From: Michael Perfetto
Sent: Saturday, March 31, 2012 5:19 AM
To: Doug Boothe
Subject: FW: Recap of SOM Meeting on Wednesday, March 21
Attachments: Basic_Compliance_Agreement_Form doc (Cegedim).docx; SOM Site Visit Customer Questionnaire 033012.docx; Indirect sales SOM SOP033012.doc

Fyi...

Michael Perfetto
VP, Sales and Marketing

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Internal VoIP number

From: Nancy Baran
Sent: Friday, March 30, 2012 5:37 PM
To: Rachelle Galant; John Duff; Umesh Solanki; Kelly Smith; John LaRocca; Michael Clarke; Michael Perfetto
Cc: Ara Aprahamian RPh; Jinping McCormick
Subject: FW: Recap of SOM Meeting on Wednesday, March 21

Minutes of 3/28/12 Weekly SOM Meeting –
In attendance: Nancy Baran, Rachelle Galant & Umesh Solanki

Compliance Agreement Forms/Process –

- The content of the Compliance Agreement Form is still under review. Michael reviewed the form and provided some cosmetic changes prior to the meeting (see attached). Michael agrees that an appropriate customer letter to accompany this compliance agreement needs to be drafted. The letter should be narrow in focus, only dealing with the appropriate handling and distribution of our products, in accordance with DEA, FDA and state law prescribing requirements.

- Compliance Agreement needs to be finalized. ***(Owners – John & Michael with input from Beth? – to be confirmed. Can we complete by next meeting-: April 4th?)***
- Cover letter to accompany agreement needs to be drafted ***(same as above)***

- Michael suggests that we do not attempt to draw too broad a letter that opens up much of the general customer relationship. He suggests that we focus on this key risk area. If the rest of the team has no issue with this, we will proceed forward with plans on distributing a compliance agreement solely for confirming SOM compliance.

    - We need to designate a resource to research and document the appropriate CEO and "Notice Party" individuals.
    - Finalize comprehensive list of customers purchasing controls (combining list provided by Ara and IT – understanding is that it will include both direct and indirect). ***(Nancy – to be complete by next meeting: April 4th)***

- *Carry-over from prior meeting as we didn't have the proper audience for discussion* -
  Buying groups – there may need to be a provision within these contracts stating that Actavis has the right to discontinue sales to any individual member if they do not meet the requirements set forth in the compliance agreement.

    - Legal and Contracts team will need to agree upon our approach to buying groups. *Owner – TBD*
    - Legal and Contracts team will need to agree upon language to be included in all contracts supporting our SOM requirements (yearly signed compliance form & ability to visit customer locations to review/audit such processes as needed.

Know-your customer –

- Attached is a copy of the current **Customer Questionnaire Form** to be used to guide discussions and capture information during site visits.

    - DEA Log pending - used to record all suspicious order activity to the DEA (including the Actavis employee, initial phone contact information of DEA representative–who, when & results along with a record of the written communication/certified mailing). ***(owner – Kelly Smith)***
    - Team to review the attached SOM Site Visit Questionnaire and provide final comments/remarks at

next meeting. The goal would be to finalize this form at next meeting ***(Owner – Project team, due April 4th)***

- Site Visit/Tour is being planned with Cardinal to take place in late April/early May. Date is TBD. Doug Plassche is Elizabeth lead. ***(Owner – Nancy is working with the customer to schedule and coordinate timing)***

DEA visit – ***no change since last meeting (we will keep open in minutes for visibility)***

- Kelly has reached out to the DEA and let them know we are interested in meeting with them. Once Kelly hears back, she will continue to coordinate the visit as discussed previously.
- Participants targeted for this visit are Kelly, Michael, Chris & Nancy.

Indirect SOM Process –

- A copy of the updated Indirect SOM SOP is attached.
  - Review Indirect SOP in advance of our meeting on 4/4 (project team)
  - Target date for direct/indirect process flow completion – April 23

Direct SOM Process –

- Nancy & Rachelle worked together reviewing sample pended orders. This will continue to provide us with better confirmation regarding the various scenarios, complexity of each and time required to investigate.

