

Drug Scheduling and Chemical Controls

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**DRUG & CHEMICAL EVALUATION SECTION
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION**

JUNE 18, 2013

Drug & Chemical Evaluation Section (ODE)



Activities:

- Conduct studies and evaluations pertaining to all aspects of drug control and chemical regulation under CSA
 - ✦ Control status determinations
 - ✦ Drug scheduling
 - ✦ Exemptions
- Generate reports regarding drug abuse, chemical diversion and emergent/changing trafficking trends
- Provide technical and regulatory control information and trending to federal, state, and local public health and law enforcement officials

Discussion

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- **Control Status Determinations**
- **Scheduling actions**
 - FDA approvals
 - Petitions
 - DEA initiated actions
 - Chemical controls
- **Exemptions**
 - Anabolic steroid products
 - Anabolic steroid veterinary implants
 - Chemical mixtures
 - Chemical preparations

Control Status Determinations

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- **Substances are evaluated as to their control status under the CSA**
 - Is the substance named?
 - Is it defined?
- **A written response is generated as to the control status**
- **If controlled , a drug code is provided**

Insert image

Control Status Inquiry

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- A control status inquiry can be placed directly with ODE. Include:
 - Chemical name
 - Chemical structure
- Mailing address can be found on the Office of Diversion Control's website

(http://www.deadiversion.usdoj.gov/21cfr/cfr/1321/1321_01.htm)

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Controlled Substance Schedules

- List of Controlled Substances
- Exempt Lists

List of Controlled Substances

- Disclaimer
- Abbreviations
- Definition of Controlled Substance Schedules
- Lists of Scheduling Actions, Controlled Substances, Regulated Chemicals (May 2013)

Scheduling Actions	Controlled Substances	List I and II Regulated Chemicals
Alphabetical Order	Alphabetical Order	Alphabetical Order
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	CSA Schedule	List Number
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Exempt Lists

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Drug Scheduling, Chemical Controls, and Exemptions

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SCHEDULING ACTIONS COMPLETED (2010-2013) AND IN-PROCESS

Types of Scheduling Actions

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- **Formal**

- HHS scheduling recommendation required
- 8-factor analysis

- **Administrative**

- Anabolic Steroids
- Synthetic Cannabinoids

- **Temporary (emergency)**

- 3 of 8 factors
- Finding “imminent hazard to public safety”
- 2 years in Schedule I

- **Congressional action (legislative)**

- Anabolic Steroid Control Acts of 1990 and 2004
- Synthetic Drug Abuse and Prevention Act of 2012 (SDAPA)

- **Compliance with international treaties**

Formal Scheduling

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As set forth under 21 U.S.C 811(h) are to be considered in the evaluation

- 1. Its actual or relative potential for abuse**
- 2. Scientific evidence of its pharmacological effects**
- 3. The state of current scientific knowledge regarding the substance**
- 4. Its history and current pattern of abuse**
- 5. The scope, duration, and significance of abuse**
- 6. What, if any, risk there is to the public health**
- 7. Its psychic or physiological dependence liability**
- 8. Whether the substance is an immediate precursor of a substance already controlled**

