Title: ACTAVIS Suspicious Order Monitoring - DIRECT Customer Sales SOP		
Number / Revision:	Effective Date:	Ref. to Corporate Procedure:
Prepared by: Signature: Date:	Reviewed / Approved by: Date:	
Issued by: Signature: Date:	Invalidated by: Signature: Date:	

1. PURPOSE

1.1. This procedure describes the process used to identify and report controlled substance suspicious orders to the Drug Enforcement Administration (DEA).

2. SCOPE

2.1. This policy applies to the sale of all Controlled Drugs sold by Actavis (Schedule II-V).
This procedure applies to the direct sales function of Controlled Drugs sold by Actavis.

3. DEFINITIONS

3.1. CONTROLLED DRUGS:

Controlled Drugs are defined as any drug or therapeutic agent-commonly understood to include narcotics, with a potential for abuse or addiction, which is held under strict governmental control, as delineated by the Comprehensive Drug Abuse Prevention & Control Act passed in 1970.

3.2. SUSPICIOUS ORDERS:

These are controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency.

21 CFR 1301.74(b) states that "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 of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

3.3. **PEND:** These are orders which have been blocked or stopped in real time because they exceeded the calculations and business rules established by Actavis. "Pended" orders are deemed "questionable" until they are investigated, during which time they are referred to as **"Orders of Interest or "OI".**

4. RESPONSIBILITY

4.1. The company's suspicious order monitoring program begins by participating in a series of due diligence activities to ensure that we "know our customer." Profiles for each of its direct customers assist Actavis in understanding its customers' buying needs and habits. This information is part of the process of identifying controlled substance orders that are suspicious. The significant efforts related to SOM demonstrate Actavis' commitment to protecting the integrity of the supply chain and to preventing the diversion of controlled substances.

4.2. The role of Ordering Monitoring Business Analyst is the initial line of accountability for identifying and investigating potentially suspicious orders by monitoring sales order data. The Order Monitoring Business Analyst is responsible for monitoring incoming orders for direct sales, outgoing data for suspicious order activity, utilizing electronic systems and following Standard Operating Procedures (SOPs).

4.3. The role of Order Monitoring Manager is to oversee the data analysis by the Order Monitoring Analysts. This role reviews, approves and escalates, as needed, all sales and distribution data reporting related to suspicious order monitoring activity.

5. RELATED DOCUMENTS

5.1. Title 21, Code of Federal Regulations, Section 1301.74(b); Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007.

6. NEW ACCOUNTS

6.1 Due diligence is performed on all new accounts by Actavis. The sales organization initiates all requests to open new customers. Prior to the internal "due diligence" process beginning, Sales will provide details that justify the request (ex: sales potential, unmet need, new member of an existing purchasing organization, etc...). Once approved by the Vice President of Sales, a series of due diligence activities will begin. A customer survey/questionnaire is the mechanism used to capture due diligence regarding an account. This information may be completed remotely or in many cases through scheduling an on-site visit. The level of due diligence will vary for customers planning to purchase controlled substances vs. those that do not.

6.2 New accounts intending to purchase controlled drugs will receive a compliance acknowledgment form. By executing this form, the organization represents it is aware of its obligations under federal and state statutes and regulations pertaining to the distribution of controlled substances, including 21 CFR 1301.74(b), and that it has in place measures to ensure compliance with such regulations.

6.2.1 Compliance acknowledgment forms are renewed periodically.

6.3 Approved accounts are entered into an order management database.

6.3.1 Payment terms are established and approved within the Finance team at Actavis.

6.3.2 Licensing information is obtained from the customer and maintained within the order management database. Preventative measures are in place to ensure controlled drugs are not shipped to any account without a valid DEA license in place.

7. PENDED ORDERS

7.1 Actavis customer orders for controlled drugs are individually analyzed via an internal computerized statistical calculation to determine whether the order may be of unusual size, whether the order may deviate substantially from a normal pattern and/or whether the order can be associated with an unusual pattern or frequency. The analysis is accomplished by a formula that uses a statistical algorithm and compares current orders from previous orders. This analysis will assign a "score" to each order based upon the analysis. This score will help to identify the level of suspicion of a pended order. An order will "pend" if any or all of these attributes are present to a statistical extent. These orders may be suspicious and must be investigated before shipping to the customer. Pended orders are referred to as "Orders of Interest."