Agenda for next meeting – ***(Wednesday, April 4th)***

1) Review open items outlined above.
2) Finalize the updated Customer Questionnaire form.
3) Continue the review of our Indirect & Direct SOP's – work on charting out the process flow.
4) Nancy will provide an update on SOM Direct Production/Parallel testing – statistics.

COMPLIANCE AGREEMENT FORM

_____ ("Customer") agrees that it will abide by all applicable laws, rules, regulations, and any other regulatory and legal requirements of ordinances and guidance of the U.S. federal Drug Enforcement Administration (DEA), the United States Food and Drug Administration (FDA), within the U.S. Department of Health & Human Services and all the states in into which it dispenses controlled substances and all the states in which it is licensed. Further, Customer agrees that is will not dispense controlled substances if it suspects that a prescription has not been is not issued for a legitimate medical purpose or in the normal course of professional practice.

In addition, Customer also Customer agrees that it understands that *Client* is required by DEA regulations to report to the local DEA Diversion field office any instances of suspicious orders of controlled substances pursuant to DEA guidelines. To this end, Customer will provide to *name of client* any information regarding Customer's its distribution of controlled substances which *client* may need to evaluate compliance with DEA regulations. *Client* reserves the right in all cases to limit or eliminate any sales of controlled substances to customers in any situation which it determines in its sole discretion pose issues or questions of proper usage and/or adequate legal compliance by the Customer.

Comment [A1]: Who is client? Actavis or the customers of our customer? If the former, then say "Actavis"

Customer agrees to directly itself monitor and remain aware of be alert to the proper usage of controlled drugs that it dispenses dispensed by it, and to exercise due diligence to ensure that its [prescribers, patients] adhere to all the legal compliance by its prescribers and patients with applicable laws and regulatory requirements. guidelines. Customer is expected to exercise its professional knowledge and expertise to keep current on all such legal and regulatory guidelines.

Customer acknowledges that *client* may provide a copy of this agreement to the DEA, other federal regulatory agencies, state regulatory agencies, or state licensing boards *when determined to be appropriate.*

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Comment [A2]: Not sure that this portion is necessary, but I will leave that to the group.

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Customer agrees that failure to comply with this Agreement may result in the termination of the relationship between *client* and Customer, in whole or in part, notwithstanding any other agreements to the contrary.

Agreed to by a duly authorized officer, partner, or principal of Customer.

Signature: _____

Full Name (print): _____

Title: _____

Date: _____

Version 1.1, December 2007

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CORPORATE / MANUFACTURER / PACKAGING / RE-PACKAGING / DISTRIBUTOR

CUSTOMER QUESTIONNAIRE

SALES & MARKETING NEW CUSTOMER COMMENTS:

SALES POTENTIAL Click here to enter text.

UNMET NEEDS Click here to enter text.

GENERAL

1. Visited By (NAME) Click here to enter text. DATE Click here to enter a date.
2. Customer Name (Manufacturer/Packager/ Re-Packager/Distributor) Click here to enter text.
3. DBA (if any) Click here to enter text.
4. Has the customer ever operated under a different name? ☐ YES ☐ NO
5. If yes, what name(s)? Click here to enter text.
6. List the Customer's Address Click here to enter text.
7. Customer's Phone Click here to enter text.
8. Customer's Fax Click here to enter text. E-Mail Address Click here to enter text.
9. Name of Person / Owner in charge. Click here to enter text.
10. DEA Registration # of Customer Click here to enter text.
11. Is DEA Registration on display?

Reg. on display	☐ YES	☐ NO
Manufacturer:	☐ YES	☐ NO
Packager	☐ YES	☐ NO
Re-Packager	☐ YES	☐ NO
Distributor	☐ YES	☐ NO

List the DEA registration number and type of activity

OTHER Click here to enter text.

