

Regulatory Update

DEA 11th Chemical Industry Conference
September 21-22, 2010
Denver, Colorado



*Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control*

Chemical Registrant Population

as of 9/2/2010

Total CSA Population: 1,357,960

- Chemical Manufacturer - 201
- Chemical Distributor - 567
- Chemical Importer - 169
- Chemical Exporter - 159

CMEA Self-Certification Status

	8/20/08	9/02/10
General Merchandise Stores	331	55
Convenience Stores	5,541	2,633
Discount Department Stores	1,758	1,805
Gas Stations	8,666	6,668
Grocery Stores	4,646	6,670
Other Health & Personal Care	175	196
Pharmacy and Drug Stores	28,957	34,626
Specialty Food Stores	14	4
Warehouse Clubs & Superstores	4,376	4,647
Total	54,375	57,308

Self-Certification Status

8/20/08

Top Ten States by Total Number

9/2/10

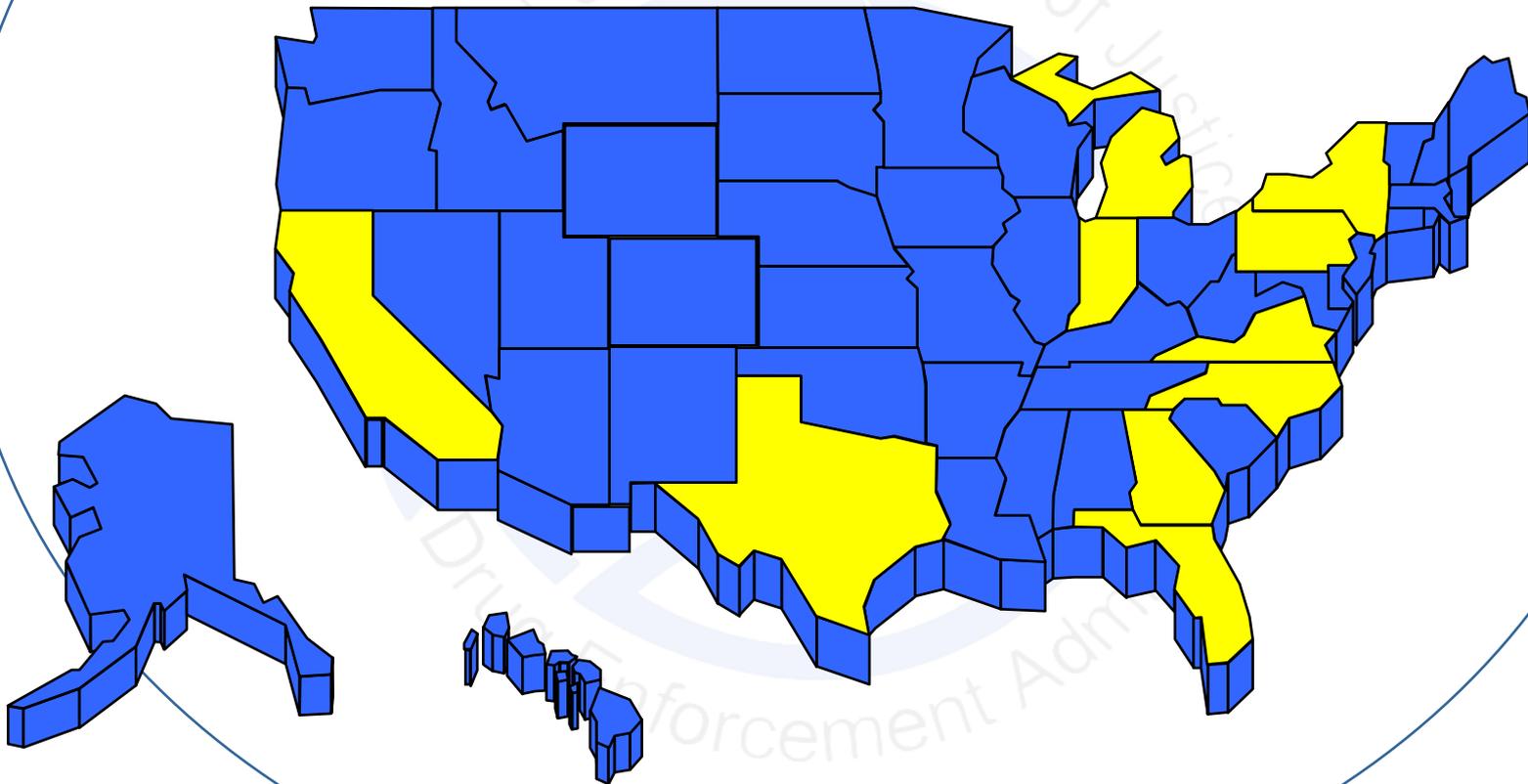
Florida	4,026
California	3,518
Texas	3,150
Pennsylvania	2,738
Georgia	2,650
New York	2,598
North Carolina	2,557
Indiana	2,436
Michigan	2,195
Virginia	1,860

