1. REFERENCE TO QMS

1.1.

2. PURPOSE

2.1. The purpose of this policy is the documentation and definition of the Controlled Substance Order Monitoring process 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.

3. SCOPE

3.1. This policy applies to the controlled substance ordering process under DEA Registration RW0237900, Actavis Pharma, Inc. 605 Tri-State Parkway, Gurnee, IL. Order processing and SOM administration is facilitated at the Parsippany, NJ Headquarters location.

4. DEFINITIONS

4.1. **Approved Customer** – A properly licensed and vetted supply chain partner with an established product purchasing relationship, to include controlled substances. These customers comprise the population monitored within the Controlled Substance Order Monitoring System.

4.2. **Controlled Substance Order Monitoring System** - a system designed to prevent product diversion through the disclosure suspicious orders of controlled substances. Such orders include but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A Controlled Substance Ordering Monitoring System is comprised of the following elements; Customer Due Diligence, Electronic Monitoring, Review & evaluation, and Investigation process, as well as Notification to appropriate agencies.

4.3. **Controlled Substance Product** – A finished form commercially packaged drug or Listed Chemical product controlled within Schedule I, II, III, IV, or V of Section 21 Code of Federal Regulations, Part 1308.

4.4. **Know Your Customer (KYC) Process** – The process in which due diligence is performed with the goal of gaining insight into our prospective or established customers business model and making good faith efforts to ensure that buying patterns are aligned with appropriate use. Key elements of the KYC process include: Questionnaire(s), review of ownership, state and federal licensing, product utilization, on-going evaluation, site visits and investigations when necessary.

4.5. **Order of Interest (OI)** – A customer controlled substance order that pends within the electronic order monitoring system for exceeding the volume threshold for one of the established benchmarks. These orders will be investigated and if justified will be cleared

and released. If an OI is determined to be suspicious will be reported to the DEA and appropriate state regulatory agency.

5. RESPONSIBILITY

5.1. Controlled Substance Compliance is responsible for the establishment and oversight of the Controlled Substance Order Monitoring Program, Know Your Customer function, order and account investigation, establishment of and maintenance of ongoing relationships with customer compliance personnel and regulatory authorities, as well as appropriate agency notifications.

5.2. Customer Service is responsible for initial customer due diligence, management of customer facing relationships, maintenance of accurate customer information, proactive communication of information pertaining to changes in customer ordering behavior to the appropriate internal stakeholders.

5.3. Order Management is responsible for initial controlled substance order review and release based on documented customer justification or tangible business rationale, escalation of orders that cannot be justified after initial analysis to appropriate investigative personnel, maintenance of effective communication with customer purchasing personnel and the proactive dissemination of information related to customer controlled substance utilization.

5.4. Global Security (Product Protection) is responsible for providing product specific expertise, communicating diversion trends, supporting investigational and vetting activities, and serving as order review/investigation contingency.

6. PROCEDURES

Controlled Substance Order Monitoring Requirements

6.1. Title 21, Code of Federal Regulations, Section 1301.74(b) requires that a DEA registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. Suspicious Orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders determined to be suspicious must be reported to the DEA upon discovery. DEA also requires that prior to distributing a controlled substance the registrant will make a good faith inquiry either with the DEA or appropriate state regulatory agency, to determine that the customer is registered to possess controlled substances. Beyond this requirement, case law expands further on the DEA position regarding due diligence. It is the DEA position that registrants are required to maintain adequate due diligence measures to protect against diversion and that the granting of a DEA registration signals only a proper application and the establishment of the required recordkeeping and security systems at the time of inspection and that the registration does not relieve a registrant of the responsibility to evaluate ongoing ordering behavior. Actavis will adhere to the requirements established within this policy to ensure that effective controls are maintained to prevent the diversion of controlled substances.

The Actavis Controlled Substance Order Monitoring Program is based on a holistic approach comprised of the following elements:

- Know Your Customer – Due Diligence
  - Initial review and approval of customer
  - Ongoing review of current business relationships
- Electronic Monitoring and Review Process of Orders
  - Evaluation based on multiple parameters
  - Review of Orders of interest & customer outreach performed by dedicated order management team
- Order & Customer Investigation
  - Investigations & Site Visits conducted by CS Compliance
- Monthly Analytics
  - Trending analysis
- Large Volume Account Relationship Management
- Suspicious Order Reporting Process

Customer Due Diligence – Know Your Customer (KYC) Program

6.2. Actavis will conduct due diligence reviews on all new accounts. Periodic due diligence will be performed on existing accounts. Existing customer due diligence will be performed on customers considered to be large volume as well as customers who have had changes in business model, or have received or are under regulatory scrutiny. The Know Your Customer Process has been established as a method for screening potential business relationships and to better know our customers, ensuring that buying patterns are aligned with proper use.

6.3. The Know Your Customer (KYC) Program includes:

6.3.1. Collection and review of Customer Service/KYC Questionnaires and executed customer compliance acknowledgement form.

6.3.2. Review of ownership, state and federal licenses, and controlled substance and non-controlled substance utilization.

6.3.3. Review and approval of all new customers prior to the sale of controlled substance products.

6.3.4. Ongoing evaluation of purchases.

6.4. New Customer On-boarding

6.4.1. Actavis will perform due diligence on all prospective accounts. Actavis will determine whether proposed customers are fully licensed by federal and state authorities to handle controlled substances. Additional information including the types of products requested, forecast information, previous suppliers, controlled vs. non-controlled purchase ratio, and other suppliers, will be obtained and reviewed as part of the determination of customer acceptance. Site photographs and internet searches will also be utilized as a component of the due diligence process.

6.4.2. Site visits and reviews will be conducted by Controlled Substance Compliance on all proposed controlled substances customers. Additional SOM program information and historical purchasing reports will be obtained for review. The prospective customer will provide a customer listing, by volume.

