Department: Distribution Operations	SOP #:065
Title: **Description of Anda's SOM Statistical Model**	

1.0 Scope

The directives contained in this SOP apply to all Anda and Anda Pharmaceutical employees that have or may have contact or involvement in the activities associated with, Information Needed to Set up a New Account. This is to include, but not be limited to:
* Sales
* Customer Service
* Regulatory Compliance

2.0 Purpose

To provide the licensing requirements to establish pharmacy, physician and wholesaler/distributor ("Customer") accounts with Anda.
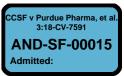
3.0 Procedure

Description of Anda's SOM Statistical Model

1. Anda uses the BuzzeoPDMA "cloud" SOM model.
2. The BuzzeoPDMA model uses a statistical approach to evaluate orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency.
3. Controlled substances distributed by Anda are identified by their active ingredient, with the exception of specific drugs which are identified by NDC number. These drugs are identified in Anda's SOM cloud system with a pend code W, which means that the customer is ordering the same product with a different strength or formulation.
4. Orders from customers are accepted and processed electronically. Prior to fulfillment, each order which contains a controlled substance is electronically transferred through a secure connection to the BuzzeoPDMA "Cloud" based server. In the BuzzeoPDMA "cloud" environment an algorithm is used to determine whether the order is an order of interest or a suspicious order for DEA reporting purposes.
5. The BuzzeoPDMA algorithm is developed by an analysis of 12 months of sales data (plus the current 30 days) which are provided by Anda for each Anda customer.

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    a. The BuzzeoPDMA SOM system cannot analyze orders for new customers. These orders must be analyzed in conjunction with Anda's ongoing due diligence procedures.

    b. This statistical based SOM system can only identify a potentially suspicious order if the customer has ordered the corresponding active ingredient at least once over the previous one year period. When this is not satisfied, the order can be evaluated using the override rule based solution that is offered by the cloud SOM system in conjunction with Anda's ongoing due diligence procedures.

      i. Refer to limited history and pending when less than 30 days history

6. Orders are evaluated in real time.

7. The BuzzeoPDMA model designed to evaluate orders and determine whether they are more likely to fit the DEA's definition of a "suspicious order" or less likely to fit the DEA's definition of a "suspicious order." In order to do this, a *"score"* is given for each product line item in an order. The "score" is based on a number of *attributes (or order qualities)* which are independent variables that represent characteristics of the item in the order. The attributes are based on *markers or data* calculated from a twelve month historical database. The model also includes *identifiers* – binary variables that must be either yes (assigned a value of 1) or no (assigned a value of 0).

8. For each order, an analysis is performed to determine whether or not the order contains a number of factors (attributes) that would be associated with a suspicious order. Each of these factors (attributes) is assigned a *numerical value.* For some factors, the factor is deemed to be more important, significant, or indicative of a potentially "suspicious order" and those factors are assigned a higher value. These higher value factors are referred to as having *weighted values.* The weighted values are expressed in mathematical terms referred to as *coefficients*. The various numerical values associated with each factor for each product line item are totaled and the totals represent the "scores." If an order has a number of factors (attributes) that have a high numerical value (thus driving up the overall score), the order may meet the DEA's definition of what is considered potentially suspicious and the BuzzeoPDMA model would indicate the order should be "pended" to allow further investigation to determine whether the order is in fact a "suspicious order" for reporting purposes.

The BuzzeoPDMA model looks at and utilizes attributes and identifiers (and their assigned numerical values) that could be considered suspicious and seeks to apply statistical techniques to establish "norms" and "deviations" in order that the overall "suspiciousness" of the order can be evaluated. The BuzzeoPDMA approach considers both the types of order qualities

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(attributes) that can make an order "suspicious" and also establishes parameters related to "normal" ordering patterns so that orders that "deviate from a normal pattern" can be readily identified. At its core, the system uses a heavily modified mixed logit regression model that returns a score or "index" – quite simply, a number between zero and one – that is used to gauge the likelihood that an item is either ordered in error or is fraudulent (the model does not distinguish between the two). Items with low scores are allowed to proceed for processing, and items with large scores are pended for review. (It should be noted that when an order is cleared or pended by the business rule set-up, the final score will be a negative score. This negative number is to highlight that the rule overrides the SOM score)

9. The BuzzeoPDMA system is dynamic rather than static meaning that the order calculation changes for each new order based upon a new order history.