7.2 Customer orders with no previous history (new customer, new NDC) will "pend" until there are purchases in two distinct months within the last six months. At that point, it becomes part of the mathematical calculations of the model.

8. CLEARING AN ORDER FROM SUSPICION

8.1 All orders of interest will be "pended" in real time. The entire controlled substance order will "pend" until investigated and either cleared of suspicion or reported to DEA.

8.2 All "pended" orders will then be initially reviewed by the SOM Analyst. The specific order information is presented on a series of reports for purposes of analysis.

8.3 Orders are typically investigated for clearance by the date submitted on a first in, first out basis with some exceptions (ex: new product launches, etc...). Reporting details on the order pending include but are not limited to: order date and time, SO#, Customer #, Customer Name, Customer Family, PO#, Total # of lines and total # of lines considered as OI, pended lines with product and quantity along with possible reason codes that best categorize why the order is being considered an Order of Interest.

8.4 The SOM Analyst will gather relevant information to begin the review process. The following information will initially be considered:

A. The customer's order history with this drug. (ex: may be a new award, new product launch, etc...). A review of anticipated purchases may be necessary to aid in the investigation.

B. Any "notes" in the customer file pertaining to the drug that has been "pended."

C. Whether other orders for this account have been "pended" before and what actions were taken on these pended orders.

8.5 After organizing this information, the SOM Analyst will first attempt a full internal investigation to determine why the order may be pending (ex: new launch, new award, product issue in the market causing increased demand, etc...). In the event an internal investigation is unable to provide adequate information to clear the pended order, the customer may be contacted. The SOM Analyst will advise the customer in general terms of why the order pended (i.e., appeared to be larger than what was frequently ordered, appeared to be more frequent or appeared to be indicative of a trend). Questions should be "open-ended" and customer accounts should not be "guided" to provide the "right" answer. All investigation results are fully documented within the order management system. Complete audit trails will exist for all documentation and releases.

8.6 Some of the types of reasons that might allow the staff to clear and order of suspicion include:

- Order error
- Purchasing Incentives/Promotions
- New customer or new product award
- Verified increased market growth (ex: new study)
- Market conditions (ex: market shortages related to raw materials, market shortage related to a change in the # of suppliers, recalls, shift in purchases from one customer location to another (ex: change in warehousing strategies).
- New or different drug
- Different size or preparation
- Seasonality

8.7 If the order cannot be cleared or if customer has had previous orders pended and provided similar reasons, the reasons will be further investigated. The SOM Analyst will consult with the Order Monitoring Manager.

8.8 In the event the Order Monitoring Manager is unable to justify the release of the pended order through additional investigation, Actavis DEA Affairs team and/or Customer Service Management may jointly participate in partnership calls with the customer to gather additional information.

8.9 Once sufficient information is obtained, the order will be released from hold.

9. REPORTING A SUSPICIOUS ORDER TO THE DEA

9.1 If an order cannot be cleared of suspicion, Actavis DEA Affairs will alert the local office of the DEA by phone of the suspicious order activity.

9.2 The order will be cancelled in its entirety and the account will be re-examined for possible closure.

9.3 Any conversations with any DEA employee will be documented to include both the Actavis and DEA participants, date of contact, customer and product order details along with a summary of the conversation and descriptions of actions to be taken.

9.4 After the DEA has been contacted by phone, a written notification will follow for all suspicious orders. All relevant information will be forwarded to the DEA, both at headquarters and the field office with jurisdiction for the customer who is ordering the controlled substances.

10. EXISTING CUSTOMER DUE DILIGENCE

10.1 Initial and follow-up site visits will be scheduled for accounts on a risk-adjusted basis.

10.2 The purpose of customer site visits is to conduct a high-level "due diligence" review of their SOM program, in an attempt to assure they are exercising regulatory controls and procedures relating to the further sale of Actavis' Controlled substances in a manner consistent with the Drug Enforcement Agency (DEA) regulations and published procedures.

10.3 A customer questionnaire/site survey form is used to document due diligence compiled either remotely or at a customer's site. The contents of a standard survey may be utilized differently based upon the type of customer being surveyed (ex: corporate headquarters vs. distribution center).

11. INTERNAL AUDIT PROGRAM

11.1 All pended orders will have a complete audit trail within the order management system.