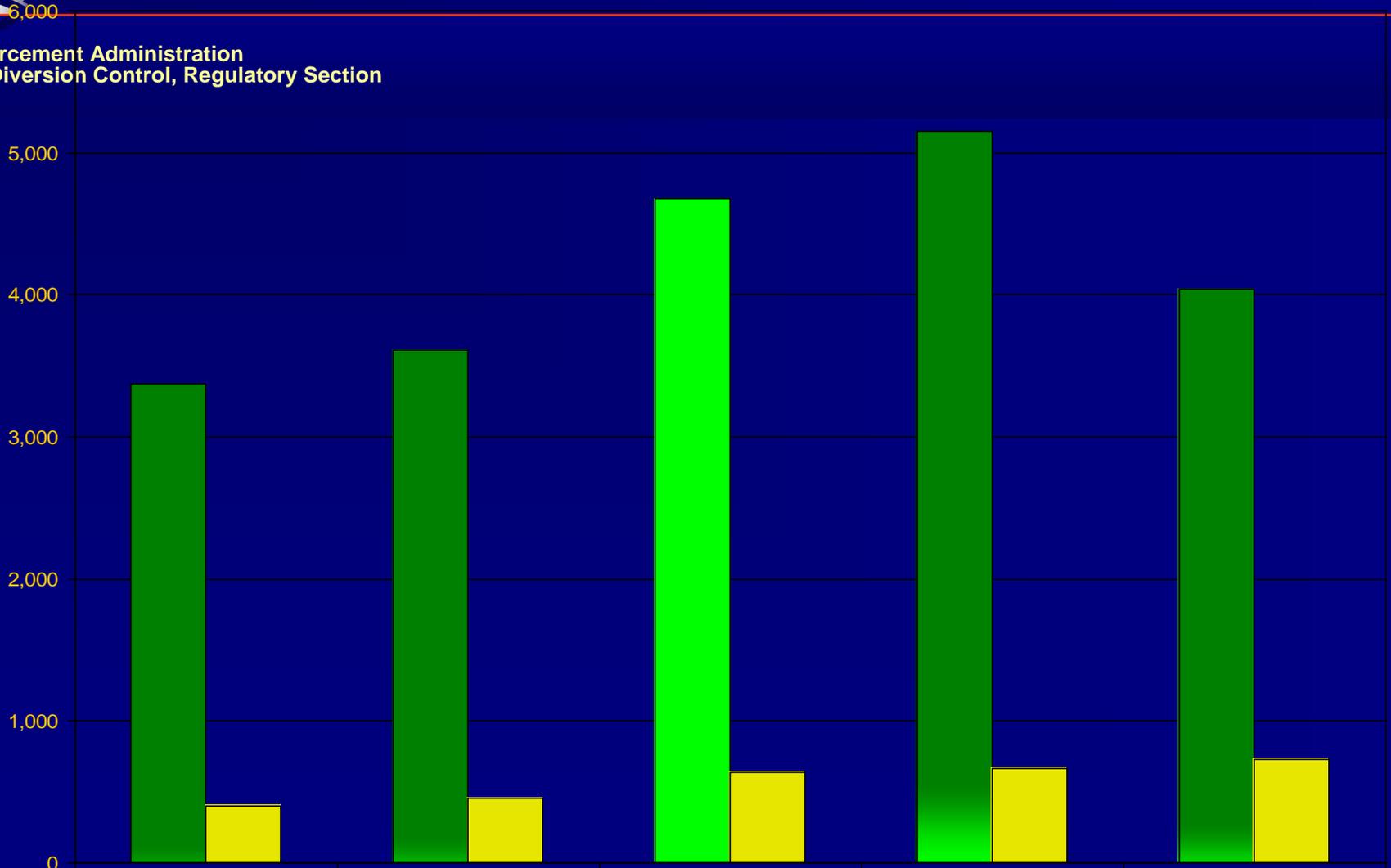
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Office of Diversion Control, Regulatory Section

	DEA-161	DEA-357	DEA-236	
			Export	Import
Schedule I & II	✓	✓		
Schedule III Narcotic	✓	✓		
Schedule III Non-Narcotic (7369 requires a PERMIT)			✓	✓
Schedule IV Narcotic	✓	✓		
Schedule IV Non-Narcotic			✓	✓
Schedule V Narcotic		✓	✓	
Schedule V Non-Narcotic			✓	✓