1.1 Attachment

1. SOM Cloud User's Manual

Technical explanation of Cloud-based SOM Statistical Model:[1]

SOM uses statistical approach to evaluate orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

For each product item a customer is ordering, SOM calculates the moving 30 days' cumulative strength of the active ingredient ordered and evaluates the calculated cumulative strength by comparing it statistically to the historic order patterns over past 12 months. This approach not only examines the current order as included in 30 days' total, but also evaluates it to see if there is any significant deviation from historic trending over past 12 months. Using active ingredient, not the NDC or specific product (unless specified by Anda for specific SOM review purposes), this approach would remain effective even when customer switches ordering from one drug to another and both drugs could contain the same controlled substance.

The SOM model running in "the Cloud" is able to score and detect the orders deviating substantially away from normal size, trending and frequency patterns. For example, patterns that are examined in the SOM model development process are listed below:

1. Extreme orders in size compared to history maximum
2. Extreme orders for customers with overall sparse order pattern
3. Growth pattern orders with significant increase in ordered quantity
4. Incremental growth orders resulting in significant ordered quantity jumps over months

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[1] This information is provided here as an example. Final formula calculations are provided in the SOM algorithm document.

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5. Swing pattern when orders suddenly reverse the downward trending. A swing pattern occurs when the customer is ordering less and has a downward order line and abruptly starts ordering a lot. It is essentially a change in patter.
6. Higher order frequency combined with higher ordered drug strength
7. Significant ordered quantity up when product family level volume spikes, a pattern happens often as a result of typically sales promotion and competition
8. Order significantly deviates from the overall downward market trending

The following lists fields that are typically utilized in calculating the scores. This table is recompiled daily (refreshed with the twelve most recent months of history).

Field	Marker Description	Additional Notes
CustomerID	The unique identifier associated with the customer	Index 1
ActiveIngredient	The Active Ingredient under review	Index 2
LastOrdDate	Date of most recent order	None
MonWOrd	A count of months with orders during the past 12 months (An integer between 1 and 12)	None
MonWOrd6	A count of months with orders during the past 6 months (An integer between 1 and 6)	None
FreqOrder6	If *MonWOrd6*>=4 then 1, otherwise 0	Indicator variable based on *MonWOrd6*
SUMX_6	Sum of the first 6 (negative) numbers: $$-\frac{n(n+1)}{2} = -\frac{6(6+1)}{2} = -21$$	Constant included for future flexibility (Value of -21)
SUMY_6	Sum of the previous 6 monthly strengths *Lag_6_Strength+Lag_5_Strength+… +Lag_1_Strength*	None

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Field	Marker Description	Additional Notes
SUMX2_6	Sum of squares of the first 6 numbers $$\frac{n(n+1)(2n+1)}{6} = \frac{6(6+1)(2*6+1)}{6} = 91$$	Constant included for future flexibility (Value of 91)
SUMY2_6	Sum of squares of the previous 6 monthly strengths $Lag\_6\_Strength^2 + Lag\_5\_Strength^2 +$ ... $+Lag\_1\_Strength^2$	None
SUMXY_6	Sum of the products X*Y (Lag*strength) of the previous 6 months -6*$Lag\_6\_Strength$ - 5*$Lag\_5\_Strength$ -... -1*$Lag\_1\_Strength$	None
Xbar6	Average Lag for 6 month time period $$\frac{SUMX\_6}{6} = \frac{-21}{6} = -3.5$$	Constant included for future flexibility (Value of -3.5)
Ybar6	Mean monthly order strength for previous 6 months $$\frac{SUMY\_6}{6}$$	None
MWO_Ybar6	Mean Monthly Order Strength for months with actual orders $$\frac{SUMY\_6}{MonWOrd6}$$	None
STDY6	Standard Deviation of Monthly Order Strengths for previous 6 months $$\sqrt{\frac{SUMY2\_6 - \frac{SUMY\_6^2}{6}}{6-1}}$$	Example calculation: SQRT((SUMY2_6-POW(SUMY_6,2))/(6-1))