DEA Registration Number Click here to enter text.

Schedules Click here to enter text. Expiration Date Click here to enter a date.

12. Is the State site license on display?

License on display	☐ YES	☐ NO
Manufacturer:	☐ YES	☐ NO
Packager	☐ YES	☐ NO
Re-Packager	☐ YES	☐ NO
Distributor	☐ YES	☐ NO

List number and type of activity

OTHER Click here to enter text.

State License Number Click here to enter text.

*Fill in N/A if question is Non Applicable to the Audit

Schedules Click here to enter text. Expiration Date Click here to enter a date.

13. Is the customer VAWD Certified by the National Association of Boards of Pharmacy (NABP)? ☐ YES ☐ NO

IF NOT, WHY NOT? _____

14. Does the customer have an FDA License? ☐ YES ☐ NO

If yes, for what activity? _____

OWNERSHIP

15. Ownership type (check one)? ☐ Sole proprietor ☐ Corporation ☐ Partnership ☐ Other

16. If corporation, indicate state of incorporation. Click here to enter text.

17. Owner(s) name Corporate Officers if Corporate Click here to enter text.

18. Owner Business Address. Click here to enter text.

19. Owner Phone Click here to enter text.

20. Owner Fax & e-mail address. Click here to enter text.

21. Number of years owner has operated business. Click here to enter text.

22. Is owner licensed by a state regulatory agency? ☐ YES ☐ NO

State License Number Click here to enter text.

IF YES, FOR WHAT ACTIVITY? Click here to enter text.

23. Does owner operate/own any other businesses? ☐ YES ☐ NO

IF YES PROVIDE THE FOLLOWING NAME: Click here to enter text.

ATTACH ADDITIONAL SHEETS AS NECESSARY ADDRESS: Click here to enter text.

If YES, provide the following: NAME: Click here to enter text.

ATTACH ADDITIONAL SHEETS AS NECESSARY ADDRESS: Click here to enter text.

PRIOR HISTORY & ASSOCIATIONS

24. Has the customer ever had a DEA registration suspended or revoked? ☐ YES ☐ NO

IF YES PROVIDE DETAILS Click here to enter text.

25. Has the owner ever had a DEA registration suspended or revoked or had an administrative, civil or criminal citation, action, etc. by the DEA and/or US Attorney?

☐ YES ☐ NO

IF YES PROVIDE DETAILS Click here to enter text.

BUSINESS INFORMATION

26. Please provide a list of names of all pharmaceutical distributors or other suppliers that the customer has used within the last 24 months.

Click here to enter text.

27. Is the customer affiliated with any other businesses that handle controlled substances or Internet websites?

☐ YES ☐ NO

IF YES PROVIDE THE FOLLOWING
ATTACH ADDITIONAL SHEETS AS NECESSARY

NAME: Click here to enter text.
ADDRESS or URL ADDRESS Click here to enter text.
PHONE: Click here to enter text.

IF YES PROVIDE THE FOLLOWING
ATTACH ADDITIONAL SHEETS AS NECESSARY

NAME: Click here to enter text.
ADDRESS or URL ADDRESS Click here to enter text.
PHONE: Click here to enter text.

28. How does customer receive business (check all that apply)

☐ Internet	☐ Fax	☐ Mail Order
☐ Phone	☐ Walk In	

For each type of business, what percentage of total business does that represent?

Internet	Click here to enter text. %	Fax	Click here to enter text. %	Mail Order	Click here to enter text. %
Phone	Click here to enter text. %	Walk In	Click here to enter text. %		

29. Which states does the customer ship to (if any).

Click here to enter text.

Do they distribute controlled, non-controlled, products that contain List I Chemicals?

☐ YES ☐ NO

ATTACH AN EXTRA SHEET IF ADDITIONAL SPACE IS REQUIRED

30. Is the customer licensed for distributions into the states into which it distributes?

☐ YES ☐ NO

LICENSE # Click here to enter text.