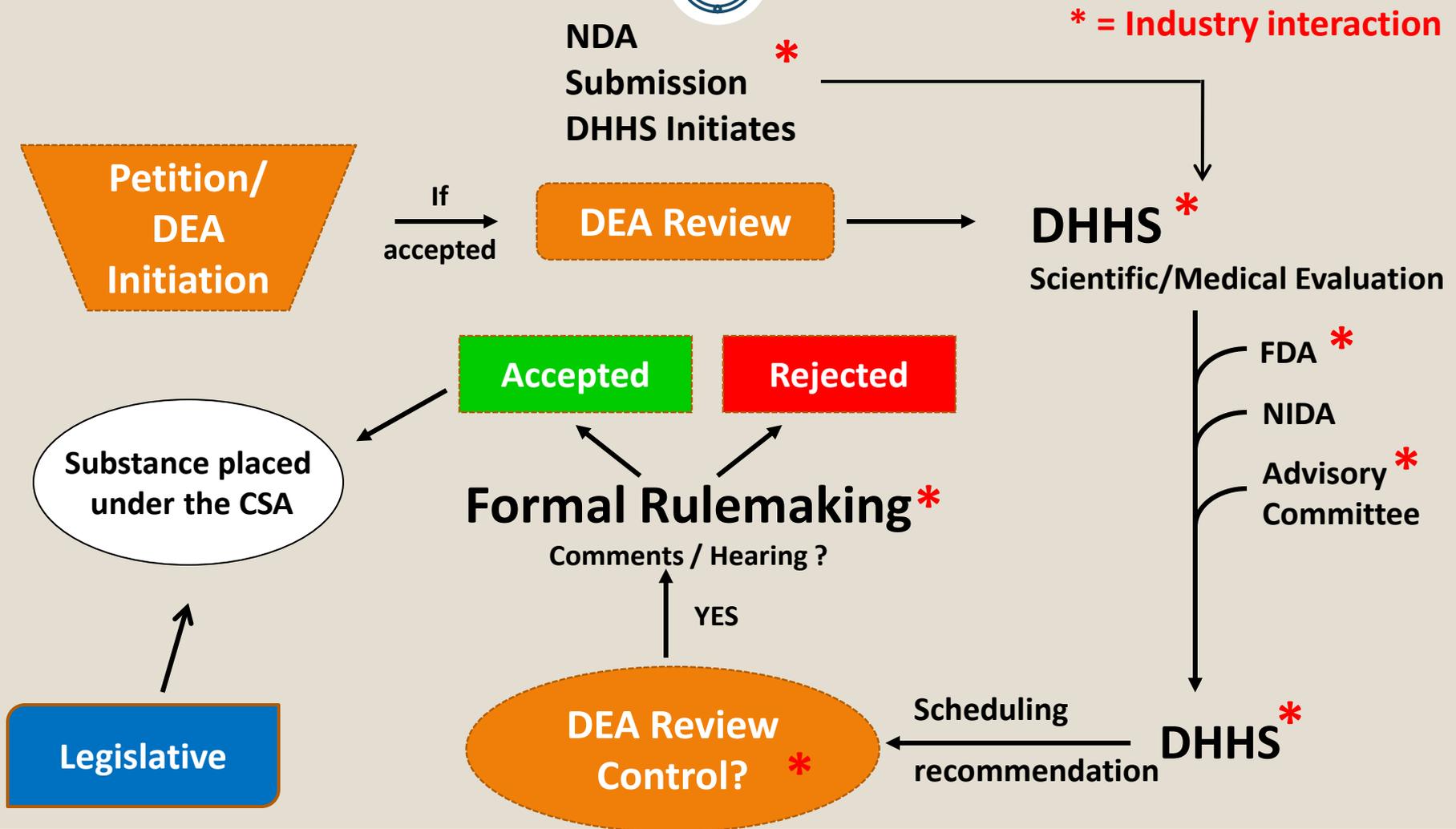
Formal Scheduling Process

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- **A substance is placed under the CSA per an 8-factor analysis**
- **DEA requirements:**
 - Conduct requirements 8-factor analysis
 - Regulatory impact analysis
 - Publish a public notice
 - Evaluate comments
 - Publish a final action
- **Schedule is based upon**

General Scheduling Flowchart

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Scheduling Actions (2010-2013) - Schedules II-V

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- Carisoprodol
 - Petition
 - 2012 – Final Rule
- Ezogabine
 - New molecular entity, Schedule V placement
 - Dec 2011 – Final Rule
- Lorcaserin
 - New molecular entity, schedule IV placement
 - May 2013 – Final Rule

Scheduling Actions in Process

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- **Propofol**

- Short-acting sedative
- Mar 2008 – petition to control
- DHHS recommends placement in Schedule IV
- Nov 1, 2010 – NPRM published
- **DEA preparing scheduling documents**

- **Tramadol**

- Opioid analgesic
- 2005 - three Petitions to schedule
- Apr 2007 - DEA submitted review to DHHS and requests recommendation
- Sep 2010 - DHHS provides a scheduling recommendation
- **DEA preparing scheduling documents**

