Document Name: Controlled Substance Compliance Policy		
Number: CSOP 001-165	Revision Number: 00	Effective Date: 26-May-2016

1. REFERENCE TO QMS

1.1. N/A

2. PURPOSE

2.1. The purpose of this procedure is to document and describe the Actavis Corporate Controlled Substance Compliance Policy that has been established in accordance with the Controlled Substances Act (CSA) and the applicable sections of the Code of Federal Regulations (CFR) as they apply to the various DEA registered activities. This procedure describes the elements that comprise the controlled substance compliance program and clearly defines the roles and responsibilities of the Corporate Controlled Substance Compliance Department (CCSC), local site compliance function, and all relevant employees engaged in a controlled substance activity.

3. SCOPE

3.1. This procedure applies to all Actavis DEA Registered locations, employees, affiliates, and subsidiaries.

4. DEFINITIONS

4.1. **Controlled Substances Act** - Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain narcotics, stimulants, depressants, hallucinogens, anabolic steroids and other chemicals is regulated.

The CSA, established a closed system of controlled substance distribution requiring each entity in the distribution chain—that is, manufacturers, distributors, importers, exporters, pharmacies, practitioners, hospitals, etc., to be accountable for the drugs provided to the ultimate user (i.e., the patient). This is accomplished through a classification system of drugs based on their potential for abuse relative to their legitimate medical use. Such classification, or drug scheduling, triggers certain registration, quota, recordkeeping, reporting, and security requirements. The closed system ensures the accountability of these drugs from the manufacturer to the patient.

4.2. **Drug Enforcement Administration** – The agency within the US Department of Justice responsible for enforcing the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

4.2.1. DEA Office of Diversion Control enforces the CSA and its implementing regulations governing legal controlled pharmaceuticals and regulated chemicals. DEA's mission with

respect to legal controlled pharmaceuticals and regulated chemicals is complex. DEA seeks to prevent, detect, and eliminate the diversion of controlled pharmaceuticals and regulated chemicals from legitimate channels to illegal use, while ensuring their availability for legal medical, scientific, and industrial purposes

5. RESPONSIBILITY

5.1. Controlled Substance Compliance Policy Statement

5.1.1. The Actavis CS Compliance Policy Statement is as follows:

5.1.2. As a responsible manufacturer and a good corporate citizen to the communities where we conduct business, Actavis takes its responsibility to prevent drug diversion very seriously.

5.1.3. Our commitment to preventing drug diversion is critical. Throughout our manufacturing and supply chain processes, we employ safeguards that work to ensure legitimate patients receive our medicines, while minimizing the risk of diversion.

5.1.4. By engaging all Actavis team members on dangers of prescription drug abuse and the many things we can do as a company to safeguard against diversion, we achieve our mission of providing high quality, critical medicines while preventing abuse.

5.1.5. Controlled Substance Compliance is the responsibility of every Actavis team member. It is achieved through teamwork and commitment. The name Actavis represents the standard of quality to our employees, our customers and the communities in which we work.

5.2. Corporate Controlled Substance Compliance (CCSC) is responsible for ensuring (and assisting where appropriate) that all business functions engaged in a controlled substance activity implement the appropriate required compliance programs. CCSC is responsible for reviewing and auditing all related programs to ensure compliance with federal regulations, established policies & procedures, standards and guidelines.

5.3. Global Security is responsible for the implementation of the physical protection program and maintenance of effective controls designed to mitigate the opportunity for diversion in accordance with regulations set forth in 21 CFR 1301.72.

5.4. Senior management at each DEA registered location is responsible for ensuring that the site has sufficient and competent controlled substance compliance personnel commensurate with the scale of operation.

5.5. Each DEA registered location is responsible for the successful implementation of policies and procedures required to perform its functions effectively and in compliance with regulatory requirements.

5.6. The Corporate Controlled Substance Compliance and local compliance teams will assist each other in ensuring their compliance.

