

**Document Identification**

BegControl: ALLERGAN\_MDL\_03535253

EndControl: ALLERGAN\_MDL\_03535257

BegAttach: ALLERGAN\_MDL\_03535253

EndAttach: ALLERGAN\_MDL\_03535257

FamilyID: ALLERGAN\_MDL\_03535253

Custodian: Napoli, Tom

**File Metadata**

File Name: SOMProjectJust2.19.15.docx

File Type: Microsoft Word 2010/2011

File Extension: .docx

File Size: 174272.00

Hash Value: CCFDA2434F742119E9BBDDC9BD87B7A02256E531

**Document Metadata**

E-Title:

E-Author: tnapoli

Date Last Modified: 2/19/2015

Date Created: 2/19/2015

Date Last Printed: 6/6/2013

E-Comments:

E-Subject:

Original Folder Path: Tom\_Napoli\WKS\tnapoli\{{User Profile}}\Desktop\Controlled Substances\Project AIM\





## Project Continuation Justification: SOM Statistical Model Development and Hosting "in the Cloud"

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This document is being submitted in support of the continuance of an important compliance related project concurrent with integration and SAP migration activities associated with the Allergan acquisition.

### Overview

Through the use of a third-party vendor (Cegedim), implement a proprietary algorithm based software system used to detect and report suspicious orders of controlled substances for purposes of reporting to the DEA.

- The system will be compliant with Code of Federal Regulations SOM Requirements Controlled Substances – 21 CFR 1301.74(b) as well as December 2007 DEA memorandum.
- The system will identify customer orders that deviate substantially from their historic ordering patterns, size, frequency, drug cocktails, and customer type.
- The system will check every controlled substance order per line item placed by customers against as several separate parameters and will assign a "score" for each product line within an order.
- The score is based on a number of attributes (order qualities) which are independent variables that represent characteristics of the item in the order. The attributes are based on data calculated from a twelve month rolling history.
- The SOM model is based on controlled substances as measured in milligram amounts of active ingredient.
- When a customer order line item is identified and placed on hold within the system as an order of interest, an instantaneous email is sent to a trained employee for review and the entire product group (for which the held order belongs to) is restricted for the customer until the order is reviewed per standard operating procedures.
- The system will have capability of producing "reason codes" indicating likely cause for order pend.
- The system will present historical ordering data in a meaningful format, facilitating efficient review and disposition.

2/19/2015

## Background

The SOM automation project initially commenced in 2011, with the primary goal of replacing our “threshold” based system with a CFR compliant model developed by Cegedim . This project was initiated in an effort to ensure compliance with Code of Federal Regulations SOM Requirements Controlled Substances – 21 CFR 1301.74(b) as well as December 2007 DEA memorandum. The regulations state 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.’*

The December 2007 memorandum further clarifies:

*“...a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient.”*

Based on this compliance need, Cegedim did in-fact develop and deliver a SOM statistical model to be incorporated into our order management system within SAP. Due to successive acquisition activities since project initiation, the implementation has been placed on hold at several junctures based on business integration needs. During the past several years, DEA has become more aggressive in its approach related to SOM/“Know your Customer,” taking action against a growing number of companies for having non-compliant SOM programs. In an effort to ensure compliance with the regulations, both the CS Compliance, Order Management teams have collaborated, making efforts to enhance compliance from customer vetting, order review/evaluation through Investigation/disposition. This manual effort is very labor intensive, as the current system is not configured with any analytical tools to support timely and accurate decision making. This approach also introduces the element of “human interaction” in the order evaluation process. Additionally, the current process can have an impact on the amount of time required to release a “pending” order that is under review, affecting customer service/Fill Rate levels.

## Cloud Based Solution

Within the last two years, Cegedim began offering an automated "Cloud based" solution for SOM. After careful evaluation and vetting by the team, it was determined that this approach would be the best fit for us going forward. This approach provides the typical benefits of a cloud based solution, flexibility, scalability, minimal impact on existing ERP and IT resources (implementation/maintenance), and a pay as you go approach. In addition to these benefits, the cloud-based compliant system offers a robust analytical component for the efficient evaluation and disposition of controlled substance orders.

Based on this decision, Cegedim was asked to provide a proposal and plan to deploy a "cloud based" SOM statistical model using algorithms similar to the sophisticated and statistically based suspicious order identification algorithms that Cegedim previously delivered.