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Field	Marker Description	Additional Notes
MWO_STDY6	Standard Deviation of Monthly Order Strengths for months with actual orders $$\sqrt{\frac{SUMY2\_6 - \frac{SUMY\_6^2}{MonWOrd6}}{MonWOrd6 - 1}}$$	Be careful to protect against MWO=1 (Zero in denominator) Example calculation: SQRT((SUMY_62-POW(SUMY_6,2)/ MonWOrd)/(MonWOrd-1))
SXY6	Sum Square Error XY $$SUMXY\_6 - \frac{SUMX\_6 * SUMY\_6}{6}$$	None
SXX6	Sum Square Error XX $$SUMX2\_6 - \frac{SUMX\_6^2}{6}$$	None
SYY6	Sum Square Error YY $$SUMY2\_6 - \frac{SUMY\_6^2}{6}$$	None
Slope6	Slope of regression line $$\frac{SXY6}{SXX6},$$ If SXY6 < 0 then use 0	None
Intercept6	Intercept of regression line $$Ybar6 - \frac{SXY6}{SXX6} Xbar6$$ If SXY6 < 0 then use Ybar6	By design this is also the expected order size of current month
MSE6	Mean Squared Error $$\left(SYY6 - \frac{SXY6^2}{SXX6} \right) \frac{1}{(6-2)}$$ If SXY6 < 0 then SYY/(6-1)	Example calculation: (SYY6-SXY6*SXY6/SXX6)/(6-2)

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Field	Marker Description	Additional Notes
FreqOrder12	If MonWOrd>=8 then 1 otherwise 0	Indicator variable based on MonWOrd
RareOrder12	1-FreqOrder12	Opposite of FreqOrder12
MaxOrderStrength	Maximum total strength of a single order in the past 12 months.	None
MaxMonthlyStrength	Largest combined strength ordered in one calendar month (of the past 12 months).	None
SUMX_12	Sum of the first 12 (negative) numbers: $$-\frac{n(n+1)}{2} = -\frac{12(12+1)}{2} = \text{-78}$$	Constant included for future flexibility (Value of -78)
SUMY_12	Sum of the previous 12 monthly strengths $Lag\_12\_Strength+Lag\_11\_Strength+...$ $+Lag\_1\_Strength$	None
SUMX2_12	Sum of squares of the first 12 numbers $$\frac{n(n+1)(2n+1)}{6} = \frac{12(12+1)(2*12+1)}{6}$$ =650	Constant included for future flexibility (Value of 650)
SUMY2_12	Sum of squares of the previous 12 monthly strengths $Lag\_12\_Strength^2+Lag\_11\_Strength^2+...$ $+Lag\_1\_Strength^2$	None
SUMXY_12	Sum of the products X*Y (Lag*strength) of the previous 6 months $-12*Lag\_12\_Strength - 11*Lag\_5\_Strength-... - 1*Lag\_1\_Strength$	None

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Field	Marker Description	Additional Notes
*Xbar*12	Average Lag for 12 month time period $\dfrac{SUMX\_12}{12} = -6.5$	Constant included for future flexibility (Value of -6.5)
*Ybar*12	Mean monthly order strength for previous 12 months $\dfrac{SUMY\_n}{n} = \dfrac{SUMY\_12}{12}$	None
*MWO_Ybar*12	Meant Monthly Order Strength for months with actual orders $\dfrac{SUMY\_n}{MonWOrd} = \dfrac{SUMY\_12}{MonWOrd}$	None
STDY12	Standard Deviation of Monthly Order Strengths for previous 12 months $\sqrt{\dfrac{SUMY2\_n - \dfrac{SUMY\_n^2}{n}}{n-1}}$ $= \sqrt{\dfrac{SUMY2\_12 - \dfrac{SUMY\_12^2}{12}}{12-1}}$	Example calculation: SQRT((SUMY2_12-POW(SUMY_12,2)/12)/(12-1))
*MWO_STDY*12	Standard Deviation of Monthly Order Strengths for months with actual orders $\sqrt{\dfrac{SUMY2\_n - \dfrac{SUMY\_n^2}{n}}{MonWOrd}}$ $= \sqrt{\dfrac{SUMY2\_12 - \dfrac{SUMY\_12^2}{MonWOrd}}{MonWOrd-1}}$	Be careful to protect against MWO=1 (Zero in denominator) Example calculation: SQRT((SUMY2_12-POW(SUMY_12,2)/MonWOrd) /(MonWOrd-1))