Scheduling Actions in Process

14

- **Alfaxalone**

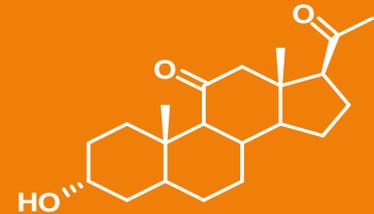
- Veterinary neurosteroid
- Jul 2012 - Received FDA scheduling recommendation
- Mar 2013- Published Notice of Proposed Rulemaking
- Finalizing Final Rule

- **Perampanel**

- Jan 2013 - Received FDA scheduling recommendation
- Drafting Notice of Proposed Rulemaking

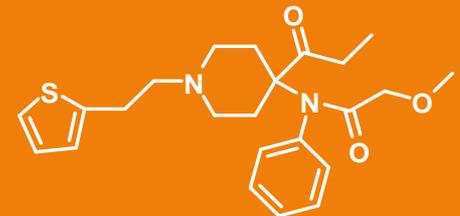
- **Thiafentanil**

- Veterinary analgesic



alfaxalone

Insert perampanel structure



thiafentanil (A-3080)

Drug Scheduling, Chemical Controls, and Exemptions

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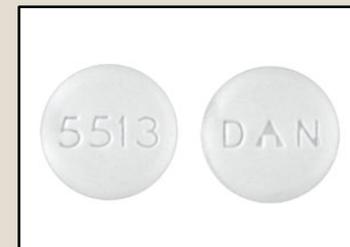
PETITIONS

Petition

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Carisoprodol (Soma)

- Centrally acting skeletal muscle relaxant
- Mar. 1996 - DEA submitted review doc to DHHS
- Feb. 1997 - DHHS convened an Advisory Committee
 - ✦ pharmacokinetic and abuse liability data were insufficient to control
- NIDA provides abuse liability data
- Oct. 2009 - DHHS provides a scheduling recommendation
- Nov. 2009 –DEA publishes a Notice of Proposed Rule Making (74 FR 59108)
- May 2010 – Announcement of hearing
- Aug 2010 – Hearing concludes
- Dec 2011 Final rule placing in Schedule IV (77 FR 77330)

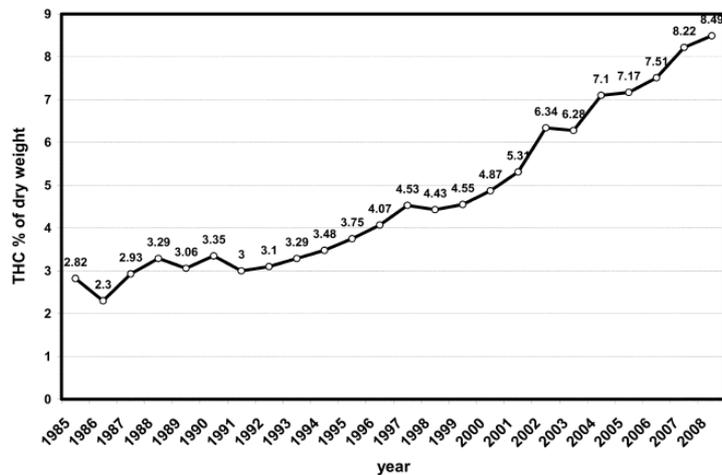


Petitions

18

- Oct. 2002 – Petition received to reschedule marijuana
- Jul. 2004 – Forwarded to DHHS
- Dec. 2006 – DHHS recommendation received
- Jul. 8, 2011 - Denial of petition to initiate proceedings to reschedule marijuana (76 FR 40552)

Figure 1. Average Percentage of Δ^9 -THC in Samples of Seized Marijuana (1985 –2008)
(Source: The University of Mississippi Potency Monitoring Project)



Meets Schedule I criteria:

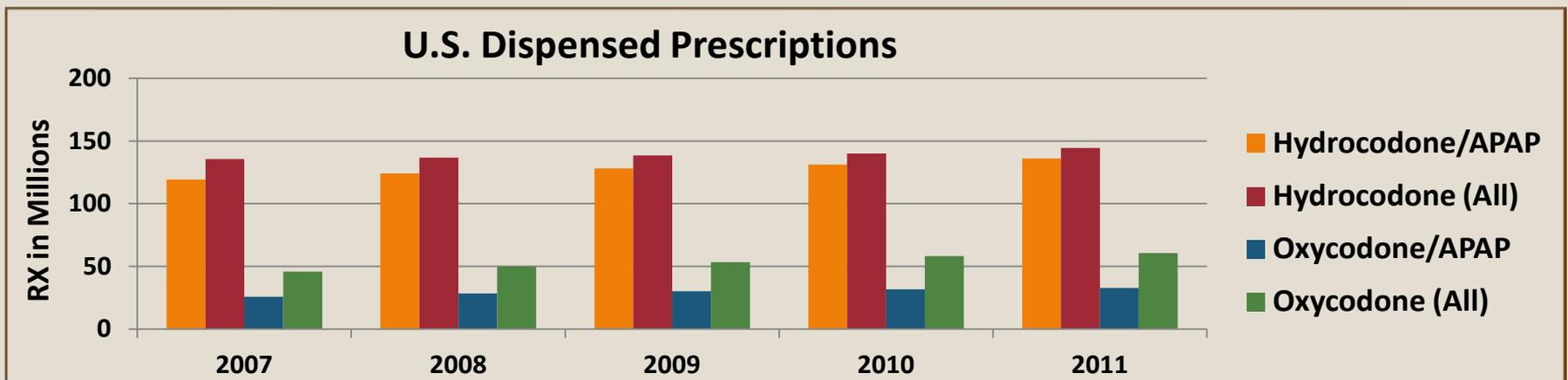
- (1) ***Marijuana has a high potential for abuse.*** *The DHHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.*
- (2) ***Marijuana has no currently accepted medical use in treatment in the United States.*** *According to established case law, marijuana has no “currently accepted medical use” because: The drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.*
- (3) ***Marijuana lacks accepted safety for use under medical supervision.*** *At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication.*

Accepted Petitions Under Review

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Hydrocodone combination products

- 1999 DEA receives citizen petition to reschedule
- 2004 DEA requests a scientific and medical review by DHHS
- 2008 DHHS provides recommendation to maintain combination products in Schedule III
- 2009 DEA communicates new information and requests re-analysis
- Jan 24-25, 2013 - DHHS convenes an Advisory Committee



Petition

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Tramadol

- Opioid analgesic
- 2005 - three Petitions to schedule
- Apr 2007- DEA submitted review doc to DHHS
- Sep 2010 – DHHS provides a scheduling recommendation
- **DEA preparing documents for public notice**

Other Petitions under Review

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- **Sibutramine**

- Schedule IV substance; petition to decontrol
- Under DHHS review

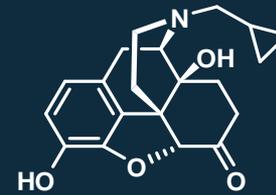
- **6 β -Naltrexol**

- Schedule II;
- naltrexone metabolite, petition to decontrol
- Under DHHS review

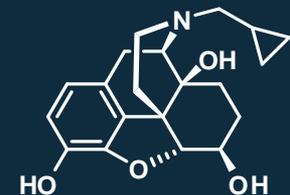
- **Generics of Marinol**

- Marinol, Schedule III
- Nov 1, 2010 – NPRM published

Public Warnings – Undeclared Ingredients



naltrexone



6 β -naltrexol

Marinol



Drug Scheduling, Chemical Controls, and Exemptions

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DEA INITIATED SCHEDULING ACTIONS

Formal Scheduling Actions by DEA

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- **ANPP**

- Fentanyl precursor
- Fentanyl-related overdose deaths
- Jun 29, 2010 - placed in Schedule II

- **5-MeO-DMT**

- Hallucinogenic tryptamine
- Dec 20, 2010 - placed in Schedule I

Insert image

- **Methylone**

- “bath salt” drug
- Oct 2011 - Temporarily scheduled
- Apr 2013 - placed in Schedule I

Scheduling of Novel Psychoactive Substances

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Temporary placement

- Placement upon finding “the substance poses an imminent hazard to public safety”
 - Mar 2011 - 5 synthetic cannabinoids
 - Oct 2011 - 3 cathinones
 - May 2013 - 3 synthetic cannabinoids

Formal placement

- Synthetic Drug Abuse Prevention Act of 2012
 - Placed 26 substances in CI
 - Provided for future scheduling
- Methylone