List all out-of-state licenses, state agencies that issued the license and the type of activity licensed for.

Click here to enter text.

ATTACH EXTRA SHEETS AS REQUIRED

31. Does customer have a suspicious order monitoring program? ☐ YES ☐ NO

32. Does the customer have an SOP that describes the SOM program? ☐ YES ☐ NO

REQUEST A

33. Does the customer allow their customers to pick up orders for controlled substances? ☐ YES ☐ NO

IF YES – DESCRIBE WHY _____

34. Does the customer require cash payments? ☐ YES ☐ NO

IF YES, WHAT % OF BUSINESS % Click here to enter text.

35. Does the customer service pharmacy, physicians, long term care facilities, hospitals, distributors, others?

Pharmacy	☐ YES	☐ NO
Physician	☐ YES	☐ NO
LTCF	☐ YES	☐ NO
Hospitals	☐ YES	☐ NO
Distributors	☐ YES	☐ NO
Other	☐ YES	☐ NO

IF OTHER - DESCRIBE Click here to enter text.

If yes, what percentage of the customer's business is attributable to each of those types of facilities?

For those customers that distribute drugs to physicians, attempt to determine type of practice, e.g. pain treatment.

ATTACH AN EXTRA SHEET IF ADDITIONAL SPACE IS REQUIRED

Pharmacy	Click here to enter text.	%
Pharmacy	Click here to enter text.	%
LTCF	Click here to enter text.	%
Hospitals	Click here to enter text.	%
Distributors	Click here to enter text.	%
Other	Click here to enter text.	%

36. Does the customer have a web site? ☐ YES ☐ NO

IF YES PROVIDE WEB ADDRESS & DESCRIBE THE WEB SITE'S FUNCTION Click here to enter text.

37. How does customer receive payment for products and in what approximate percentage??

Cash	☐ YES	☐ NO	% of Revenue	Click here to enter text.
Check	☐ YES	☐ NO	% of Revenue	Click here to enter text.
Transfer	☐ YES	☐ NO	% of Revenue	Click here to enter text.
Other	☐ YES	☐ NO	% of Revenue	Click here to enter text.

IF OTHER PROVIDE DETAILS Click here to enter text.

38. What % of the customer's distributions/sales are controlled substances? % Click here to enter text.

39. Does the customer have a Registration Verification Program? Determine if the program tracks their customer's name, address and DEA registration number, Schedule, and expiration date of their customer's DEA registration. ☐ YES ☐ NO

LIST THE CUSTOMER'S TOP 10 CUSTOMERS AND THEIR % OF CONTROLLED SUBSTANCE PURCHASERS

CUSTOMER'S NAME	CONTROLLED SUBSTANCES ORDERED	% OF TOTAL PRESCRIPTION DRUGS	CUSTOMER'S DEA #
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
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Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

DESCRIPTION OF NEIGHBORHOOD

41. Describe the area where the customer is located — Click here to enter text.
42. Is the customer located within a strip mall, shopping center, — ☐ YES ☐ NO
43. Describe the premises, including front and back exteriors and interior. — Click here to enter text.

    ATTACH **PHOTOGRAPHS** OF ALL AREAS
44. General description of neighborhood. — Click here to enter text.
45. Describe how the customer ships drugs to their customers. — Click here to enter text.
46. Do they use their own delivery vehicles and employee drivers? — ☐ YES ☐ NO
47. If they use their own vehicles and employee drivers, are the controlled substances stored within the vehicles in the evening; either at the registered location or at the driver's residence, hotel, etc.? — ☐ YES ☐ NO
48. Is there any evidence of Internet activity (e.g. shipping supplies, FedEx boxes, etc.)? — ☐ YES ☐ NO

QUOTA

A DEA SCHEDULE II REGISTERED MANUFACTURER, PACKAGER AND/OR REPACKAGER IS REQUIRED TO OBTAIN A QUOTA FROM THE DEA.