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Field	Marker Description	Additional Notes
SXY12	Sum Square Error XY $$SUMXY\_12 - \frac{SUMX\_12 * SUMY\_12}{12}$$	None
SXX12	Sum Square Error XX $$SUMX2\_12 - \frac{SUMX\_12^2}{12}$$	None
SYY12	Sum Square Error YY $$SUMY2\_12 - \frac{SUMY\_12^2}{12}$$	None
Slope12	Slope of regression line $$\frac{SXY12}{SXX12}, \text{ If } SXY12 < 0 \text{ then use } 0$$	None
Intercept12	Intercept of regression line $$Ybar12 - \frac{SXY12}{SXX12} Xbar12$$ If $SXY12 < 0$ then use Ybar12	By design this is also the expected order size of current month
MSE12	Mean Squared Error $$\left(SYY12 - \frac{SXY12^2}{SXX12}\right)\frac{1}{(12-2)}$$ If $SXY12 < 0$ then use $SYY12/(12-1)$	None
Trend4SumY	Sum of the strengths from months with lag -12, -11, -2 and -1 *Lag_12_Strength+Lag_11_Strength + +Lag_1_Strength+ Lag_2_Strength*	This is calculated on the two most distant and two most recent months only

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Field	Marker Description	Additional Notes
Trend4SumY2	Sum of the squared strengths from months with lag -12, -11, -2 and -1 $Lag\_12\_Strength^2 + Lag\_11\_Strength^2 + +Lag\_1\_Strength^2 + Lag\_2\_Strength^2$	This is calculated on the two most distant and two most recent months only
Trend4Ybar	Average of the strengths from months with lag -12, -11, -2 and -1 $$\dfrac{Trend4SumY}{4}$$	None
Trend4STDY	Standard Deviation of strengths from months with lag -12, -11, -2 and -1 $$\sqrt{\dfrac{Trend4SumY2 - \dfrac{1}{4}Trend4Ybar^2}{3}}$$	None
Freqorder6	If *MonWOrd6* ≥ 4, this is set to the value 1. It is equal to 0 otherwise.	None
Freqorder12	If *MonWOrd* ≥ 8, this is set to the value 1. It is equal to 0 otherwise.	None
Rareorder12	Given by the value 1 − Freqorder12	None
Lag_12_Strength	Total Strength of orders 12 months ago	Combined strengths for the active ingredient for the entire calendar month
Lag_11_Strength	Total Strength of orders 11 months ago	None
Lag_10_Strength	Total Strength of orders 10 months ago	None
Lag_9_Strength	Total Strength of orders 9 months ago	None
Lag_8_Strength	Total Strength of orders 8 months ago	None

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Field	Marker Description	Additional Notes
Lag_7_Strength	Total Strength of orders 7 months ago	None
Lag_6_Strength	Total Strength of orders 6 months ago	None
Lag_5_Strength	Total Strength of orders 5 months ago	None
Lag_4_Strength	Total Strength of orders 4 months ago	None
Lag_3_Strength	Total Strength of orders 3 months ago	None
Lag_2_Strength	Total Strength of orders 2 months ago	None
Lag_1_Strength	Total Strength of orders last month	None

Additionally, the following field is computed at the time of the order. That data will be combined with the data in the trending table and electronically fed to the formula for the SOM system in order to produce a "pending" event or to clear the order electronically.

CumulStrength	The total amount ordered for this active ingredient (including the current order) thus far this 30 days ~~calendar month~~.

Attributes Used in the SOM Model

The following attributes are typical of those used in SOM "cloud" models. Attributes are listed in two classes: *binary indicators* (having values of either 0 or 1) and *continuous variables*.

