

## PURPOSE

To define the requirements and establish guidelines for the evaluation, vetting, and relationship standards with controlled substance customers.

## SCOPE

This policy applies to all Actavis facilities registered with the Drug Enforcement Administration (DEA) to handle controlled substance products and all facilities establishing regulated controlled substance business with customers.

## DEFINITIONS

Customer: Any persons (defined as any individual, corporation, government or governmental agency, business trust, partnership, association or other legal entity) that has, previously had, or seeks to have a relationship with Actavis Inc. (herein Actavis) for the purpose of purchasing any and all substances regulated by the Controlled Substances Act of 1970.

Audit: A physical and/or documented evaluation performed by DEA Affairs and/or designated third party auditor for verification of compliance and conformance to applicable DEA regulations and/or corporate policies and procedures for all regulated activities.

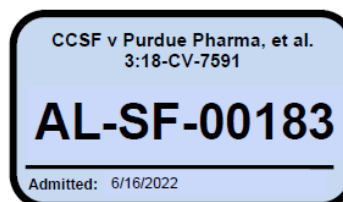
Auditor: An Actavis employee and/or consultant that possesses the education, training, and experience, or any combination thereof that enables them to perform audits of departments/facilities/customers engaged in DEA regulated activities, to ensure compliance with DEA regulations and/or corporate policies and procedures as applicable.

Suspicious Orders: Controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency and List I chemical orders which may involve extraordinary quantity uncommon method of payment or deliver or any other suspicious circumstance.

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."

21CFR 1310.05 (a) (1) states that "Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

- (1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the





regulated person believes may indicate that the listed chemical will be used in violation of this part.”

Pend: Orders which have been blocked or stopped in real time pending evaluation by DEA Affairs.

Vetting: The process in which DEA Affairs and/or authorized consultants evaluate a customer in regards to (but not limited to) compliance with all DEA regulations and/or corporate policies and procedures.

WHAT OTHER DEFINITIONS NEED TO BE ADDED?

### RELATED DOCUMENTS

Title 21, Code of Federal Regulations, All Sections

Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007

### PROCEDURE

#### 1.0 Customer Establishment (New)

1.1 Upon the request to purchase any controlled substance from a customer that has no previously established relationship with Actavis, Customer Service will notify DEA Affairs in writing.

1.1.1 Customer Service will provide DEA Affairs with (at a minimum) the following:

- Customer Name/DEA Registration Number
- Location and contact information
- Order specifics (Product/Size)

1.2 Customer Service will “pend” the order until approval is/is not granted by DEA Affairs to ship the order. Orders not approved will be cancelled.

1.3 Upon receipt of the aforementioned information, DEA Affairs will request (in conjunction with Customer Service) a “partnership call” for the purposes of establishing a relationship with the customer.

1.3.1 Prior to the “partnership call”; DEA Affairs and/or authorized personnel will perform an open source/business intelligence review of the company for the purposes of obtaining customer history, business practices, etc.

**1.3.2** During the “partnership call”; DEA Affairs and Customer Service will ascertain any relevant additional information regarding the potential customer and their practices. Additionally, specific information will be requested by DEA Affairs in terms of the potential customers business practices in regards to:

Compliance Overview:

- Team Structure
- Management Point of Contact

Suspicious Order Monitoring (SOM) Overview

- Due Diligence/Know Your Customer (KYC) Program
- Systematic Approach
- Order Review/Investigation and Disposition
- Associated Policies

Vetting/Distribution Limits Policy

**1.3.3** Upon conclusion of the call, if warranted based on the above information, DEA Affairs will provide the customer with the following:

- Compliance Communication (Attachment A)
- Customer Questionnaire (Attachment B) - includes but not limited to:
  - Customer information on specified products
  - Customer profiles

NOTE: The order will remain in pending status until receipt and satisfactory review of the above.

**1.4** Once determined to be a legitimate customer that meets the aforementioned requirements, the order will be released and the customer monitored through the established Actavis SOMS and KYC program.

**2.0 Established Customers**

**2.1** Customers with previously established relationships will be periodically reviewed by DEA Affairs for the purpose of ensuring all aforementioned compliance communication is up to date.

**2.1.1** If it determined that there is no current compliance communication, DEA Affairs will coordinate with Customer Service to establish a Point of Contact with the respective customer and the required communication will be requested.

**2.1.2** Additional information may be requested from the customer at any time based on (but not limited to): an increase in orders pending in the SOMS program; a change in ordering history; the addition or subtraction of customers.

**2.1.3** On a periodic and/or as needed basis, DEA Affairs and/or an authorized consultant may conduct an on-site visit to identify and examine a customer's facility and operations.

### **3.0 Customer Audits**

**3.1** At any time and for any reason, DEA Affairs and/or authorized consultants may conduct an on-site visit to identify and examine the facility. Coordination will be handled in accordance with the identified Point of Contact

**3.1.1** Information to be considered during audits may include and is not limited to:

- Customer (non-proprietary) information to include: site inspections, questionnaires, scorecard results; notes
- Due Diligence practices/policies/procedures
- SOMS procedures
  - o Review process; order disposition; required notifications

**3.2** All information obtained will be maintained by DEA Affairs and periodically updated based on partnership calls/audits with the customer.