## Project Overview

Cegedim has developed a suspicious order monitor (SOM) statistical model that will be hosted "in the cloud" and based on Actavis' order data. The cloud based SOM model will enhance Actavis' efforts to comply with DEA's SOM requirement as detailed in Title 21 CFR Part 1301.74(b), Title 21 CFR Part 1310.05 (a) (1), and various DEA guidance memoranda. The cloud based SOM system will need to be "called" from Actavis' existing SAP order management system and will provide order status indications to determine whether orders should be shipped or held ("pending") for further appraisal. Additionally, Cegedim will provide a web-based order review and evaluation module that will allow Actavis' compliance personnel to review and analyze details of pending orders so that defensible decisions can be made for clearing and shipping pending orders or alternatively reporting the order to DEA as a suspicious order.

This project will result in a statistically sound SOM model for Actavis as a result of three major activities:

1. Extensive data review and analysis of Actavis' existing order history data (so that historical ordering patterns, etc. can be fully understood and utilized in future order evaluations),
2. Modeling and development of a statistically viable and supportable SOM model based on this data, and
3. Deployment of the SOM model and order review and evaluation module in a cloud based environment.

### SOM project scope:

- Teleconference Discovery/Kickoff Meeting(s) - Cegedim will meet via teleconference with Actavis for a discussion and assessment of the items needed to develop a defensible SOM model. This discovery meeting will include a thorough discussion and review of current processes, Actavis profiles, current IT systems, and order history and Customer insight. Additionally, the Cegedim team will provide details of the model "call out" functionality so that appropriate planning can occur by Actavis' IT team for the limited IT modification required to Actavis' existing order management system.
- Development and deployment of a customized statistical based SOM model for Actavis "in the cloud."
- Development and deployment of a web-based order review and evaluation module.
- Interaction with Actavis' IT team during model development to ensure model interaction with your system is understood and planned for.
- Development of supporting documentation and justification.
- Development of automated SOM form within our current SAP environment

### Assumptions:

- Actavis' IT group is responsible for minimal modification to Actavis' existing order management system based on documented requirements; Specifically: 1) Construction of a simple secured https call to send each order to the Cegedim system, and 2) A second secured https call to retrieve information from the Cegedim system, on orders that are within established criteria and may be cleared for release.
- Cegedim's cloud system communicates exclusively via https calls originating from Actavis' order management system. Initially, the order is sent either individually or as part of a batch transfer. A secondary call from Actavis' system requests the status of all orders.

**SOM Cloud Cost Model (Costs have not been reviewed/negotiated with Procurement)**

|  | <b>Fee</b>  | <b>Comments</b>   |
|--|---|---|
| <b>Migration cost</b> (one-time charge) – Development and deployment of SOM cloud service, custom tailored to client’s unique customer and product base, previous ordering histories, etc. | <b>\$39,500/one time</b>                              | \$14,500 full model retunement to get data / model current with recent Actavis order history plus \$25,000 migration and deployment to the Cloud costs. |
| <b>Ongoing Processing</b> , quarterly charge – for performing and supporting the cloud-based order review and evaluation process   | <b>\$12,500/quarter</b> (based on a 3-year agreement) | Replaces any current maintenance agreement.   |
| <b>Full Model “Retunement”</b> (recommended at least once yearly to ensure SOM review is occurring in the most regulatory-compliant and business-efficient manner)                         | <b>\$14,500/per retunement</b>                        | Actavis will determine frequency and timing of these events after the initial required event.   |

Alternatives to Cloud-Based SOM implementation

- Place project on hold and resume in 2016. This option is not recommended as we continue to assume compliance risk.

As a DEA registrant, Actavis is required to maintain compliance with the Controlled Substances Act and implementing regulations. Our commitment to preventing drug diversion is critical. We must ensure that effective controls are implemented throughout our manufacturing, testing, research & development, and supply chain processes to ensure that legitimate patients receive our medicines, and they are not diverted as a result of our day-to-day operations. Key among these effective controls is a statistically based automated SOM model at the center of a holistic program working in concert with appropriate customer due diligence, order review and investigations processes and policies. For this reason, it is important that the project to replace the threshold- based system with a statistically defensible, cloud- based model continue on the current track for implementation within 2015. The implementation of a cloud-based solution requires a minimal amount of IT integration and dedicated resources. Utilizing a team comprised of a project lead, two business process SME’s (CS Compliance/Order Mgmt.) as well as dedicated IT business system analyst, this project can be successfully completed. The implementation, testing and acceptance of the cloud- based model within 2015 will also allow for a seamless transition to the legacy Allergan instance of SAP.