# PERMITS PROCESSED

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

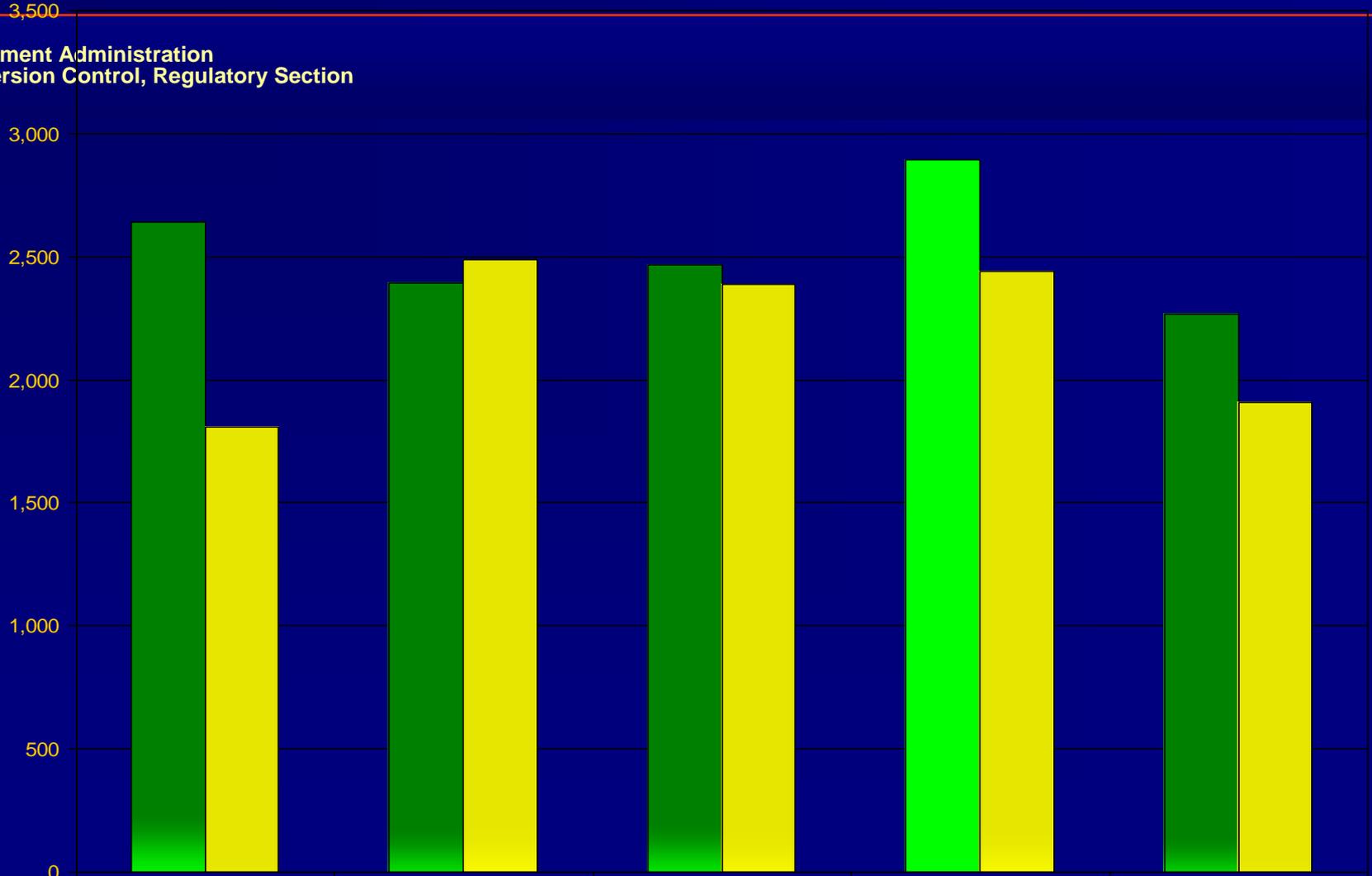


	2005	2006	2007	2008	2009
Exports Permits	3,372	3,611	4,678	5,149	4,035
Imports Permits	403	453	637	663	729



# DECLARATIONS PROCESSED

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section



	2005	2006	2007	2008	2009
■ Export Declarations	2,642	2,391	2,469	2,896	2,264
■ Import Declarations	1,806	2,489	2,390	2,439	1,906



# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Estimates and Assessments are not quotas per se, they are the maximum amount that each country establishes for each [internationally controlled] drug to meet the medical and scientific needs in their country.