Binary indicators

1) **Scheduled**: If the Active Ingredient is scheduled then this is set to the value 1. It is set to value 0 otherwise.

2) **PSE**: If the active ingredient is pseudoephedrine then this is set to the value 1. It is set to the value 0 otherwise.

3) **LessMax**: If CumulStrength $\leq$ MaxMonthlyStrength then this is set to the value 1. It is set to the value 0 otherwise.

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4) **TwoMonthOK**: If
(CumulStrength+Lag_1_Strength) <= 1.02*(Lag_3_Strength +Lag_4_Strength)
then this is set to the value 1. It is set to the value 0 otherwise.

Continuous variables

1) **Zscore6range**: this is calculated one out of three ways:

   a. if **STDY6** > 3, the formula is $\dfrac{CumulStrength - Ybar6}{STDY6}$

   b. If **STDY6** ≤ 3 but **Ybar6** > 0, the formula is $\dfrac{CumulStrength - Ybar6}{Ybar6}$

   Note: (in both a. and b. above) if **Zscore6range** > 10, it is fixed at 10. If **Zscore6range** < -10, it is fixed at -10.

   c. If **Ybar6** = 0, the value is fixed at 0.

2) **Predzscore6range**: is calculated one out of two ways:

   a. if SYY6 > 0, the formula is $\dfrac{CumulStrength - Intercept6}{\sqrt{MSE6 * 1.86666}}$

   Note: if **Predzscore6range** > 10, it is fixed at 10. If **Predzscore6range** < -10, it is fixed at -10.

   b. If SYY6 = 0, the value is fixed at 0.

3) **Zscore12MAXrange**: is calculated one out of three ways:

   a. if CumulStrength > MaxMonthlyStrength *and* STDY12 > 0, the formula is $\dfrac{CumulStrength - MaxMonthlyStrength}{STDY12}$.

   b. if CumulStrength > MaxMonthlyStrength *and* STDY12 = 0, the formula is $\dfrac{CumulStrength - MaxMonthlyStrength}{MaxMonthlyStrength}$

   Note: (in both a. and b. above) if **Zscore12MAXrange** > 10, it is fixed at 10. If **Zscore12MAXrange** < -10, it is fixed at -10.

   c. if CumulStrength ≤ MaxMonthlyStrength, this has the value 0.

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4) **Zscore12range**: this is calculated one out of two ways:

    a. if STDY12 > 3, the formula is $\dfrac{CumulStrength - Ybar12}{STDY12}$

    b. If STDY12 ≤ 3, the formula is $\dfrac{CumulStrength - Ybar12}{Ybar12}$

       Note: (in both a. and b. above) if **Zscore12range** > 10, it is fixed at 10. If **Zscore12range** < -10, it is fixed at -10.

5) **Trend4ZscoreRange**: is calculated one of three ways:

    a. if CumulStrength **>** Trend4Ybar *and* Trend4STDY > 0, the formula is
$$\frac{CumulStrength - Trend4Ybar}{Trend4STDY} \; .$$

    b. if CumulStrength **>** MaxMonthlyStrength *and* Trend4Ybar>0, the formula is
$$\frac{CumulStrength - Trend4Ybar}{Trend4Ybar}$$
       Note: (in both a. and b. above) if **Trend4ZscoreRange** > 10, it is fixed at 10. If **Trend4ZscoreRange** < -10, it is fixed at -10.

    c. Otherwise this has the value 0.

Similarly, SOM could also calculate the trending change, customer order deviation and order frequency and makes comparison statistically with order distribution over past 12 months.

The SOM Model
Given the attributes previously defined, SOM model **could be** represented by the following formula:

$$P = \frac{e^{-A}}{1 + e^{-A}}$$

In the above formula to calculate the p-value, the value "*e*" represents the mathematical constant 2.718281828459. The variable "*A*" is the combination of various coefficients and attributes previously defined.
A p-value score of …. (value to be determined after the model development is completed) or higher, for example, is identified as suspicious, pended, and should be investigated further.

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4.0 Revision History
SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
February 13, 2017	065	Emily Schultz	Original Issue
February 2, 2018	065	Sabrina Solis	Review

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