49. Does the customer have a quota for Schedule II controlled substances? — ☐ YES ☐ NO ☐ N/A
50. Does the customer provide a certification to their supplier? — ☐ YES ☐ NO ☐ N/A

51. If the customer will provide, list the manufacturers that supply the customer with their Schedule II controlled substances. Click here to enter text.

DESCRIBE THE SOM PROGRAM IN DETAIL – USE ADDITIONAL SHEET(S) IF REQUIRED

21 CFR 1301.74 (b) 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.

Describe the Customer's SOM program:

Click here to enter text.

IN ADDITION:

Does the program track orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual	☐ YES	☐ NO
Does the program stop an order that exceeds a threshold, cut the order and then the customer distributes the balance?	☐ YES	☐ NO
Does the program only track orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency that exceed an established threshold and/or a number which is established after adding a standard deviation?	☐ YES	☐ NO

SECURITY IN DETAIL – USE ADDITIONAL SHEET(s) IF REQUIRED

21 CFR 1301.71 AND 1301.72 describe the security requirements in detail.

Describe the Customer's security: Click here to enter text.

Schedule II

VAULT:	Does the vault meet the requirements as described in the regulations?	☐ YES	☐ NO
SAFE:	Does the safe meet the requirements as described in the regulations?	☐ YES	☐ NO
ALARMS:	Do the alarms meet the requirements as described in the regulations?	☐ YES	☐ NO

Employee and non-employee access controls.

Do the access controls meet the requirements as described in the regulations? ☐ YES ☐ NO

Describe the Customer's security:

Click here to enter text.

Describe the adequacy of the security.

Click here to enter text.

DEA CHECKLIST

A. Compliance Letter Sent to Customer ☐ YES ☐ NO

Click here to enter text.	Click here to enter a date. Click here to enter text.	
BY WHOM	**DATE/TIME**	**RECEIVED BACK** ☐ YES ☐ NO

B. Local DEA Field Office Contacted

Click here to enter text.	Click here to enter text.	Click here to enter a date. Click here to enter text.
ACTAVIS EMPLOYEE WHO MADE CONTACT	**NAME OF AGENT CONTACTED:**	**DATE / TIME**

RESULTS: Click here to enter text.

C. Registered Letter Sent to DEA with return receipt (Attach copy of letter and registered receipt to this form):

Click here to enter text.	Click here to enter a date.	Click here to enter a date.

ACTAVIS EMPLOYEE WHO SENT NOTIFICATION LETTER	DATE SENT:	DATE RECEIVED BY DEA

ATTACH COPY OF SITE VISIT SYNOPSIS, INCLUDING COMMENTS AND RECOMMENDATIONS, TO THIS FORM

DRAFT

ACTAVIS Suspicious Order Monitoring – Indirect Customer Sales SOP

1. PURPOSE

This procedure describes the process used to analyze and monitor customer purchases from wholesalers and distributors.

2. SCOPE

- This policy applies to the indirect sale of Controlled Drugs sold by Actavis (Schedule II- V), that are identified as "products of interest" by the SOM Steering Committee.
- This procedure applies to the indirect sales function of Controlled Drugs sold by Actavis.

3. DEFINITIONS

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.

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."

INDIRECT CUSTOMER: This is a customer who does not purchase products directly from the Actavis warehouse. An indirect customer purchases product from a wholesaler or distributor. Actavis will commit to monitoring indirect customers who purchase an average quantity of 5,000 units of a CII controlled substance on a yearly basis.

PRODUCTS OF INTEREST: This is an Actavis product that is identified and agreed upon by the SOM Steering Committee, to be at higher risk for abuse and diversion and should be monitored by additional measures. An identified product of interest will be subject to Suspicious Order Monitoring – Indirect Customer Sales SOP. A product of interest can be declassified as a "product of interest" by the SOM Steering Committee.