6. PROCEDURE

Compliance Program Requirements

6.1. Regulatory Liaison and Policy Matters

6.1.1. While there are a number of individuals throughout the Actavis organization that have certain DEA related responsibilities and opportunities to interact with the DEA, Corporate CS Compliance has the primary and general responsibility for Actavis' relationship with the DEA. Corporate CS Compliance must be made aware of all contacts between any Actavis employee and the DEA, via prompt written notification.

6.1.2. Corporate CS Compliance is responsible for monitoring the regulatory landscape, interpreting regulatory changes with the assistance of groups such as Legal and Government Affairs, in the development of proactive strategies in anticipation of proposed rulemaking initiatives and translating regulations to the operations. The Corporate CS Compliance group is responsible for liaison with DEA Headquarters and units such as Liaison & Policy (ODLP), Regulatory (to include Import/Export), and Quota (ODE).

6.1.3. The site controlled substance compliance function has the primary responsibility for establishing and maintaining a positive and professional relationship with the local DEA office. It is within the scope of the site compliance representative's role to interact with the local DEA office regarding general matters pertaining to the normal course of business.

6.2. Recordkeeping and Reporting

6.2.1. All DEA registered site controlled substance compliance functions are responsible for establishing local procedures ensuring that recordkeeping obligations within 21 CFR 1304 are met. Policies shall be inclusive of:

6.2.1.1. General maintenance of records

6.2.1.2. Required Elements

6.2.1.2.1. Accurately reflect the actual movement of materials through legitimate channels of product lifecycle.

6.2.1.2.2. Readily Retrievable

6.2.1.2.3. Separately maintained for each registered activity

6.2.1.3. Material Accountability- Manufacturing (all stages) Transfer/Distribution, import/export, lab dispensing/usage, and disposal.

6.2.1.4. Procurement

6.2.1.4.1. DEA form 222 process administration

6.2.1.4.2. License verification

6.2.1.4.3. Certification of available quota

6.2.1.5. Required Inventories

6.2.1.6. Continuing Records

6.2.1.7. Electronic Records

6.2.1.8. Record retention

6.2.2. ARCOS Reports

6.2.2.1. All DEA registered manufacturing and distribution location CS Compliance functions are responsible for the preparation and submittal of ARCOS (Automation of Records, Consolidated Ordering System) reports on a quarterly basis.

6.2.2.2. The Corporate CS Compliance department will work closely with the sites and provide any necessary assistance, ensuring that these important reports are submitted accurately and in a timely manner.

6.2.3. Year-end Reports (YER)

6.2.3.1. All DEA registered manufacturing site CS Compliance functions are responsible for collaborating with the Corporate CS Compliance department in the preparation and submittal of the Year-End Activity Reports.

6.2.3.2. The Corporate CS Compliance department will coordinate, prepare, and submit the final report prior to April 1st of each year.

6.2.3.3. The site CS Compliance function will provide the corporate team with the required information in a complete and accurate manner facilitating successful timely submission.

6.2.4. Theft & Loss Reports (DEA Form 106)

6.2.4.1. The Corporate CS Compliance department is responsible for the submission of Theft & Loss reports to the appropriate DEA office.

6.2.4.2. Site Global Security management is responsible for coordinating investigations into suspected theft or loss and will make initial notification to the appropriate DEA office.

6.2.4.3. The site and Corporate CS Compliance departments will participate and support investigational efforts.

6.3. Procurement Quota

6.3.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for facilitating the procurement quota process for all site commercial and product development activities.

6.3.2. The Corporate CS Compliance department will collaborate with the appropriate internal stakeholders to obtain required information and sales/forecast data necessary for both annual and adjusted quota requests.

6.3.3. The DEA registered manufacturing site CS compliance function will ensure that local procedures are established for the management of quota for both commercial and product development purposes, ensuring that allocations are not exceeded and utilized for intended purpose.