Drug Scheduling, Chemical Controls, and Exemptions

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CHEMICAL CONTROLS

Chemical Controls

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- **Ergocristine**

- Precursor used in the illicit manufacture of Lysergic Acid Diethylamide, as a List I Chemical
- May 2, 2011 – List I Chemical
 - ✦ all transactions regardless of size, shall be regulated

- **Phosphorous Chemical Mixtures**

- Chemicals used in the illicit manufacture of methamphetamine
- July 5, 2011- Final Rule, Effective
- Concentration limits on chemical mixtures containing red phosphorus and/or hypophosphorous acid and its salts.
 - ✦ Chemical mixtures containing <80% or less red phosphorus and mixtures containing hypophosphorous acid and its salts (hypophosphite salts) in a concentration of 30 percent and less, are exempt
 - ✦ Provides legitimate industry with an exemption application

Drug Scheduling, Chemical Controls, and Exemptions

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EXEMPTIONS

Exemptions

- **Exclusion of Veterinary Anabolic Steroid Implant Products**
 - (21 CFR 1308.26)
- **Anabolic Steroid Products**
 - (21 CFR 1308.34)
- **Chemical mixtures**
 - (21 CFR **XXX**)
- **Chemical preparations**
 - (21 CFR 1308.24)
- **Prescription drugs**
 - (21 CFR 1308.32)

Veterinary Steroidal Implants

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- **Approved anabolic steroid implants for livestock**
 - Excluded under 21 CFR 1308.26(a)
 - Application
 - DEA publishes a public notice in FR
- **Note: exemption is for the finished product and does not included the in-process**



Anabolic Steroid Product Exemption

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- **Section 1308.33 provides for an application**
- **The application:**
 - 1) The name and address of the applicant;
 - 2) The name of the product;
 - 3) The chemical structural formula or description for any anabolic steroid contained in the product;
 - 4) The complete description of dosage and quantitative composition of the dosage form;
 - 5) A description of the delivery system, if applicable;
 - 6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;
 - 7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;
 - 8) The label and labeling of the immediate container and the commercial containers, if any, of the product;
 - 9) The units in which the dosage form is ordinarily available; and
 - 10) The facts which the applicant believes justify exemption
- **DEA transmits application to HHS for scientific review and recommendation**
- **Publishes in the Federal Register the recommendation for the public**

Anabolic Steroid Products Exemption

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- Exemptions are product and company specific
- Last exemption granted on April 16, 2008 (73 FR 14178)
- Current listing of exemptions can be found on Office of Diversion Control's website

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Exemption for Chemical Mixtures

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- **Section 1310.13 -Application**
- **The Administrator may, by publication of a Final Rule in the Federal Register, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:**
 - The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
 - The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered

Chemical Mixture Exemption Evaluation

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- DEA receives an application
- Notifies applicant if application is accepted for filing
- Evaluates the application
 - qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals);
 - Justification for exempt status for the chemical mixture or group of mixtures. How the mixture meets the exemption criteria?
- If granted, a notice is published in the FR
 - Effective upon publication
 - However, allows for interested parties to comment regarding finding of fact

Chemical Preparation Exemption

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- **Section 21 CFR 1308.23: Exemption of certain chemical preparations; application**
 - preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal
 - Contains no narcotic controlled substance
 - Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse
- **DEA conducts an evaluation of the application**

Exempt Chemical Preparation Facts



- Listing of ECPs on Office of Diversion Control's website
 - May 2013
- 9,800 exemptions to date
- FY2012, evaluated 309 products
 - 244 approvals
 - 65 denials

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

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Exempt Prescription Products

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- **Provides for any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in:**
 - 1308.12 (e);
 - 1308.13 (b) or (c);
 - 1308.14;
 - 1308.15
- exempt from application of all or any part of the Act**
- **Section 1308.31 provides the application requires for exemption of a nonnarcotic prescription product**

Exempt Prescription Products



- DEA notifies applicant of receipt of application
- If accepted for filing, a notice is published in FR which provides for comment
- DEA evaluates the application and comments
- DEA publishes a Final Order in the FR, the findings of fact and conclusions

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Contact Info

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Drug & Chemical Evaluation Section

Office of Diversion Control

Drug Enforcement Administration

Main number: (202) 307-7183

Links: www.dea.gov/diversion/fed_regs/index.html