Florida	4,315
California	4,121
New York	3,779
Texas	3,279
Pennsylvania	2,836
Georgia	2,402
Ohio	2,359
North Carolina	2,321
Indiana	2,113
Virginia	1,781

Self-Certification Status

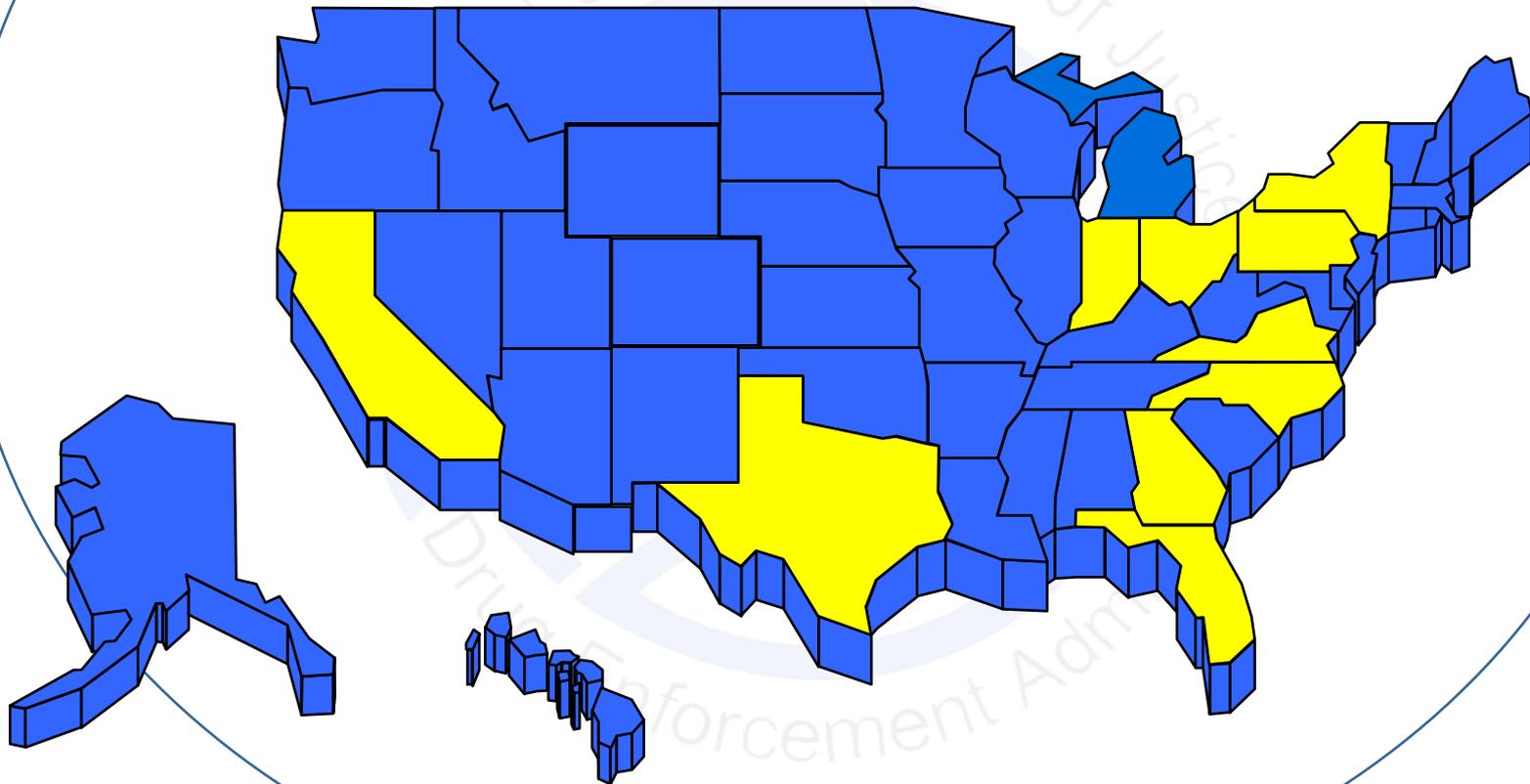
as of 8/20/2008

Top Ten States by Total Number



Self-Certification Status as of 9/2/2010

Top Ten States by Total Number





Unified Agenda

Unified Agenda

- aka Semiannual Regulatory Agenda
- Published in the Federal Register
 - 2 X per year, usually April & October
- Summarizes the rules and proposed rules that each agency expects to issue during the next year