Estimates are set for Narcotic Drugs and Assessments are set for Psychotropic Substances.

The Competent National Authority of each country is responsible for providing Estimates and Assessments to the International Narcotics Control Board (INCB); the DEA, specifically the Drug and Chemical Evaluation Section, bears this responsibility for the United States.

# ESTIMATES & ASSESSMENTS



Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

INCB - Windows Internet Explorer

http://www.incb.org/

INCB

International Narcotics Control Board

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## About INCB

- > Mandate
- > Membership
- > INCB President
- > INCB Secretariat
- > INCB Sessions
- >  INCB Brochure

## News

- > Missions & Activities
- > Press Releases
- > Speeches
- > Other issues
- > A century of international drug control
- > International drug control into the 21st Century
- > INCB NEWSLETTER

## Annual Reports

## Welcome to the Web Site of the International Narcotics Control Board (INCB)

The International Narcotics Control Board (INCB) is the independent and quasi-judicial control organ monitoring the implementation of the United Nations drug control conventions. [More ...](#)

20 February 2009

### INCB REPORTS 2008

- [Annual Report 2008](#)  
*Report of the INCB on Follow-up to the 20th Special Session of the General Assembly (UNGASS)*
- [Precursors Report 2008](#)
- [Narcotic Drugs Technical Report 2008](#)
- [Psychotropic Substances Technical Report 2008](#)

### FOR THE MEDIA

- [Requests for interviews](#)
- [INCB at a glance](#)

## Narcotic Drugs

- > 1961 Convention
- > Status of treaty adherence
- > "Yellow List"/ Forms
- > Internet seizures **NEW**
- > Status of estimates
- > Technical Reports
- > Statistical tables **NEW** (downloadable excel format)
- > Questionnaires

### Highlights and latest news

- 24 August 2009 [Prof. Ghodse of INCB participates in Global Cancer Summit, in Dublin \(Ireland\)](#)
- 16-19 August 2009 [Mission to Jordan](#)
- 13 August 2009 [INCB President Prof. Sevil Atasoy meets Dr. Margaret Chan, Director-General of WHO, in Geneva \(Switzerland\)](#)
- 12 August 2009 [INCB President Prof. Sevil Atasoy visits](#)

# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

http://www.incb.org/pdf/e/conv/convention\_1961\_en.pdf - Windows Internet Explorer

http://www.incb.org/pdf/e/conv/convention\_1961\_en.pdf

http://www.incb.org/pdf/e/conv/convention\_1961\_e...

2. Parties shall furnish the information referred to in the preceding paragraph in such manner and by such dates and use such forms as the Commission may request.

*Article 19*

ESTIMATES OF DRUG REQUIREMENTS

1. The Parties shall furnish to the Board each year for each of their territories, in the manner and form prescribed by the Board, estimates on forms supplied by it in respect of the following matters:

- a) Quantities of drugs to be consumed for medical and scientific purposes;
- b) Quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention;
- c) Stocks of drugs to be held as at 31 December of the year to which the estimates relate;
- d) Quantities of drugs necessary for addition to special stocks;
- e) The area (in hectares) and the geographical location of land to be used for the cultivation of the opium poppy;
- f) Approximate quantity of opium to be produced;
- g) The number of industrial establishments which will manufacture synthetic drugs; and
- h) The quantities of synthetic drugs to be manufactured by each of the establishments referred to in the preceding subparagraph.

