

Regulatory Section

DEA Headquarters

ODG

Regulatory Section/ODG
Barbara Boockholdt, Chief
202-307-7669

ODGI/Import Export
(Sean Mahoney, Chief)
202-307-7969

ODGR/Regulatory Unit
(Jim Arnold, Chief)
202-353-1414

Import/Export Unit

ODGI

ODGI

Tabulating & Encapsulating Machines

Chemical Imports/Exports/DEA 486

Medical Missions

Regular Customer Investigations

INCB Pre-Export Notifications

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

DEA Form-236 (Import & Export Declarations)

Regulatory Unit

ODGR

ODGR

Section 303 Investigations/Hoasca Tea
Employment Waivers/Theft Loss Reports
Section 303 /DHHS Letters of Exclusion
Quota Reviews

ODGR

Drug Abuse Treatment Issues/DATA Waived
Physicians/Methadone/Theft Loss Reports

Code H Drug Codes

Civil Fines/Order to Show Cause Data Bases

Security Coordinator

ODG

Items of
Interest & Special Concern

"Code H" Items

2010	GHB
2012	GHB Product
7360	Marihuana
7369	Marinol
7370	THC
7405	MDMA
9650	Poppy Straw
9670	CPS

DATA Waived Physicians 21 CFR 1301.28 (b)(1)(iii) Effective June 23, 2008

- Permits Certain Qualifying Physicians to Treat Up to 100 Patients
- The total number...shall not exceed ...30 (patients) unless...
- Qualifying: "...if he is licensed under State law and has specific medical certification, training, or experience in maintenance or detoxification treatment as specified in the CSA".

Suspicious Orders: 21 CFR 1301.74 (b)

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.
- The registrant shall inform the Field Division Office ...in his area of suspicious orders when discovered by the registrant.

Suspicious Orders

- Suspicious Orders Include:
 - Orders of Unusual Size
 - Orders Deviating Substantially from a normal pattern
 - Orders of Unusual Frequency

“Hydrocodone”

Schedule III
Hydrocodone Products

Investigations

- Pre-Registration Investigations
(Manufacturers/Distributors)
List of Customers/Suppliers
Will you be selling to pharmacies?
Are any of your customers Internet
pharmacies?
(Explain: Illegal Internet Pharmacies)
Suspicious Orders

Investigations

- Scheduled Investigations
(Manufacturers/Distributors)
Updated List of Customers/Suppliers
ARCOS
Quota Reviews
Verifications
Suspicious Orders

Pre-Registration Investigations (Drugs)
Scheduled Investigations
Administrative Actions
"Code H Items"/HQS Approval
Orders to Show Cause
Civil Cases/Fines/
Settlement Agreements
Section 303 Investigations
Employment Waivers
DATA Waived Physicians

Memoranda of Agreement/
Memoranda of Understanding
HQS Security Coordination
Quota Reviews
Reports of Investigation
Theft/Loss of Controlled Substances
Importers/Exporters
Sale or Transfer of Tableting/Encapsulating
Machines
Toluene/MEK/Acetone Quarterly Reports
Mail Order Reports

ODEQ

Exempt Registrations

ODRA

DEA 106's

(Theft and Loss Reports)

Distributor Initiative

Administrative/Civil

Downstream Customers

McKesson - \$13.2 million

Chain Pharmacies