Sections included in this document

1. Purpose/Scope

This document provides additional instructions to support the procedures for managing device registrations as listed in FMD 92, to be followed by ALL district offices, Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO) in processing registrations from Center for Devices and Radiological Health (CDRH) FMS (Field Management Services).

2. Responsibility

It is the responsibility of the District OEI Coordinator, District Medical Device Monitor, Medical Device Registration Coordinator or designee to manage device registrations in accordance with this work instruction.

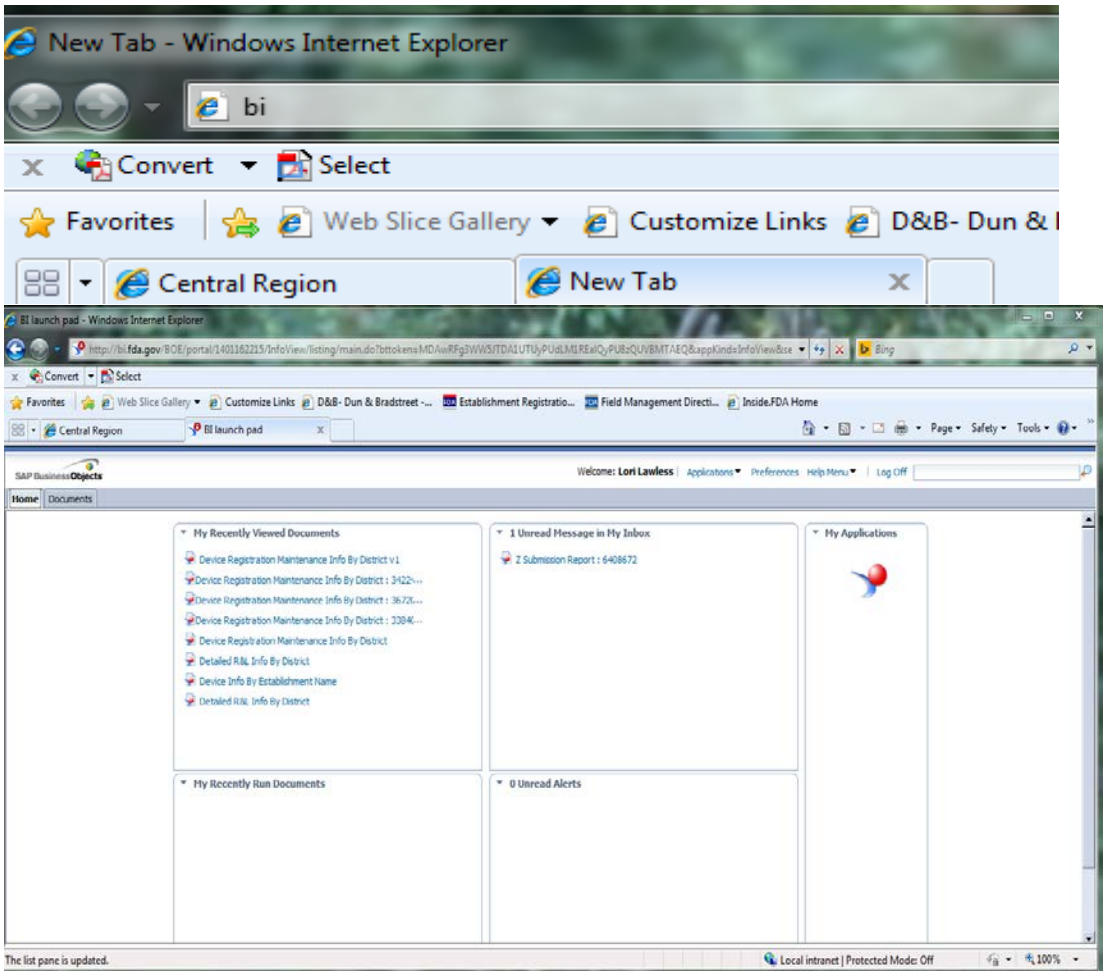
District includes both domestic and foreign areas.

Note: The document refers to District Registration Monitor throughout, but is referring to the above statement.