6.4.3. Due Diligence Process

Prior to the sale of controlled substances to a new customer, the CS Compliance team in partnership with Customer service and Product Protection will perform an assessment consisting of the following actions:

6.4.3.1. Internet Search – Searches will be conducted of open sources to include social media and industry related sites.

6.4.3.2. Credit History Check – In coordination with Customer Service, a thorough credit analysis will be performed.

6.4.3.3. Review of Ownership, State and Federal Licenses – A search will be conducted of state and federal regulatory agencies ensuring proper licensure, as well as any discipline such as suspensions, revocations or fines.

6.4.3.4. DEA Website Search - A search will be conducted on the DEA Diversion website, www.deadiversion.usdoj.gov, for administrative, criminal or civil actions taken by the DEA against the registrant or their highest volume customers.

6.4.3.5. CLEAR (Consolidated Lead Evaluation and Reporting) Record Search- A thorough check of public and proprietary records, and integrated web searching, including social network sites, providing information not found in public records will be performed for each prospective customer.

6.4.3.6. Pharmaceutical Security Institute Inquiry – Search of all internal PSI databases and files, including:

6.4.3.6.1. Counterfeiting Incident System (CIS)

6.4.3.6.2. Open source index on pharma crime going back to 2002

6.4.3.6.3. PSI archives (1991-2001)

6.4.3.6.4. Prior inquiries file

6.4.3.6.5. Open source research checks include Lexis Nexis and PACER (US federal court records)

6.4.3.7. Sales Data Review and Analysis – An evaluation of the prospective customer's sales data will be completed for the controlled substance products requested. The following data will be reviewed;

6.4.3.7.1. Six months total historical sales for each product

6.4.3.7.2. Percentage of projected Actavis product sales

6.4.3.7.3. Top 50 customers for each product

6.4.3.7.4. Percentage of overall controlled v. non-controlled

6.4.3.7.5. Controlled substances purchased through other manufacturers. (Primary/Secondary)

6.5. Due Diligence – Existing Customers

6.5.1. Biennially, the Controlled Substance Compliance team will conduct a reassessment of each controlled substance customer. This assessment will include the completion of an updated compliance acknowledgement form, as well as a review of any changes within the compliance program and associated policies. Historical sales information for the previous six months will be requested as well as a current listing of their top 50 customers. Due diligence reviews may also be initiated as a result of adverse events or changes in customer business model.

6.6. Electronic Monitoring and Review Process of Orders

6.6.1. Actavis utilizes a proprietary system integrated within the company enterprise resource platform, SAP, for the purpose of monitoring controlled substance customer ordering behavior and identifying orders deviating substantially from the norm.

6.6.2. The system identifies customer orders that deviate substantially from their historic ordering patterns, size, class of trade, and customer thresholds.

6.6.2.1. The system checks every controlled substance order per line item placed by customers against the established benchmarks.

6.6.2.2. Product dosage unit thresholds are calculated for a specific customer based on historical product dosage unit data.

6.6.2.3. Multipliers are utilized to account for variability in customer buying behavior by specific customer and class of trade.

6.6.3. When a customer order line item is identified and placed on hold within the system as an order of interest, an instantaneous communication is sent to a trained Order Management SOM Specialist for review and the entire order is placed on hold.

6.6.3.1. Every order of interest undergoes a thorough review performed by SOM Specialist or Manager.

6.6.3.2. Orders that cannot be justified utilizing current historical ordering analysis or feedback from Marketing require further information from the customer.

6.6.3.3. Customers are engaged by the SOM Specialist or Manager to clarify and identify potential suspicious orders resulting from Orders of Interest.

6.6.3.4. All Orders of Interest requiring further investigation after contact with customers are escalated to the Controlled Substance Compliance Department for further investigation.

6.6.3.5. Controlled Substance Compliance investigations staff will perform a thorough investigation and will engage with customer compliance representatives with the objective of providing resolution.

6.6.3.6. Orders that are deemed as suspicious after investigation are presented for review by Senior Leadership including, Legal, Sales/Marketing, Operations & Compliance.

6.6.3.6.1. Immediately following leadership review suspicious orders are reported to the DEA as well as appropriate State Board of Pharmacy.

6.7. Data Analytics

6.7.1. On a periodic regular basis Controlled Substance Compliance staff will perform prospective and retrospective analyses through the use of physical data. Data is utilized:

6.7.1.1. To guide and support decision making process in the order review process.

6.7.1.2. To guide and support customer vetting and investigations

6.7.1.3. To support trend analysis

6.7.2. On a Monthly basis, CS Compliance will review Charge-back data for key products with the objective of ensuring that pharmacy level customers are not purchasing excessive quantities of controlled drug products from multiple supplier sources.

6.7.2.1. Charge-back data provides a limited view of Actavis product usage only.

6.7.3. On a quarterly basis Controlled Substance Compliance will review key controlled substance dosage unit purchase history for the top ten customers by volume.

6.8. Large Volume Customer Review Process

6.8.1. On an as-needed basis a team of designated personnel will review and make decisions regarding product volume increases for large wholesale distribution and chain pharmacy customers as they arise. The objective of the team is for the evaluation of requested needs for controlled product increases by a particular customer.

6.8.2. The team is comprised of decision makers including:

6.8.2.1. Customer Service

6.8.2.2. Sales & Marketing

6.8.2.3. CS Compliance

6.8.2.4. Order Management

6.8.3. Documented justification and team consensus is required for the approval of controlled substance product volume increases.

7. RELATED DOCUMENTS (Optional, if not used, state N/A - Delete green text)

7.1.

8. REFERENCES

8.1. N/A

9. CHANGE HISTORY

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
		See effective date in header	1.