Department: Distribution Operations	SOP #:040
Title: Orders of Interest Monitoring System/Suspicious Order Monitoring	

1.0 SCOPE

The directives contained in this SOP apply to all Anda DEA Compliance Analysts who are involved in the review of a sales order deemed to be of "interest". Orders of Interest are captured using historical sales information with a user defined time frame by looking at past averages of the following using a user defined multiplier:

- DEA Registrant's average dosage units ordered per month of a specific chemical family
- DEA Registrant's average dosage units per order of a specific chemical family
- The average dosage units per order by that class of trade for a specific chemical family
- Order frequency per rolling 30 day period

2.0 PURPOSE

To document the procedures involved in reviewing Held Orders of Interest/Suspicious Orders.

3.0 PROCEDURE

I. Determine the type of hold an order has been stopped for

- DEA Registrant's average dosage units ordered per month of a specific chemical family
- DEA Registrant's average dosage units per order of a specific chemical family
- The average dosage units per order by that class of trade for a specific chemical family
- Order frequency per rolling 30 day period

II. **Refer to TPS – Customer Maintenance License Info (TPS 2.2.4.1)**

- Pay particular attention to City/State of request
- Determine if a Customer Questionnaire is on file (customer flagged "Y")

III. **Review Customer Compliance Notes (TPS 2.2.4.1/Shift+F4&F8)**

- Determine if customer had previously been reviewed or grandfathered in to control eligibility
- Review Compliance notes regarding: historical requests, trends, approvals or denials
- Review any comments regarding changes to account, ownership, licensure

IV. **Review Customer Questionnaire**

- Open Customer Questionnaire on shared drive if already saved. (O:\Florida\Anda\Warehouse\Compliance\Customer Questionnaire)
- Determine type of pharmacy reviewing: volume, location, age, etc.
- Determine types of customers serviced by pharmacy, including review of identified physicians submitting controlled substance prescriptions, pharmacy proximity to healthcare facilities and physician practices and pharmacy procedures for ensuring that products are being dispensed for legitimate medical purposes by physicians who are in good standing with no history of regulatory violations or suspicious professional practices.

V. **Review Summarized Dispensing Data from Pharmacy if on file**

- Determine the way in which data is summarized: patient & script, descending pill quantity dispensed (by product or NDC), alphabetical, number of RX's
- Determine the level of control volume for time frame
- Determine ratio of controls versus non-controls
- Evaluate top products dispensed
- Determine particular products or NDC's dispensed most frequently

VI. **Review TPS- Controlled Substance Inquiry (2.4.3.12)**

- Determine if Anda will be a primary source of controls, etc.
- Review purchasing trends on a monthly basis by product & product family
- Evaluate percentage of control business on a monthly basis (average)

The following are release reasons for held orders

1. Increased supply to new or existing customer/patient
2. Increased supply to new facility
3. Consistent with customer order pattern and/or within CS increase granted
4. Increasing stock due to promotion or pricing change
5. First time order of product

6. Consistent with customer class order pattern
7. Administration release. Customer call not required.
8. Released unchanged with DEA/State Authority concurrence

2.3 Orders that exceed the above criteria and cannot be released with an appropriate reason listed above will be reported to the local DEA/State Authority office for the applicable distribution center.

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4.0 REVISION HISTORY

SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
December 2011	040	Michael Cochrane	Original Issue
April 5, 2012	040.01	Michael Cochrane	Review