6.4. Import & Export

6.4.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for coordinating and facilitating the controlled substance import & export process.

6.4.2. The Corporate CS Compliance department will collaborate with the appropriate internal stakeholders to obtain required information required to execute compliant transactions in support of commercial, product development, and analytical activities.

6.4.3. The DEA registered manufacturing site CS compliance function will function as a conduit for the flow of information for the appropriate site activity and will ensure that transactions are documented and communicated to the Corporate CS compliance department in a timely manner ensuring that reporting obligations are achieved.

6.5. Regulatory Inspections

6.5.1. Corporate CS Compliance and site CS compliance function will ensure that policies mandating how the site will manage and handle a DEA inspection are implemented.

6.5.2. The site controlled substance compliance representative will be designated to manage all controlled substance audit activities. The controlled substance compliance representative will act as liaison with DEA investigators when they are on-site and afterwards.

6.5.2.1. The Corporate CS Compliance department will provide additional support and resources to the site inspection, including the gathering of information and documentation, providing overviews of compliance functions, corporate officer information as well as personnel resources to assist with or coordinate on-site activities.

6.5.3. The site controlled substance compliance representative will also designate a team of individual subject matter experts to support the various activities subject to audit. The team will be comprised of individuals responsible for certain areas, i.e. Security, Manufacturing, Quality Control, Quality Assurance, Warehouse, R&D. review and update procedures periodically.

6.5.4. Corporate Controlled Substance Compliance will Coordinate annual mock DEA inspections of each DEA registered location. Inspections will encompass an accountability audit, record and report review, and security review.

6.5.4.1. Site controlled substance compliance and security representatives will conduct random and periodic internal audits of the daily controlled substance activities.

6.6. Suspicious Order Monitoring System

6.6.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for establishing and maintaining the Suspicious Order Monitoring System as well as reporting those orders that are determined to be suspicious in nature.

6.6.2. The Controlled Substance Order Monitoring process is based on the DEA requirements contained within 21 CFR 1301.74 and subsequent guidance letters detailing the responsibility of the registrant to design and operate a system to disclose suspicious orders of controlled substances and Listed Chemicals as well as the performance of customer due diligence both prior to the establishment of and during the business relationship.

6.7. CS Compliance Internal Audit

6.7.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for establishing and maintaining the Corporate Controlled Substance Audit Program.

6.7.2. The site CS Compliance function will participate in scheduled annual or "for cause" audits and collaborate with Corporate CS Compliance on the establishment and execution of corrective action plans or alternate remediation for any identified findings/observations.

6.7.3. The site CS Compliance function will establish an internal audit program for on-going periodic site compliance posture assessment

6.8. Training & Awareness

6.8.1. The Corporate CS Compliance department and site compliance function will collaborate on the development and delivery of annual focused compliance training.

6.8.2. The site CS compliance function will maintain and administer the controlled substance compliance new hire orientation program.

6.8.3. In conjunction with Corporate Communications, the Corporate CS Compliance department will administer and coordinate awareness & engagement activities via the *"It Starts With Me"* program.

6.9. Power of Attorney

6.9.1. The Corporate CS Compliance department is responsible for administering Power of Attorney, authorizing individuals at the registered locations to issue orders for Schedule I and II controlled substances via DEA form 222.

6.9.2. The Corporate CS Compliance department is responsible for training the designated site employees on the proper procedures for executing and Official Order form (222) prior to granting Power of Attorney.

6.9.3. The site CS Compliance function will ensure that an adequate number of appropriate individuals are designated as Power of Attorney to meet the needs of the operation.

7. RELATED DOCUMENTS

7.1. N/A

8. REFERENCES

8.1. N/A

9. CHANGE HISTORY

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-33285089	00	See effective date in header	1. New Procedure

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ADDITIONAL APPROVERS (Outside Livelink)

The below signatures have been obtained and are available on Quality Management System SharePoint site.

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I have reviewed this document and hereby approve it - Date and Signature	

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