2. a) Subject to the deductions referred to in paragraph 3 of article 21, the total of the estimates for each territory and each drug except opium and synthetic drugs shall consist of the sum of the amounts specified under subparagraphs *a)*, *b)* and *d)* of paragraph 1 of this article, with the addition of any amount required to bring the actual stocks on hand at 31 December of the preceding year to the level estimated as provided in subparagraph (c) of paragraph 1;

- 9 -



# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

http://www.incb.org/pdf/e/list/form\_bp\_e.pdf - Windows Internet Explorer

http://www.incb.org/pdf/e/list/form\_bp\_e.pdf

**Form B/P**  
or  
 **Modification**

**Assessment of annual medical and scientific requirements  
for substances in Schedules II, III and IV of the  
Convention on Psychotropic Substances of 1971**

(to be furnished to the International Narcotics Control Board (INCB) pursuant to  
Economic and Social Council resolutions 1981/7, 1991/44, 1993/38 and 1996/30)

Country or territory: \_\_\_\_\_ Date: \_\_\_\_\_

Competent office: \_\_\_\_\_

Name of officer responsible: \_\_\_\_\_

Title or function: \_\_\_\_\_ Signature: \_\_\_\_\_

These assessments should be effective as of: \_\_\_\_\_



# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

http://www.incb.org/pdf/e/estim/2009/EstAug09.pdf - Windows Internet Explorer

http://www.incb.org/pdf/e/estim/2009/EstAug09.pdf

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Dipipanone	35 000	Methadone intermediate	26 000 000
Ecgonine	1	Morphine	110 529 737
Etorphine	50	Noracetylmethadol	2
Fentanyl	100 000	Norlevorphanol	52
Heroin	70 000	Normethadone	2
Hydrocodone	1 000	Opium	414 669 072
Hydromorphone	10 000	Oxycodone	56 220 030
Levorphanol	300	Oxymorphone	450 190
Methadone	7 000 000	Pethidine	9 753 000
Methadone intermediate	7 000 000	Remifentanil	3 000
Morphine	9 700 000	Sufentanil	10 300
Morphine-N-oxide	14	Thebaine	69 517 194
Norlevorphanol	2	Trimeperidine	2
Opium	432 000	<b>Uruguay</b>	
Oxycodone	400 000	Alfentanil	1
Oxymorphone	31 500	Codeine	44 240
Pethidine	1 000 000	Dextropropoxyphene	102 400
Pethidine intermediate A	2 500 000	Dihydrocodeine	2 560
Pholcodine	1 001 000	Ethylmorphine	1 920
Remifentanil	2 500	Fentanyl	128
Sufentanil	1 000	Hydrocodone	691
Thebaine	20 000 000	Methadone	1 805
<b>United Republic of Tanzania</b>		Morphine	15 360
Cannabis	2	Oxycodone	51
Cannabis resin	2	Pethidine	10 000
Cocaine	2	Remifentanil	26
Codeine	100 000	Sufentanil	5
Dextromoramide	40 000	<b>Uzbekistan</b>	
Dextropropoxyphene	35 000	Codeine	400
Etorphine	10	Fentanyl	50
Fentanyl	20	Morphine	5 000
Heroin	2	Remifentanil	10
Methadone	2	Sufentanil	20
Morphine	20 000	Thebaine	30
Opium	2	Trimeperidine	12 000
Pethidine	100 000	<b>Vanuatu</b>	
Thebaine	2	Codeine	7 000
<b>United States of America</b>		Dextropropoxyphene	3 000
Acetylmethadol	2	Dihydrocodeine	21
Alfentanil	8 000	Diphenoxylate	21
Allylprodine	2	Fentanyl	3
Alphacetylmethadol	2	Morphine	210
Alphameprodine	2	Opium	21
Alphamethadol	3	Oxycodone	21
Alphaprodine	2	Pethidine	10



# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

http://www.incb.org/pdf/e/assess/Assessments\_Updated\_31\_August\_2009.pdf - Windows Internet Explorer