4. RESPONSIBILITY

To be determined –

5. RELATED DOCUMENTS

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. INDIRECT CUSTOMERS BUYING FROM MULTIPLE SOURCES

6.1 Monthly analysis should be performed by using the Valuetrack "Safe and Secure" Module, or a comparable program, to monitor for pharmacies or other individual stores buying Actavis controlled substances of the same product from more than one wholesaler or distributor during a two-week period.

6.2. If activity is observed of a single store/pharmacy buying the same product from three or more sources (wholesalers/distributors) during the two-week time period, Actavis will then contact the point of sale wholesalers or distributors to alert them to this activity. Depending on the frequency and purchase quantity of the indirect customer, Actavis can initiate actions to prevent the indirect customer from receiving product.

6.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

7. INDIRECT CUSTOMERS BUYING HIGH QUANTITIES OF CONTROLLED PRODUCTS

7.1 Actavis indirect customer sales will be monitored through Valuetrack "Safe and Secure" module, or a comparable program, on a monthly basis. The sales will

be monitored for higher than average purchases of a single product based on the previous 3 months of purchases.

7.2 If a pharmacy or individual store's previous 30- day purchases exceed 50% higher than their established 3 month average, notification will be sent by Actavis to the point of sale wholesaler or distributor highlighting the current order quantity and historical average. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again in 14 days time.

7.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

8.0 INDIRECT CUSTOMERS BUYING DISPROPORTIONATE AMOUNT OF CONTROLLED SUBSTANCES

8.1 Actavis indirect customer sales will be monitored through Valuetrack "Safe and Secure" module, or a comparable program, on a monthly basis. The sales will be monitored for disproportionate amounts of controlled substances purchased from a single pharmacy or end user store, compared to their historical purchases or what is expected/forecasted from the end user store. Certain stores may have a higher expected utilization of controlled substances due to their internal warehousing strategy.

8.2 If any substantial change in product mix purchases is observed (with a higher amount of controlled substance purchased), Actavis will then send a notification to the point of sale wholesaler or distributer with the current product mix and how that has changed from their prior utilization. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again in 14 days time.

8.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

9.0 MONTHLY MEETINGS WITH HIGH VOLUME WHOLESALERS

9.1 Actavis will hold monthly meetings with the top volume wholesalers who sell to individual stores and pharmacies to discuss retailers/customers of interest. Participating in this meeting could be representatives from one or more of the

Actavis functional areas: Sales and Marketing, Customer Service, Legal, and Compliance.

9.2 During the meetings any outstanding notices of indirect customers buying from multiple sources, higher than normal quantities, or disproportionate activity will be discussed. Actavis will take any items that have not been addressed to the team's satisfaction to the Actavis SOM Steering Committee for further action.

10.0 REPORTING SUSPICIOUS ACTIVITY TO THE DEA

10.1 Depending on the frequency and severity of the indirect individual customer ordering, Actavis can reserve the right to stop sending the product of interest to the point of sale wholesaler, and can notify the DEA to the suspicious activity of the indirect customer, and the point of sale wholesaler. This action will be performed at the recommendation of the SOM Steering Committee.

ASSUMPTIONS

Monthly monitoring of individual products: It was determined to monitor each product of interest on a monthly basis as an initial setpoint into the indirect monitoring SOP. This will ensure Actavis can dedicate resources to the effort, while ensuring the occurrences can be investigated and addressed in a timely manner.

Multiple wholesalers, three or more: Individual pharmacies usually purchase their products from a primary wholesaler, and also a backup wholesaler in the event product is not available at their primary. If a pharmacy is seen buying product from three or more wholesalers, then the activity is potentially suspicious and needs to be investigated.

Average quantity over 3 months: Pharmacy purchasing historical quantities will be defined as a rolling three month period. This is enough time to smooth out highs and lows in the buying patterns for pharmacy, new products on the market, and also enough time to pick up on and adjust for market trends and shortages.

High activity defined as 50% above historical average: Actavis determined that high purchasing activity is defined as 50% above the established three month historical average, as a setpoint that was high enough to detect large orders that was outside the normal limits of the purchasing cycle.