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Agency Rule List - Spring 2010

Department of Justice

Agency	Agenda Stage of Rulemaking	Title	RIN
DOJ/LA	Prerule Stage	National Standards to Prevent, Detect, and Respond to Prison Rape	1105-AB34
DOJ/LA	Proposed Rule Stage	Consolidation of Regulations Governing Administrative Forfeiture for Department of Justice Law Enforcement Agencies; Application of Department Regulations to Seizures for Forfeiture by ATF	1105-AA74
DOJ/LA	Proposed Rule Stage	Procedures for Suspension and Removal of Panel Trustees and Standing Trustees	1105-AB12
DOJ/LA	Proposed Rule Stage	Conforming OWW Grant Programs Regulations to Statutory Changes	1105-AB15
DOJ/LA	Proposed Rule Stage	Research Misconduct	1105-AB25
DOJ/LA	Proposed Rule Stage	Disclosure or Production of Records or Information	1105-AB27
DOJ/LA	Proposed Rule Stage	Uniform Forms for Periodic Reports for Chapter 11 Cases	1105-AB30
DOJ/LA	Proposed Rule Stage	Claims Under the Radiation Exposure Compensation Act; Requirements for Submission of Identification Records	1105-AB35
DOJ/LA	Final Rule Stage	Procedures for Review of Denial of Claims of Standing Trustee for Actual, Necessary Expenses	1105-AB16
DOJ/LA	Final Rule Stage	Application Procedures and Criteria for Approval of Nonprofit Budget and Credit Counseling Agencies by U.S. Trustees	1105-AB17
DOJ/LA	Final Rule Stage	Production of Certain Information or Testimony by State or Local Law Enforcement or Prosecutive Officials Serving on a Department of Justice Task Force	1105-AB21
DOJ/LA	Final Rule Stage	Applicability of the Sex Offender Registration and Notification Act	1105-AB22
DOJ/LA	Final Rule Stage	Standards for the Administrative Collection of Claims	1105-AB26

DOJ/FBI	Long-Term Actions	Implementation of Sections 104 and 109 of the Communications Assistance for Law Enforcement Act--Notice of Actual and Maximum Capacity: Paging, MSS, SMR, and ESMR	1110-AA22
DOJ/DEA	Proposed Rule Stage	Chemical Mixtures Containing Listed Forms of Phosphorus	1117-AA66
DOJ/DEA	Proposed Rule Stage	Limited Exemption for Peyote Use in Traditional Ceremonies With a Traditional Indian Religion by Members of Federally Recognized Indian Tribes	1117-AA97
DOJ/DEA	Proposed Rule Stage	Registration Requirements for Individual Practitioners Operating in a "Locum Tenens" Capacity	1117-AB21
DOJ/DEA	Proposed Rule Stage	Identification of Institution-Based Individual Practitioners	1117-AB22
DOJ/DEA	Proposed Rule Stage	Control of Ergocristine, a Chemical Precursor Used in the Illicit Manufacture of Lysergic Acid Diethylamide, as a List I Chemical	1117-AB24
DOJ/DEA	Proposed Rule Stage	Implementation of the Methamphetamine Production Prevention Act of 2008	1117-AB25
DOJ/DEA	Proposed Rule Stage	Voluntary Surrender of Certificate of Registration	1117-AB27
DOJ/DEA	Proposed Rule Stage	Schedules of Controlled Substances: Exempted Prescription Product; River Edge Pharmaceutical, Servira	1117-AB28
DOJ/DEA	Final Rule Stage	Electronic Prescriptions for Controlled Substances	1117-AA61
DOJ/DEA	Final Rule Stage	Chemical Mixtures Containing Gamma-Butyrolactone	1117-AA64
DOJ/DEA	Final Rule Stage	Retail Sales of Scheduled Listed Products; Chemical; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products	1117-AB05
DOJ/DEA	Final Rule Stage	Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation	1117-AB06
DOJ/DEA	Final Rule Stage	Removal of Thresholds for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropranolamine	1117-AB10
DOJ/DEA	Final Rule Stage	Record Requirements for Chemical Distributors	1117-AB14
DOJ/DEA	Final Rule Stage	Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance	1117-AB16
DOJ/DEA	Final Rule Stage	Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008	1117-AB20
DOJ/DEA	Final Rule Stage	Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thénylfentanyl as Controlled Substances	1117-AB26
DOJ/DEA	Long-Term Actions	Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropranolamine	1117-AA62
DOJ/DEA	Long-Term Actions	Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration	1117-AB18
DOJ/DEA	Completed Actions	Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropranolamine	1117-AB07
DOJ/DEA	Completed Actions	Registration Requirements for Importation and Manufacture of Prescription Drug Products	