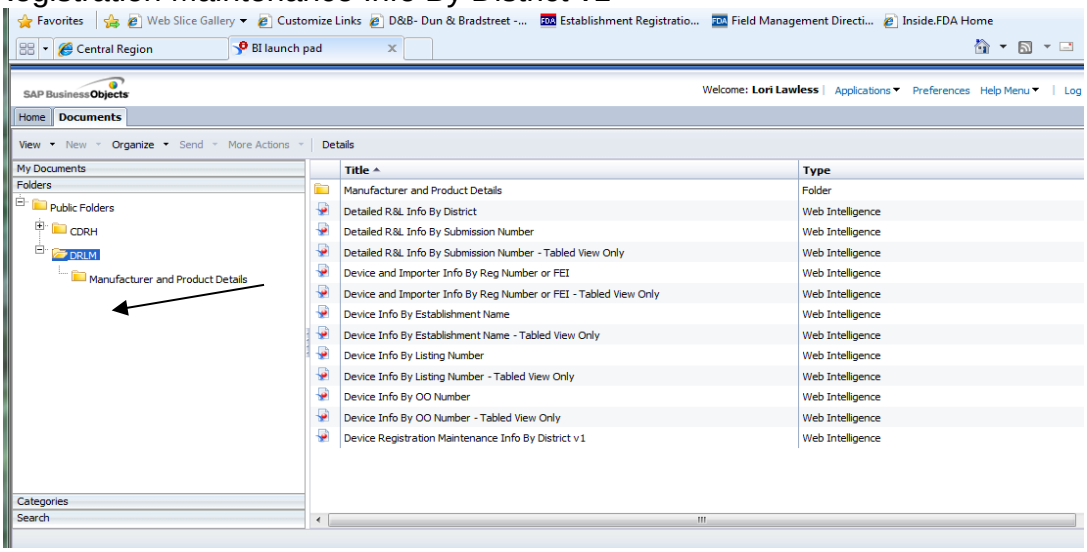
3. Procedure

3.1 Running the CDRH Business Objects Report

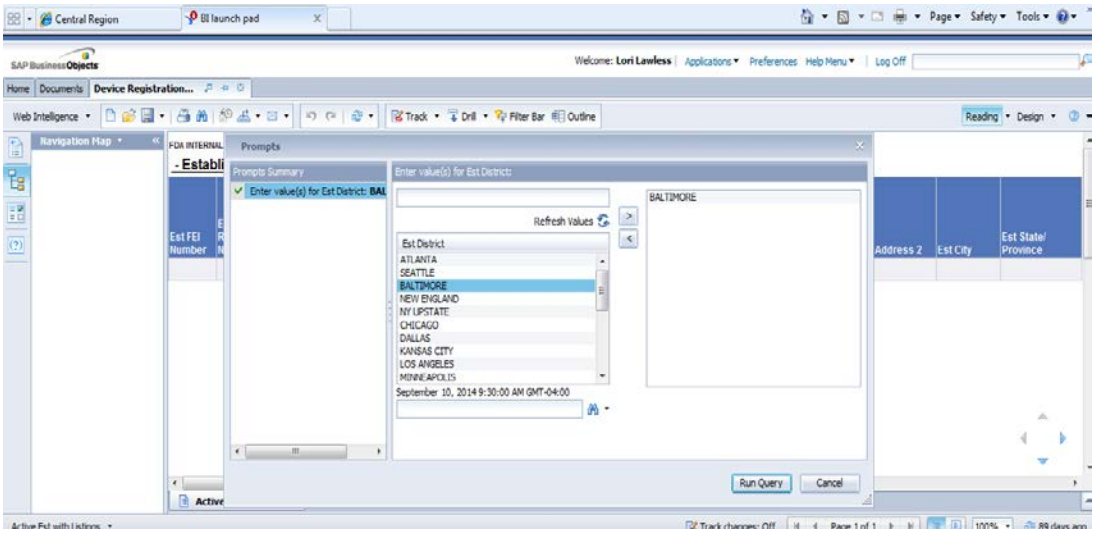
Step 1: In the Internet Browser, Type BI in the address bar and click return. This will take the user to the Device Universe Business Objects (also known as CDRH Adhoc Reporting System (CARS))



Step 2: Go to “Documents”, “Folders”, “Public Folders”, “DRLM”, ““Device Registration Maintenance Info By District v1”



Step 3: Run the report for the specific district.



Step 4: Export the document to Excel.

Step 5: Tab 1 is a list of all active, registered firms in a district with ALL the firm's listings/establishment types.

Step 6: Tab 2 is a list of all active, registered firms, with ONLY the highest device classification/establishment types.

Step 7: Sort Tab by "Registration Date", newest to oldest. Use this information to update FACTS as applicable.

Step 8: Tab 3 is all inactive firms in the district (that have either canceled their registration or not re-registered during the designated time frames).

Step 9: Sort Tab 3 by "Est Year Reg Expires". The Registration Monitor should work with district management to follow-up on these firms to determine if the firm is still involved in an FDA regulated activity. This follow-up could include contact the firm by telephone, email, or visit.

Note: Just because a firm does not register, does not mean that the firm is no longer involved in an FDA regulated activity.

Step 10: Update FACTS as appropriate.

3.2 Registration maintenance in FACTS

Step 1: At least bi-annually, run ORADSS canned report "REG6_RegistrationforMedicalDev" for the district.

Step 2: Export the results to EXCEL (in .csv format), and sort by "Registration Date".

Step 3: Review firms that do not have current registration information in FACTS/FMS.

Step 4: The district should follow up on these firms to determine if the firm is still involved in an FDA regulated activity and update FACTS/FMS as appropriate.

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4. Glossary/ Definitions

A. CDRH: Center for Devices and Radiological Health
B. CFN: Central File Number
C. FEI: Field Establishment identifier
D. FACTS: Field Accomplishment Tracking System
E. FURLS: FDA Unified Registration and Listing System
F. OEI: Official Establishment Inventory

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5. Supporting Documents

A. FMD 92 "Agency Establishment Registration and Controls Procedure"
B. FMD 130 "OEI Development and Maintenance Procedure"

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6. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	7/2/15	LORI LAWLESS, NATIONAL OEI COORDINATOR	Kate Bent, Director OPRM

* - D: Draft, I: Initial, R: Revision, C: Cancel

7. Change History

Version	Change
1.0	Initial