http://www.incb.org/pdf/e/assess/Assessments\_Updated\_31\_August\_2009.pdf

http://www.incb.org/pdf/e/assess/Assessments\_Updated\_31\_August\_2009.pdf

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### PSYCHOTROPICS ASSESSMENTS IN GRAMS AS AT 31 AUGUST 2009

<i>Substance</i>	<i>Grams</i>	<i>Substance</i>	<i>Grams</i>
Pentazocine	100 000	Ethchlorvynol	100
Phenobarbital	3 000 000	Ethinamate	2
<b><u>United States of America</u></b>		Ethyl loflazepate	1
2C-B	7	Etilamfetamine	1
Allobarbitol	132	Fencamfamin	1
Alprazolam	4 160 000	Fenetylline	1
Amfepramone	1 742 869	Fenproporex	1
Amfetamine	7 933 900	Fludiazepam	1
Amineptin	1	Flunitrazepam	10
Aminorex	18	Flurazepam	687 420
Amobarbital	576	GHB	23 600 000
Barbital	3 878 830	Glutethimide	5 082
Benzfetamine	889 000	Halazepam	8
Bromazepam	11	Haloxazolam	1
Brotizolam	1	Ketazolam	5
Buprenorphine	1 971 065	Lefetamine (SPA)	1



# ESTIMATES & ASSESSMENTS

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Please note: the DEA deems Buprenorphine to be a Narcotic Drug; the INCB deems it to be a Psychotropic Substance.

The Controlled Substances imported into the U.S. that have bumped up against U.S. Assessments during the past two years are:

- Buprenorphine
- Mazindol
- Phendimetrazine
- Phentermine
- Temazepam
- Zolpidem



# CLINICAL TRIALS MATERIAL

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Controlled substances in schedules I to V can be imported into the U.S. for clinical trials providing the importer meets the requirements of 21 CFR Part 1300. Ditto for exports.

An Importer, after approval from the DEA, can import small amounts of controlled substances into the U.S. for clinical trials; Be prepared to provide a letter of explanation for any amounts you are requesting to be imported.



# CLINICAL TRIALS MATERIAL

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

Just because the DEA may permit the import of a controlled substance in schedule I or II or any narcotic controlled substance in schedule III, IV, or V for clinical trials doesn't mean the DEA will do the same for commercial purposes.

General questions regarding the import and export of controlled substances for clinical trials should be directed to ODGI; Humdingers should be addressed by letter and directed to Mr. Mark Caverly, Chief, Liaison and Policy Section, Office of Diversion Control.



# P.I.T.A. ISSUES

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

The DEA would be very appreciative if importers and exports of controlled substances would report their return information (closure information) to the DEA within 30 days after a transaction occurs.

Return Information is required to be reported to the DEA for re-exports within 30 days after the initial export from the U.S. per 21 CFR § 1312.22 (c)(7).



# P.I.T.A. ISSUES

Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

http://www.incb.org/pdf/e/conv/convention\_1971\_en.pdf - Windows Internet Explorer

http://www.incb.org/pdf/e/conv/convention\_1971\_en.pdf

http://www.incb.org/pdf/e/conv/convention\_1971\_e...

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*Article 16*

REPORTS TO BE FURNISHED BY THE PARTIES

1. The Parties shall furnish to the Secretary-General such information as the Commission may request as being necessary for the performance of its functions, and in particular an annual report regarding the working of the Convention in their territories including information on:
  - a) Important changes in their laws and regulations concerning psychotropic substances;  
and
  - b) Significant developments in the abuse of and the illicit traffic in psychotropic substances within their territories.
2. The Parties shall also notify the Secretary-General of the names and addresses of the governmental authorities referred to in sub-paragraph *f*) of article 7, in article 12 and in paragraph 3 of article 13. Such information shall be made available to all Parties by the Secretary-General.
3. The Parties shall furnish, as soon as possible after the event, a report to the Secretary-General in respect of any case of illicit traffic in psychotropic substances or seizure from such illicit traffic which they consider important because of:
  - a) New trends disclosed;
  - b) The quantities involved;
  - c) The light thrown on the sources from which the substances are obtained; or
  - d) The methods employed by illicit traffickers.

Copies of the report shall be communicated in accordance with sub-paragraph *b*) of article 21.
4. The Parties shall furnish to the Board annual statistical reports in accordance with forms prepared by the Board:
  - a) In regard to each substance in Schedules I and II, on quantities manufactured, exported to and imported from each country or region as well as on stocks held by manufacturers;
  - b) In regard to each substance in Schedules III and IV, on quantities manufactured, as well as on total quantities exported and imported;
  - c) In regard to each substance in Schedules II and III, on quantities used in the



# IMPORT/EXPORT UNIT

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Drug Enforcement Administration  
Office of Diversion Control, Regulatory Section

# Questions?

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