Legal Authority: [21 USC 802](#); [21 USC 830](#); [21 USC 871\(b\)](#)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/19/2002	67 FR 47493
Correction	08/19/2002	67 FR 53842
Correction	09/05/2002	67 FR 56776
ANPRM Comment Period End	09/17/2002	
NPRM	11/12/2008	73 FR 66815
NPRM Comment Period End	01/12/2009	
Final Action	07/00/2010	
Final Action Effective	08/00/2010	

Additional Information: DEA-222

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Small Entities Affected: No

Federalism: No

Included in the Regulatory Plan: No

Public Comment URL: www.deadiversion.usdoj.gov

RIN Data Printed in the FR: No

Related RINs: Related to 1117-AA31

Agency Contact:

Mark W. Caverly

Chief, Liaison and Policy Section

Department of Justice

Drug Enforcement Administration

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-222P]

RIN 1117-AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

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

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing that chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, be automatically exempt from regulatory controls under the Controlled Substances Act (CSA). DEA is seeking through this rulemaking to exempt only those chemical mixtures that do not represent a significant risk of diversion. If finalized as proposed, this regulation would result in GBL chemical mixtures, in concentrations greater than 70 percent, becoming

controlled substance gamma-hydroxybutyric acid (GHB).

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption. As a result, 21 CFR 1310.13 provides for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration criteria.

DATES: Written comments must be postmarked and electronic comments sent on or before January 12, 2009.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-222p" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent

wordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

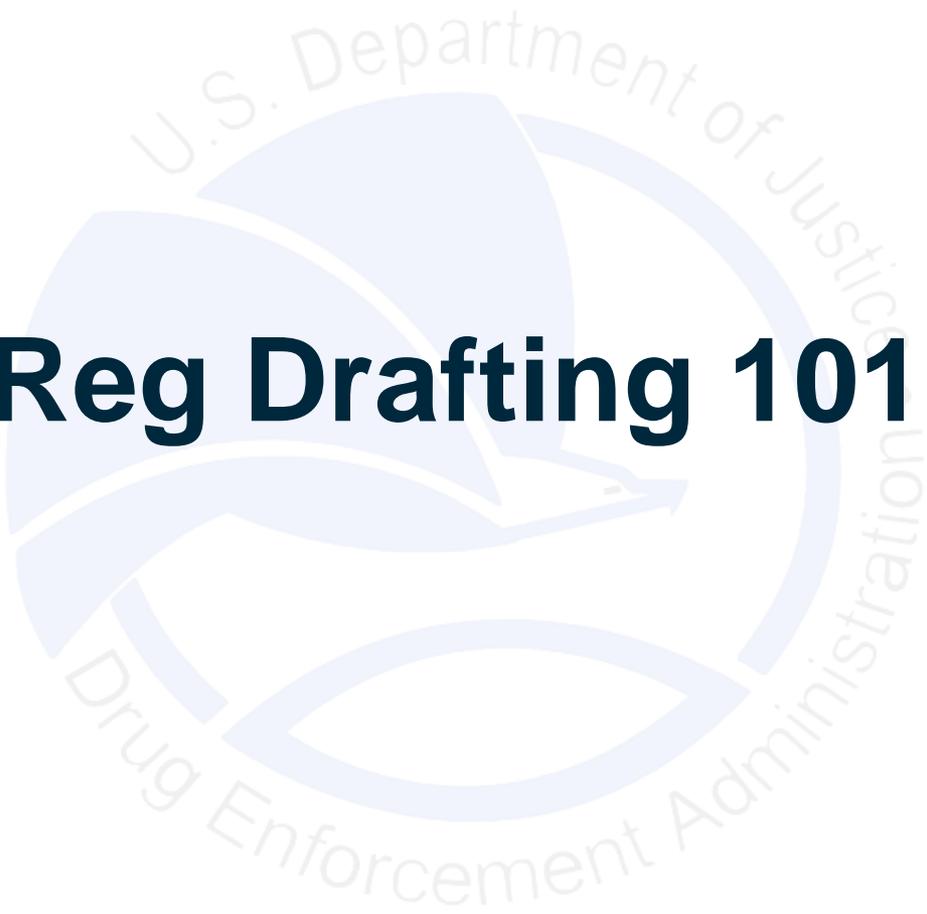
Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential

Chemical DEA Rulemakings

DEA #	Title	Status	Last Action Date
DEA-211	Security Requirements for Handlers of PSE, EPH, PPA	On Hold	10-28-2004
DEA-222	Chemical Mixtures Containing GBL	Final Rule	Effective 7-29-2010
DEA-291	Retail Sales of SLCP; Self Certification of Regulated Sellers	Final Rule DOJ Review	8-2-2010
DEA-292	CMEA, Notice of Transfers Following Imp/Exp	IFR FR Drafting	4-9-2007
DEA-320	Control of Ergocristine as a List I Chemical	NPRM	2-4-2010
DEA-328	Implementation of MPPA	NRPM	3-23-2010
DEA-334	Listing of Exempt Chemical Mixtures	Final Rule Cleared to Publish	7-2-2010
DEA-340	Assessment of Annual Need	Drafting	



Reg Drafting 101

Rulemaking Process

What is a Rule?

An agency statement of general applicability and future effect designed to implement or interpret law or policy

Rulemaking Process

Why do we engage in rulemaking?

- Legislation
- Industry Operation or Practice Changes
- Advances in Technology
- Repetitive petitions for exemption
- Executive Orders and memoranda
- Petitions for Rulemaking
- New Methods of Diversion

Rulemaking Process

Notice of Proposed Rulemaking

- Initiating Event
- Agency Research and Drafting
- Internal DEA review/approval
- DOJ review and clearance
- OMB/Interagency review and clearance
- Publication in the *Federal Register* for comment

Rulemaking Process

Final Rule Major Steps

- Public Comments
- Final rule drafted by Agency w/ response to comments
- Internal DEA review/approval
- DOJ review and clearance
- OMB/Interagency review and clearance
- Publication in the *Federal Register*

Combat Methamphetamine Epidemic Act

- Passed by Congress in 2/2006 to control eph, pse and ppa sales
- Signed by the President in 3/2006
- Regulations published in 9/2006 for implementation



Chemical Handler's Manual

Drug Enforcement Administration
Chemical Handler's Manual

SECTION I - INTRODUCTION

Disclaimer

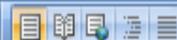
This chemical handler's manual is intended to summarize and explain the basic requirements for the handling of List I and List II chemicals under the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-890, and the DEA regulations, Title 21, Code of Federal Regulations (21 C.F.R.), Parts 1300 to 1316. Pertinent citations to the law and regulations are included in this manual.

Printed copies of the complete regulations implementing the CSA (21 C.F.R. Part 1300 to End) may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402

Both the C.F.R. and the Federal Register (which includes proposed and final regulations implementing the CSA) are available on the internet through the U.S. Government Printing Office (GPO) website. This website, which provides information by section, citation, and keywords, can be accessed at:

www.gpoaccess.gov



Disclaimer

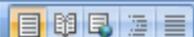
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United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control



Chemical Handler's Manual

A Guide to Chemical Control Regulations



Drug Enforcement Administration
Chemical Handler's Manual

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Mark W. Caverly

Chief, Liaison and Policy Section

This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, to assist those persons who handle schedule listed chemical products and List I and II chemicals in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to regulated chemicals.

Drug Enforcement Administration
Chemical Handler's Manual

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Need to Obtain or Renew
DEA Registration?
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**NATIONAL
TAKE-BACK**



What's New

- [Additions to Listing of Exempt Chemical Mixtures](#) (September 2, 2010)
- [Archimica, Inc.](#) (September 1, 2010)
- [Rhodes Technologies](#) (September 1, 2010)
- [Austin Pharma LLC](#) (September 1, 2010)
- [American Radiolabeled Chemicals, Inc](#) (September 1, 2010)
- [Cody Laboratories](#) (September 1, 2010)
- [Archimica, Inc.](#) (September 1, 2010)
- [Chattem Chemicals Inc](#) (September 1, 2010)
- [Cambrex Charles City, Inc.](#) (September 1, 2010)
- [Cambrex Charles City, Inc.](#) (September 1, 2010)
- [Chattem Chemicals Inc](#) (September 1, 2010)

Registration Support

Registration Number Toll Free: 1-800-882-9539

Save time by applying for and/or renewing your DEA Registration online. Data will be entered through a secure connection to the ODWIF online web application system.

Minimum requirements:
Credit Card and a web browser that supports 128-bit encryption.

Email Registration Questions to DEA.Registration.Help@usdoj.gov
[Field Offices with Registration Specialists](#)

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